

Intraoperative Transducer



BK MEDICAL
Mileparken 34
2730 Herlev
Denmark
Tel.:+45 4452 8100 / Fax:+45 4452 8199
www.bkultrasound.com
Email: info@bkultrasound.dk

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 Intraoperative Transducer Type 8815 and must be used together with *Care, Cleaning & Safety* which contains important safety information.



Figure 1. Intraoperative Transducer Type 8815.

Indications for Use

8815 is an intraoperative transducer (for *Breast, Liver, Pancreas, Biliary system* and *Kidney, including Pediatric application*) suitable for ultrasound-guided interventional procedures.

Needle guide UA1336 provides guidance for needles or other interventional devices during an ultrasound-guided procedure. UA1336 positions the needle relative to the transducer, so that the needle image is in a specified position in the ultrasound image during procedures that require precise needle placement or biopsy.



WARNING

Do not use the transducer for applications where it may come in direct conductive contact with the patient's heart.

Scanning Plane

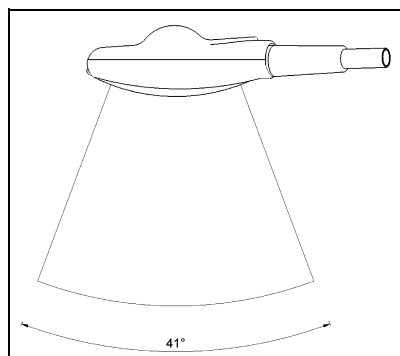


Figure 2. Scanning plane for 8815.

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.

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*.

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, 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 BF 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.

Note: Sterile, disposable sheaths are recommended for intraoperative use. In the United States of America, it is recommended that probe sheaths have been market-cleared. In Canada, use only licensed probe sheaths.



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.

Note: For Intraoperative Applications

Apply sterile gel to the tip of the transducer or fill the cover with 1 to 2ml of sterile water. This improves the screen images by preventing image artifacts caused by air bubbles.

Pull the transducer cover over the transducer.



WARNING

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

Changing Orientation

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

Holding the Transducer for Intraoperative Scanning

Hold the transducer between two fingers and the thumb (see Figure 3) or any position which is comfortable for your hand and move the transducer smoothly over the surface of the organ to produce the best screen image.

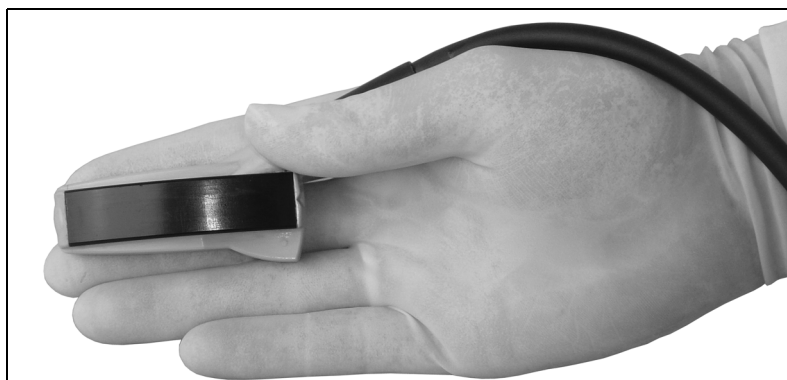


Figure 3. Holding 8815 for scanning.

Puncture Facilities

Intraoperative transducer 8815 is designed to support biopsy and other interventional procedures using single-use needle guide UA 1336. The needle guide is illustrated in the following pages with a brief description of its use and operating instructions.



WARNING

It is essential for the patient's safety that only the correct needle guide is used with 8815. Never use unauthorized combinations of transducers and needle guides or other manufacturers' needle guides.

Single-Use Needle Guide UA1336

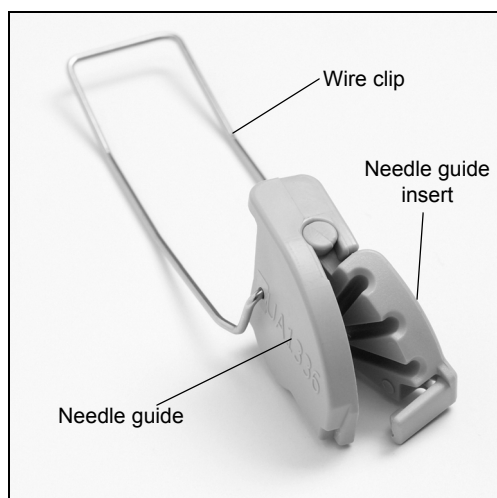


Figure 4. Needle guide UA1336 assembled with 3-angle insert.

Needle guide UA1336 is supplied together with two needle guide insert palettes. Each palette contains a set of 9 needle guide inserts, one 3-angle and one free-angle.

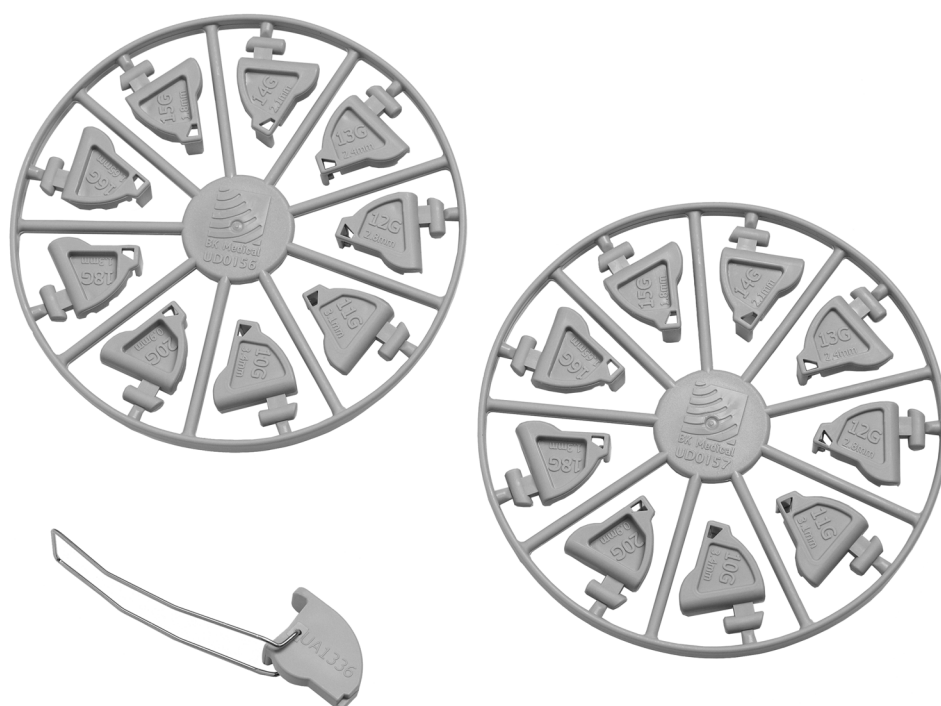


Figure 5. Two needle guide insert palettes supplied together with needle guide UA1336.

The 3-angle inserts each contain three channels. These channels allow the needle to be positioned at 25°, 45° or 65° to the image axis of the 8815.

The free-angle inserts are slotted to allow the positioning of the needle at any angle between 25° and 65° to the image axis of the 8815 while making sure that the needle follows the plane of the image.

The puncture line pattern is shown in Figure 6. The distance between the guide channel of the needle guide to the first dot on the scan image puncture line is 12-15mm depending on which angle is chosen. The distance between the dots is 5 mm.

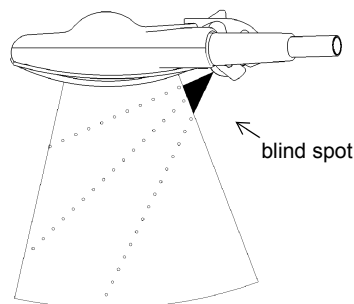


Figure 6. Illustration showing the puncture line and blind spot (See 4th “WARNING” on page 12).

Sterile Needle Guide UA1336

Needle guide UA 1336 and the needle guide insert palettes are supplied sterile in peel packs and are for single-use only. Contents are only sterile if the package is intact. The needle guide, the inserts and both palettes **must** be discarded after use.



WARNING

Disposable components are packaged sterile and are intended for single-use only.

Do not use if:

- Integrity of packaging is violated.
- Expiration date has passed.
- Package label is missing.

The sterile-packed needle guides must be stored at a temperature range from +15°C (+57°F) to +25°C (+77°F) and at a storage humidity of 30% to 80%.



WARNING

Sterile-packed components must be stored in a safe environment and kept out of direct sunlight. Large temperature changes during storage may cause condensation and violate the integrity of the packaging.

Please refer to *Care, Cleaning and Safety* for an example of how to open a sterile-packed product.

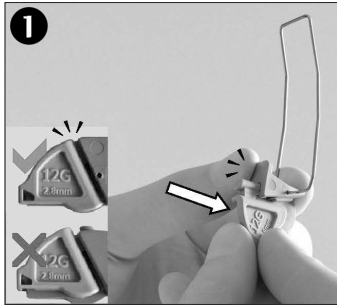


WARNING

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

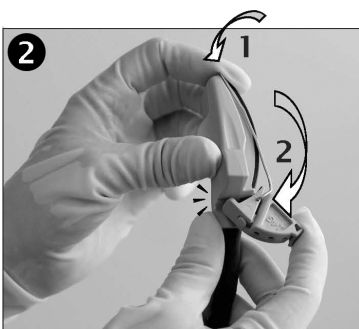
Assembling the Needle Guide and Mounting it on the Transducer

Apply a small amount of scanning gel to the tip of the transducer and carefully cover the transducer with a sterile cover (for readability, the transducer here is shown without transducer cover).



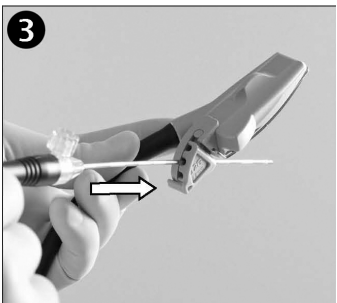
1 Select the required needle guide insert by breaking it off the palette.

Find the wedge shaped channel in the needle guide and slide the insert into the channel in the needle guide from above until it clicks into place and aligns with the needle guide.



2 Taking care not to damage the transducer cover or the surface of the transducer array, gently place the wire clip over the small nodule on the tip of the transducer. Gently place and clip the needle guide into place as shown.

Caution: Ensure the needle guide is positioned correctly.

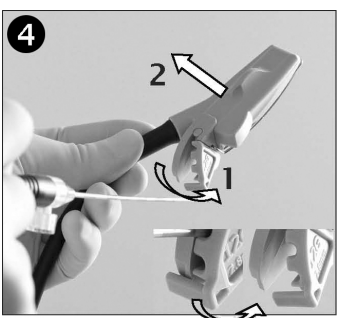


3 Carefully insert the needle into the needle channel.

Caution: Do not let it scrape the inside of the needle channel.

Releasing the Needle During Biopsy

You can release the needle during biopsy so that the needle guide and transducer can be removed from the patient, leaving only the needle in place.



4 Hold the transducer with your left hand. With your right hand, carefully push the needle guide insert sideways until it opens up. Carefully move the transducer and needle guide away from the needle.

**WARNING**

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

Performing Puncture and Biopsy

**WARNING**

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

Before beginning a puncture or biopsy procedure, always check that the type number of the transducer and the type number or description of the needle guide 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. You must take extra care when taking a free-angle biopsy because the expected needle path is not shown.

**WARNING**

The 8815 transducer cannot monitor the first 1.2-1.5 cm of the puncture line (the blind spot, see Figure 6). Extra care should be taken during insertion until the needle tip echo can be seen on the image.

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.

Note: Sterile, disposable sheaths are recommended for intraoperative use; and in the U.S.A. it is recommended that probe sheaths have been market-cleared. In Canada, use only licensed probe sheaths.

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.

RF and Microwave Ablation

When performing RF or Microwave ablation, you must always follow the instructions provided by the manufacturer of the 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 ablation needle into the patient and before you energize the needle.

If you use metal needle guides to guide RF or Microwave 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 ablation 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 ablation 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.

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



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