bk medical

User Guide

E11C3b Transducer

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CE 0543
For Professional Users Only

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The connector label of 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 representative or by contacting us directly.

E11C3b = Ref. Type 9008

Contents

English source version
16-01662-03

Introduction

This is the user guide for the E11C3b transducer, and it must be used together with ***Care and Cleaning*** which contains important safety information.

⚠ Physicians only	**Caution** Rx-c1 United States Federal law restricts this device to sale by or on the order of a physician.

Intended use

The transducer is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body.

Indications for Use

E11C3b is suitable for transrectal prostate imaging. It is also suitable for elastography.

E11C3b contains two arrays — one for transverse (T) imaging, and one for sagittal (S) imaging. The advantage of being able to view two planes simultaneously with one transducer is that the true position of the needle can be seen during puncture and biopsy and a suspicious lesion can be viewed in both planes.

Patient Population

The patient population is adults.

⚠	**Caution** T-c2 The tip of the transducer is very delicate. Handle the transducer gently, especially when you put it down on a hard surface, for example. Also, be careful not to bump the tip.

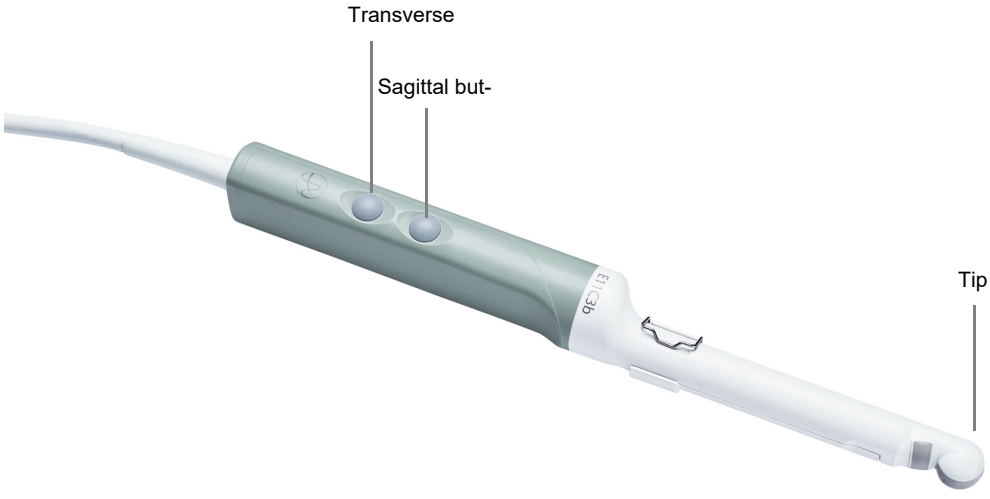

Figure 1. E11C3b transducer

Imaging Plane

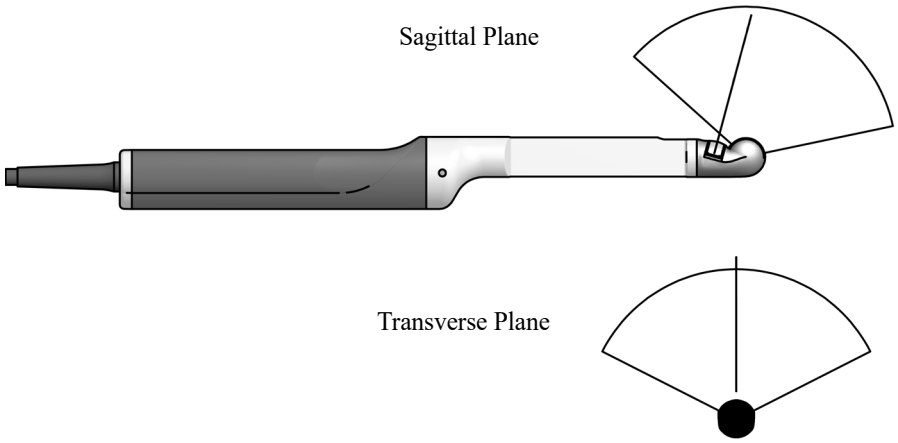

Figure 2. Imaging planes for E11C3b.

General Information

Product specifications, acoustic output data and data about EMC (electromagnetic compatibility) for this transducer can be found in the ***Product Data Sheet*** and the ***Technical Data (BZ2100)*** that accompany this user guide.

⚠	**WARNING** GS-w2 If at any time the system malfunctions, or the image is severely distorted or degraded, or you suspect in any way that the system is not functioning correctly: • Remove all transducers from contact with the patient. • Turn off the system. Unplug the system from the wall and make sure it cannot be used until it has been checked. • Do not try to repair the system yourself. • Contact your BK service representative or hospital technician.

⚠	**WARNING** GS-w5 Do not run over transducer cables with system wheels or other heavy equipment. This can damage the cable, leading to degradation and/or corruption of the ultrasound image.

⚠	**WARNING** AO-w1 To avoid tissue damage, always keep the exposure level (the acoustic output level and the exposure time) as low as possible.

Service and Repair

⚠	**WARNING** SR-w1 Service and repair of BK electromedical equipment must be carried out only by the manufacturer or BK authorized service 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 electrician or hospital technician should verify the safety of all equipment.

Caring for the Transducer

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

Reprocessing

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

Complete details and procedures can be found in ***Care and Cleaning*** that accompanies this user guide.

A list of reprocessing 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** Reproc-w2 Users of this equipment have an obligation and responsibility to provide the highest possible degree of infection control to patients, co-workers and themselves. The instructions in this book are meant as a guide. To avoid cross-contamination, follow all infection control policies (including for reprocessing, packing and storage) for personnel and equipment that have been established for your office, department or hospital.

Starting Imaging

Before use, all equipment must be reprocessed according to expected use.

⚠	**WARNING** T-w5 To prevent electrical shock and damage to the transducer, the connector pins in the transducer plug must always be completely dry before you connect to a system.

Connecting the Transducer

WARNING GS-w4a

It is essential for the patient's safety that only the correct equipment is used.

- Do not use other manufacturers' transducers with BK ultrasound systems.
- Do not use BK transducers with other manufacturers' systems.
- Do not use unauthorized combinations of transducers and needle guides.

The transducer is connected to the system using the array transducer socket on the system. To connect, flip the system's locking lever to the right. Align the transducer plug to the system socket and insert securely. Flip the system's locking lever to the left to lock it.

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

Changing Frequency

The multifrequency imaging (MFI) control enables you to select the imaging frequency. See the applicable system user guide for instructions.

Using a Transducer Cover

BK recommends the use of a sterile transducer cover to reduce the risk of cross-contamination. See the ***Product Data Sheet*** for a list of available transducer covers. Follow local guidelines for the use of transducer covers in your area.

NOTE: *In the United States of America, it is recommended to use transducer covers that have been market cleared. In Canada, use only licensed transducer covers. In Europe, transducer covers must be CE-marked.*

WARNING TC-w1

Some transducer covers can contain latex. Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA advises 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 or fill the cover with 1 to 2 ml of sterile water. This improves screen imaging by preventing image artifacts caused by air bubbles.

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 imaging and re-apply frequently.

Follow these precautions when putting sterile covers on a transducer:

- Wear sterile gloves.
- When using a puncture attachment, place it gently over the cover and secure it, following the instructions for the puncture attachment.
- Verify that the cover has not been damaged in the process. If it has, repeat the procedure with a new transducer cover.

⚠	**Caution** T-c3 Use only water-based gel (sterile if you are using a sterile transducer cover). Products containing parabens, petroleum, or mineral oils may harm the transducer or transducer cover.

Using the Transducer Control Buttons

To change the imaging plane, press the button corresponding to that plane (see Figure 1). Pressing the button activates (starts) or freezes (stops) imaging in that plane. One button enables the sagittal or longitudinal array. A second button enables the transverse array.

Changing Orientation

To change the orientation of the image on the monitor, refer to the applicable system user guide for instructions. The globe engraving on the transducer relates to the globe icon in the top left corner of the monitor image.

Imaging with E11C3b

E11C3b is designed for simultaneous biplane imaging of the prostate.

⚠	**WARNING** Colo-w1 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.

Simultaneous Biplane Imaging

E11C3b can transmit transverse (T) and sagittal (S) images simultaneously. When you tap the system's **Live Dual** button, simultaneous live transmission is automatically activated.

Transverse or Sagittal Imaging

Tap **Live Dual** to toggle simultaneous live transmission on or off. When simultaneous transmission is off, you can change which plane is active and which is frozen by tapping the dual view button.

Imaging Without Puncture or Biopsy

When E11C3b is used for transrectal imaging without the puncture facilities, the dummy bracket UA1325-w must be in place to give the transducer a smooth surface and minimize discomfort for the patient. The dummy bracket clicks into position on the transducer to cover the open channel (see Figure 3).

Figure 3. E11C3b and the dummy channel bracket UA1325-w.

Note: *The dummy bracket must be removed before E11C3b is prepared for disinfection. The bracket can be disinfected using the same methods as explained later under UA1326.*

Puncture and Biopsy Facilities

Puncture and biopsy are possible with E11C3b. The appropriate puncture attachments are illustrated in the following pages with a brief description of their uses and operating instructions. The transducer has an open channel into which the appropriate puncture accessories fit when the dummy channel bracket (UA1325-w) has been removed (see Figure 3).

For Transrectal Puncture

With E11C3b, you can perform transrectal puncture and biopsy by imaging in simultaneous biplane (imaging in both the transverse and sagittal planes).

The biopsy guide is available in both a non-sterile reusable version (light green) and a sterile-packed single-use version (dark green).

Non-sterile biopsy guides (light green)

The dummy channel bracket UA1325-w and the reusable biopsy guides (UA1324 and UA1326) are non-sterile when supplied. They must be reprocessed following the procedure in ***Care and Cleaning***.

The dummy channel bracket and reusable biopsy guide may be damaged during use or processing, so they must be checked before use for cracks or irregularities in the surface. They should also be checked thoroughly once a month following the procedure in ***Care and Cleaning***.

Sterile biopsy guides (dark green)

The sterile single-use biopsy guide UA1322-S and UA1322-S14 come assembled in peel packs. Contents are only sterile if the package is intact.

⚠	**WARNING** Sterile-w1 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

⚠	**WARNING** Sterile-w2 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.

The sterile-packed biopsy guides must be stored at a temperature range from +5 °C (+41° F) to +25 °C (+77 °F) and at a storage humidity of 0% to 80%.

⚠	**WARNING** D-w1 For disposal of contaminated items such as transducer covers or needle guides or other disposable items, follow disposal control policies established for your office, department or hospital.

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

Simultaneous Biplane

The sterile biopsy guide UA1322-S, UA1322-S14 and reusable biopsy guide UA1326 are used for simultaneous biplane imaging.

Figure 4. Reusable biopsy guide UA1326.

The puncture line for UA1322-S, UA1322-S14 and UA1326 on E11C3b is shown in Figure 5. UA1322-S and UA1326 have a bore diameter of 1.6 mm, suitable for 17-gauge needles. UA1322-S14 has a bore diameter of 2.1 mm, suitable for 14-gauge needles.The puncture line is angled at 19° to the transducer's axis.

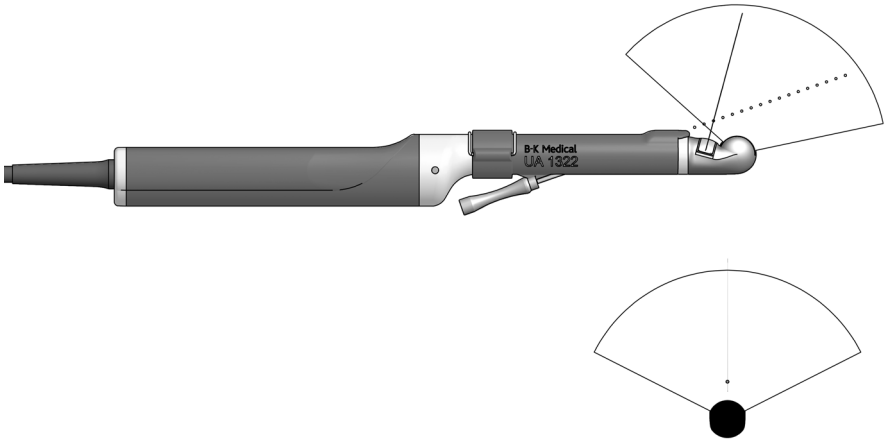

Figure 5. Illustration of the puncture line for biopsy guide UA1322-S, UA1322-S14 and UA1326.

Mounting a Transrectal Biopsy Guide

To mount a biopsy guide on E11C3b:

1. If a dummy channel bracket is mounted on the transducer, remove it.
2. Pull a transducer cover containing a suitable amount of imaging gel over the transducer.
3. Slide the needle guide into the biopsy channel bracket.
4. Insert the assembled needle guide and biopsy channel bracket into the open channel on the transducer. A small nodule on the end of the channel bracket fits into an indentation in the channel on the transducer to help you place the bracket correctly. Click the channel bracket into position on the transducer and lock it into place (see Figure 6).

Figure 6. Biopsy channel bracket and needle guide mounted on E11C3b.

⚠	**WARNING** P-w9 Ensure that the channel bracket and needle guide are correctly positioned. Never insert the needle guide while the transducer is inside the patient.

For Transperineal Puncture

The metal puncture attachment UA1324, shown in Figure 7, is designed for transperineal puncture and biopsy. When UA1324 is being used, the dummy channel bracket UA1325-w (shown in Figure 3) must be in place.

Puncture attachment UA1324 must be autoclaved or disinfected by immersion in a suitable solution.

UA1324 consists of a needle guide and a mounting ring with clamp. The needle guide comprises 9 parallel guide channels, spaced 5 mm apart, each with an internal diameter of 2.1 mm, suitable for a 14-gauge needle. The guide is parallel to the centerline of the transducer.

Note: *The needle guide can be adjusted 70 mm lengthwise with respect to the mounting ring, using the adjustment screw.*

Figure 7. Puncture attachment UA1324.

Mounting the Transperineal Puncture Attachment

To mount the transperineal puncture attachment, ensure that the dummy channel bracket UA1325-w is in place. Pull a sterile transducer cover over the transducer. Loosen the clamp on UA1324, and slide the attachment over the tip of the transducer until it meets the steel stud on the side of the transducer. The puncture attachment should be correctly positioned so that the groove slides easily over stud. No force should be used when attaching the puncture attachment to the transducer.

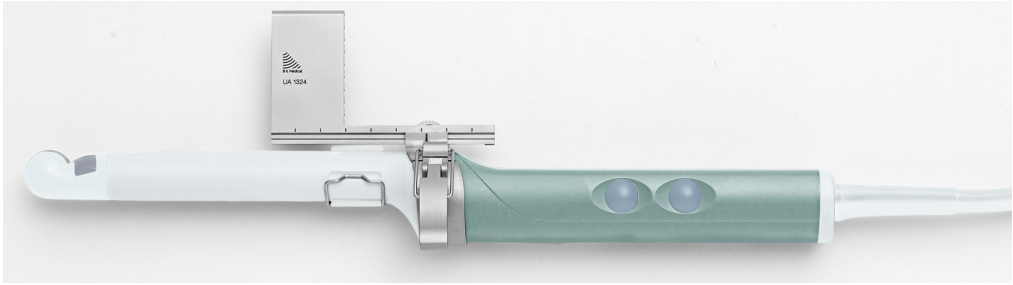

Figure 8. Puncture attachment UA1324 mounted on E11C3b.

The puncture lines for UA1324 on E11C3b are shown in Figure 9.

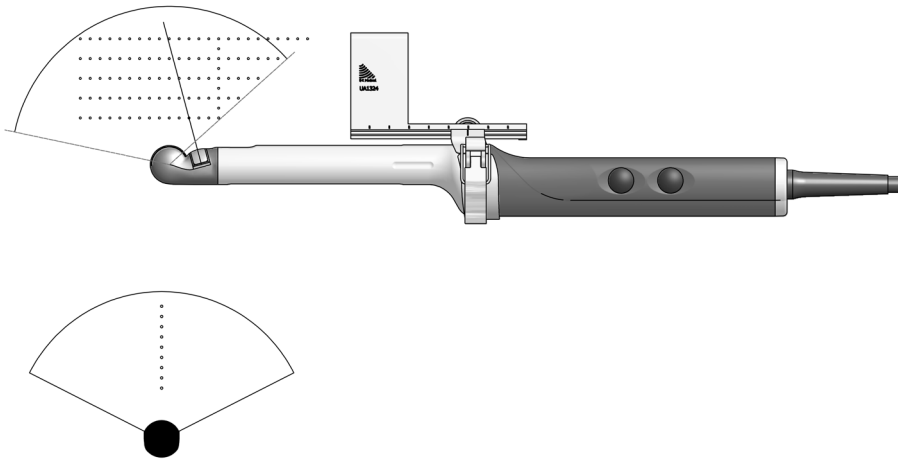

Figure 9. Illustration of the puncture line for puncture attachment UA1324.

Performing Puncture and Biopsy

⚠	**WARNING** P-w1 Before you start imaging, verify that the type number or name of the transducer and the type number or description of the needle guide you are using match the number displayed on the monitor. Also make sure that the needle guide is positioned correctly. If the numbers do not match, or if the needle guide position is not correct, the puncture line on the monitor may not correspond to the true puncture path in the tissue. In case of any inconsistency, stop imaging, turn off the system, and contact your BK service representative.

⚠	**WARNING** P-w4 The puncture line on the image is an indication of the expected needle path. To avoid harming the patient, the needle tip echo should be monitored at all times so any deviation from the desired path can be corrected.

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.

Superimpose puncture line

Tap **Biopsy** to superimpose a puncture line on the image.

If more than one puncture line is available, refer to the applicable system 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.

The puncture line will differ depending on the imaging plane orientation. In the sagittal plane, the puncture path is indicated by a line of dots. The distance between each puncture dot is 5 mm.

In the transverse plane, a single dot indicates the point at which the needle will transect the imaging plane.

⚠	**WARNING** TC-w4 If you detach the needle guide during interventional procedures, the transducer cover could be damaged. To avoid cross-contamination, cover the transducer with a new transducer cover before reattaching the needle guide.

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

⚠	**WARNING** P-w5 Avoid unnecessary tissue damage. When performing a biopsy, always make sure that the needle is fully drawn back inside the needle guide before moving the transducer.

Cleaning after Puncture and Biopsy

⚠	**WARNING** Reproc-w3 Immediately after use, you must pre-clean the device until visually clean (including device lumens if existing). Conduct the thorough cleaning process as soon as possible after use in order to prevent bioburden drying on the surface. Dried bioburden can lead to inefficient cleaning, disinfection and sterilization, causing a risk of cross-contamination.

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 system user guide for further details.

⚠	**WARNING** D-w1 For disposal of contaminated items such as transducer covers or needle guides or other disposable items, follow disposal control policies established for your office, department or hospital.

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