bk ultrasound
powered by analogic

User Guide
Type 8820e

Convex Array Transducer

English
BB1414-G
May 2016

CE 0543
For Professional Users Only

WORLD HEADQUARTERS

Mileparken 34
DK-2730 Herlev
Denmark
Tel.:+45 44528100 / Fax:+45 44528199
www.bkultrasound.com
Email: info@bkultrasound.com

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 Convex Array Transducer Type 8820e, and must be used together with *Care, Cleaning & Safety* which contains important safety information.

8820e is an abdominal transducer suitable for obstetric examinations, and bladder and kidney studies.

Figure 1. Convex Array Transducer Type 8820e

Scanning Plane

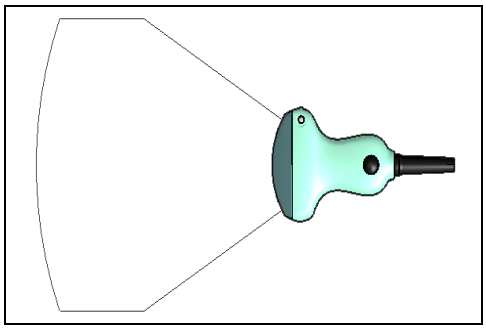

Figure 2. Scanning plane of 8820e

General Information

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

Acoustic output data and data about EMC (electromagnetic compatibility) for these transducers 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 regular 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 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 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 material.

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 Facilities

Puncture and biopsy are possible with 8820e. The 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 8820e. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers' puncture attachments.

UA1250

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

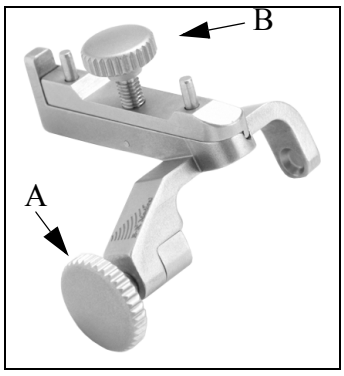

Figure 3. Puncture attachment UA1250

To mount biopsy attachment UA1250 ready for use:

Note: *When mounted the attachment lock screw (item A in Fig. 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 Fig. 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 Fig. 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 56 mm. The distance between the dots is 10 mm (see Fig. 9).

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

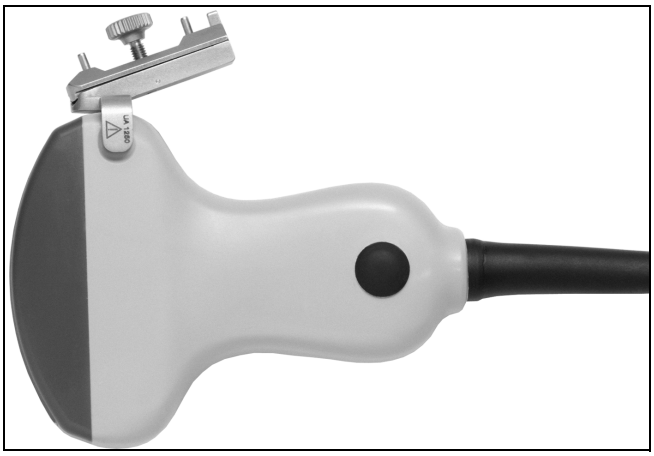

Figure 4. Puncture attachment UA1250 mounted on 8820e

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

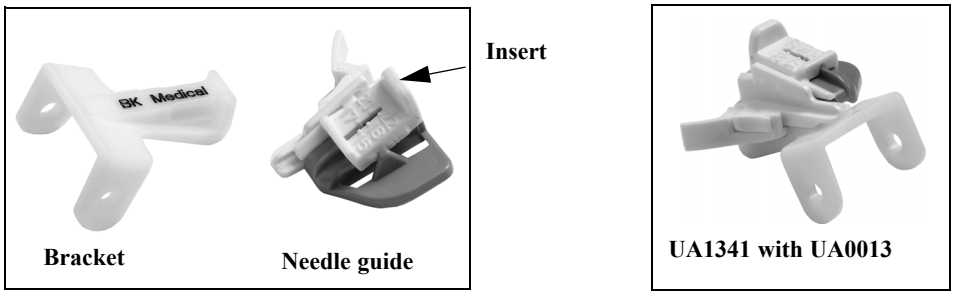

Figure 5. UA1341 and needle guide UA0013

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 guides

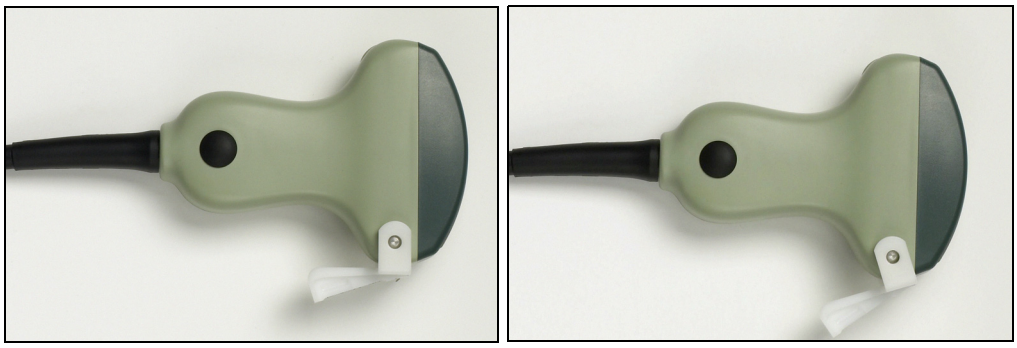

Figure 6. Puncture is possible at an insertion angle of 18°(left) or a wider insertion angle 36.5°(right). Here shown without transducer cover.

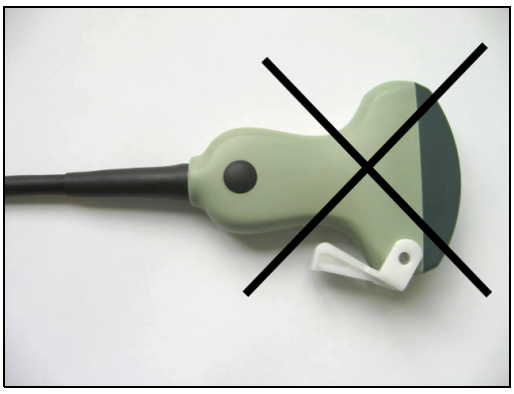

Figure 7. Bracket mounted incorrectly

Figure 8. Type 8820e with single-use needle guide (UA0013) attached

Performing Puncture and Biopsy

Transcutaneous 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 you attach 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.

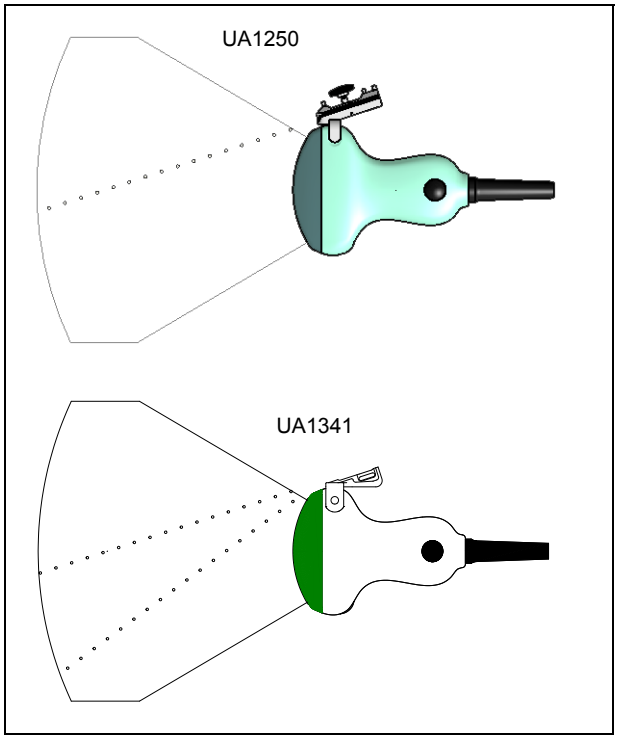

Figure 9. Puncture lines for UA1250 and UA1341 with 8820e

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 or puncture attachments, disinfection and sterilization processes may not be effective. Therefore, you must clean puncture attachments 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.

BK Medical ApS, Mileparken 34, 2730 Herlev, Denmark. T +45 4452 8100 F +45 4452 8199

bk ultrasound

powered by analogic

BK Ultrasound
8 Centennial Drive
Peabody
MA 01960
USA
T +1 978-326-1300
bkultrasound.com

North America
Sales & Service
BK Ultrasound
8 Centennial Drive
Peabody
MA 01960
USA
T +1 978-326-1300
F +1 978-326-1399
bkultrasound.com

Europe and Rest of World
Sales, Service & Design Center
BK Ultrasound
Mileparken 34
2730 Herlev
Denmark
T +45 4452 8100
F +45 4452 8199
bkultrasound.com

Asia
Sales & Service
Analogic Medical Equipment
(Shanghai) Co., Ltd.
1377, Lan Dian Road
Pu Dong New District
Shanghai
China 201132
T +86 21 2089 0333
bkultrasound.com

Canada
Design Center
Ultrasonix Medical Corporation
130-4311 Viking Way
Richmond
BC V6V 2K9
Canada
T +1 866-437-9508
F +1 604-279-8559
bkultrasound.com