

Convex Array Transducer



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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.

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Introduction

This is the user guide for Convex Array Transducer Type 8823 and must be used together with *Care, Cleaning & Safety* which contains important safety information.

8823 is an abdominal transducer suitable for intercostal examinations.

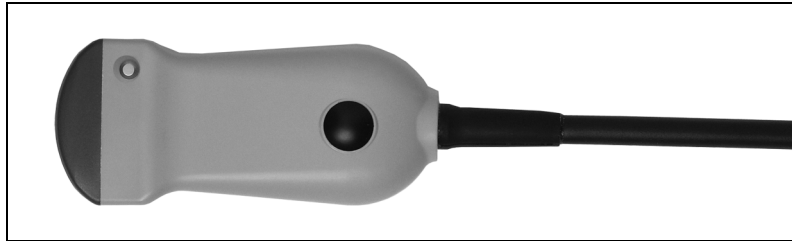


Figure 1. Convex Array Transducer Type 8823.

Scanning Plane

The scanning plane for 8823 is shown in Figure 2.

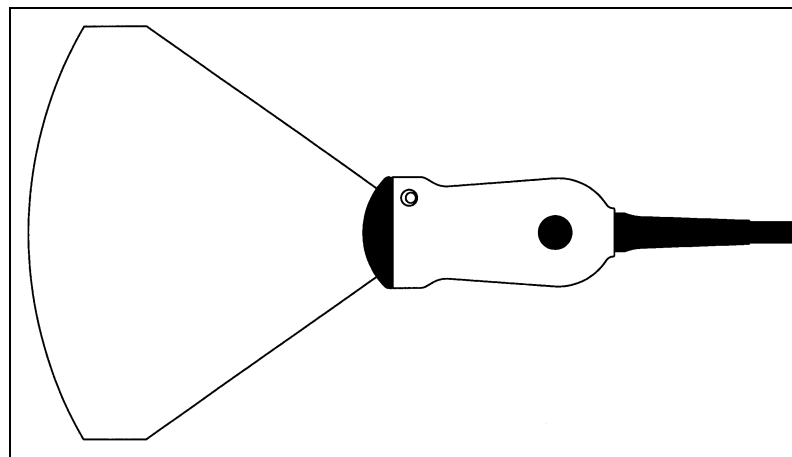


Figure 2. Scanning plane of 8823.

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.

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 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 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.



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 transducer has a control button that you can press to **Start** or **Stop** scanning (freeze frame). 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.

Puncture and Biopsy Facilities

Puncture and biopsy are possible with The 8823 transducer. The puncture attachments are illustrated in the following pages with a brief description of their use and operating instructions.



WARNING

It is essential for the patient's safety that only the correct puncture attachment is used with 8823. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers' puncture attachments.

UA 1250

The puncture attachment (see Figure 3) comprises an attachment bracket, an attachment lock screw (item A in Figure 4), a needle guide, a needle-guide lock screw (item B in Figure 4) and a variable diameter holder for fine needles (0.6 mm or 24 gauge) and large bore needles (2.4 mm or 13 gauge). The guide channel is angled at 18° to the transducer's image axis.

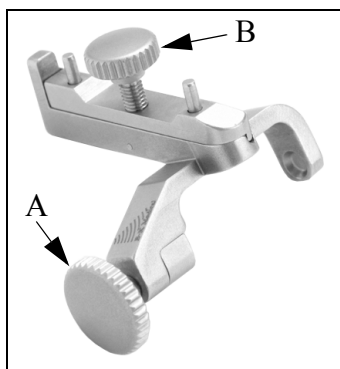


Figure 3. Puncture attachment UA 1250.

To mount biopsy attachment UA1250 ready for use:

Note: When mounted the attachment lock screw (item A in Figure 3) should be on the side of the transducer handle opposite to the transducer's control button.

- 1 Mount the attachment bracket on the transducer. Fit the indentations in the sides of the bracket over the raised metal knobs on either side of the transducer handle.
- 2 Fix the attachment bracket in position by tightening the attachment lock screw (item A in Figure 3). Tighten the screw up to its “locking point”, after which it will not be possible to tighten the screw anymore.
- 3 The biopsy attachment should now be fixed solidly to the transducer’s handle.
- 4 Using the needle guide locking screw (item B in Figure 3), adjust the needle guide according to the size of needle to be used.

The distance from the guide channel entrance of the puncture attachment to the first dot on the scan image puncture line is 52 mm. The distance between the dots is 10 mm, see Figure 8 for details.



Figure 4. 8823 with UA1250 mounted.

All parts of the puncture attachment UA1250 can be autoclaved or disinfected by immersion in a suitable solution. See *Care, Cleaning & Safety* that accompanies this user guide.

UA1341

The puncture attachment kit comprises a reusable plastic bracket (UA1341) and sterile, single-use needle guides (UA0013). Be careful not to discard the reusable bracket together with the single-use needle guides. The bracket can be disinfected by immersion in a suitable solution.



WARNING

Sterile needle guides are disposable products intended for single use only.

To mount puncture attachment UA1341 ready for use:

- 1 Attach the bracket (UA1341) to the transducer.
- 2 Pull a transducer cover over the transducer and bracket.

- 3 Attach insert onto needle guide (UA0013).
- 4 Attach and lock the needle guide to the bracket.
- 5 Activate the needle guide quick-release.

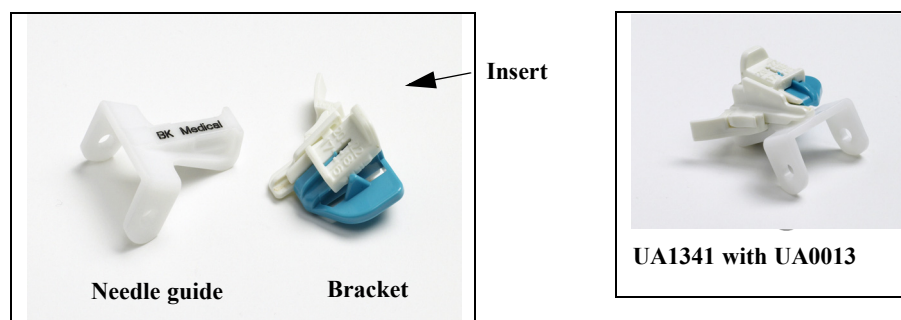


Figure 5. UA1341 and needle guide UA0013.

Please consult the Reference Guide that accompanies the single-use needle guides for more detailed instructions on how to assemble the puncture attachment and needle guide.



Figure 6. 8823 with reusable bracket and transducer cover.

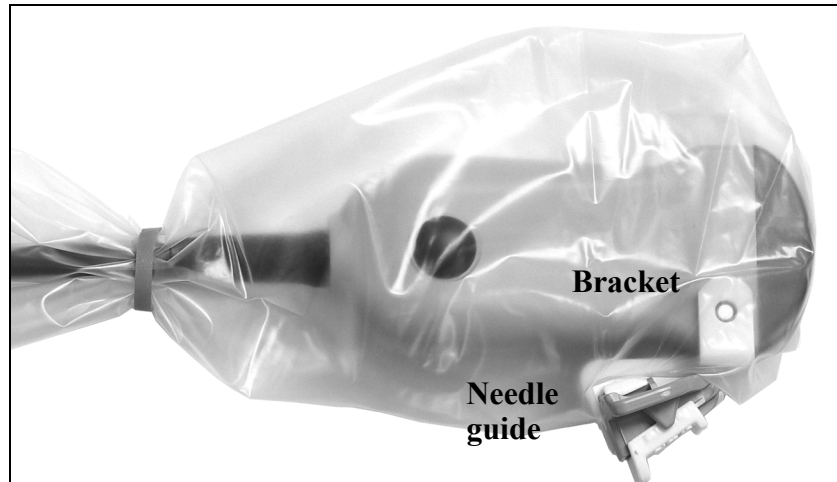


Figure 7. 8823 with single-use needle guide (UA0013) attached.

The distance from the guide channel entrance of the puncture attachment to the first dot on the scan image puncture line is 52 mm. The distance between the dots is 10 mm, see Figure 8 for details.

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.

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.

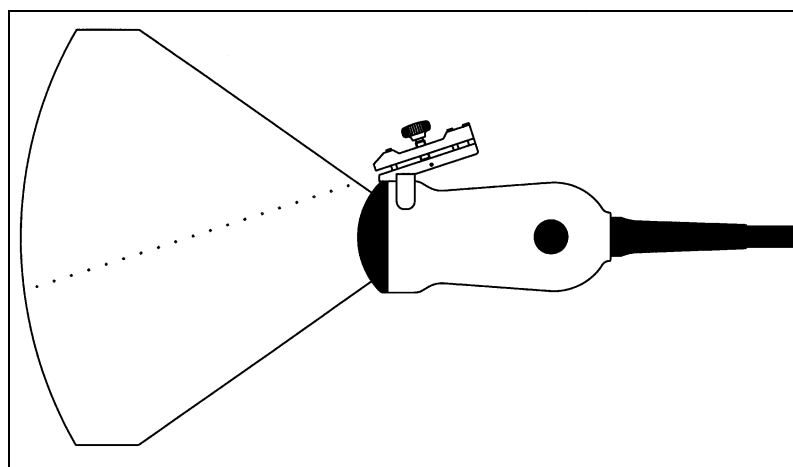


Figure 8. Puncture line for UA1250 or UA1341 with 8823.

The transducer and puncture attachment can be removed without disturbing the position of the needle during puncture.

RF Ablation

When performing RF ablation, you must always follow the instructions provided by the manufacturer of the RF ablation equipment. Be sure to pay attention to all warnings.

Do not use excessive force when you insert the needle into the needle guide.

Do not tighten adjustable needle guides so much that they can damage the needle.

If possible, carefully release and remove the needle guide from the transducer after you insert the RF needle into the patient and before you energize the needle.

If you use metal needle guides to guide RF ablation, you must make sure that the insulation on the needle is not damaged when the needle is moved back and forth in the needle guide.



WARNING

Carefully examine the RF needle before each insertion, to make sure that the insulation is intact. Make sure that the needle is not damaged during insertion. If the insulation is scratched, replace the needle with a new RF needle.

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, 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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