The connector label on a BK Medical transducer contains information about the date of manufacture.

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.
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English source version

16-01265-EN-07
Introduction

This is the user guide for the E14C4t transducer, and it must be used together with the Care and Cleaning user guide which contains important safety information.

<table>
<thead>
<tr>
<th>Caution Rx-c1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians only</td>
</tr>
<tr>
<td>United States Federal law restricts this device to sale by or on the order of a physician.</td>
</tr>
</tbody>
</table>

Intended use

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

Indications for Use

E14C4t combines simultaneous biplane imaging and endfire imaging in a single transducer. E14C4t is designed for transrectal and transvaginal procedures. It is also suitable for elastography and contrast imaging.

Patient Population

The patient population is adults.

<table>
<thead>
<tr>
<th>Caution T-c2</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

Figure 1. E14C4t transducer
Imaging Plane

E14C4t contains two curved arrays — one for transverse imaging, and one for sagittal and endfire imaging. The sagittal array of the E14C4t has a total arc of 210°. In both simultaneous biplane imaging and endfire imaging, the imaging plane uses a 140° section of the arc. It is important to note that simultaneous biplane imaging and endfire imaging use different sections of the sagittal array. Figure 2 illustrates which section of the array simultaneous biplane and endfire use.

![Figure 2. Imaging plane for E14C4t.](image)

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.

<table>
<thead>
<tr>
<th>WARNING GS-w2</th>
</tr>
</thead>
<tbody>
<tr>
<td>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:</td>
</tr>
<tr>
<td>• Remove all transducers from contact with the patient.</td>
</tr>
<tr>
<td>• Turn off the system. Unplug the system from the wall and make sure it cannot be used until it has been checked.</td>
</tr>
<tr>
<td>• Do not try to repair the system yourself.</td>
</tr>
<tr>
<td>• Contact your BK service representative or hospital technician.</td>
</tr>
</tbody>
</table>
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 details.

Starting Imaging

Before use, all equipment must be reprocessed according to expected use.
**Connecting the Transducer**

**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 G5-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 Multi-Frequency Imaging (MFI) facility 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.

### 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.

### 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 endfire array. A long press on this button also activates endfire imaging.

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.

### Imaging with E14C4t

#### Simultaneous Biplane Imaging

E14C4t can transmit transverse (T) and sagittal (S) images simultaneously. When you press bk3000/bk5000’s Split key or tap LIVE DUAL on bkSpecto, simultaneous live transmission is automatically activated. On the bk3000/bk5000 screen, this is indicated by a green dot in front of Simultan.
Transverse or Sagittal Imaging

Click Simultan/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 on bk3000/bk5000 by pressing the Split key or by placing the cursor on the image you want to be active and pressing the Select key. On the bkSpecto, you tap the dual view button to toggle between the views.

Endfire Imaging

E14C4t can perform endfire imaging. A long press on the transducer’s Sagittal/Endfire button activates endfire imaging. On the screen, this is indicated by the letter E, which appears to the right of the transducer number. To switch imaging plane on bk3000/bk5000, click E and select transverse (T) or sagittal (S). On the bkSpecto, tap T or S on the touchscreen.

When you activate endfire imaging, one image appears (and by default, simultaneous imaging is off). You must enable split screen imaging as there is no defined isocenter in this context. When you press the system’s Split key/tap DUAL, two images appear on the screen. The endfire image appears and either a transverse or sagittal image appears, depending on what was last used during imaging.

Click Simultan/tap LIVE DUAL to toggle simultaneous live transmission on or off.

Imaging Without Puncture or Biopsy

When E14C4t 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. E14C4t and the dummy channel bracket UA1325-w.](image)

Note: The dummy bracket must be removed before E14C4t is prepared for disinfection. The bracket can be disinfected using the same methods as explained later under UA1326.

Adjusting Image Area and Using Expanded Sector (Trapezoidal View)

The width of the image area can be adjusted using the Width key on the system’s control panel. See the applicable system user guide for instructions.
With the Expanded Sector feature you can increase the transverse sector angle from a default width of 140° to 180°.

![Figure 4. Dotted lines indicate expanded transverse sector on E14C4t.](image)

**Puncture and Biopsy Facilities**

Puncture and biopsy are possible with E14C4t. 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 E14C4t, you can perform transrectal puncture and biopsy by imaging in one of three ways:

- **Simultaneous biplane** (imaging in both the transverse and sagittal planes).
- **Endfire** (imaging in the sagittal plane).
- **Dual** (combines both the simultaneous biplane and endfire imaging in one biopsy guide).

All the biopsy guides for transrectal puncture have a bore diameter of 1.6 mm, suitable for 17- and 18-gauge needles.

For transrectal puncture, biopsy guides are available in both non-sterile reusable versions and sterile-packed single-use versions.

**Non-Sterile Biopsy Guides (Light Green)**

The dummy channel bracket UA1325-w and the reusable biopsy guides (UA1326, UA1327 and UA1328) are non-sterile when supplied. This is also the case with Puncture attachment UA1324. They must all be reprocessed following the procedure in *Care and Cleaning*.

The dummy channel bracket and reusable biopsy guides 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 guides (UA1322-S, UA1322-S14, UA1323-S and UA1329-S) come assembled in peel packs. Contents are only sterile if the package is intact.

Recommended needle length is 20 cm (7.8 inches) for anesthetic procedures and 25 cm (9.8 inches) for biopsy procedures.

<table>
<thead>
<tr>
<th>WARNING Sterile-w1</th>
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</thead>
<tbody>
<tr>
<td>Single-use components are packaged sterile and are intended for single-use only.</td>
</tr>
<tr>
<td>Do not use if:</td>
</tr>
<tr>
<td>• integrity of packaging is violated</td>
</tr>
<tr>
<td>• expiration date has passed</td>
</tr>
<tr>
<td>• package label is missing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>WARNING Sterile-w2</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

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%.

<table>
<thead>
<tr>
<th>WARNING D-w1</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

Simultaneous Biplane

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

Figure 5. Reusable biopsy guide UA1326.

The puncture line for UA1322-S, UA1322-S14 and UA1326 on E14C4t is shown in Figure 6.
UA1322-S and UA1326 have a bore diameter of 1.6 mm, suitable for 18-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 6. Illustration of the puncture line for biopsy guide UA1322-S, UA1322-S14 and UA1326.*

**Endfire**

The sterile single-use biopsy guide UA1323-S and reusable biopsy guide UA1327 are used in endfire imaging.

*Figure 7. Reusable biopsy guide UA1327.*

The puncture line for UA1323-S and UA1327 on E14C4t is shown in Figure 8. The needle guide is parallel to the centerline of the transducer.

*Figure 8. Illustration of the puncture line for biopsy guides UA1323-S and UA1327.*

**Dual**

The sterile single-use biopsy guide UA1329-S and reusable biopsy guide UA1328 are used in dual imaging. The angle of insertion at 0° is marked with a blue band. On screen, you will see this corresponds to the color of the puncture line displayed on the image.

*WARNING* P-w8

Before beginning a puncture or biopsy procedure using dual scanning, ensure that the color of the puncture line on the scanner monitor matches that of the needle guide you will insert your needle into.
The puncture lines for UA1328 and UA1329-S on E14C4t are shown in Fig. 10. The needle guides are angled at $0^\circ$ and $19^\circ$ to the transducer’s axis.

During endfire imaging, only the endfire biopsy line can be displayed on screen.

**Mounting a Transrectal Biopsy Guide**

To mount a biopsy guide on E14C4t:

1. If a dummy channel bracket is mounted on the transducer, remove it.
2. Pull a sterile transducer cover containing a suitable amount of sterile 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 11).

**WARNING**

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.
For Transperineal Puncture

The metal puncture attachment UA1324, shown in Figure 12, 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.

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.

Mounting the Transperineal Puncture Guide

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 the stud. No force should be used when attaching the puncture attachment to the transducer.
Figure 13. Puncture attachment UA1324 mounted on E14C4t.

The puncture lines for UA1324 on E14C4t are shown in Figure 14.

Figure 14. 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. |
| | Superimpose puncture line  
Press the system **Puncture** or **Biopsy** control button 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 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

<table>
<thead>
<tr>
<th>WARNING Reproc-w3</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

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.

3D Imaging

3D imaging with the E14C4t is possible:
- Freehand – where the transducer is combined with the appropriate 3D system software.

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.

<table>
<thead>
<tr>
<th>WARNING D-w1</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
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