bk medical
a GE Healthcare company

User Guide

Care and Cleaning

Information for the BK Medical Product Range

English
BB1564-BE
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For healthcare professional users only

LEGAL MANUFACTURER

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The serial number of a BK Medical product contains information about the year of manufacture.

New disinfection and sterilization methods are constantly being developed, and we work to make our products compatible with as many methods as possible. You can find the latest information about caring for our products, including disinfection and sterilization compatibility, on our website. New information may have been added since you received this book.

BK Medical Customer Satisfaction

Input from our customers helps us improve our products and services. Your opinions are important to us. You are always welcome to contact us via your BK Medical representative or by contacting us directly.

Should any serious incident occur in relation to your BK Medical device, you should report this to the manufacturer and your local competent authority.

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An electronic copy of this document in the official language of your member state can be accessed through our website.

English source version
BB1564-BE

Chapter 1: Warnings and Cautions

Warnings

⚠ Keep plug dry	**WARNING** T-w5 To prevent electrical shock and damage to the transducer, the connector pins in the transducer plug must always be completely dry before you connect to a system.
⚠ Transducer, holder and container must be clean	**WARNING** Reproc-w1 To avoid contamination, clean transducers before inserting them into storage containers for transportation. To avoid cross-contamination, make sure that transducer holders and storage containers are clean before inserting clean transducers.
⚠ Infection control – follow established procedures	**WARNING** Reproc-w2 Users of this equipment have an obligation and responsibility to provide the highest possible degree of infection control to patients, co-workers and themselves. The instructions in this book are meant as a guide. To avoid cross-contamination, follow all infection control policies (including for reprocessing, packing and storage) for personnel and equipment that have been established for your office, department or hospital.
⚠ Pre-clean immediately after use	**WARNING** Reproc-w3 Immediately after use, you must pre-clean the device until visually clean (including any lumens). Conduct the thorough cleaning process as soon as possible after use in order to prevent soil drying on the surface. Dried soil can lead to inefficient cleaning, disinfection and sterilization, causing a risk of cross-contamination.
⚠ Reprocessing	**WARNING** Reproc-w4 Extra care must be taken when cleaning this transducer, as there is no automatic cleaning system that can reprocess the entire transducer.
⚠ Screen contamination	**WARNING** Reproc-w5 To avoid contamination of the speaker area, do not touch this area when you turn the monitor to the horizontal or vertical position.
⚠ Only approved methods	**WARNING** Reproc-w6 Not all reprocessing methods described in this user guide are applicable to all BK's different devices. Please refer to the section "Appendix: Reprocessing information and tables" for a complete overview for each device. BK device materials are not suitable to be processed in automated washer-disinfection processes, except for those devices stated as approved for automated disinfection using Advantages Plus from Medivators. To prevent risk for the patient and damage to the device, use only recommended reprocessing methods.
⚠ Neurosurgical covers	**WARNING** TC-w2 For neurosurgical applications, 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, they must be licensed by Health Canada.

⚠	**WARNING** TC-w7 Use only approved non-pyrogenic, sterile transducer covers. This means that in the USA they must be market cleared by the FDA and in Europe they must be CE-marked. In Canada, they must be licensed by Health Canada.
⚠ Creutzfeldt-Jakob	**WARNING** C-J-w1 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.
⚠ Remote Control	**WARNING** RC-w1 The remote control requires surface disinfection or sterilization as a minimum. The inside battery compartment cannot be classified as disinfected or sterile. Follow procedures established for your hospital, clinic or institution to avoid cross-contamination when inserting or removing batteries.
⚠ Do not use damaged equipment	**WARNING** Check-w1 To ensure safe operation, do not use the equipment if you find any signs of damage. Contact your BK service representative. If a transducer is dropped, and even if it shows no visible signs of damage, BK recommends that you call your BK service representative. They will check the transducer and perform appropriate testing for the type of damage that has occurred.
⚠ Damaged and Reprocessing	**WARNING** Check-w2 Equipment may be damaged by use or incorrect reprocessing. It is important to check it at least once a month (or more often, if it undergoes sterilization) to ensure that it can be effectively reprocessed. If there are any pits or cracks on any equipment surfaces, reprocessing may not give a sterile or disinfected product and equipment can suffer internal damage as a result of misuse.
⚠ Check of Type BF transducers	**WARNING** Check-w3 To prevent electrical shock, all transducers with a (BF) Body Floating symbol comply with Safety Standard IEC60601-1 for leakage currents. Check the transducer once a year to ensure that this quality is met consistently throughout the transducer's lifetime. This check must be carried out only by qualified personnel. Contact your BK service representative if you need any help checking your transducers.
⚠ Contaminated items	**WARNING** D-w1 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.

Cautions

⚠ Physician required in USA	**Caution** Rx-c1 United States law restricts this device to sale by or on the order of a physician.

⚠ Heat, dust, sunlight, condensation	**Caution** S-c1 To prevent damage to the system, avoid excessive heat, dust and direct sunlight. Also do not use the system if there is visible condensation on it. Wait until it reaches room temperature.
⚠ Handle with care	**Caution** T-c1 To prevent damage, handle equipment carefully. • Don't strike or drop the transducer on a hard surface. Equipment dropped on a hard surface may not be repairable. • Don't step on a cord or run over it with the wheels of the system.
⚠ Keep plug dry	**Caution** Plug-c1 To prevent damage to a transducer or system, protect the plug from contact with liquid.
⚠ Immersion: Cover plug – Lid ON	**Caution** Plug-c2 To prevent damage to the transducer, cover the plug with the watertight protection device before you immerse the transducer and plug in liquid.
⚠ Keyboard panel not watertight	**Caution** S-c2 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.
⚠ Gas Processing: Do not cover plug - Lid OFF	**Caution** Plug-c3 Do NOT use a watertight protection device with any form of gas processing. The transducer can be seriously damaged if a watertight protection device is used.
⚠ Do not autoclave transducers	**Caution** Reproc-c2 Never autoclave the transducers or remote control; this will damage them.
⚠ Examine plug and waterproof protection for damage	**Caution** Plug-c4 Before you reprocess the transducer, inspect the watertight protection device and the transducer plug. If you find any signs of damage, do not immerse the plug. If liquid comes into contact with the plug connector pins, the transducer may be destroyed. Examine the edges of the plug case that contact the lid and also the watertight protection device for cracks and marks. Examine the rubber seal of the plug lid. Look for deep scratches and grooves, holes or tears, brittleness, and looseness anywhere. The transducer or watertight protection device must be checked by a BK service representative if you find signs of damage.

⚠ Test for leaks before immersing	**Caution** Test-c1 You should use the leakage tester to test for leaks. If a transducer is not completely watertight, immersing it can seriously damage it.
⚠ Keep watertight plug lid dry	**Caution** Test-c4 Do not let the watertight plug lid get wet during the testing procedure. Keep it out of the tank. If water gets inside the watertight plug lid, moisture can be transferred from the lid to the plug connector pins during reprocessing. This can damage the transducer.
⚠ Do not immerse if pressure drops	**Caution** Test-c3 If the pressure drops to zero after you use the pump, do not place the transducer in the tank.
⚠ If you see bubbles, do not release pressure	**Caution** Test-c5 If you see any bubbles, remove the transducer from the tank before you release the pressure.
⚠ Do not use test lid for reprocessing	**Caution** Test-c2 The lid part of the leakage tester is for testing only. Do not use it when you reprocess the transducer.
⚠	**Caution:** T-c5 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.

Chapter 2: Markings on the Systems, Transducers and Accessories

Safety Symbols and Information on the Equipment

Table 1 contains brief explanations of the symbols and information used to label the equipment. (Some labels in the table may appear on the transducer.)

The manufacturer disclaims all responsibility for the operating safety, reliability, and performance of the equipment if these symbols and warnings are disregarded in any way.

Table 1 Markings on the system, transducers and accessories.

Symbol	Name	Description
CE 2460	CE Mark	The device complies with all required EU regulations and directives. The four digit number identifies the notified body.
MD	Medical Device	Device used for medical purpose.
Rx	Rx only	Federal (U.S.A) law restricts sale of this device to physicians or other qualified medical professionals.
	Manufacturer	Indicates the medical device manufacturer.
	Caution	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.
	Follow instructions for use	Read the user guide or other instructions for important safety warnings.
	Control of pollution	Environmentally Friendly Use Period for ROHS is 25 years.
	China Recycle	Corrugated cardboard for recycling.

Table 1 Markings on the system, transducers and accessories.

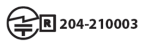
	Crossed out wheeled bin	Within the EU, when you discard waste of electrical and electronic equipment, you must send it to appropriate facilities for recovery and recycling.
	ESD (electrostatic discharge)	Do not touch pins in connectors with this symbol unless you follow ESD precautionary procedures.
	Specified Radio Equipment	(On remote control UA2361). This equipment conforms to Japanese Radio Law regulations concerning frequency and power.
	Catalog number	For BK Medical, this is the "Type number" of a product.
	Serial number	Manufacturer's serial number for the specific device.
	Batch code	Manufacturer's batch or lot number for a product.
	Type BF	BF: Isolated from ground. (Used on transducers.) Maximum patient leakage current under • Normal condition ≤100µA • Single-fault condition ≤ 500µA
	Type BF	BF, defibrillator-proof.
	Type B	B: Non- isolated from ground. (Used on transducers.) Maximum patient leakage current under. • Normal condition ≤100µA • Single-fault condition ≤ 500µA
IP57	Ingress protection	(On remote control.) Protected against immersion up to 1 m. Dust-protected.
	Handle with care	The tip of the transducer is very delicate. Be very careful not to bump the tip.
	Do not re-use	Single-use device. Do not try to process for reuse. Reuse can result in cross-contamination or can compromise the function of the product.

Table 1 Markings on the system, transducers and accessories.

	Warning: Do not push	Instability during transport. Do not use excessive force to push the system. Excessive force when pushing over uneven surfaces can cause the system to overbalance and tip.
	Warning: Keep hands clear	Show caution when you adjust the system monitor.
	Maximum weight for system with accessories	Safe working load. The weight in kilos of the system including transducers.
	STERILE	Device is in a sterile condition.
	Sterilized using ethylene oxide.	Device has been sterilized using ethylene oxide.
	Do not resterilize	Do not resterilize. Resterilization can cause degradation of the materials and compromise the function of the product.
	Non-sterile	Device is not in a sterile condition.
	Contains latex.	Contains natural rubber latex or latex is present.
	Not made with natural rubber latex	Not made with natural rubber latex.
	Do not use if package or label is damaged	Do not use if product sterilization barrier or its packaging is compromised.
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	Transport dry	Packing material indication.Indicates a medical device that needs to be protected from moisture.

Table 1 Markings on the system, transducers and accessories.

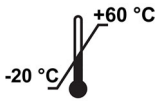
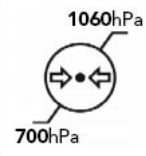
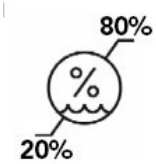
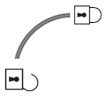
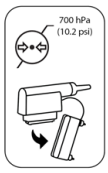
	Keep away from sunlight	Packing material indication.Indicates a medical device that needs to be protected from light sources.
	Tip N Tell	Tilt indicators. Note: Different models shown
	Do not stack	Indicates a medical device that should not be stacked.
	This way up	Indicates transport orientation.
	Temperature limit	Storage and transport temperature: -20 °C to +60 °C Packing material indication. Keep temperature between the upper and lower limits listed (-20 °C to +60 °C)
	Atmospheric pressure limitation	Storage and transport atmospheric pressure: 700 hPa to1060 hPa Packing material indication. Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Humidity limitation	Storage and transport humidity: 20% to 80%. Packing material indication. Keep relative humidity between the upper and lower limits listed.
	Quantity	The quantity of items contained in the package appears next to the symbol.
	Date of manufacture	Symbol always accompanied by the date device was manufactured (4 digits for year, 2 digits for month, and 2 digits for day).
	Use-by date	Last date on which a marked item can be used: expiration date (4 digits for year, 2 digits for month, and 2 digits for day).

Table 1 Markings on the system, transducers and accessories.

	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.
	Battery direction	Indicates battery direction AA LR6 1.5V
	Lock-Unlock	On the watertight plug lid, indicating the locked and unlocked position for the locking pins that hold the lid onto the plug.
	Immersion reprocessing – lid must be on	Watertight plug lid must be attached during immersion.
	Gas reprocessing – lid must be off	Watertight plug lid must not be attached during gas reprocessing or whenever pressure is below 700 hPa (10.2 psi).

Chapter 3: Introduction & Safety

Introduction

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

Follow established procedures

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

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.

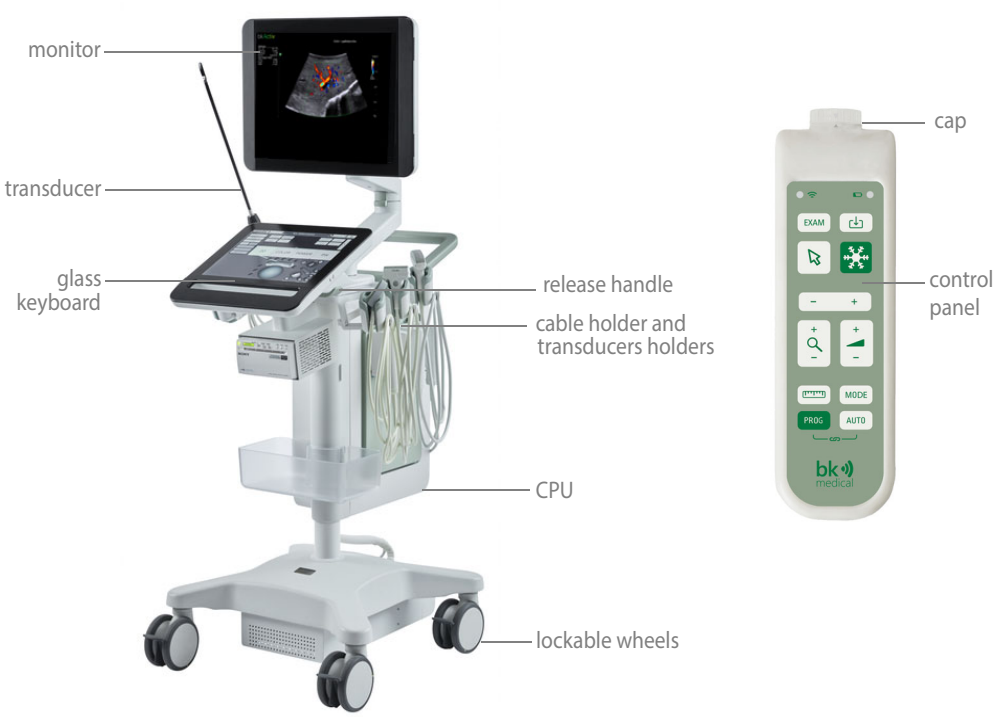
NOTE: *Notes contain other information that you should be aware of.*

Please find a complete list of warnings and cautions starting on page 6.

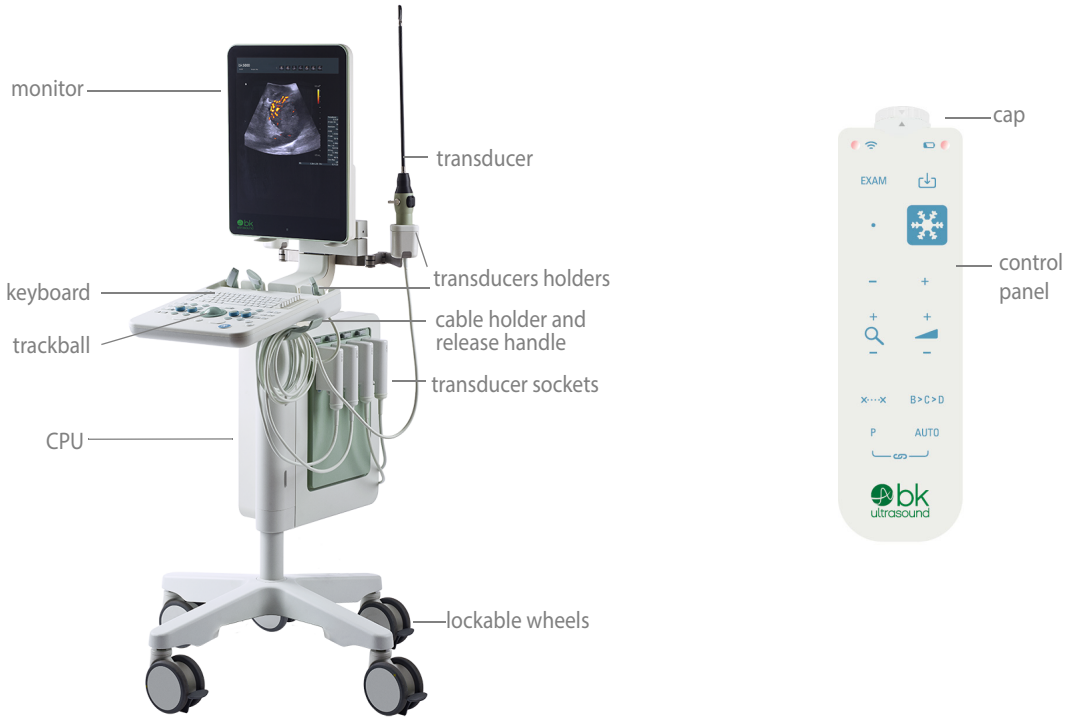
General Safety

⚠ Physician required in USA	**Caution** Rx-c1 Federal law in North America restricts this equipment to sale or use by or on the order of a physician.

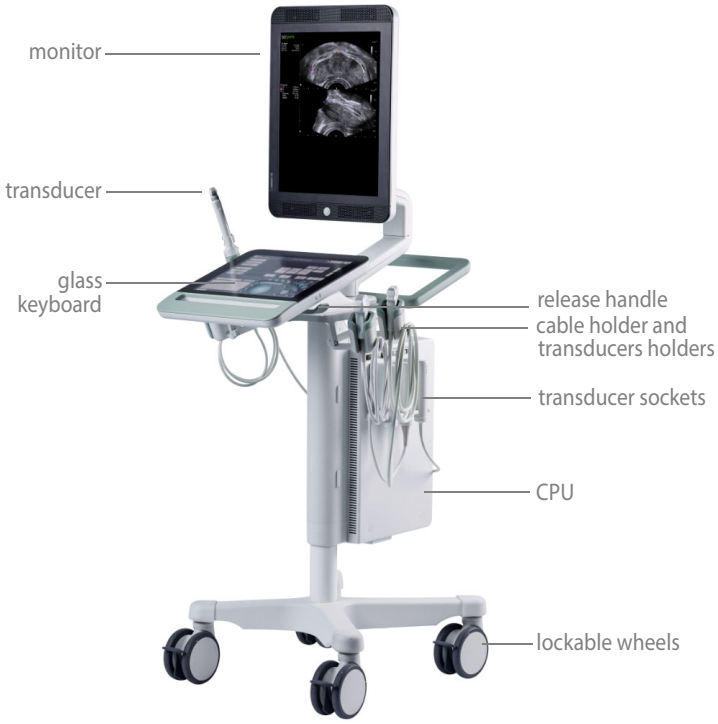
bkActiv and UA2370 Remote Control



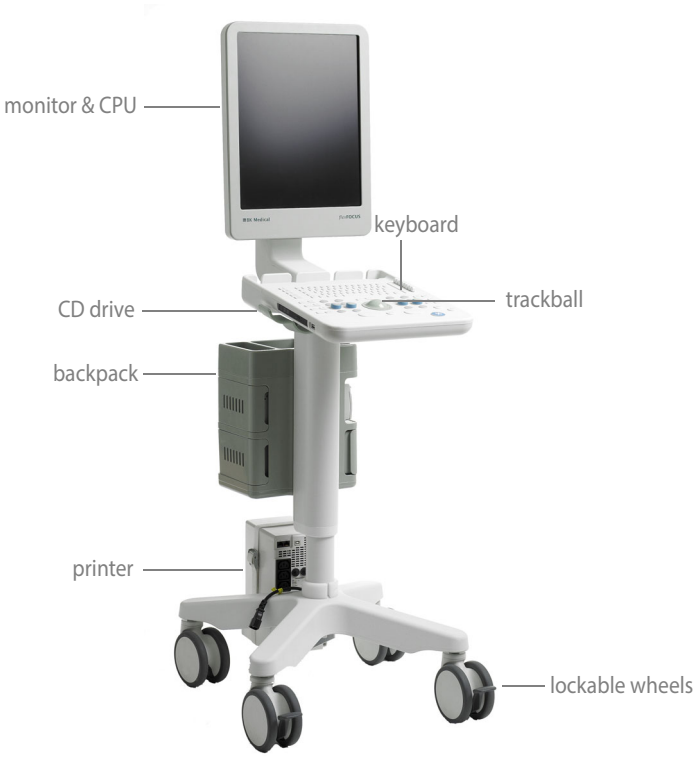
The bk3000/bk5000 and UA2361 Remote Control



bkSpecto



The Flex Focus 1202 System



Battery-Powered Systems

The BK battery-powered systems are equipped with high capacity lithium batteries.

General Recommendations for Battery-Powered Systems

BK recommends that health care professionals and health care facilities take the following steps to help reduce the potential for injury to patients, staff and visitors:

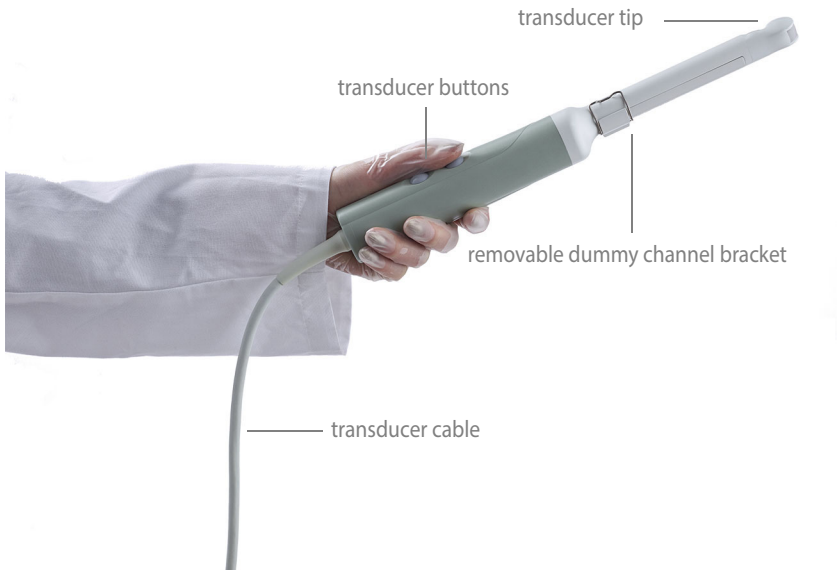
- Do not block any vents.
- Do not tape or attach any object or material to the battery compartment.
- Keep flammable and explosive objects away from battery-powered systems.
- When systems are not in use, but charging, make certain the these systems are located in easily visible, fire retardant, non-confined locations away from patient care areas and open sources of oxygen.
- Do not use batteries that do not charge properly. Ensure that batteries are replaced at the recommended replacement intervals. A caution will be displayed on the screen.
- Preventative maintenance information can be found in Chapter 5.
- Notify your BK service representative of damaged batteries.

The FDA has received medical device reports of health hazards associated with batteries used in mobile medical carts and their chargers. These events, which range from smoke production and overheating to equipment fires, can occur with lithium batteries. Note that lithium battery fires are very difficult to extinguish.

In such cases,

- Immediately report the fire according to your hospital protocol. Follow hospital protocol for addressing an energized electrical fire.
- Do not touch the battery.
- Unplug or power off the system if it is safe to do so.
- Remove the system from patient and visitor areas, as safely as possible.

BK Transducers (E14C4t as an example)



Care and Maintenance

⚠ Handle with care	**Caution** T-c1 To prevent damage, handle equipment carefully. • Don't strike or drop the transducer on a hard surface. Equipment dropped on a hard surface may not be repairable. • Don't step on a cord or run over it with the wheels of the system.

⚠ Keep plug dry	**WARNING** T-w5 To prevent electrical shock and damage to the transducer, the connector pins in the transducer plug must always be completely dry before you connect to a system.

Inspection

All transducers, 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 “Chapter 5: Checking and Maintaining Ultrasound Equipment”.

Service and Repair

If for any reason you must return a transducer to BK Medical, please clean as for storage (if possible). If the transducer is damaged and cannot be reprocessed, clean using disinfection wipes (following the manufacturer’s guidelines) prior to packing and shipping.

Storing Devices When Not in Use

Ensure that the device does not get damaged while in storage.

For transducers, this can be achieved by using a tray with fittings to hold the transducer and the system connector in place (see "Overview of InstruSafe Instrument Protection Trays for BK Devices" on page 77).

If using a container with foam (such as the box the transducer was supplied in), avoid contaminating the foam by ensuring that the transducer is clean, disinfected and dry before placing it in the case. Always reprocess the transducer prior to use.

⚠ Transducer, holder and container must be clean	**WARNING** Reproc-w1 To avoid contamination, clean transducers before inserting them into storage containers for transportation. To avoid cross-contamination, make sure that transducer holders and storage containers are clean before inserting clean transducers.

General Storage Conditions

- All devices must at least be thoroughly cleaned and thoroughly dried prior to storage
- Devices must be organized in such way that they cannot damage one another
- Devices must be stored in a way that maintains the reprocessing level (e.g. sterile, high-level disinfected), or else it must be reprocessed again prior to use. Follow the local/national guidelines
- Devices must be stored in a dark, dry, clean and dust-free place
- Avoid major temperature fluctuations to prevent the accumulation of moisture on the device surfaces
- Keep the device protected at all times from sharp objects that may damage the device or packaging
- Do not store devices together with or nearby chemicals, as there might be corrosive vapors
- Keep the device protected from sharp objects that may damage the device or packaging
- The watertight connector lid should not be left on for an extended storage period

See temperature and humidity limits for devices on page 24.

Transportation

- In order to prevent damage to the transducer head, lens or connector, use a rigid tray with a lid and internal fittings that keep the transducer and the system connector in place
- Place the transducer in the tray carefully to prevent kinking of the cable
- Before closing the lid, make sure that no part of the transducer is protruding from the tray
- Wrap the tray in plastic material containing air pockets (such as Bubble Wrap), and pack the wrapped tray in a cardboard carton

If using a container with foam (such as the box the transducer was supplied in), avoid contaminating the foam by ensuring that the transducer is clean, disinfected and dry before placing it in the case.

Transducer Holders

Transducer holders can be used for short-term storage of non-critical transducer types, e.g. linear and curvilinear probes. The transducer holders on the system should be cleaned regularly following local guidelines. Semi-critical and critical transducer types, e.g. endocavity and surgical, should be stored in appropriate containers to maintain their level of reprocessing.

Operating and Storage Environment

Systems

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

Table 2 Environmental limits for systems.

	Maximum	Minimum
Storage temperature	+60°C (+140°F)	-20°C (-4°F)
Operating temperature	+40°C (+104°F)	+10°C (+50°F)
Atmospheric pressure	1060 hPa (15.4 psi)	700 hPa (10.2 psi)
Humidity	80% RH	20% RH

⚠ Heat, dust, sunlight, conden-sation	**Caution** S-c1 To prevent damage to the system, avoid excessive heat, dust and direct sunlight. Also do not use the system if there is visible condensation on it. Wait until it reaches room temperature.

Transducers

Table 3 shows the environmental limits for transducers (and remote controls) during operation and storage.

Table 3 Environmental limits for transducers.

	Maximum	Minimum
Storage temperature for: T7P2m	+55°C (+131°F)	-25°C (-13°F)
Storage temperature for: all other transducers	+70°C (+158°F)	-25°C (-13°F)
Storage humidity	90% RH	
Operating temperature	+40°C (+104°F)	+10°C (+50°F)
Operating pressure	1060 hPa (15.4 psi)	700 hPa (10.2 psi)
Temperature during reprocessing for: T7P2m	+55°C (+131°F)[a]	NA (not applicable)
Temperature during reprocessing for: all other transducers	+60°C (+140°F)[a]	NA (not applicable)
Pressure during gas processing for: 2052, 8838, 20R3	NA	500 hPa (7.3 psi)
Pressure during gas processing	NA	100 hPa (1.5 psi)

a. Max rate of temperature increase: 15°C/min (27°F/min)

Accessories

For single-use accessories, follow guidelines for proper storage and handling, as shown by symbols on package label.

Covers

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 and vaginal imaging.
- Follow the procedures that have been established for your hospital, clinic or institution for covers used in conjunction with puncture procedures.

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). In Europe, transducer sheaths must be CE-marked.*

Sterile Covers

BK Medical supplies a range of sterile single-use transducer covers. See the transducer Product Data sheet for appropriate covers for your transducer.

Follow these precautions when putting sterile covers on a transducer:

- Wear sterile gloves.
- When using a puncture attachment, place it gently over the cover and secure it, following the instructions for the puncture attachment (found in 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.

⚠	**WARNING** TC-w7 Use only approved non-pyrogenic, sterile transducer covers. This means that in the USA they must be market cleared by the FDA and in Europe they must be CE-marked. In Canada, they must be licensed by Health Canada.

Neurosurgical Applications

Special considerations apply to transducer covers for neurosurgical applications.

⚠ Neurosurgical covers	**WARNING** TC-w2 For neurosurgical applications, 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, they must be licensed by Health Canada.

Using Sterile Covers on a System

Sterile covers may be used on systems and system accessories (for example, bkFusion hardware) according to local guidelines and standards. It is important that any cover you use on the system does not affect the readability of the monitor and does not interfere with the touch functionality of the screen or keyboard. Test covers *before* using them during surgical procedures.

Chapter 4: Reprocessing Information and Methods

Personnel must be trained

Personnel in Sterile Processing Departments, as well as nurses, physicians, sonographers and others, may be responsible for reprocessing medical devices. Anyone who reprocesses medical devices should be thoroughly trained in the proper local procedures.[1]

Infection control – follow established procedures

WARNING Reproc-w2

Users of this equipment have an obligation and responsibility to provide the highest possible degree of infection control to patients, co-workers and themselves. The instructions in this book are meant as a guide. To avoid cross-contamination, follow all infection control policies (including for reprocessing, packing and storage) for personnel and equipment that have been established for your office, department or hospital.

Creutzfeldt-Jakob

WARNING C-J-w1

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.

General Information

NOTE*: Reprocessing methods are harsh and can shorten the life of the equipment. Equipment that undergoes reprocessing should be checked regularly. See "Chapter 5: Checking and Maintaining Ultrasound Equipment" on page 49.*

Use the same chemistry each time

BK Medical recommends using the same reprocessing chemistry each time to minimize material degradation caused by chemical interactions from various cleaning, disinfection and sterilization processes.

Reprocessing may cause cosmetic changes to the device material that do not necessarily impact the functionality of the device. The most usual cosmetic changes are color changes in the device materials.

Keep plug dry

WARNING T-w5

To prevent electrical shock and damage to the transducer, the connector pins in the transducer plug must always be completely dry before you connect to a system.

Damage and reprocessing

WARNING Check-w2

Equipment may be damaged by use or incorrect reprocessing. It is important to check it at least once a month (or more often, if it undergoes sterilization) to ensure that it can be effectively reprocessed. If there are any pits or cracks on any equipment surfaces, reprocessing may not give a sterile or disinfected product and equipment can suffer internal damage as a result of misuse.

1. BK Medical does not provide reprocessing training.

Levels of Reprocessing

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

The CDC (Centers for Disease Control and Prevention) in the USA and the RKI (Robert Koch Institute) in Germany classify medical devices according to their use. For each classification, they specify the level of disinfection/sterilization processing that is required before use. Table 4 summarizes this information.

Table 4 Levels of reprocessing based on device use.

Device Classification	Use	Required Reprocessing
Noncritical	Device contacts intact skin	Cleaning and disinfection
Semi-critical	Device contacts mucous membranes (for example, endocavity applications)	Immediate cleaning and disinfection (in the USA, high-level disinfection or sterilization)
Critical	Device enters otherwise sterile tissue (for example, intraoperative applications) Device contacts otherwise sterile tissue (for example, to take a biopsy)	Immediate cleaning and sterilization (In some regions: Cleaning, disinfection and sterilization)

General Precautions

For all types of reprocessing, be sure to observe the environmental limits in Table 3 on page 25. If these limits are exceeded, the transducer may be damaged:

⚠ Automated cleaning and disinfection	**WARNING** Reproc-w6 BK device materials are not suitable to be processed with automated washer-disinfector processes, except for those devices stated as approved for automated disinfection using Advantages Plus from Medivators. To prevent damage to the device and risk for the patient, use only reprocessing methods recommended by BK Medical.

Device-specific methods are listed in the reprocessing tables starting on page 66.

If all parts of the complete device are not reprocessed with the same reprocessing steps at the same time, care should be taken not to cross-contaminate the parts of the device, which have already been reprocessed. Some BK transducers are not fully immersible, as the connector cannot be immersed. These parts are therefore to be reprocessed with a wiping method only, and care must be taken to avoid cross-contamination.

Protecting Transducer Plugs during Immersion

⚠ Keep plug dry	**Caution** Plug-c1 To prevent damage to a transducer or system, 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. The transducer must be made watertight.

⚠ Immersion: Cover plug – Lid ON	**Caution** Plug-c2 To prevent damage to the transducer, cover the plug with the watertight protection device before you immerse the transducer and plug in liquid.

Reprocessing Transducers

Proper cleaning is essential to the success of any disinfection or sterilization procedure. Transducers must be cleaned immediately after use and before disinfection and/or sterilization.

⚠ Pre-clean immediately after use	**WARNING** Reproc-w3 Immediately after use, you must pre-clean the device until visually clean (including any lumens). Conduct the thorough cleaning process as soon as possible after use in order to prevent soil drying on the surface. Dried soil can lead to inefficient cleaning, disinfection and sterilization, causing a risk of cross-contamination.

Before cleaning transducers, always remove covers, accessories and attachments, including dummy attachments. Then clean the transducer and reusable attachments thoroughly. See the cleaning steps listed in the following pages.

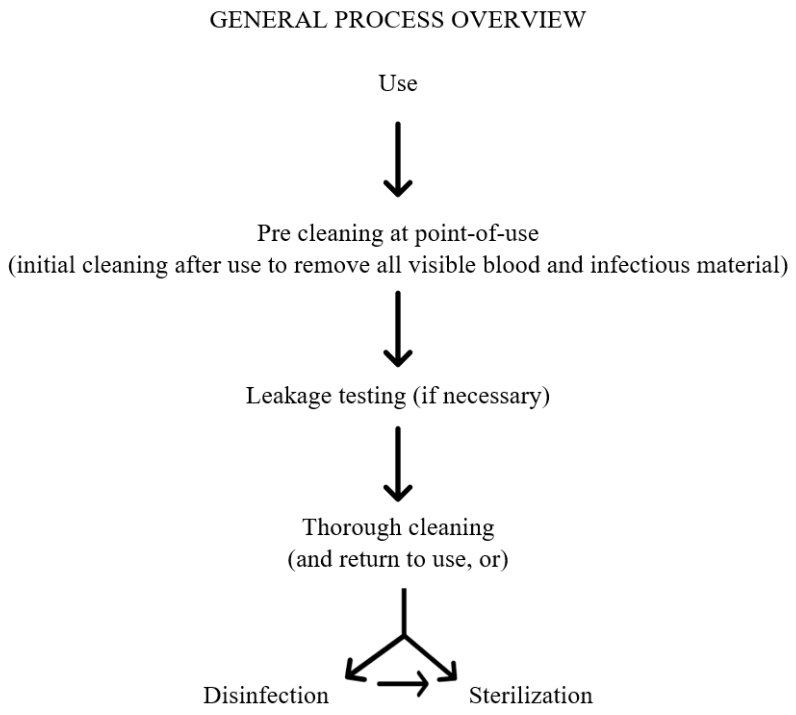


Figure 1. Overview of reprocessing steps. The level of reprocessing required depends on the device classification and the local regulations.

The general cleaning process should include the following overall steps, performed as efficiently as possible. You must also follow your local and/or national guidelines.

1. Pre-cleaning at point of use.
2. Leakage testing.
3. Thorough cleaning including rinsing.
4. Disinfection and/or sterilization (Some countries require disinfection prior to sterilization).

Pre-Cleaning (Point-of-Use Processing)

NOTE: *Some transducers are extremely delicate and require handling with extra care during reprocessing. See "Extra Information for Cleaning the Transducer N20P6" on page 35.*

For pre-cleaning of transducers, follow your local and/or national guidelines.

NOTE: *If you are pre-cleaning a transducer and immersing or rinsing it in step 2, 3 and/or 4, test the transducer for leakage after you unplug it and before you put it in liquid (immersion or rinsing with running water). The leakage testing procedure is described on page 54.*

Procedure for pre-cleaning:

1. Unplug the transducer from the system.
2. Immediately remove any cover, puncture guides or other attachments and disassemble all parts.

3 Moisten a clean, soft, non-abrasive cloth, gauze, or sponge with water or detergent solution. If you use a detergent solution, the solution must be made according to the detergent manufacturer's instructions.

4 Use the moistened cloth, gauze or sponge to wipe off any gel or biological material. Remove all visible contamination.

Note that the cloth or sponge should be disposed of, sterilized, or high-level disinfected after each use.

5 If the device has a lumen, make sure that you brush it with a moistened brush (brush size compatible with the lumen) until the lumen is visually clean.

6 If you have used a detergent solution, follow the manufacturers instructions regarding rinsing and wiping.

7 If transportation is required, transport the pre-cleaned transducer to the reprocessing area in a closed container that prevents exposure of staff, patients, or the environment to potentially infectious materials. Containers, sinks, and basins should be large enough that the transducer will not be damaged.

Leakage Testing

For a full description of the leakage tester, see “Leakage Testing Procedure” on page 54.

Thorough cleaning

Validated detergents are listed in the tables starting on page 63. Dilute and use according to the detergent manufacturer's instructions.

NOTE: *Some transducers are extremely delicate and require handling with extra care during reprocessing.See “Extra Information for Cleaning the Transducer N20P6” on page 35.*

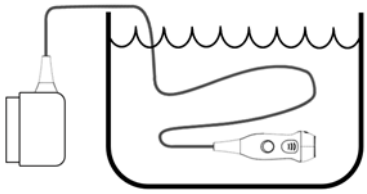
Manual cleaning by Immersion

Procedure for Thorough cleaning by immersion:

1 Fill a sink or bowl with freshly-made detergent solution.

2 Immerse the transducer and, if possible, the cable and plug. Make sure that the watertight plug lid is attached correctly and the transducer has been tested for leakage. See “Leakage Testing Procedure” on page 54.

NOTE: Some transducer types are not provided with a plug lid, and therefore the connector must not be immersed.



See “Transducers Excluded from Leakage Testing” on page 53.

NOTE: *To prevent the splashing of contaminated fluid and aerosolization of bioburden, the device should be submerged in the detergent solution when you perform all subsequent cleaning steps.*

3 Use a soft, non-abrasive brush (for example, a surgical nail brush) to thoroughly clean all parts of the transducer, paying special attention to the tip, any lumens, buttons, lever, edges or grooves.

4 To clean transducer lumens, use a brush appropriate to the size of the lumen. Brush the lumen thoroughly with a circular movement for about 10 seconds (at least three times); make sure that all inner surfaces of the lumen have been brushed. Repeat from the other end of the lumen. After each passage, remove any visible debris from the brush before reinserting it.

NOTE: *When cleaning the transducer lumen, rub gently with the brush to avoid causing damage.*

5 Flush all channels with the detergent solution to remove debris. If any debris is noted in the flushing solution repeat the previous step.

6 Continue soaking the transducer and any internal lumens until the total detergent contact time specified by the manufacturer is reached.

7 Visually inspect for any remaining soil and if necessary repeat the steps, starting at step 3.

8 Make sure to follow the rinse (and neutralization) instructions from the detergent manufacturer for rinsing the device and all removable parts.

If insufficient instructions are supplied, then, as a minimum, thoroughly rinse the device and all removable parts with running water (preferably deionized or distilled or RO water (purified by reverse osmosis)) with a flow rate of approximately 2 l/min and a temperature of 10-40 °C (50-104 °F) until all signs of residual debris and cleaning solution are removed (for approximately 1 min).

Ensure that any lumens, buttons, lever, edges or grooves are thoroughly rinsed and that the lumen is flushed with water at least 2 times.

9 Dry the transducer thoroughly. Remove water from all exterior surfaces using a clean disposable soft lint-free cloth. Also, remove water from all lumens using a clean disposable soft, lint-free cloth or swab. If a drying cabinet is used, the temperature must not exceed 60 °C (140 °F).

The transducer is now ready for disinfection or sterilization.

Manual cleaning by Wiping

For thorough cleaning by wiping, follow wipe manufacturer's instructions. Make sure to clean all surfaces and comply with the prescribed contact time. Many devices have different features (e.g. lumens, corners, cavities, etc.) that render wiping methods inadequate. It is important to evaluate on each device whether or not wiping can ensure an efficient result before choosing to use a wiping method.

Manual Disinfection

NOTE: *Some transducers are extremely delicate and require handling with extra care during reprocessing.See "Extra Information for Cleaning the Transducer N20P6" on page 35.*

Before you disinfect a transducer, it must be thoroughly cleaned. This includes being pre-cleaned at point of use and then cleaned, rinsed and dried. See "Pre-Cleaning (Point-of-Use Processing)", starting on page 31, for more information. Validated and material compatible reprocessing methods are listed in the tables starting on page 63.

Manual Disinfection by Immersion

To disinfect by immersion:

1. Use a disinfectant method that has been approved (or evaluated for material compatibility) for the transducer. See "Appendix: Reprocessing Information and Tables" on page 63.
2. Follow the disinfectant manufacturer's instructions for procedure and immersion times.

   Make sure that the solution passes through any built-in lumens or grooves. If necessary, use a suitable brush to make sure there are no air bubbles in the channel.
3. If specified by the disinfectant manufacturer, rinse off the disinfectant thoroughly with water (preferably deionized or distilled or RO (purified by reverse osmosis) water) with a temperature between 10 °C (50 °F) and 40 °C (104 °F), thoroughly flushing any channels. Follow the disinfectant manufacturer's instructions for procedure and volume of water.

   For high-level disinfectants, the water should be sterile, and you should wear sterile gloves.
4. Dry the transducer thoroughly. Remove water from all exterior surfaces using a clean disposable soft lint-free cloth. Also, remove water from all lumens using a clean disposable soft, lint-free cloth or swab. For high level disinfection, the cloth and the swab need to be sterile. If a drying cabinet is used, the temperature must not exceed 60 °C (140 °F).
5. Examine the transducer and the cable and connector for signs of damage.

Manual Disinfection by Wiping

For manual disinfection by wiping, follow the wipe manufacturer's instructions. Make sure to disinfect all surfaces and comply with the prescribed contact time. Many transducers have different features (e.g. lumens, corners, cavities, etc.) that render wiping methods inadequate. It is important to evaluate each device as to whether or not wiping can ensure an efficient result before choosing to use a wiping method.

Extra Information for Cleaning the Transducer N20P6

The coated metal shaft on the N20P6 transducer may be damaged or deteriorated during reprocessing, therefore it is always required that extra care is taken during cleaning and handling. Use only a moistened soft cloth or soft sponge when cleaning the metal shaft.
Additional points to note when reprocessing the N20P6:

- Alway place the transducer in the silicone fittings in the tray. Be careful that the metal shaft and the lens do not touch or scrape the tray when placing or removing the transducer.
- There should not be other items in the tray with the transducer.
- There should not be other items in the sink with the transducer.
- Use a sponge or a soft brush to clean the transducer handle.
- Do not use automated dryers or drying cabinets.

NOTE *Always use cloths, sponges, and brushes that are clean, soft and non-abrasive.*

Reprocessing Accessories

All reusable accessories; e.g. biopsy guides, clamps, puncture attachments and the dummy attachments will require reprocessing before use, according to the intended use for the accessory. The required processing level is defined in table 4, page 29 and includes pre-cleaning, cleaning and disinfection, and disinfection and/or sterilization.

Proper cleaning is essential to the success of any disinfection or sterilization procedure. Accessories must be cleaned immediately after use and before disinfection or sterilization.

Reprocessing information, precautions, and levels of reprocessing described for transducers are also relevant for accessories. Reprocessing steps are described from page 35. Recommended reprocessing methods are shown on page 75

Unless this guide contains alternative instructions, follow the accessory manufacturer's instructions for cleaning and disinfecting any accessories such as movers and steppers and brachy matrices.

For reprocessing of accessories, follow your local and/or national guidelines.

Pre-Cleaning Accessories

1 Before cleaning, always detach the accessory from the transducer and disassemble as much as possible so each part can be reprocessed separately.

2 Pre-clean immediately at point-of-use to prevent drying prior to thorough cleaning.

3 Moisten a clean, soft, non-abrasive cloth, gauze, or sponge with water or detergent solution. If you use a detergent solution, the solution must be made according to the detergent manufacturer's instructions.

4 Use the moistened cloth, gauze or sponge to wipe off any gel or biological material. Remove all visible contamination.

5 If the accessory has lumens, edges, or grooves, ensure these are cleaned with a moistened brush until they are visually clean.

6 If a detergent solution is used, follow the manufacturer’s instructions regarding rinsing.

Cleaning Accessories

The recommended reprocessing methods are shown on page 75.

1 Fill a sink or bowl with freshly-made detergent solution, following detergent manufacturer’s guidelines. The temperature of the solution should be between 10 °C (50 °F) and 40 °C (104 °F).

2 Immerse accessories and clean all surfaces with a suitable soft brush or sponge.

3 If the accessories have lumens, edges or grooves, use a brush. Ensure that the size of the brush is compatible with the lumen. Clean the lumen thoroughly with a moistened brush using circular movements for about 10 seconds (at least three times), and make sure that all the inner surfaces of the lumen have been brushed. Repeat this starting from the other end of the lumen until it is visually clean.

4 Rinse thoroughly with running water (preferably deionized or distilled or RO water (purified by reverse osmosis)) at a temperature between 10 °C (50 °F) and 40 °C (104 °F), until all signs of residual debris and cleaning solution are removed. Follow the detergent manufacturer’s rinse (and neutralization) instructions.

5 Visually inspect for any remaining soil and repeat steps starting at step 2, if necessary.

6 Dry thoroughly. Remove water from all exterior surfaces with a clean disposable soft lint-free cloth. Also remove water from all lumens using a clean disposable soft lint-free cloth or swab.

7 Examine the accessory for signs of damage.

The accessory is now ready for disinfection or sterilization.

Disinfecting Accessories

The cleaning steps need to be carried out prior to disinfection. The recommended reprocessing methods are shown on page 75.

1 Follow the disinfectant manufacturer’s instructions for procedure and immersion times. Make sure the solution passes through any lumens, edges or grooves. If necessary, use a suitable brush to ensure there are no air bubbles.

2. If specified by the detergent manufacturer, rinse off the detergent thoroughly with water and flush any channels thoroughly. Follow the disinfectant manufacturer's instructions for the procedure and for the volume of water. For high-level disinfectants, the water should be sterile.
3. Dry the accessories thoroughly. Remove water from all exterior surfaces with a clean disposable soft lint-free cloth. Also remove water from all lumens using a clean disposable soft lint-free cloth or swab. For high-level disinfection the cloth and the swab need to be sterile.
4. Examine the accessory for signs of damage.

Sterilizing Accessories

After the accessory has been cleaned and/or disinfected, most accessories can be sterilized. Recommended sterilization methods are shown on page 75. Follow the manufacturer's instructions for the procedure.

Specific Requirements for Accessories

Reusable Water Standoff System for Anorectal 3D Transducer and 20R3 Transducer

The following parts of the water standoff system must be cleaned as described in "Reprocessing Accessories" on page 35:

- water standoff collar (UA0671)
- rectosigmoidoscope and obturator (UA0672 or UA0673)
- O-rings (UA0674)

The water standoff collar, O-rings, rectosigmoidoscope and obturator can be autoclaved.

NOTE: *Separate the O-rings from the water standoff collar before cleaning and disinfecting as well as before autoclaving.*

Magnetic Wheel Mover UA0513

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

Cleaning and Disinfecting the System

Precautions

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

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

⚠ Keyboard panel not watertight	**Caution** S-c2 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.

Always turn off the system power before cleaning. If possible, disconnect or unplug the power cord.

Follow the manufacturer's instructions for any cleaning and disinfection products you use.

Cleaning the System

See a list of validated and material compatible system cleaning products on page 66.

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

To clean the system cabinet (including battery compartment):

1. If your system has a hand rest, remove it and reprocess it separately. You can also remove transducer holders and the gel holder for reprocessing.
2. Use a soft non-abrasive cloth moistened with a mild, general purpose, non-abrasive detergent solution - or use a wipe product manufactured for this purpose. For more information, see "Reprocessing Methods for bkActiv/bk3000/bk5000/bkSpecto and Flex Focus Systems" on page 66, or see the system Product Data sheet.
3. Wipe the system.
4. If necessary, use a damp cloth to remove any detergent residue.
5. Wipe dry with a lint-free cloth.
6. The trackball can also be removed for cleaning. See below.

To clean the monitor and/or touch screen:

1. Use a soft cloth and, if necessary, a product listed in the system Product Data sheet.
2. Gently wipe the monitor face/touch screen.

   Make sure not to scratch the monitor/touch screen.

To clean the control panel:

1. Moisten a soft, non-abrasive cloth with a mild, general purpose, non-abrasive detergent solution - or use a wipe product manufactured for this purpose.
2. Wipe the control panel.
3. Use a cotton swab to clean around keys or controls. Use a toothpick to gently remove solids from between keys and controls.

When cleaning the operator control panel, make sure not to spill or spray any liquid on the controls, into the system cabinet, or in the transducer sockets.

To clean the trackball:

The trackball can be removed completely for cleaning and disinfection.

- To remove the trackball, rotate the ring around the trackball counterclockwise and lift it off. Remove the trackball.
- After you replace the trackball, replace the ring and rotate it clockwise to tighten it.

Disinfecting the System

- All parts of the system, including the monitor and battery compartment, can be wiped down with validated disinfectants. For more information, see "Reprocessing Methods for Remote Controls UA2361 and UA2370" on page 76, or see the system Product Data sheet.

Reprocessing Remote Controls UA2361 and UA2370

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

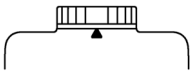
The interior of the remote cannot be cleaned and is therefore not to be considered cleaned, disinfected or sterilized. Take care when inserting batteries.

⚠ Remote Control	**WARNING** RC-w1 The remote control requires surface disinfection or sterilization as a minimum. The inside battery compartment cannot be classified as disinfected or sterile. Follow procedures established for your hospital, clinic or institution to avoid cross-contamination when inserting or removing batteries.

For validated reprocessing methods for the remote control, see "Reprocessing Methods for Remote Controls UA2361 and UA2370" on page 76.

Before cleaning or immersing in disinfectant (including STERIS SYSTEM 1 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.

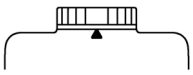


Cleaning Remote Controls UA2361 and UA2370

Proper cleaning is essential for the success of any disinfection or sterilization procedure. Equipment must be cleaned immediately after it is used and before it is disinfected or sterilized. Use a method that has been approved (or evaluated for material compatibility) for the remote control. See "Reprocessing Methods for Remote Controls UA2361 and UA2370" on page 76.

To clean remote controls (surface cleaning only):

1. 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.



2. Immediately rinse or wipe off any visible contamination (such as biological substances) with a detergent solution or water between 10 °C (50 °F) and 40 °C (104 °F), using a brush if necessary.

3 Clean with a detergent (see "Reprocessing Methods for Remote Controls UA2361 and UA2370" on page 76) and a soft-bristled nail brush (like surgeons use) or cloth to remove proteins/soil. Follow detergent manufacturer's guidelines.

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

5 Dry with a disposable cloth or air dry.

6 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 (following recommended steps above).

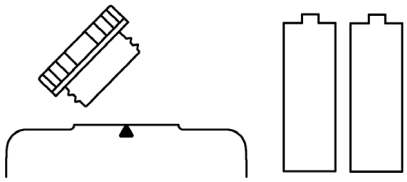
After the remote control has been cleaned, it can be disinfected or sterilized. See "Reprocessing Methods for Remote Controls UA2361 and UA2370" on page 76 for more information.
We recommend that you clean and disinfect batteries using a slightly moist wipe before sterilizing the batteries.

Before and after each processing, you must check remote controls for surface pits and cracks.

Before you put a remote control into a STERRAD or V-Pro System:

- Unscrew the cap and remove the batteries. Leave the cap off.
- Reprocess the batteries *with* the remote control and 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.*



Automated Reprocessing Methods

Proper cleaning is essential for the success of any disinfection or sterilization procedure. 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 reprocessed further.

NOTE: *The following validated automated reprocessing methods state the number of reprocessing cycles used in the validation. The validated number of cycles is not the maximum number of possible cycles for the device, unless this is specifically stated. In general, the maximum number of cycles cannot be stated, as this depends on the usage and handling of the device (e.g. use, all reprocessing steps, storage and transport). By thoroughly performing the checks described in "Chapter 5: Checking and Maintaining Ultrasound Equipment" on page 49, any signs of damage will determine the maximum number of cycles.*

Automated Endoscope Reprocessor – Medivators® Advantage Plus

High-level disinfection

Medivators® Advantage Plus is a high level disinfection reprocessing system for cleaned immersible, reusable, heat-sensitive medical devices. The reprocessing cycle includes a washing step, which in the USA has FDA clearance for pre-cleaned devices. A number of BK Medical transducers have been validated in Medivators Advantage Plus with Medivators Intercept (detergent), Medivators Rapicide PA High-Level Disinfectant and flushing with 70% isopropyl alcohol.

Number of Cycles Validated for Transducers

Medivators AER reprocessing has been validated for 100 cycles.

Recommended Cycles

- Medivators Advantage Plus Endoscope Reprocessing System: Lid on

⚠ Immersion: Cover plug – Lid ON	**Caution** Plug-c2 To prevent damage to the transducer, cover the plug with the watertight protection device before you immerse the transducer and plug in liquid.

Follow the manufacturer's instructions for using Medivators AER systems.

STERIS SYSTEM 1 Models

Liquid chemical sterilization

STERIS SYSTEM 1 models (STERIS SYSTEM 1[1], SYSTEM 1E, SYSTEM 1 PLUS[1] and SYSTEM 1 EXPRESS[1]) are low temperature systems for liquid chemical sterilization of cleaned, immersible, and reusable critical and semi-critical heat-sensitive medical devices. These processes involve immersing items in a circulated solution containing a sterilant concentrate (S40™) that contains peracetic acid, followed by rinses.

A number of BK Medical transducers have been designed to be compatible with STERIS SYSTEM 1 models. The transducer plugs must be fitted with a watertight protection device during processing with STERIS systems. See "Chapter 6: Watertight Protection Devices" on page 57.

Number of Cycles Validated

STERIS SYSTEM 1 models have been validated for 100 cycles.

Recommended Cycles

The following cycles are recommended for BK Medical devices:

1. STERIS SYSTEM 1, SYSTEM 1 Plus and SYSTEM 1 Express have not been market cleared by the FDA.

Transducers

• STERIS SYSTEM 1:	Lid on
• STERIS SYSTEM 1E:	Lid on
• STERIS SYSTEM 1 Plus:	Lid on
• STERIS SYSTEM 1 Express:	Lid on

Remote Control (surface sterilization)

• STERIS SYSTEM 1:	Batteries inside, lid on
• STERIS SYSTEM 1E:	Batteries inside, lid on
• STERIS SYSTEM 1 Plus:	Batteries inside, lid on
• STERIS SYSTEM 1 Express:	Batteries inside, lid on

Follow the manufacturer's instructions for using STERIS systems. Follow the information from the manufacturer of the system about the correct use of the tray for each version of the system 1 (can be found on www.steris.com).

STERIS Quick Connect Table:

Transducer	**SYSTEM 1** - rest of world	**SYSTEM 1E** - USA only	**SYSTEM 1 Plus & 1 Express**
8808	Quick Connect: QMC1733INT Tray: C1220S1	Quick Connect: QMC1733E Tray: C1220E	Quick Connect: QMC1733INT Tray: C1220INT

STERRAD Systems

STERRAD 100S, 200, STERRAD NX, STERRAD 100NX

Gas sterilization

STERRAD® systems use low-moisture and low-temperature hydrogen peroxide gas plasma technology to process heat- and moisture-sensitive medical devices. The systems are intended for terminal sterilization of properly cleaned, rinsed, and thoroughly dried reusable medical devices.

Number of Cycles Validated for Transducers

STERRAD system processing has been validated for 100 cycles.

Number of Cycles Validated for Remote Control

Because of material degeneration, STERRAD system processing has been validated for a maximum of 50 processing cycles for the remote control.

Recommended Cycles

The following cycles are recommended for BK Medical devices:

Transducers

STERRAD 100NX	Standard cycle	Lid off
	Express cycle	Lid off
STERRAD NX	Standard cycle	Lid off
STERRAD 100S	Short cycle	Lid off (for US: one cycle only)
STERRAD 200	Short cycle	Lid off

Remote Control (surface sterilization). Batteries and lid to be sterilized separately.

STERRAD NX and 100NX	Standard cycle	Lid off
STERRAD 100S	Short cycle	Lid off (for US: one cycle only)
STERRAD 200	Short cycle	Lid off

⚠ Gas Processing: Do not cover plug - Lid OFF	**Caution** Plug-c3 Do NOT use a watertight protection device with any form of gas processing. The transducer can be seriously damaged if a watertight protection device is used.

Follow the manufacturer's instructions for using STERRAD systems, including instructions for packaging devices before processing them. Packing used should comply with the current version of EN ISO 11607 or the local regulations.

APTIMAX trays are indicated for use in the STERRAD Sterilization System. Instrusafe trays (see "Overview of InstruSafe Instrument Protection Trays for BK Devices" on page 77) have been approved for STERRAD processing of BK devices.

NOTE: *When using a tray, ensure that no parts of the device are pressed hard against the sides of the tray.*

STERIS V-PRO Systems

V-PRO maX, V-PRO 1 Plus, V-PRO 60 and V-PRO 1

V-PRO systems use low-moisture and low-temperature vaporized hydrogen peroxide technology to process heat- and moisture-sensitive medical devices. They are intended for terminal sterilization of properly cleaned, rinsed, and thoroughly dried reusable medical devices.

A number of BK Medical transducers have been designed to be compatible with the V-PRO systems.

Recommended Cycles

The following cycles are recommended for BK Medical devices:

Transducers

V-PRO maX	Non lumen cycle or Flexible cycle	Lid off
V-PRO 1 Plus	Non lumen cycle	Lid off
V-PRO 60	Non lumen cycle	Lid off

Remote Control (batteries and lid to be sterilized separately)

V-PRO maX	Lumen cycle	Lid off
V-PRO 1 Plus	Lumen cycle	Lid off
V-PRO 60	Lumen cycle	Lid off
V-PRO 1	Standard cycle	Lid off

Number of Cycles Validated: STERIS V-PRO systems reprocessing has been validated for 100 cycles.

Gas Processing: Do not cover plug - Lid OFF	**Caution** Plug-c3 Do NOT use a watertight protection device with any form of gas processing. The transducer can be seriously damaged if a watertight protection device is used.

Follow the manufacturer's instructions for using STERIS V-PRO systems, including instructions for packaging devices before processing them.Packing used should comply with the current version of EN ISO 11607 or the local regulations.

STERIS trays no. VP0040, VP0041, VP0042, VP0043 and VP0044 have been approved for V-PRO processing of BK devices.
Instrusafe trays (see "Overview of InstruSafe Instrument Protection Trays for BK Devices" on page 77) have been approved for V-PRO processing of BK devices.

NOTE: *When using a tray, ensure that no parts of the device are pressed hard against the sides of the tray.*

STERIZONE VP4

STERIZONE® VP4 sterilizer uses vaporized hydrogen peroxide (H_2O_2) and ozone (O_3) in a multiphase process to sterilize heat-sensitive medical devices. The sterilizer is intended for terminal sterilization of properly cleaned, rinsed, and thoroughly dried reusable medical devices.

A number of BK Medical transducers have been validated to be compatible with the STERIZONE VP4 sterilizer. Please see the list on page 69 and page 70.

Recommended Cycles

The sterilizer offers a single preset sterilization cycle (Cycle 1) designed for the sterilization of a wide variety of loads.

Transducers

STERIZONE VP4	Only one possible cycle	Lid off

Number of Cycles Validated: STERIZONE VP4 processing has been validated for 100 cycles.

Gas Processing: Do not cover plug - Lid OFF	**Caution** Plug-c3 Do NOT use a watertight protection device with any form of gas processing. The transducer can be seriously damaged if a watertight protection device is used.

Follow the manufacturer's instructions for using STERIZONE VP4 systems, including instructions for packaging devices before processing them. Packing used should comply with the current version of EN ISO 11607 or the local regulations.

NOTE: *When using a tray, ensure that no parts of the device are pressed hard against the sides of the tray.*

Matachana 130LF, Webeco FA90, Webeco FA95

Low Temperature Steam Formaldehyde Systems (LTSF)

The LTSF systems are formaldehyde sterilizers using 2% formaldehyde. A number of BK Medical transducers have been designed to be compatible with these systems. Please see the list on page 69 and page 70.

Recommended Cycles

Always use the "60°C sterilization program" cycle for sterilization of approved BK Medical devices:

Transducer Sterilization:

System:	Cycle:	LTSF Valve:
Matachana 130LF	Cycle: 60°C sterilization program	EasyENDOVALVE: Matachana art.-no 76324 (or previously Webeco art.-no. 046763)
Webeco FA90	Cycle: 60°C sterilization program	
Webeco FA95	Cycle: 60°C sterilization program	

Transducer Series: Please see the list on page 69 and page 70.
Connector lid and LTSF valve must be attached during processing.

bk3000/bk5000:	BK connector lid UA1418 with Matachana art.-no 76324 valve  

Flex Focus:	BK connector lid UA1419 with Matachana art.-no 76324 valve 

Number of Cycles Validated: The LTSF systems have been validated for 100 cycles.

Prior to sterilization, attach the LTSF valve to connector lid UA1418 or UA1419. When using a sterile barrier system (e.g. wrapping), the transducer and valve must be placed into the sterile barrier system together.

After sterilization, the transducer and valve must remain wrapped for transport and storage. Immediately before use, unwrap the device, aerate the inside of connector lid by turning the screw on the valve, and unscrew the LTSF valve from the connector. Remove the connector lid and valve and place them in a protective bag.

Follow the manufacturer's instructions for using and reprocessing LTSF systems and the LTSF valve, including instructions for packaging devices before processing them. Packing used should comply with the current version of EN ISO 11607 or the local regulations.

Autoclaving

All BK Medical steel puncture attachments can be autoclaved after cleaning. (See “Reprocessing Accessories” on page 35.) Autoclaving sterilizes using steam (from water) under pressure. Other transducer accessories may be autoclavable (contact your local BK representative for information). See “Material Compatible Reprocessing Methods for Guides, Attachments and bkFusion Hardware” on page 75.

⚠ Do not autoclave transducers	**Caution** Reproc-c2 Never autoclave the transducers or remote control; this will damage them.

To sterilize steel parts by autoclaving:

Packaging for autoclaving

1 Pack all cleaned parts in a pouch suitable for steam sterilization, or in a tray with paper wrap according to the current version of EN ISO 11607 “Packaging for Terminally Sterilized Devices”, or according to local hospital procedure. Follow the pouch manufacturer’s specifications or the local regulations for how to pack and seal the pouches.

Autoclaving, parameters

2 Autoclave all parts of the puncture attachment or accessory, including reusable needles and needle guides. The suggested process parameters for sterilizing attachments 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

To sterilize non-steel parts by autoclaving:

For non-steel parts that can be autoclaved, follow the above steps, but be aware that exceeded temperatures can deform (bend) and otherwise damage the plastic parts. See page 75 for information on which non-steel parts cannot be autoclaved, and how to reprocess parts that cannot be autoclaved.

Chapter 5: Checking and Maintaining Ultrasound Equipment

Ultrasound equipment requires regular checks and maintenance. Table 5 contains a list of required checks.

NOTE: *If you find any cracks or irregularities on the transducer, please contact your local BK Medical representative.*

Table 5 Required checks of ultrasound equipment.

What to check	When to check
Transducer, connector, cable, remote control, attachments and reusable puncture guides for cracks and irregularities See: *"Check of Equipment Between Each Use" on page 50.*	Between each use
Transducer for leakage See: *"Checking the Transducer for Leakage" on page 52.*	See recommended frequency on page 52
Watertight protection device and transducer plug's waterproof gaskets and seal for cracks and marks See: *"Checking the Plug and Watertight Protection Devices Before Immersion" on page 52.*	Before immersing the transducer and/or the plug for cleaning or disinfection **OR** at least monthly (or more often in cases of heavy use)
Preventive maintenance and performance test of entire system See: *"Yearly Preventive Maintenance and Performance Test" on page 55.*	Yearly
Type BF transducers to make sure they still comply with requirements See: *"Yearly Check of Type BF Transducers" on page 56.*	

Check of Equipment Between Each Use

For reprocessing methods to be effective, external surfaces must be in good condition. Transducers (including connector, cable, remote control, attachments and reusable puncture guides) should be checked between each use for signs of damage.

How often

For critical-use and semi-critical applications, you should carry out a detailed check for damage between each use. For non-critical applications, this check can be performed daily. For a list of applications, please see the Recommended Leakage Testing Frequency table on page 53.

⚠ Damage and reprocessing	**WARNING** Check-w2 Equipment may be damaged by use or incorrect reprocessing. It is important to check it at least once a month (or more often, if it undergoes sterilization) to ensure that it can be effectively reprocessed. If there are any pits or cracks on any equipment surfaces, reprocessing may not give a sterile or disinfected product and equipment can suffer internal damage as a result of misuse.

Damage signs

Check the device for the following signs of damage. (Some checks are only relevant for some types of devices as e.g. transducers).

- Pits or cracks anywhere
- Deep scratches on any surfaces
- Visual damages in bond lines on the device
- 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 or cable bonding around the cable flex relief
- Deformation or other damage (might be caused by excessive heat, e.g. autoclaving)
- Blistering on the surface of the remote control

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*

NOTE: *Use good light and a magnifier when checking the transducer*

⚠ Do not use damaged equipment	**WARNING** Check-w1 To ensure safe operation, do not use the equipment if you find any signs of damage. Contact your BK service representative. If a transducer is dropped, and even if it shows no visible signs of damage, BK recommends that you call your BK service representative. They will check the transducer and perform appropriate testing for the type of damage that has occurred.

Transducer IQ Test

Transducers also need to be carefully inspected for ultrasound image uniformity as part of maintenance (e.g. loss of transducer elements). For Phase Array transducers visual inspection can be done via the 'Paper Clip'[1] test. For all other type of transducers 'In Air-Reverberation'[1] test can be used instead.

Transducers 20R3, 8838, and 2052

Before you use one of these transducers, thoroughly inspect the connector plug and the rubber gasket on the plug (this refers to the small, round plug).

Transducers 20R3, X14L4, 8838, and 2052

Damage to the surface of these transducers may lead to oil leaking from the transducer.

Transducer 8666-RF, 8809, X18L5s, and I12C4f

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

1. See Diagnostic Ultrasound - Physics and Equipment ISBN 9781138892934

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 inside and it must make a tight seal with the plug[1].

Inspect the equipment for signs of damage to the plug, lid and the rubber sealing.

⚠ Examine plug and waterproof protection for damage	**Caution** Plug-c4 Before you reprocess the transducer, inspect the watertight protection device and the transducer plug. If you find any signs of damage, do not immerse the plug. If liquid comes into contact with the plug connector pins, the transducer may be destroyed. Examine the edges of the plug case that contact the lid and also the watertight protection device for cracks and marks. Examine the rubber seal of the plug lid. Look for deep scratches and grooves, holes or tears, brittleness, and looseness anywhere. The transducer or watertight protection device must be checked by a BK service representative if you find signs of damage.

Checking the Transducer for Leakage

⚠ Do not use damaged equipment	**WARNING** Check-w1 To ensure safe operation, do not use the equipment if you find any signs of damage. Contact your BK service representative. If a transducer is dropped, and even if it shows no visible signs of damage, BK recommends that you call your BK service representative. They will check the transducer and perform appropriate testing for the type of damage that has occurred.

Before you immerse a transducer, check the transducer for cracks and irregularities. See “Check of Equipment Between Each Use” on page 50 for more information.

⚠ Immersion: Cover plug – Lid ON	**Caution** Plug-c2 To prevent damage to the transducer, cover the plug with the watertight protection device before you immerse the transducer and plug in liquid.

If the transducer is fitted with a watertight lid, it is recommended to use the appropriate leakage tester (UA1414 or UA1404) to verify that the transducer is watertight.

⚠ Test for leaks before immersing	**Caution** Test-c1 You should use the leakage tester to test for leaks. If a transducer is not completely watertight, immersing it can seriously damage it.

1. Some transducer types are not provided with a plug lid, and therefore the connector must not be immersed. See “Transducers Excluded from Leakage Testing” on page 53.

Recommended Leakage Testing Frequency

Check transducers for leakage regularly, as a leakage may impair the performance and safety of the equipment. Recommended leakage testing frequency depends on the design and use of the transducer.

Transducers Excluded from Leakage Testing

8819 8830 8837 8670 2052 8838 5C1e 14L3e 20R3 5P1e	Excluded due to transducer design or no immersible plug lid

Leakage Testing Table

Transducer Classification	Applications	Before rinse and/or immersion	Leakage testing after each use	Minimum leakage testing frequency
Non-critical use	Abdominal Adult Cephalic (Transcranial) Cardiac Adult Fetal, including Obstetrics Musculoskeletal Vessel (Peripheral Vessel) Small Parts (also called Small Organs) Neonatal Cephalic	Always	No	Recommended every 3 months
Semi-critical use	Transrectal Transvaginal	Always	No	Recommended every 3 months
Critical use	Intraoperative Intraoperative (Neuro)	Always	Yes	Recommended after each use

Leakage Testing Setup

After the transducer plug is covered with a special test lid, air is pumped into the transducer. The transducer and covered plug are then placed in a tank filled with water. If bubbles appear, it is a sign that the transducer, cable, or plug contains a hole and is not watertight.

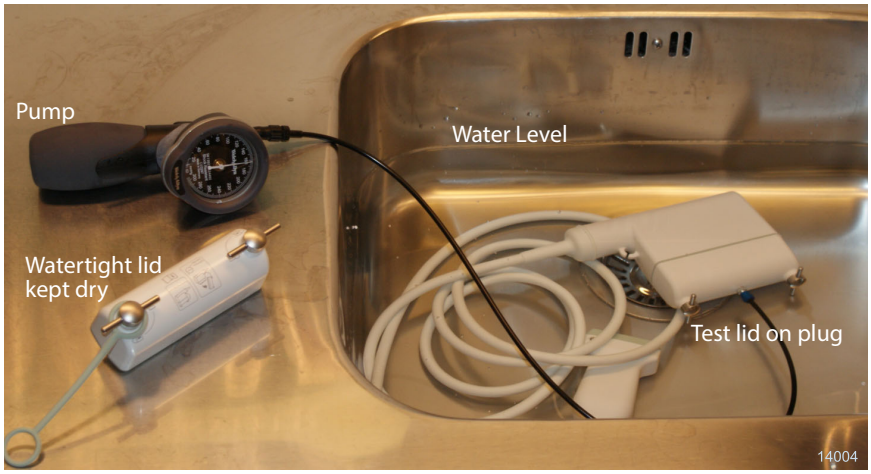


Figure 2. Example of a leakage testing setup with UA1414. Look for bubbles in the water.

⚠ Keep watertight plug lid dry	**Caution** Test-c4 Do not let the watertight plug lid get wet during the testing procedure. Keep it out of the tank. If water gets inside the watertight plug lid, moisture can be transferred from the lid to the plug connector pins during reprocessing. This can damage the transducer.

Leakage Testing Procedure

To test a transducer for leaks:

1. Visually check the edge of the plug and the seal on the lid to make sure that they will fit tightly. Place the test lid on top of the plug with the locking pins unlocked (pointing at the open lock sign). Make sure that the lid is properly aligned and seated on top of the plug.
2. Firmly attach the test lid, as described in “Watertight Plug Lids” on page 58.
3. Pump slowly to increase the pressure up to a relatively stable level of 150 mm Hg. Keep pumping until the pressure is stable. If the pressure does *not* stabilize, 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.
4. Once 150 mm Hg is reached, observe the pressure for 45 seconds.

⚠ Do not immerse if pressure drops	**Caution** Test-c3 If the pressure drops to zero after you use the pump, do not place the transducer in the tank.

⚠ Keep plug dry	**WARNING** T-w5 To prevent electrical shock and damage to the transducer, the connector pins in the transducer plug must always be completely dry before you connect to a system.

5 If the pressure appears stable, place the transducer and covered plug in the water tank for 45 seconds. Water temperature should be between +10 °C and +40 °C.

6 With the transducer in the water tank, observe carefully to make sure that no bubbles escape from the transducer.
NOTE: *A few small bubbles may escape from the housing/gasket interface when the transducer is placed in the tank - this is not a leak. A leak is indicated by a constant, steady stream of escaping bubbles.*

⚠ If you see bubbles, do not release pressure	**Caution** Test-c5 If you see any bubbles, remove the transducer from the tank before you release the pressure.

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

8 When leakage testing is finished, dry the transducer and connector before releasing the pressure and removing the test lid.

9 If the transducer will be further processed in liquid (for example, cleaned manually), attach the watertight plug lid (not the test lid) properly.

Leakage Testing Kits

There are two leakage testing kits, UA1404 and UA1414.

Check your product's Product Data Sheet for the appropriate leakage testing kit.

It is not likely that the tester will need cleaning, but you can wipe the lid with a mild detergent, then wipe it with tap water, and then dry with a soft cloth. Do not try to clean the pump.

⚠ Do not use test lid for reprocessing	**Caution** Test-c2 The lid part of the leakage tester is for testing only. Do not use it when you reprocess the transducer.

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

⚠ Check of Type BF transducers	**WARNING** Check-w3 To prevent electrical shock, all transducers with a (BF) Body Floating symbol comply with Safety Standard IEC60601-1 for leakage currents. Check the transducer once a year to ensure that this quality is met consistently throughout the transducer's lifetime. This check must be carried out only by qualified personnel. Contact your BK service representative if you need any help checking your transducers.

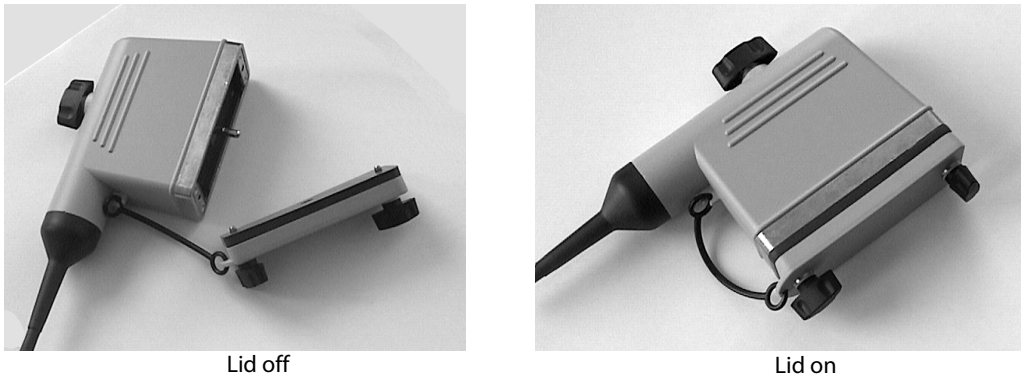
Chapter 6: Watertight Protection Devices

⚠ Examine plug and waterproof protection for damage	**Caution** Plug-c4 Before you reprocess the transducer, inspect the watertight protection device and the transducer plug. If you find any signs of damage, do not immerse the plug. If liquid comes into contact with the plug connector pins, the transducer may be destroyed. Examine the edges of the plug case that contact the lid and also the watertight protection device for cracks and marks. Examine the silicone seal of the plug lid. Look for deep scratches and grooves, holes or tears, brittleness, and looseness anywhere. The transducer or watertight protection device must be checked by a BK service representative if you find signs of damage.

Watertight Plug Lids

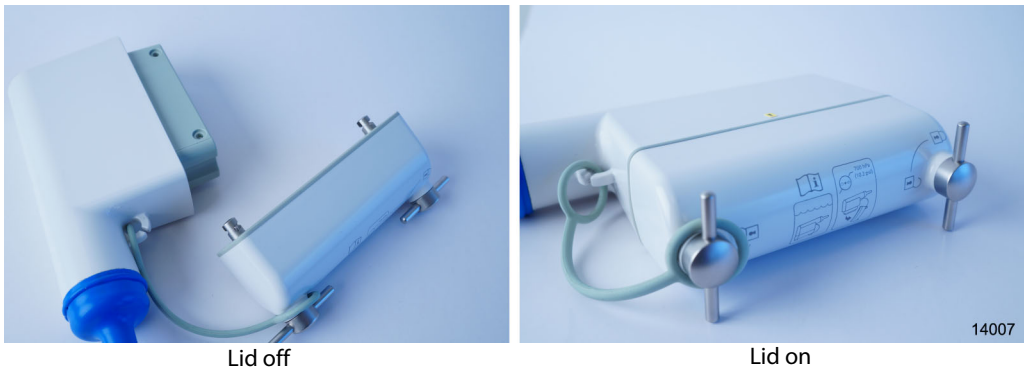
Some BK Medical transducers are supplied with a watertight plug lid that is designed to protect the transducer connector plug during immersion in liquids (including Medivators and STERIS system processing). When the lid is fitted, the entire transducer (including the covered plug) can be reprocessed using approved liquid-based methods.

There are three types of watertight plug lids: Type 1, Type 2 and the Watertight Plug Cover (see page 60).



Lid off Lid on

Figure 3. Watertight Plug Lid Type 1.



Lid off Lid on

Figure 4. Watertight Plug Lid Type 2.

How to Attach and Detach Watertight Plug Lid Type 1

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.*

To attach 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 over-tighten them.

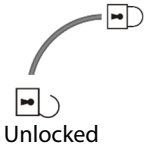
Do not fully tighten one screw before tightening the other screw, and do not put the lid on crooked, as these actions can damage the threads in the screw holes.

To detach the watertight plug lid:

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

How to Attach and Detach Watertight Plug Lid Type 2

To attach the watertight plug lid:



1. Place the lid on top of the plug with the locking pins unlocked (pointing at the open lock sign). Make sure that the lid is properly aligned and seated on top of the plug.
2. Turn both locking pins 90° clockwise to the locked position.

To detach the watertight plug lid:

1. Turn the locking pins 90° counterclockwise so they are unlocked.
2. Remove the lid from the plug.

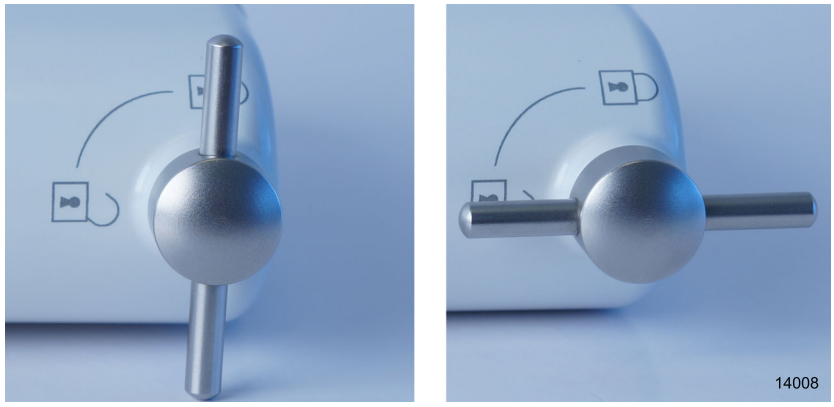


Figure 5. Locking pins in locked and unlocked positions.

How to Attach the Watertight Plug Cover

Single-element transducers Type 2052 and 8838 come with a special watertight plug cover.

Protect plug before immersing

Screw the cover on tightly before you immerse the plug.

Figure 6. Watertight Plug Cover.

Chapter 7: 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 flat panel 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-w1 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.

Appendix: Reprocessing Information and Tables

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).

Transducer Compatibility

The **Transducer Reprocessing Methods** table shows which reprocessing methods your transducer can withstand, assuming that you follow the process manufacturer's instructions.

⚠	**Caution:** T-c5 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: *Unless otherwise indicated, the table shows chemical (and physical) compatibility only – see the process manufacturer's own user instructions for information about the biological effectiveness of the method.*

Legend to the Transducer Reprocessing Methods table	
•	means the transducer can withstand the process (when used according to manufacturer's instructions).
(blank)	means the transducer cannot withstand the process (or that it has not yet been tested with the process)

Product and Process Manufacturers

Product	Manufacturer
3E-Zyme	Medisafe UK limited
Accel Prevention	Virox Technologies Inc.
Adaspor Single Shot	Cantel Medica (Italy) S.R.L.
Aniosyme DD1	Laboratoires Anios
Antigermix S1	Germitec
Astra VR	CIVCO Medical Solutions
Bodedex forte	BODE Chemie GmbH
Bomix Plus	BODE Chemie GmbH
Cavi Wipes/ CaviCide	Metrex Research
Cidex ADS/ Cidex OPA	Advanced Sterilization Products (ASP)
CIDEZYME/Enzol	Advanced Sterilization Products (ASP)
CIDEZYME XTRAMulti-Enzymatic Detergent/ CIDEZYME GL Enzymatic Detergent	Advanced Sterilization Products (ASP)
Cleanisept Wipes Forte	Dr. Schumacher GmbH
Clinell Sporicidal wipes	GAMA Healthcare Ltd
Distel Wipes	Tristel Solutions Limited
Empower	Metrex
Ethanol 70%	None specific
Gigasept AF, Gigasept FF/Gigasept FF (Neu), Gigasept PAA concentrate	Schülke & Mayr GmbH
Gigazyme	Schülke & Mayr GmbH
Glutaraldehyde 2% - 3.4%	None specific
Incidin OxyFoam S Incidin OxyWipe S	Ecolab Deutschland GmbH
Intercept Wipes	MEDIVATORS Inc
Isopropanol 70%	MEDIVATORS Inc
Korsolex Basic	BODE Chemie GmbH
Korsolex Endo-Cleaner 0.5%/ Korsolex Endo-Disinfectant 1%	BODE Chemie GmbH
Korsolex Extra/ Korsolex Endo-Cleaner 0.5%	BODE Chemie GmbH
Metrizyme	Metrex
Mikrozid AF liquid	Schülke & Mayr GmbH
Meliseptol Wipes sensitive	B. Braun Medical AG
Metricide/ Metricide 28/ Metricide Plus 30/ Metricide OPA Plus	Metrex

Product	Manufacturer
Mikrozid PAA wipes	Schülke & Mayr GmbH
MATRIX Biofilm Remover	Whiteley
Meliseptol Foam	B. Braun Medical AG
Mikrobac Tissues	BODE Chemie GmbH
Neodisher Endo SEPT PAC/ Neodisher Septo PAC/ Neodisher Septo 3000/ Neodisher Endo Sept GA/ Neodisher MediClean Forte/ Neodisher Septo DN	Chemische Fabrik Dr. Weigert GmbH & Co. KG
Nu-Cidex	Advanced Sterilization Products (ASP)
OPAL	Whiteley Medical
Prolystica 2x concentration. Enzymatic	STERIS Corporation
Perasafe/ Rely+On Perasafe	DuPont
Rapicide/ PA Disinfectant	MEDIVATORS Inc
Rapicide OPA/28	MEDIVATORS Inc
RENO sterilizers (RENO-20, RENO-30, RENO-D50) - Cycle: Eco	Renosem Co., Ltd
RENO sterilizers (model RENO-S90, RENO-S130, RENO-S130D) -Cycle: Non-lumen for devices without hole/lumen - Cycle: Eco for devices with hole/lumen, e.g. 8666-RF, 9066	Renosem Co., Ltd
RENO sterilizers (model RENO-S90, RENO-S130, RENO-S130D) -Cycle: Non-lumen for devices without hole/lumen - Cycle: Eco for devices with hole/lumen, e.g. 8666-RF, 9066	Renosem Co., Ltd
Revital-Ox Resert/Resert XL HLD	STERIS Corporation
Revital-Ox detergent products: - Revital-Ox Bedside Complete -Revital-Ox 2X Concentrate Enzymatic Detergent - Revital-Ox Enzymatic Detergents	STERIS Corporation
Sani Cloth Plus Wipes/ Sani Cloth Super Wipes/ Sani-Cloth AF3 wipes	PDI
Sekusept Aktiv/ Sekusept MultiEnzyme P	Ecolab Deutschland GmbH
Steranios 2%, 2% N.G., 2% E.C.S	Laboratoires Anios
STERIS System 1/STERIS System 1E	STERIS Corporation
STERIS V-PRO 1/STERIS V-PRO 1 Plus/STERIS V-PRO 60/STERIS V-PRO maX	STERIS Corporation
STERIZONE VP4	TSO_3 Inc.
STERRAD 100S/ 200/ STERRAD NX/ STERRAD 100NX	Advanced Sterilization Products (ASP)
Suma Med Enzyme	Diversey
TD100 & TD5	CS Medical
Thermosept PAA	Schülke & Mayr GmbH
Tristel Duo ULT (previously called Tristel Duo for Ultrasound) / Tristel Fuse for Stella (previously called Tristel Fuse for Instruments)/ Tristel Trio Wipe System	Tristel Solutions Limited
Trophon EPR / Trophon2	Nanosonics Ltd.
Wavicide 01	Medical Chemical Corp.
Matachana 130LF, Webeco FA90, Webeco FA95	Matachana Group

Reprocessing Methods for bkActiv/bk3000/bk5000/bkSpecto and Flex Focus Systems

BK Medical Systems - **EXCEPT SCREEN**. For bkActiv, bk3000, bk5000, bkSpecto, and Flex Focus systems		
Validated Products	Cleaning/Disinfection	Manufacturer
Tristel Duo ULT wipes	Cleaning & Disinfection	Tristel Solutions Ltd
Ethanol 70% (wiping)	Disinfection	None specific
Isopropanol 70% (wiping)	Disinfection	None specific
Material Compatible Products[a]	Cleaning/Disinfection	Manufacturer
Any mild, non-corrosive, pH neutral (pH≈7) detergent product intended for wiping ultrasound devices/systems are considered to be material compatible with the system	Cleaning	None specific
Distel Wipes	Cleaning & Disinfection	Tristel Solutions Ltd

a. Always follow product manufacturer's instructions, and use a slightly damp, soft, lint-free cloth or wipe to avoid liquid intrusion into the screen, keyboard or system. Do not pour liquid directly onto any part of the system.

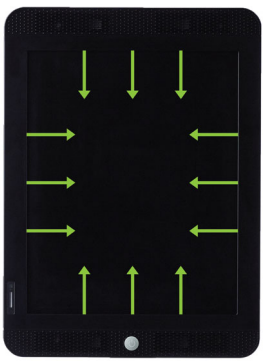
BK Medical Systems. For **GLASS SCREENS** on **bk3000, bk5000, Flex Focus 700, and Flex Focus 800 systems**		
Validated Products[a b]	Cleaning/Disinfection	Manufacturer
Tristel Duo ULT wipes	Cleaning & Disinfection	Tristel Solutions Ltd
Ethanol 70% (wiping)	Disinfection	None specific
Isopropanol 70% (wiping)	Disinfection	None specific
Material Compatible Products[a]	Cleaning/Disinfection	Manufacturer
Any mild, non-corrosive, pH neutral (pH≈7) detergent product intended for wiping ultrasound devices/systems are considered to be material compatible with the system	Cleaning	None specific
Distel Wipes	Cleaning & Disinfection	Tristel Solutions Ltd

BK Medical Systems. For **LCD SCREENS** on **bkActiv, bkSpecto, Flex Focus 200, Flex Focus 400, and Flex Focus 500 systems**		
Validated Products [a b]	Cleaning/Disinfection	Manufacturer
Ethanol 70% (minimum) (wiping)	Disinfection	None specific

a. Always follow product manufacturer's instructions, and use a slightly damp, soft, lint-free cloth or wipe to avoid liquid intrusion into the screen. Do not pour liquid directly onto the screen.
b. Remove any remaining marks on the screen by wiping with Ethanol, and drying with a dry, lint-free, soft cloth while the screen is still moist.

Recommended Reprocessing Method for LCD Screens

1. Use a lint-free, soft cloth/wipe to wipe the screen (e.g. clean room wipe class: Level 100/ISO 5)
2. Wipe the screen in the direction shown in the figure - from the outside towards the center of the screen
3. If necessary use a soft, lint-free cloth/wipe, slightly moistened with an approved cleaner/disinfectant and wipe the screen
4. Remove any remaining marks on the screen by wiping with Ethanol, and drying with a dry, lint-free, soft cloth while the screen is still moist



LCD screen wiping direction

NOTE: *Avoid liquid intruding under the screen.*

⚠ Screen contamination	**WARNING** Reproc-w5 To avoid contamination of the speaker area, do not touch this area when you turn the monitor to the horizontal or vertical position.

Validated Reprocessing Methods and Material Compatible Reprocessing Methods for the T7P2m (9027) Transducer

Tip until 100 cm marker - submersible	Handle and cable part - not submersible, wiping only	Connector (and white flex relief) - not submersible, wiping only
		
Validated methods		
3E-Zyme		
Revital-Ox Resert XL HDL		
Material Compatible Methods		
Mild pH neutral detergent	Mild pH neutral detergent wipe	Mild pH neutral detergent wipe
Aniosyme DD1	Clinell Sporicidal wipes	Tristel Trio Wipes System
Cidex ADS, OPA and Nu-Cidex	Ethanol (EtOH) 70% wipes	Ethanol 70% wipes
Cidezyme / Enzol	Isopropyl alcohol (IPA) 70% wipes	IPA 70% wipes
Empower	Mikrozid® PAA wipes	
Gigasept AF, Gigasept FF (Neu) and Gigasept PAA concentrate	Sani-Cloth AF3 wipes	
Korsolex extra	Tristel Trio Wipes System	
Metricide, Metricide 28, Metricide OPA Plus and Metricide Plus 30		
Metrizyme		
Neodisher MediClean forte/ Neodisher Septo 3000		
Perasafe		
Prolystica 2x conc.		
Revital-Ox Resert XL HDL		
Sekusept Aktiv		
Steranios 2%, 2% N.G., 2% E.C.S		
TD100 & TD5		
Tristel Trio Wipe System		
Wavicide 01		

⚠ Reprocessing	**WARNING** Reproc-w4 Extra care must be taken when cleaning this transducer, as there is no automatic cleaning system that can reprocess the entire transducer.

Material Compatible Reprocessing Methods for bkFusion Hardware

Do not immerse electronics unit, transmitter, sensor or cables.

	EM Transmitter Stand (wheelbase and pole)	See "Reprocessing Methods for bkActiv/bk3000/bk5000/bkSpecto and Flex Focus Systems" on page 66
	Shelf for EM Control Unit	See "Reprocessing Methods for bkActiv/bk3000/bk5000/bkSpecto and Flex Focus Systems" on page 66
	EM Control Unit	See "Material Compatible Reprocessing Methods for Guides, Attachments and bkFusion Hardware" on page 75
	EM Sensor and Cable UA2371	
	EM Transmitter	
	Universal Bedside Clamp	

	Mount for EM Transmitter	pH neutral (pH 6-8), non-corrosive cleaning products intended for wiping medical devices Ethanol wiping
	EM Transmitter Stand (articulated arm)	**Cleaning:** 1. Wipe with a soft, non-abrasive cloth moistened with a mild, pH neutral (pH 6-8), non-abrasive detergent solution - or use a wipe manufactured for this purpose. 2. Wipe with soft cloth moistened with cold water 3. Wipe dry with a lint-free cloth **Disinfection:** 1. Use ethanol or isopropanol 70% wipes and spray
	Sensor Clamp UA2377	See "Material Compatible Reprocessing Methods for Guides, Attachments and bkFusion Hardware" on page 75
	Sensor Clamp UA2378	
	Sensor Clamp UA2399	

Validated Reprocessing Methods for bkActiv/bk3000/bk5000 and bkSpecto Transducer Series

Validated Reprocessing Methods[a b] *(Follow local regulations for minimum reprocessing. Check table 4 on page 29)*		Transducers																														
		Surface											Endocavity						Intraoperative							Neuro-surgery			Phased Array		Special		
		5C1e[c] (9085)	6C2 (9040)	6C2s (9023)	9C2 (9002)	14L3 (9051)	14L3e[c] (9086)	13L4w (9011)	10L2w (9022)	18L5 (9070)	18L5s (9081)	8L2 (9032)	E14C4t (9018)	E14CL4b (9048)	E11C3b (9008)	E13C2 (9029)	E10C4 (9019)	20R3 (9052)	Rob12C4 (9096)	I14C5I (9015)	I14C5T (9016)	I12C5b (9024)	I12C5 (9034)	I12C4f (9066)	I13C3f (9076)	N20P6 (9007)	N13C5 (9062)	N11C5s (9063)	5P1 (9077)	5P1e[c] (9087)	X18L5s (9009)	X14L4 (9038)	X12C4 (9026)
Manual Cleaning	3E-Zyme	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Manual Disinfection	Korsolex Basic	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Ethanol 70% (wiping)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Revital-Ox Resert/Resert XL HLD	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Tristel Fuse For Stella	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•		•	•	•	•	•			•	•	•	•	•	•	•
Automated Disinfection	Medivators Advantage Plus Intercept (detergent), Rapicide PA Disinfectant flush: 70% isopropyl alcohol		•	•	•	•		•	•	•		•	•		•	•	•			•	•	•	•				•	•	•		d		•
Sterilization	STERIS System 1, 1 Plus and 1 Express STERIS System 1E		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	STERIS V-Pro 1 Plus, V-Pro 60 *Non lumen cycle*		•	•	•	•		•	•	•		•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•		•		•
	STERIS V-Pro maX *Non lumen cycle or Flexible cycle*		•	•	•	•		•	•	•		•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•		•		•
	Sterrad 100NX *Standard cycle*		•	•	•	•		•	•	•		•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•		•		•
	Sterrad 100NX *Express cycle*		•	•	•	•		•	•	•		•	•	•	•	•	•		•	•	•	•	•	•	•		•	•	•		d		•
	Sterrad NX *Standard cycle*		•	•	•	•		•	•	•		•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•		•		•
	Sterrad 100S *One cycle only (USA), Short cycle (rest of the world)*		•	•	•	•		•	•	•		•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•		•		•
	Sterrad 200 *Short cycle*		•	•	•	•		•	•	•		•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•		•		•
	Matachana 130LF, Webeco FA90, Webeco FA95 (60°C cycle)												1	1		1	1			1	1	1											

a. Cleaning is an important first step for all transducer types. Every transducer used in a critical procedure must be sterilized as the final reprocessing step.
b. Follow product manufacturer's instructions and do not exceed transducer-specified limits. See Table 3 on page 25 for more information.
c. Note that the transducer connector is not immersible.
d. Use of reprocessing method is not CE marked for X18L5s.

1. Use a suitable connector lid and valve from the system manufacturer. See page 45.

Material Compatible Reprocessing Methods for bkActiv/bk3000/bk5000 and bkSpecto Transducer Series

	Material Compatible Reprocessing Methods[a b c] *(Follow local regulations for minimum reprocessing. Check table 4 on page 29)*	Transducers																												
		Surface											Endocavity						Intraoperative							Neuro-surgery			Phased Array		Special		
		5C1e[d] (9085)	6C2 (9040)	6C2s (9023)	9C2 (9002)	14L3 (9051)	14L3e[d] (9086)	13L4w (9011)	10L2w (9022)	18L5 (9070)	18L5s (9081)	8L2 (9032)	E14C4t (9018)	E14CL4b (9048)	E11C3b (9008)	E13C2 (9029)	E10C4 (9019)	20R3 (9052)	Rob12C4 (9096)	I14C5I (9015)	I14C5T (9016)	I12C5b (9024)	I12C5 (9034)	I12C4f (9066)	I13C3f (9076)	N20P6 (9007)	N13C5 (9062)	N11C5s (9063)	5P1 (9077)	5P1e[d] (9087)	X18L5s (9009)	X14L4 (9038)	X12C4 (9026)
	Bodedex forte	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	CIDEZYME XTRA Multi-Enzymatic Detergent/ CIDEZYME GL Enzymatic Detergent	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	pH neutral (pH 6-8), non-corrosive cleaning products intended for medical devices	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Intercept Wipes/Intercept Detergent	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Gigazyme	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Korsolex Endo-Cleaner 0,5%	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	MATRIX Biofilm Remover	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Neodisher MediClean Forte	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Prolystica 2x concentration. Enzymatic	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Revital-Ox Bedside Complete/2X Concentrate Enzymatic Detergent/Enzymatic Detergents	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Sekusept MultiEnzyme P	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Suma Med Enzyme	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Disinfection (continued o nnext page)	Accel Prevention (wipes, ready-to-use liquid, concentrate)		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			•	•
	Adaspor Single Shot		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			•	•
	Antigermix S1												•	•	•	•	•																
	Astra VR (with approved disinfectant)												•	•	•	•	•															•	
	Bomix Plus		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Cavi Wipes/CaviCide	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Cidex OPA		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Cleanisept Wipes Forte		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Gigasept FF		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Glutaraldehyde 2% – 3.4%		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Incidin OxyFoam/Incidin OxyWipe S		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Isopropanol 70% (wiping)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Korsolex Endo Disinfectant 1%/Korsolex Extra		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Meliseptol Foam		•	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Meliseptol Wipes Sensitive	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Metricide OPA Plus		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Mikrobac Tissues		•	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Mikrozid AF Liquid	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Neodisher Endo Sept GA		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Neodisher Endo SEPT PAC/Neodisher Septo PAC		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Neodisher Septo DN		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Nu-Cidex		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Table continues on next page																																

a. Cleaning is an important first step for all transducer types. Every transducer used in a critical procedure must be sterilized as the final reprocessing step.
b. Follow product manufacturer's instructions and do not exceed transducer-specified limits. See Table 3 on page 25 for more information.
c. "Material compatible" indicates that BK Medical has evaluated the device's material compatibility with the reprocessing method when reprocessed according to the reprocessing product or reprocessing system's instructions for use. Efficacy is not covered by this statement.
d. Note that the transducer connector is not immersible.

Material Compatible Reprocessing Methods[a b c] *(Follow local regulations for minimum reprocessing. Check table 4 on page 29)*		Transducers																														
		Surface											Endocavity						Intraoperative							Neurosurgery			Phased Array		Special		
		5C1e[d] (9085)	6C2 (9040)	6C2s (9023)	9C2 (9002)	14L3 (9051)	14L3e[d] (9086)	13L4w (9011)	10L2w (9022)	18L5 (9070)	18L5s (9081)	8L2 (9032)	E14C4t (9018)	E14CL4b (9048)	E11C3b (9008)	E13C2 (9029)	E10C4 (9019)	20R3 (9052)	Rob12C4 (9096)	I14C5I (9015)	I14C5T (9016)	I12C5b (9024)	I12C5 (9034)	I12C4f (9066)	I13C3f (9076)	N20P6 (9007)	N13C5 (9062)	N11C5s (9063)	5P1 (9077)	5P1e[d] (9087)	X18L5s (9009)	X14L4 (9038)	X12C4 (9026)
	OPAL		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Rapicide/Rapicide OPA/28		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Rely+On Perasafe		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Sani Cloth Plus Wipes/Sani Cloth Super Wipes	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Sekusept Aktiv		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Steranios 2%, 2% N.G., 2% E.C.S		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Thermosept PAA		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Tristel Duo ULT /Tristel Trio Wipe System		•	•	•	•		•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•
	Trophon EPR / Trophon2 *(Fit transducer completely above line mark)*		•	•	•	•		•	•	•		•	•		•	•	•												•			
Sterilization	RENO-20/RENO-30/RENO-D50: ECO Cycle		•	•	•	•		•	•	•		•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•		•	•
	RENO-S90, RENO-S130, RENO-S130D: Non Lumen Cycle		•	•	•	•		•	•	•		•	•	•	•	•	•		•	•	•	•	•			•	•	•	•		•	•
	RENO-S90, RENO-S130, RENO-S130D: ECO Cycle																							•	•							

a. Cleaning is an important first step for all transducer types. Every transducer used in a critical procedure must be sterilized as the final reprocessing step.
b. Follow product manufacturer's instructions and do not exceed transducer-specified limits. See Table 3 on page 25 for more information.
c. "Material compatible" indicates that BK Medical has evaluated the device's material compatibility with the reprocessing method when reprocessed according to the reprocessing product or reprocessing system's instructions for use. Efficacy is not covered by this statement.
d. Note that the transducer connector is not immersible.

Validated Reprocessing Methods for the Flex Focus Transducer Series

Validated Reprocessing Methods[a] [b] *(Follow local regulations for minimum reprocessing. Check table 4 on page 29)*		Transducers																									
		Intraoperative									Endocavity								Surface								
		8666-RF	8809	8815	8816	8824	8826	8836	8862	8863	2052	8667	8808	8808e	8818	8819[c]	8838	8848	8670[c]	8811	8820e	8822	8823	8830[c]	8837[c]	8870
Manual Cleaning	3E-Zyme	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Manual Disinfection	Korsolex Basic	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•	•
	Ethanol 70% (wiping)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Revital-Ox Resert/Resert XL HLD			•	•	•	•	•	•	•	•			•	•	•	•	•			•	•	•	•			
	Tristel Fuse for Stella		•	•	•	•	•		•	•			•	•	•		•	•									•
Automated Disinfection	Medivators Advantage Plus Intercept (detergent), Rapicide PA Disinfectant, flush: 70% isopropyl alcohol		•	•	•	•	•		•	•		•		•	•	•				•	•	•	•	•			•
Sterilization	STERIS System 1,1 Plus, and 1 Express[d] STERIS System 1E	•	•	•	•	•	•	•	**4**	**4**	•	•	**5**	•	•		•	•		•		•	•				•
	STERIS V-Pro 1 Plus, V-Pro 60 *Non lumen cycle*	•	**2**	•	•	•	•	•	•	•		**10**		•	•	•		•		•	•	•	•	•	•		•
	STERIS V-Pro maX *Non lumen cycle or Flexible cycle*	•	**2**	•	•	•	•	•	•	•		**10**		•	•	•		•		•	•	•	•	•	•		•
	STERIZONE VP4	**1**		•	•	•	•	•							**6**			**7**									
	Sterrad NX & 100NX *Standard cycle*	**1**	**2**	**3**	**3**	**3**	•	•	•	•					**6**			**7**									
	Sterrad 100S *One cycle only (USA), Short cycle (rest of the world)*	•	•	•	•	•	•	•	•	•					•			•					•				
	Sterrad 200 *Short cycle*	•	•	•	•	•	•	•	•	•					•			•					•				
	Matachana 130LF, Webeco FA90, Webeco FA95 (60°C cycle)			**8**	**8**	**8**						**8/9**		**8**	**8**			**8**									

a. Cleaning is an important first step for all transducer types. Every transducer used in a critical procedure must be sterilized as the final reprocessing step.
b. Follow product manufacturer's instructions and do not exceed transducer-specified limits. See Table 3 on page 25 for more information.
c. Transducer connector is not immersible.
d. STERIS SYSTEM 1, SYSTEM 1 Plus and SYSTEM 1 Express are not market cleared by the FDA.

1. Valid for transducers with a serial number higher than 1911238. If in doubt, contact your BK representative.
2. Valid for transducers with a serial number higher than 3991000. If in doubt, contact your BK representative.
3. Valid for transducers with a serial number higher than 1910000. If in doubt, contact your BK representative.
4. In Canada, do not use STERIS SYSTEM 1E for this transducer.
5. Use together with Quick Connect QMC1733INT and tray: C1220S1 for STERIS SYSTEM 1; Quick Connect QMC1733INT and tray: C1220INT for SYSTEM 1 Plus / 1 Express and Quick Connect QMC1733E and Tray: C1220E with SYSTEM 1E.
6. Valid for transducers with a serial number higher than 3890001. If in doubt, contact your BK representative.
7. Valid for transducers with a serial number higher than 3900001. If in doubt, contact your BK representative.
8. Use a suitable connector lid and valve from the system manufacturer. See page 45.
9. Valid for transducers with a serial number higher than 3018205. If in doubt, contact your BK representative.
10. Valid for transducers with a serial number higher than 1912156. If in doubt, contact your BK representative.

Material Compatible Reprocessing Methods for the Flex Focus Transducer Series

	Material Compatible Reprocessing Methods[a b c] *(Follow local regulations for minimum reprocessing. Check table 4 on page 29)*	Transducers																								
		Intraoperative									Endocavity								Surface							
		8666-RF	8809	8815	8816	8824	8826	8836	8862	8863	2052	8667	8808	8808e	8818	8819[d]	8838	8848	8670[d]	8811	8820e	8822	8823	8830[d]	8837[d]	8870
	Bodedex forte	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	CIDEZYME XTRA Multi-Enzymatic Detergent/ CIDEZYME GL Enzymatic Detergent	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	pH neutral (pH 6-8), non-corrosive cleaning products intended for medical devices	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Intercept Wipes/Intercept Detergent	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Gigazyme	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Korsolex Endo-Cleaner 0,5%	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	MATRIX Biofilm Remover	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Neodisher MediClean Forte	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Prolystica 2x concentration. Enzymatic	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Revital-Ox Bedside Complete/2X Concentrate Enzymatic Detergent/Enzymatic Detergents	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Sekusept MultiEnzyme P	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Suma Med Enzyme	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Disinfection (continued o nnext page)	Accel Prevention (wipes, ready-to-use liquid, concentrate)			•	•		•	•	•	•	•			•	•	•	•	•			•	•	•	•		
	Adaspor Single Shot			•	•		•	•	•	•	•			•	•	•	•	•			•	•	•	•		
	Antigermix S1														•			•								
	Astra VR (with approved disinfectant)											•		•	•	•	•	•								
	Bomix Plus	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Cavi Wipes/CaviCide	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Cidex OPA	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Cleanisept Wipes Forte	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Gigasept FF	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•
	Glutaraldehyde 2% – 3.4%	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Incidin OxyFoam/Incidin OxyWipe S			•	•	•	•	•	•	•	•			•	•	•	•	•			•	•	•	•		
	Isopropanol 70% (wiping)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Korsolex Endo Disinfectant 1%/Korsolex Extra	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•		•	•	•
	Meliseptol Foam	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Meliseptol Wipes Sensitive	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Metricide OPA Plus	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Mikrobac Tissues	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Mikrozid AF Liquid	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Neodisher Endo Sept GA	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Neodisher Septo DN	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Nu-Cidex			•	•	•	•	•	•	•	•			•	•	•	•	•								
	Table continues on next page																									

a. Cleaning is an important first step for all transducer types. Every transducer used in a critical procedure must be sterilized as the final reprocessing step.
b. Follow product manufacturer's instructions and do not exceed transducer-specified limits. See Table 3 on page 25 for more information.
c. "Material compatible" indicates that BK Medical has evaluated the device's material compatibility with the reprocessing method when reprocessed according to the reprocessing product or reprocessing system's instructions for use. Efficacy is not covered by this statement.
d. Transducer connector is not immersible.

Material Compatible Reprocessing Methods[a b c] *(Follow local regulations for minimum reprocessing. Check table 4 on page 29)*		Transducers																								
		Intraoperative									Endocavity								Surface							
		8666-RF	8809	8815	8816	8824	8826	8836	8862	8863	2052	8667	8808	8808e	8818	8819[d]	8838	8848	8670[d]	8811	8820e	8822	8823	8830[d]	8837[d]	8870
	OPAL	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•
	Rapicide	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	RAPICIDE OPA/28	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Rely+On Perasafe	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			•	•	•	•		•
	Sani Cloth Plus Wipes/Super Wipes	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Sekusept Aktiv			•	•		•	•	•	•	•			•	•	•	•	•			•	•	•	•		
	Steranios 2%, 2% N.G., 2% E.C.S	•	•	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•	•	•	•	•	•
	Thermosept PAA			•	•		•	•	•	•	•			•	•	•	•	•			•	•	•	•		
	Tristel Duo ULT		•	•	•	•	•	•	•	•	•		•	•	•		•	•								
	Tristel Trio Wipe System		•	•	•	•	•	•	•	•	•		•	•	•		•	•								
	Trophon EPR / Trophon2 *(Fit transducer completely above line mark)*											•		•	•	•				•	•	•	•			
Sterilization	RENO-20/RENO-30/RENO-D50: ECO Cycle	•		•	•	•	•	•	•	•		1		•	•	•		•		·	•	•	•	•		•
	RENO-S90, RENO-S130, RENO-S130D: Non Lumen Cycle			•	•	•	•	•	•	•		1		•	•	•		•		·	•	•	•	•		•
	RENO-S90, RENO-S130, RENO-S130D: ECO Cycle	•																								

a. Cleaning is an important first step for all transducer types. Every transducer used in a critical procedure must be sterilized as the final reprocessing step.
b. Follow product manufacturer's instructions and do not exceed transducer-specified limits. See Table 3 on page 25 for more information.
c. "Material compatible" indicates that BK Medical has evaluated the device's material compatibility with the reprocessing method when reprocessed according to the reprocessing product or reprocessing system's instructions for use. Efficacy is not covered by this statement.
d. Transducer connector is not immersible.

1. Valid for transducers with a serial number higher than 1912156. If in doubt, contact your BK representative.

Material Compatible Reprocessing Methods for Guides, Attachments and bkFusion Hardware

	Material Compatible Reprocessing Methods[a]	Attachments, Needle Guides															bkFusion Hardware					
		UA0671	UA0672	UA0673	UA1232	UA1239	UA1250	UA1251	UA1256	UA1282	UA1324	UA1325	UA1325-W	UA1326	UA1327	UA1328	UA1349	UA2377 Sensor Clamp	UA2378 Sensor Clamp	UA2399 Sensor Clamp[b]	UA2371 EM Sensor and Cable	Universal Bedside Clamp	EM Transmitter and Control unit[c]
Cleaning[d]	pH neutral (pH 6-8), non-corrosive cleaning products intended for medical devices	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Intercept Detergent	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	3E-Zyme	•	•	•		•	•	•	•	•	•	**1**	**1**	**1**	**1**	**1**	•	**1**	**1**	**1**			
	Gigazyme	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Korsolex Endo-Cleaner 0,5%	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Neodisher MediClean Forte	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Sekusept MultiEnzyme P	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
Disinfection[c]	Accel Prevention (wipes, ready-to-use liquid, concentrate)	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Adaspor Single Shot	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Bomix Plus	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Cidex OPA	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Gigasept FF	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Glutaraldehyde 2% – 3.4%	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Isopropanol 70% / Ethanol 70% (wiping)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
	Korsolex Endo Disinfectant 1%	•	•	•		•	•	•	•	•	•	•	•	•	•		•	•	•	•			
	Korsolex Extra	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Korsolex Basic	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Rapicide PA	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Metricide OPA Plus	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Neodisher Endo Sept GA	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Neodisher Endo SEPT PAC/Neodisher Septo PAC	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Neodisher Septo DN	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Nu-Cidex	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	OPAL	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Rapicide	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Rapicide OPA/28	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Rely+On Perasafe	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Revital-Ox Resert/Resert XL HLD	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Sekusept Aktiv	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Thermosept PAA	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	Tristel Fuse For Stella	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
Sterilization[c]	Ethylene Oxide (ETO)																				•		
	STERIS System 1, 1E, 1 Plus and 1 Express	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•			
	STERIS V-Pro 1 Plus/ V-Pro 60/V-Pro maX	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	**1**	**1**	**1**			
	Sterrad NX/100NX/100S/200	•	•	•		•	•	•	•	•	•	•	•	•	•	•	•	**1**	**1**	**1**			
Autoclaving (See "Autoclaving" on page 46)		•	•	•	•	•	•	•	•	•	•	**1**	**1**	**1**	**1**	**1**	•						

a. "Material compatible" indicates that BK Medical has evaluated the guides and attachments for material compatibility with the reprocessing method when reprocessed according to the reprocessing product or reprocessing system's instructions for use. Efficacy is not covered by this statement.
b. Separate the clamp into two components before reprocessing.
c. This hardware is not suitable for sterilization. To use the hardware in a sterile environment, consider using a sterile cover.
d. Follow product manufacturer's instructions.

1. This method has been validated for this particular guide, attachment, or bkFusion hardware. For the correct reprocessing steps, see chapter beginning on page 27

Reprocessing Methods for Remote Controls UA2361 and UA2370

		Reprocessing Methods	Lid and Batteries
Material Compatible Methods[a]	Manual Cleaning	Non-corrosive, pH neutral (pH 6-8) cleaning products intended for medical devices	Lid on
	Manual Disinfection	Ethanol 70% (wiping)	Batteries inside the remote control Lid on
		Cavi Wipes	
		CaviCide	
		Cidex OPA	
		Gigasept FF	
		Glutaraldehyde 2%	
		Isopropanol 70% (wiping)	
		Korsolex Basic	
		Korsolex Endo Disinfectant 1%	
		Korsolex Extra	
		Meliseptol Foam	
		Metricide OPA Plus	
		Nu-Cidex	
		Rapicide OPA/28	
		Rely+On Perasafe	
		Sani Cloth Plus Wipes	
		Sani Cloth Super Wipes	
Validated methods[a, b, c]	Manual Cleaning	3E-Zyme	Lid on
	Sterilization	STERIS SYSTEM 1 STERIS SYSTEM 1 Plus STERIS SYSTEM 1 Express STERIS SYSTEM 1E	Batteries inside the remote control Lid on
		STERIS V-PRO 1 *Standard Cycle*	Batteries *with* but not *inside* the remote control Lid off
		STERIS V-PRO 1 Plus STERIS V-PRO maX STERIS V-PRO 60 *Lumen cycle*	Batteries *with* but not *inside* the remote control Lid off
		STERRAD 100S AND 200 *Standard Cycle (USA)* *Short Cycle (rest of world)*	Batteries *with* but not *inside* the remote control Lid off
		STERRAD NX STERRAD 100NX *Standard Cycle*	Batteries *with* but not *inside* the remote control Lid off

a. Follow product manufacturer's instructions and do not exceed remote control-specified limits.
b. STERIS SYSTEM 1, SYSTEM 1 PLUS, and SYSTEM1 Express are not market cleared by the FDA.
c. Because of material degeneration, STERRAD systems processing has been validated for a maximum of 50 reprocessing cycles with the remote control.

Overview of InstruSafe Instrument Protection Trays for BK Devices

The listed InstruSafe protection trays can be used for the storage, transportation and efficient sterilization of the majority of BK transducers with V-PRO and STERRAD sterilizers. Some V-PRO and STERRAD sterilizers have a small chamber, so ensure tray dimensions fit the processing chamber of your sterilizer.

Always follow manufacturers' instructions.

NOTE: *You must always place the transducer in the silicone fittings. Be careful that the transducer does not touch or scrape on the tray. There should not be other items in the tray with the transducer.*

Prior to use, check transducer compatibility "Validated Reprocessing Methods for bkActiv/bk3000/bk5000 and bkSpecto Transducer Series" on page 69, and "Material Compatible Reprocessing Methods for bkActiv/bk3000/bk5000 and bkSpecto Transducer Series" on page 70, plus tray compatibility[a], with exact sterilization models and cycles.

TRANSDUCER	TRAY[a]	DIMENSIONS
20R3, 2052	UA2500	63.18 cm (L) x 34.29 cm (W) x 6.03 cm (H)
I12C4f, I13C3f, 8666-RF	UA2501	63.18 cm (L) x 34.29 cm (W) x 6.03 cm (H)
X18L5s, 8809	UA2502	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
I14C5T, I12C5, 8816	UA2503	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
I12C5b, 8824	UA2504	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
Rob12C4, X12C4, 8826	UA2505	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
9C2, 18L5, 13L4w, 8670, 8811, 8870	UA2506	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
E14CL4b, E10C4, 8819, 8848	UA2507	63.18 cm (L) x 34.29 cm (W) x 6.03 cm (H)
N13C5, N11C5, 8862	UA2508	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
8836	UA2440	60.64 cm (L) x 24.45 cm (W) x 6.03 cm (H)
N11C5s, 8863	UA2509	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
6C2s, 8823	UA2510	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
E14C4t, E11C3b, 8808e, 8808, 8818	UA2511	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
I14C5I, 8815	UA2512	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
5P1, 8837	UA2513	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
8L2, 14L3	UA2514	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
E14C4, 8667	UA2447	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
6C2, 10L2w, 8820e, 8822, 8830	UA2516	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)
X14L4, 8838	UA2449	60.64 cm (L) x 24.45 cm (W) x 6.03 cm (H)
N20P6	UA2517	49.85 cm (L) x 24.45 cm (W) x 6.03 cm (H)

a. Manufactured by Summit Medical. Refer to www.instrusafe.com for further information, approved systems, cycles and trays.

Reprocessing Table for Craniotomy Transducer 8862 and Burr-Hole Transducer 8863

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

This table tells you where to find specific information about reprocessing these transducers.

Abbreviations used:	**C&C**: *Care and Cleaning* **UG**: Transducer User Guide

Reprocessing Information for Neurosurgical Transducers 8862 & 8863

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).	C&C	Pre Cleaning (Point-of use Processing).
		Rinsing			Note: Soaking is not recommended. Rinse under running water.	C&C	Pre Cleaning (Point-of use Processing).
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.	C&C	Manual Cleaning.
		Automated (Machine) Cleaning		X			Automatic Reprocessing Methods.
		Ultrasonic Cleaning		X			

(Sheet 1 of 3)

Reprocessing Information for Neurosurgical Transducers 8862 & 8863

Process	Process Stage	Process Step	Recom'd	Not Recom'd	Specific information to be provided by manufacturer (attach details)	Document	Section
Disinfection	Liquid Chemical	Manual	X		Specify compatible liquid chemicals that can be used.	C&C	Material Compatible Reprocessing Methods.
			X		Specify validated exposure time to liquid chemical.	PD C&C	Manual Disinfection.
					Specify water quality for rinse and minimum volume for rinsing.	C&C	Manual Disinfection.
	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.).	C&C	Manual Disinfection.
					Specify maximum temperature the medical device can withstand.		Automatic Reprocessing Methods.
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.	C&C	Checking and Maintaining Ultrasound Equipment.
Steam Sterilization				X			

(continued) (Sheet 2 of 3)

Reprocessing Information for Neurosurgical Transducers 8862 & 8863

Process	Process Stage	Process Step	Recom'd	Not Recom'd	Specific information to be provided by manufacturer (attach details)	Document	Section
EO Sterilization				X			
Other Sterilization Processes					Specify sterilization process including cycle and conditions for which device has been validated.		Automatic Reprocessing Methods.
	STERRAD®		X			C&C	STERRARD Systems.
	STERIS™ SYSTEM 1 Amsco™ V-PRO		X X		There is only one type of sterilization cycle.	C&C	STERIS SYSTEM 1 and 1E. STERIS Amsco V-PRO Systems.
Device to be Sterilized in Container Provided by Manufacturer				X			

(continued) (Sheet 3 of 3)

CE-Marking Information

All BK Medical devices, except those listed below, are certified in accordance with the Medical Device Directive 93/42/EEC:

- Transducer N20P6 (9007)

The following BK Medical devices are certified in accordance with the Medical Device Regulation (EU) 2017/745:

- The bkSpecto Ultrasound System (1300)
- Transducer 5P1e (9087)

Index

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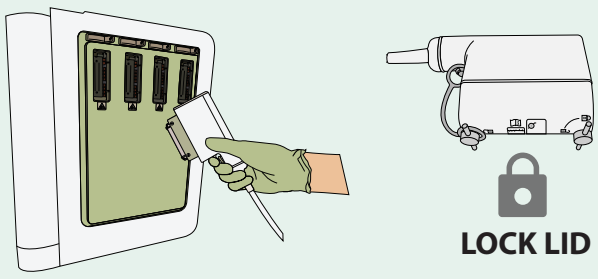
REPROCESSING SELECTED CRITICAL-USE TRANSDUCERS

bk medical

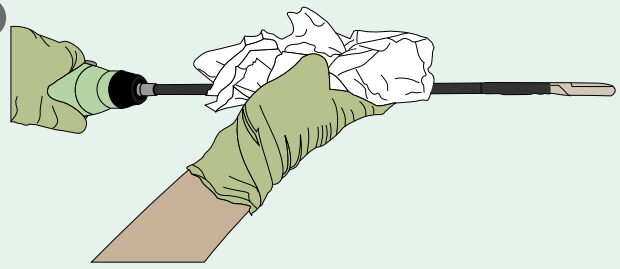
PRECLEANING (MUST BE PERFORMED IMMEDIATELY AFTER USE)

1



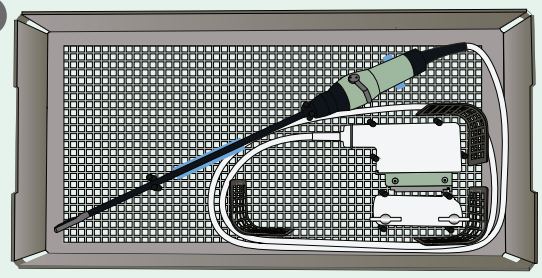
- Disconnect the device from the system.
- Attach and lock the watertight lid.

2



- Remove any covers and needle guides.
- Remove gel or biological material with a cloth/sponge moistened with detergent*.

3

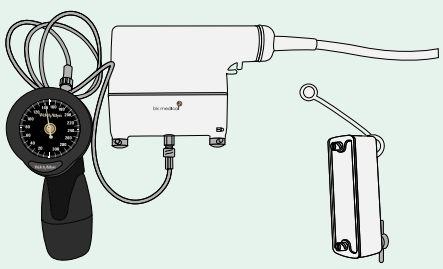


- For transportation, fasten the pre-cleaned device in the closed appropriate tray.

LEAKAGE TESTING

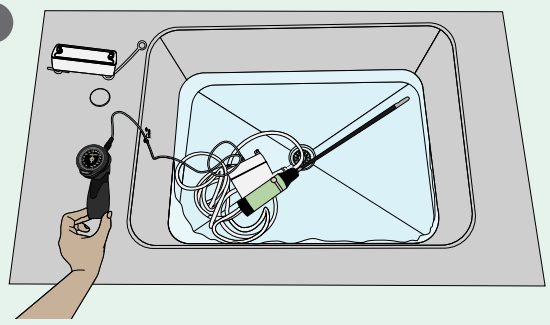
⚠ LEAKAGE TESTING MUST OCCUR **PRIOR** TO IMMERSION IN WATER ⚠ LEAKAGE TESTING MUST OCCUR **BETWEEN EVERY USE**

4



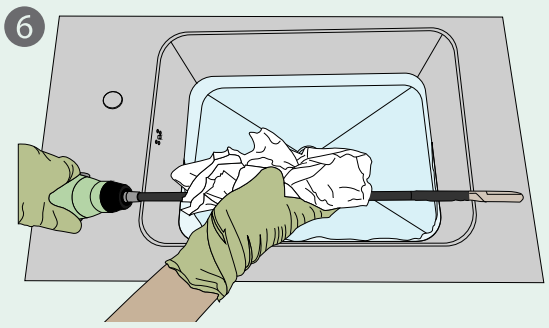
- Check the whole device for damage.
- If undamaged, attach the leakage tester lid to the transducer connector, and detach the watertight lid.
- Pump slowly to increase the pressure to 150mm Hg, then observe pressure for 45 seconds.

5



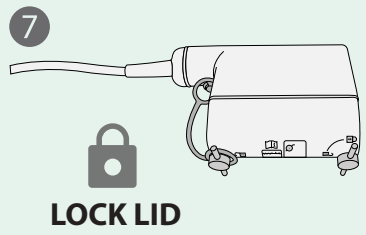
- Keep the watertight lid dry.
- If pressure is not stable, DO NOT immerse the device. If the pressure is stable, immerse the whole device in a water bath.
- Check for escaping bubbles.
  NOTE: A leak is indicated by a constant, steady stream of escaping bubbles.

6



- Remove the whole device from the water bath and dry it with a soft, lint-free cloth.

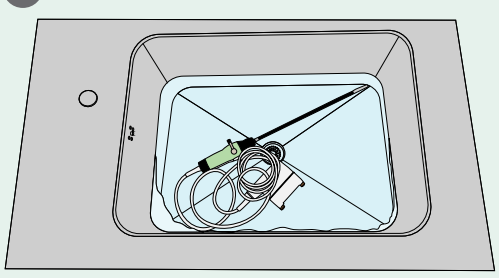
7



- Release pressure, then detach the leakage tester lid. Reattach and lock the watertight lid.

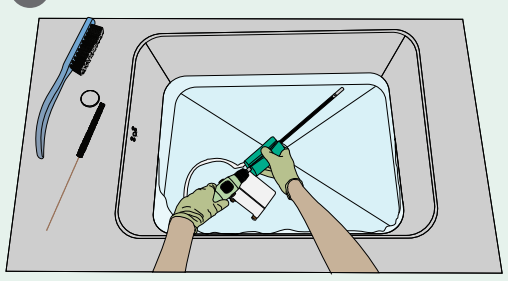
THOROUGH CLEANING

8



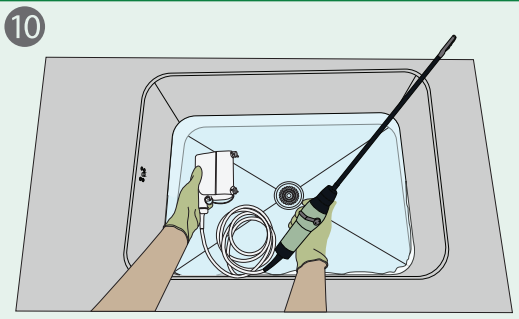
- Fill sink with a detergent solution*, following the detergent manufacturer's instructions.
- Make sure the watertight lid is attached and locked, then immerse the whole device.

9



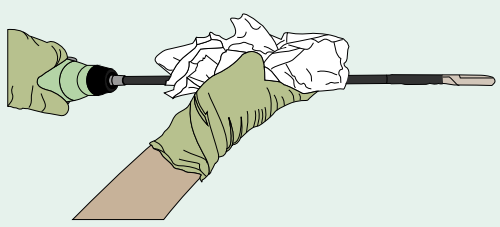
- Use a soft brush/sponge to clean the whole device (including lumens if applicable).
- Soak the device, following detergent manufacturer's instructions.

10



- Check if the device is completely clean. If necessary, repeat steps 8 and 9.
- Rinse the device, following detergent manufacturer's instructions.

11



- Dry the complete device with a soft, lint-free cloth, air dry, or use a drying cabinet.

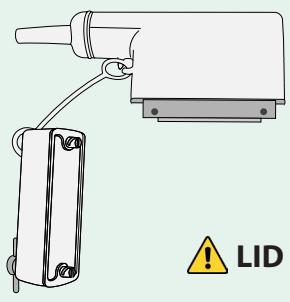
⚠ **DO NOT EXCEED 60°C (140°F)**

AUTOMATED STERILIZATION See newest Care and Cleaning guide for complete list of disinfection and automated sterilization methods

GAS CHEMICAL STERILIZATION

With the following methods the watertight lid must be OFF, or the device will be damaged.
Follow method* manufacturer's instructions.

METHOD	CYCLE
STERRAD 100S	Short Cycle (US: one cycle only)
STERRAD 200	Short Cycle
STERRAD NX / 100NX	Standard Cycle
STERIS V-PRO maX	Non-lumen Cycle/Flexible Cycle
STERIS V-PRO 1 STERIS V-PRO Plus STERIS V-PRO 60	Non-lumen Cycle

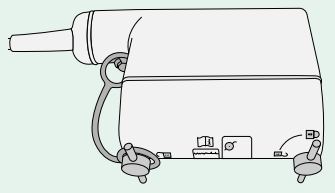


⚠ **LID OFF**

LIQUID CHEMICAL STERILIZATION

With the following methods the watertight lid must be ON, or the device will be damaged.
Follow method* manufacturer's instructions.

METHOD
STERIS SYSTEM 1
STERIS SYSTEM 1E
STERIS SYSTEM 1 PLUS
STERIS SYSTEM 1 EXPRESS



⚠ **LID ON**

**Use BK approved products and methods. Follow the product/method manufacturer's instructions.*
This guide is a summary of the essential steps necessary to properly reprocess specific BK Medical transducers. Always refer to the Care and Cleaning guide on www.bkmedical.com for detailed reprocessing information and lists of BK approved products and methods.

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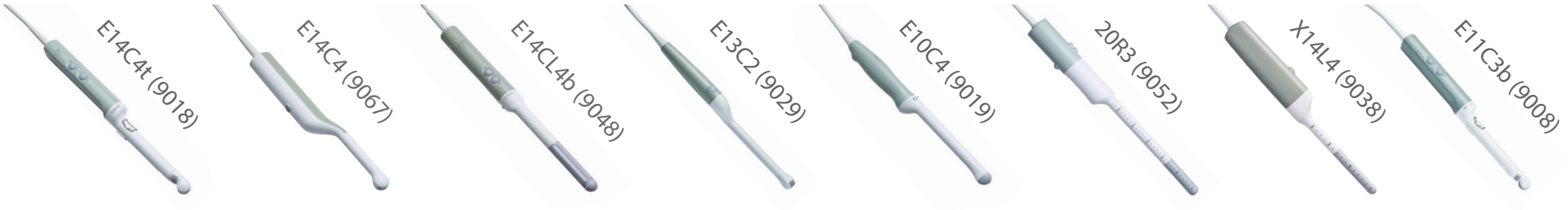
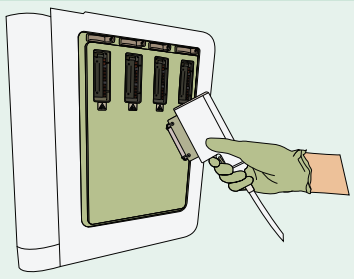
REPROCESSING SELECTED SEMI-CRITICAL TRANSDUCERS

bk medical



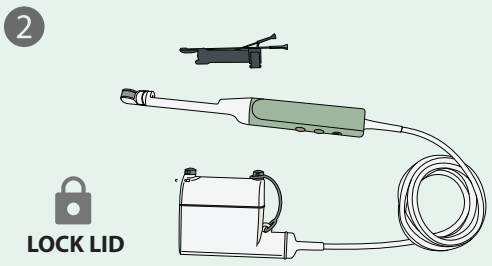
PRECLEANING (MUST BE PERFORMED IMMEDIATELY AFTER USE)

1



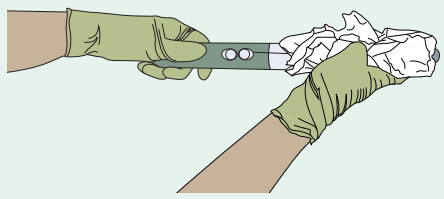
- Disconnect the device from the system.

2



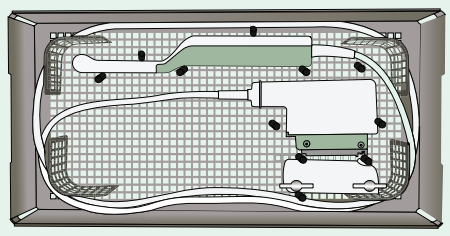
- Remove any covers and needle guides.
- Attach and lock the watertight lid.

3



- Remove gel or biological material with a cloth/sponge moistened with detergent*.

4

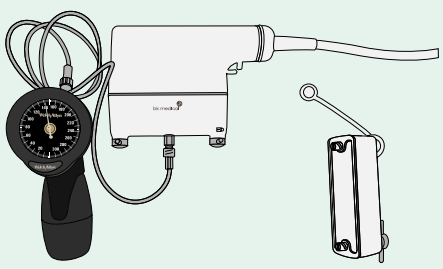


- For transportation, fasten the pre-cleaned device in a closed container.

LEAKAGE TESTING

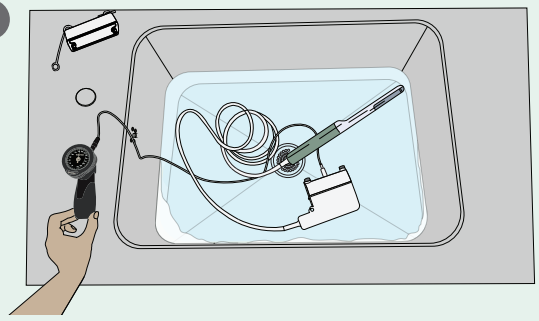
⚠ LEAKAGE TESTING MUST OCCUR **PRIOR** TO IMMERSION IN WATER ⚠ LEAKAGE TESTING MUST OCCUR **EVERY 3 MONTHS**

5



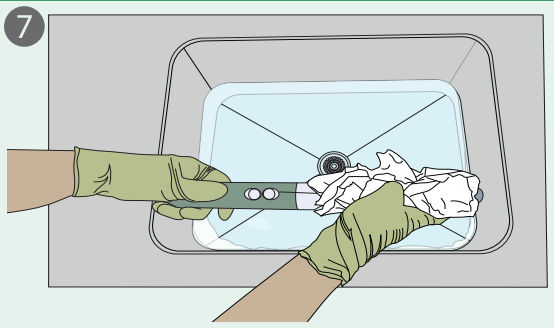
- Check the whole device for damage.
- If undamaged, detach the watertight lid and attach the leakage tester lid to the transducer connector.
- Pump slowly to increase the pressure to 150mm Hg, then observe pressure for 45 seconds.

6



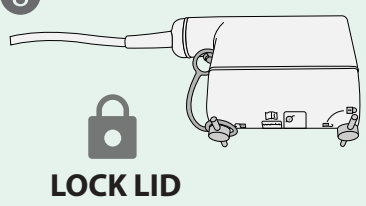
- Keep the watertight lid dry.
- If pressure is not stable, DO NOT immerse the device. If the pressure is stable, immerse the whole device in a water bath.
- Check for escaping bubbles.
  NOTE: A leak is indicated by a constant, steady stream of escaping bubbles.

7



- Remove the whole device from the water bath and dry it with a soft, lint-free cloth.

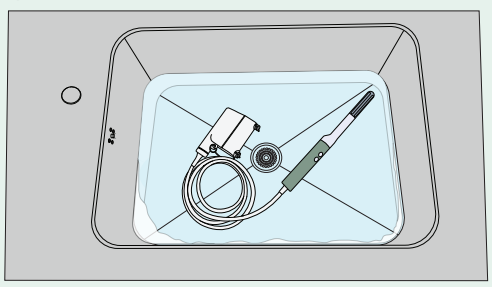
8



- Release pressure, then detach the leakage tester lid. Reattach and lock the watertight lid.

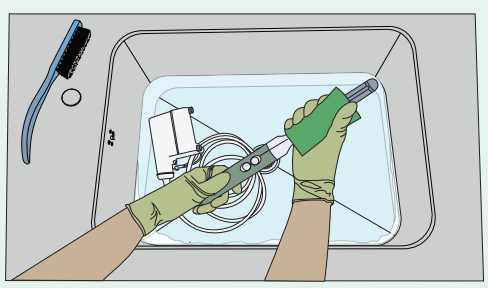
THOROUGH CLEANING

9



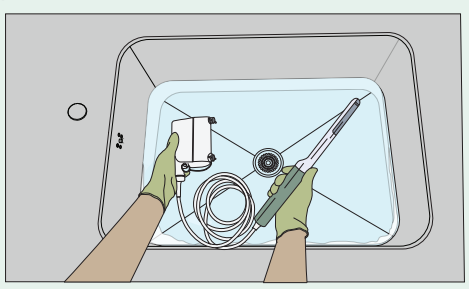
- Fill sink with a detergent solution*, following the detergent manufacturer's instructions.
- Make sure the watertight lid is attached and locked, then immerse the whole device.

10



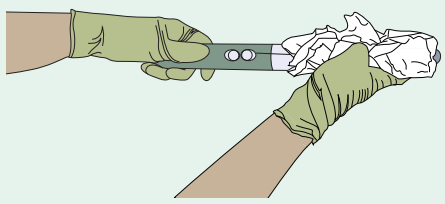
- Use a soft brush/sponge to clean the whole device (including lumens if applicable).
- Soak the device, following detergent manufacturer's instructions.

11



- Check if the device is completely clean. If necessary, repeat steps 9 and 10.
- Rinse the device, following detergent manufacturer's instructions.

12



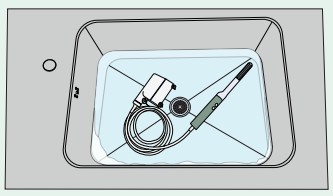
- Dry the complete device with a soft, lint-free cloth, air dry, or use a drying cabinet.

⚠ **DO NOT EXCEED 60°C (140°F)**

DISINFECTION AND STERILIZATION See newest Care and Cleaning guide for complete list of disinfection and automated sterilization methods

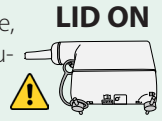
HIGH LEVEL DISINFECTION

IMMERSION DISINFECTION



- Disinfect and rinse the device, following disinfectant* manufacturer's instructions.

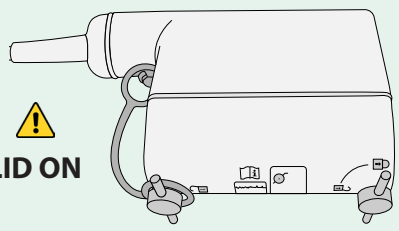
LID ON ⚠



With disinfection methods the watertight lid must be ON, or the device will be damaged. Follow method* manufacturer's instructions.

AUTOMATED DISINFECTION

⚠ LID ON

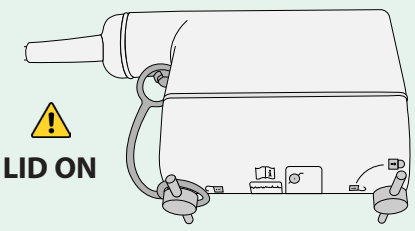


With disinfection methods the watertight lid must be ON, or the device will be damaged. Follow method* manufacturer's instructions.

AUTOMATED STERILIZATION

LIQUID CHEMICAL STERILIZATION

⚠ LID ON

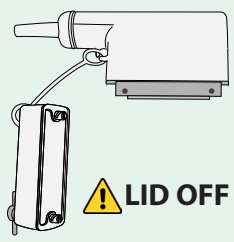


With liquid chemical methods the watertight lid must be ON, or the device will be damaged. Follow method* manufacturer's instructions.

GAS STERILIZATION

⚠

- Note that the X14L4 and the 20R3 transducers cannot be processed with gas sterilization!



With gas processing methods the watertight lid must be OFF, or the device will be damaged. Follow method* manufacturer's instructions. Use special lid for formaldehyde sterilization.

**Use BK approved products and methods. Follow the product/method manufacturer's instructions.*

This guide is a summary of the essential steps necessary to properly reprocess specific BK Medical transducers. Always refer to the Care and Cleaning guide on www.bkmedical.com for detailed reprocessing information and lists of BK approved products and methods.

16-121782-EN-02 05/19

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