

Endocavity Biplane Transducer



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The connector label on a BK Medical transducer contains information about the date of manufacture.

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.

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English source version
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Introduction

This is the user guide for Endocavity Biplane Transducer Type 8848 and must be used together with *Care and Cleaning*, which contains important safety information.

8848 is suitable for transrectal scanning, transvaginal scanning, all transperineal interventional procedures including brachytherapy and cryotherapy treatments.

Type 8848 contains two arrays — a convex array for transverse (T) scanning, and a linear array for sagittal (S) scanning. Both arrays can be used separately or they can be used simultaneously. When using the simultaneous biplane feature, you are able to view two planes at once with a single transducer, and this helps determine the true position of the needle and its tip during puncture and biopsy.

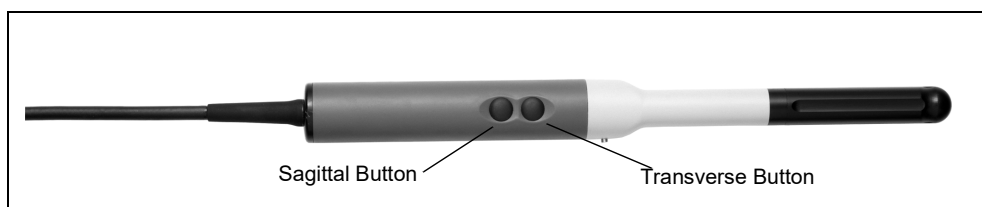


Figure 1. Transducer Type 8848.

Scanning Plane

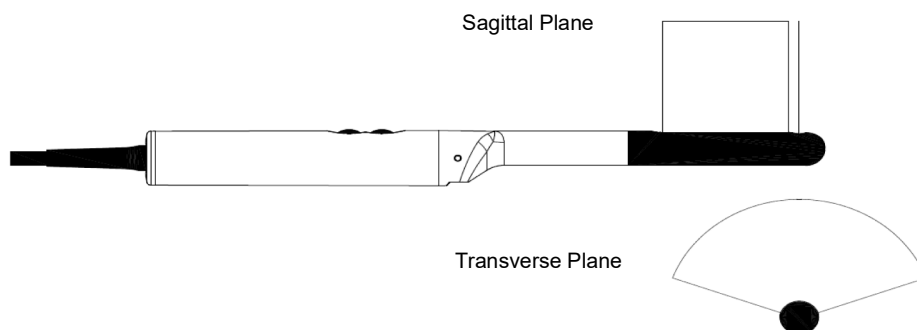


Figure 2. Scanning plane for Type 8848.

General Information

Product specifications for this transducer can be found in the Product Data sheet that accompanies this user guide.

Acoustic output data and data about EMC (electromagnetic compatibility) for this transducer are on the Technical Data CD that accompanies this user guide. A full explanation of acoustic output is given in your scanner user guide.

**WARNING**

If at any time the scanner malfunctions, or the image is severely distorted or degraded, or you suspect in any way that the scanner is not functioning correctly:

- Remove all transducers from contact with the patient.
- Turn off the scanner. Unplug the scanner from the wall and make sure it cannot be used until it has been checked.
- Do not remove the scanner cover.
- Contact your BK Medical representative or hospital technician.

**WARNING**

Always keep the exposure level (the acoustic output level and the exposure time) as low as possible.

Caring for the Transducer

The transducer may be damaged during use or processing, so it must be checked before use for cracks or irregularities in the surface. It should also be checked thoroughly once a month following the procedure in *Care and Cleaning*.

Service and Repair

**WARNING**

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

Cleaning and Disinfection

To ensure the best results when using BK Medical equipment, it is important to maintain a strict cleaning routine.

Full details of cleaning and disinfection procedures can be found in *Care and Cleaning* that accompanies this user guide. A list of disinfectants and disinfection methods that the transducer can withstand are listed in the Product Data sheet.

Sterile cover is available. See the Product Data sheet for more details.

**WARNING**

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

Starting Scanning

All equipment must be cleaned and disinfected before use.

Connecting the Transducer



WARNING

Keep all plugs and sockets absolutely dry at all times.

The transducer is connected to the scanner using the array Transducer Socket on the scanner. To connect, the transducer plug's locking lever should first be in a horizontal position. Align the plug to the scanner socket and insert securely. Turn the locking lever clockwise to lock in place.

When connected, the transducer complies with Type BF requirements of EN60601-1 (IEC 60601-1).



WARNING

To avoid patient injury or damage to a transducer, extra caution may be required when you use a mechanical stepper cradle or robotic accessory with the transducer. This is particularly important when adjusting the cradle/bed position after the transducer has been inserted into the patient. The stepper cradle or robotic accessory may exert excessive force when the transducer position is adjusted, which could harm the patient or damage the transducer.

Changing Frequency

The Multi-Frequency Imaging (MFI) facility enables you to select the scanning frequency. See the applicable scanner user guide for instructions. The selected frequency is displayed at the top of the screen.

Using a Transducer Cover

The transducer should be enclosed in a transducer cover or a standard condom. See the Product Data sheet for a list of available transducer covers.



WARNING

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), FDA is advising health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly.

Apply sterile gel to the tip of the transducer. This improves the screen images by preventing image artifacts caused by air bubbles.

Pull the transducer cover over the transducer.

Gel also creates a good acoustic contact between the skin and the transducer; therefore, apply a small amount to the outside of the cover prior to scanning. Re-apply the gel frequently to ensure good screen images.

**WARNING**

Use only water-soluble agents or gels. Petroleum or mineral oil-based materials may harm the cover materials.

Using the Transducer Control Button

The transducer has two control buttons, one for the sagittal array and one for the transverse array (See Figure 1). Pressing the button activates (starts) or freezes (stops) scanning in that plane. Press the button for more than one second to make a copy of the image. Each time the button is pressed, a “beep” is emitted.

Changing Orientation

To change the orientation of the image on the monitor, refer to the applicable scanner user guide for instructions.

Endorectal Scanning with 8848

Type 8848 is designed for simultaneous biplane scanning of the prostate.

**WARNING**

Do not use excessive force during insertion. Do not make excessive lateral movements during or after insertion. Risk of injury or tissue damage to the patient could occur under certain circumstances. A digital palpation of the rectum may need to be carried out by a clinician prior to insertion or use of the probe as a precautionary measure.

Adjusting Scan Area and Using Expanded Sector (Trapezoidal View)

The width of the image area can be adjusted using the Width key on the scanner’s control panel. See the applicable scanner user guide for instructions.

With the Expanded Sector feature and the 8848, you can increase the transverse sector angle from a default width of 140° to 180°. And, you can increase the default sagittal view of 65mm to a trapezoidal view, which provides an additional 15° on each side.

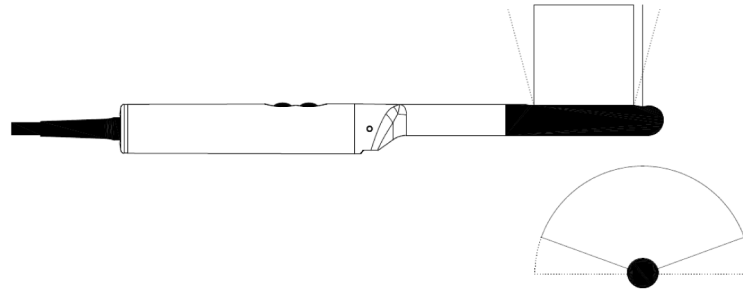


Figure 3. Dotted lines indicating expanded sectors on transducer type 8848.

Puncture Facilities

Puncture and biopsy is possible with Type 8848 transducer. The appropriate puncture attachments are illustrated in the following pages with a brief description of their uses and operating instructions.



WARNING

It is essential for the patient's safety that only the correct puncture attachment is used with Type 8848. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers' puncture attachments.

UA 1232

This metal puncture attachment (see Figure 4) is designed for transperineal puncture and biopsy. It consists of a needle guide and a mounting ring with a lock screw. The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for an 14 Gauge needle.

The guide channels are angled at 0° to the transducer's longitudinal axis and 90° to the transverse scanning plane.

Note: The needle guide can be adjusted 90mm lengthwise with respect to the mounting ring using the adjustment screw.

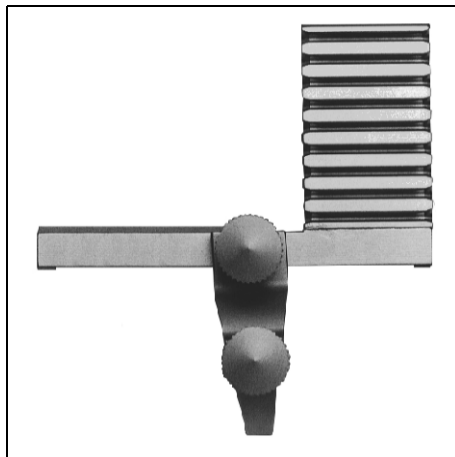


Figure 4. The puncture attachment UA1232.

To mount the transperineal puncture attachment, loosen the lock screw and slide the attachment over the tip of the transducer until the lock screw pressure-pad meets the steel stud on the side of the transducer. The puncture attachment should be correctly positioned (see Figure 5) before the lock screw is tightened. No force should be used when attaching the puncture attachment to the transducer.

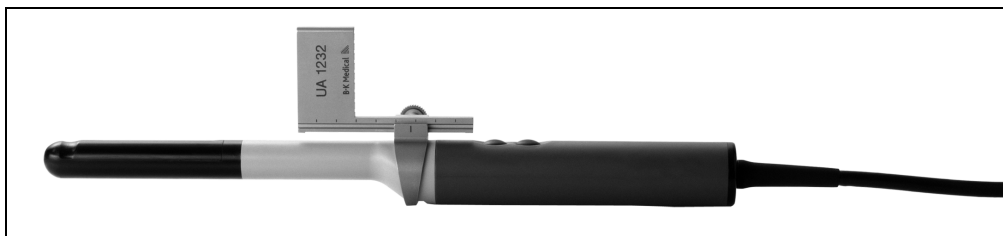


Figure 5. Type 8848 with puncture attachment UA1232.

All parts of the puncture attachment can be autoclaved or disinfected by immersion in a suitable solution.

Performing Puncture and Biopsy



WARNING

It is essential for the patient's safety that only the correct puncture attachments, as described in this guide, are used. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers puncture attachments.

Before beginning a puncture or biopsy procedure, always check that the type number of the transducer and the type number or description of the puncture attachment match exactly those displayed on the scanner monitor.



WARNING

The puncture line on the scan image is an indication of the expected needle path. The needle tip echo should be monitored at all times so any deviation from the desired path can be corrected.

Cover the transducer with a sterile transducer cover.

If the transducer cover is damaged when attaching the puncture attachment, replace it with a new cover.

See the Product Data sheet for a list of available transducer covers.

Press the scanner **Puncture** or **Biopsy** control button to superimpose a puncture line on the scan image.

If more than one puncture line is available, refer to the applicable scanner user guide for instructions on how to change which one appears.

Move the transducer until the puncture line transects the target. Insert the needle and monitor it as it moves along the puncture line to the target. The needle tip echo will be seen as a bright dot on the screen.

**WARNING**

If the needle guide is detached from the transducer during interventional procedures, cover the transducer with a new transducer cover.

**WARNING**

When performing a biopsy, always make sure that the needle is fully drawn back inside the needle guide before moving the probe.

To remove the puncture line from the scan image, refer to the applicable scanner user guide for instructions

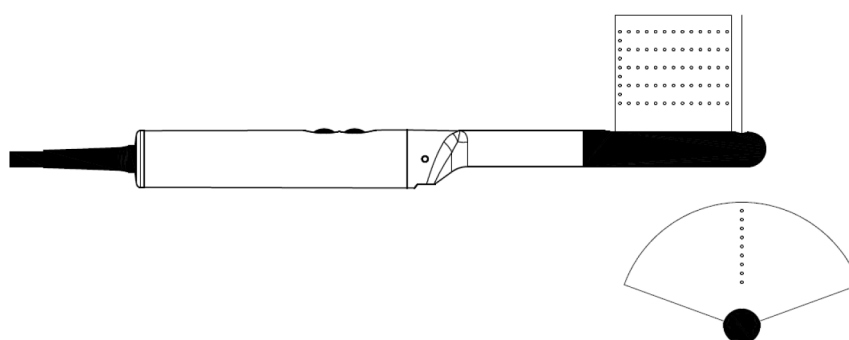


Figure 6. Illustration of the puncture lines for puncture attachment UA1232.

Prostate Volume Determination

Refer to the Scanner User Guide for instructions on how to carry out a prostate volume determination, and the best procedure to use.

Radioactive Source Implantation

Transducer Type 8848 can be used with the CMS Accuseed™ Brachystepper System and with CIVCO AccuCare stepper units for radioactive seed implantation.

Please consult the appropriate stepper documentation for instructions on Source Implantation, including Preplanning, Needle Loading and Implantation.

The 8848 should be prepared for transrectal scanning and biopsy as described earlier in this guide, and mounted and "locked" in the stepping unit.

The volume study of the prostate is performed, the radiation dose planned and the needles loaded.

**WARNING**

Always place the cradle in the "locked" position before seed implantation. When the cradle is in this position, the matrix on the stepping unit corresponds with the matrix puncture pattern in the transverse plane on the scanner's monitor.

To superimpose the source matrix on to the monitor, refer to the scanner user guide for further details.

Before starting source implantation, anchor the prostate to the matrix using thread or needles to prevent it moving during needle placement.

Always place the needles individually, starting at the top of the matrix according to the predetermined sequence.

Using a transverse view of the prostate, advance the needle. Change to the sagittal plane to find the position of the needle on the screen and monitor it during insertion.

When the needle is in place, the radioactive sources can be expelled into the gland. The needle is then removed. The sagittal plane can be used to check the position of the radioactive sources. Repeat this sequence until implantation is complete. The anchors can then be removed.

Cleaning after Puncture and Biopsy

If biological materials are allowed to dry on the transducer, disinfection and sterilization processes may not be effective. Therefore, you must clean transducers immediately after use.

Use a suitable brush to make sure that biological material and gel are removed from all channels and grooves. See *Care and Cleaning* for cleaning instructions.

Disposal

When the transducer is scrapped at the end of its life, national rules for the relevant material in each individual land must be followed. Within the EU, when you discard the transducer, you must send it to appropriate facilities for recovery and recycling. See the applicable scanner user guide for further details.

**WARNING**

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

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