bk medical
a GE Healthcare company

User Guide
Type 8822

Vascular Transducer

English
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For Professional Users Only

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

BK Medical Customer Satisfaction

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

Contents

Introduction

This is the user guide for Vascular Transducer Type 8822 and must be used together with *Care, Cleaning & Safety* which contains important safety information.

Indications for Use

The 8822 is a linear 3-9 MHz vascular transducer, which is designed for deep vein and peripheral vascular examinations. The UA1239 needle guide can be used to guide punctures and biopsies.

Figure 1. Vascular Transducer Type 8822.

Scanning Plane

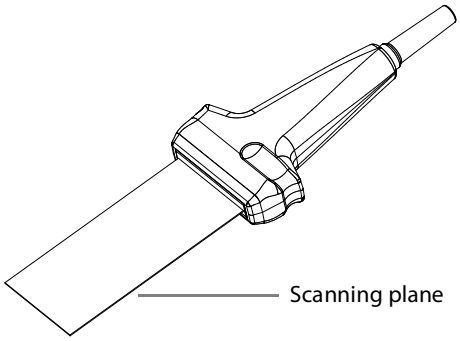

Figure 2. Scanning plane for Type 8822.

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 in Technical Data (BZ2100) that accompanies this user guide. A full explanation of acoustic output data 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.

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.

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, Cleaning & Safety*.

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, Cleaning & Safety* 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 covers are available. See the Product Data sheet for more information.

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 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 B requirements of EN60601-1 (IEC 60601-1).

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.

Latex allergy

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 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 control button on the transducer controls the scanning.

Press the button to **Start** or **Stop** scanning (freeze frame). Press the button for more than one second to make a copy of the image.

The transducer makes a "beep" sound each time you press the button.

The button function can be customized. For more information, see the user guide for the scanner.

Changing Orientation

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

Puncture and Biopsy Facilities

WARNING

It is essential for the patient's safety that only the correct needle guide is used with Type 8822. Never use unauthorized combinations of transducers and needle guides or other manufacturers' needle guides.

Needle Guide UA1239

The UA1239 needle guide (Figure 3) is designed for guiding puncture and biopsy when used with Type 8822 (see Figure 4).

It consists of:

- A bracket for attaching the needle holder to the transducer.
- The needle holder, which features a three-winged shaft that can be rotated in the barrel of the needle holder to accomodate different sized needles.

Use the screw to adjust the angle of penetration.

Use 0.9 mm (20 Gauge), 1.3 mm (18 Gauge), or 2.1 mm (14 Gauge) needles with the needle guide.

Figure 3. Needle guide UA1239.

The bracket has a 30°, 45°, or 60° angle of insertion to the image axis; these are shown on the image as lines of dots.

To mount the UA1239 on the 8822:

1. Hold the transducer in your left hand with the black operating button facing away from you.
2. Hold the UA1239 in your right hand with the adjusting screw facing towards you, the two “legs” pointing to the left, and the movable swing arm pointing down.
3. Slide the two legs down over the transducer into the recessed grooves.
4. Lock the swing arm into position at the neck end of the transducer. An audible click indicates when the needle guide is securely attached.

Figure 4. The needle guide mounted on Type 8822.

⚠ **WARNING**

Ensure the bracket is positioned correctly.

To alter the angle of the needle-guide holder:

1. Loosen the adjustable screw by turning it one quarter revolution counter-clockwise.
2. Select the desired angle (60°, 45°, 30°).

3 Re-tighten the adjustable screw.

To select the correct needle barrel:

1 Raise the three-winged handle up out of its socket and rotate it until the desired barrel is next to the small, black triangular marking on the top of the needle guide holder.
2 Push the three-winged handle fully back down into its socket.
3 Slide in the desired needle (or catheter).

To detach the needle during interventional procedures:

1 Raise the three-winged handle approximately 3 mm and rotate counter-clockwise through 60° until halted by the small metal nub.
2 The needle (or catheter) can now be released from the needle guide attachment.

All parts of the needle guide 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 needle guide, replace it with a new cover.

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

Superimpose puncture line

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.

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

WARNING

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

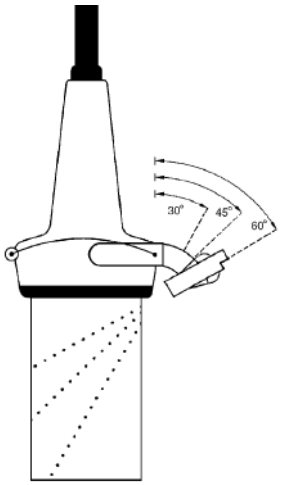

Figure 5. Puncture lines for UA1239 on Type 8822.

Cleaning after Puncture and Biopsy

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

Use a suitable brush to make sure that biological material and gel are removed from all needle guides and other channels and grooves. See *Care, Cleaning & Safety* 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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