

E13C2 Transducer



LEGAL MANUFACTURER

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The connector label on 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 Medical representative or by contacting us directly.

E13C2 = Ref. Type 9029

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Introduction

This is the user guide for E13C2 and must be used together with the *Care and Cleaning* user guide 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.
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Intended use

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

Indications for use

E13C2 is suitable for transrectal prostate and transvaginal uterus imaging. It is also suitable for contrast imaging and elastography.

Needle guide UA1339 provides needle guidance for biopsy.

Patient Population


The patient population is adults.




Figure 1. E13C2 transducer.


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.

	<p>WARNING GS-w2</p> <p>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:</p> <ul style="list-style-type: none"> • 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.
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	<p>WARNING AO-w1</p> <p>To avoid tissue damage, always keep the exposure level (the acoustic output level and the exposure time) as low as possible.</p>
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Service and Repair

	<p>WARNING SR-w1</p> <p>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.</p>
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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 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 Multi-frequency 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.*


	<p>WARNING TC-w1</p> <p>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.</p>
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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.

	<p>Caution T-c3</p> <p>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.</p>
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	<p>WARNING Colo-w1</p> <p>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.</p>
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Using the Transducer Control Button

The control button on the transducer controls the imaging.

Press the button to **Start** or **Stop** imaging (freeze frame). Press the button for more than one second to make a copy of the image.

Changing Orientation

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

Puncture and Biopsy Facilities

Puncture and biopsy are possible with the E13C2 transducer. The needle guides are illustrated in the following pages with a brief description of their use and operating instructions.

The needle guide is intended for transrectal puncture and biopsy.

You will need:

- reusable needle guide UA1349 or single-use needle guide UA1339
- 17-gauge biopsy needles for use with both needle guides.

Needle guide UA1339 has an inner diameter of 1.7 mm and reusable needle guide UA1349 has an inner diameter of 1.5 mm, both of them suitable for up to 17-gauge needles. Needle guide UA1339 is supplied sterile and is for single use only.

The needle guide is angled 0° towards the long axis of the transducer (i.e. towards the mid-axis of the scan image with E13C2). The distance from the entrance to the needle guide and the first puncture line dot on the scan image is 166 mm, as shown in Fig. 4. The dots are 5 mm apart.


All parts of the UA1349 needle guide can be autoclaved or disinfected by immersion in a suitable solution.




Figure 2. Reusable needle guide UA1349.

Single-Use Sterile Needle Guide UA1339

Needle guide UA1339 is supplied sterile in peel packs and is for single-use only. Contents are sterile only if the package is intact. The needle guide must be discarded after use.

	<p>WARNING Sterile-w1</p> <p>Single-use components are packaged sterile and are intended for single-use only.</p> <p>Do not use if:</p> <ul style="list-style-type: none">• Integrity of packaging is violated• Expiration date has passed• Package label is missing
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	<p>WARNING Sterile-w2</p> <p>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.</p>
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The sterile-packed needle guide must be stored at a temperature range from +5°C (+41°F) to +25°C (+77°F) and a storage humidity of 0% to 80%.


	<p>WARNING D-w1</p> <p>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.</p>
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Figure 3. Single-use needle guide UA1339.


To take a biopsy:


1. Enclose the transducer in a transducer cover.
2. Click the needle guide into place.
3. Insert a needle into the needle guide.

Ensure the needle guide is securely in place and the tip of the needle guide lies close to the front of the transducer.

The minimum needle length is 25 cm for a biopsy gun with needle guides UA1339 and UA1349.

Performing Puncture and Biopsy

	<p>WARNING P-w1</p> <p>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.</p>
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	<p>WARNING P-w4</p> <p>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.</p>
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If not sterilized, 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.

See the *Product Data Sheet* for a list of available transducer covers.


Press the **Puncture Guide** button on the system to superimpose a puncture line on the scan 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 as it moves along the puncture line to the target. The needle tip echo will be seen as a bright dot on the screen.

	<p>WARNING TC-w4</p> <p>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.</p>
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To remove the puncture line from the scan image, refer to the applicable system user guide for instructions.

	<p>WARNING P-w5</p> <p>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.</p>
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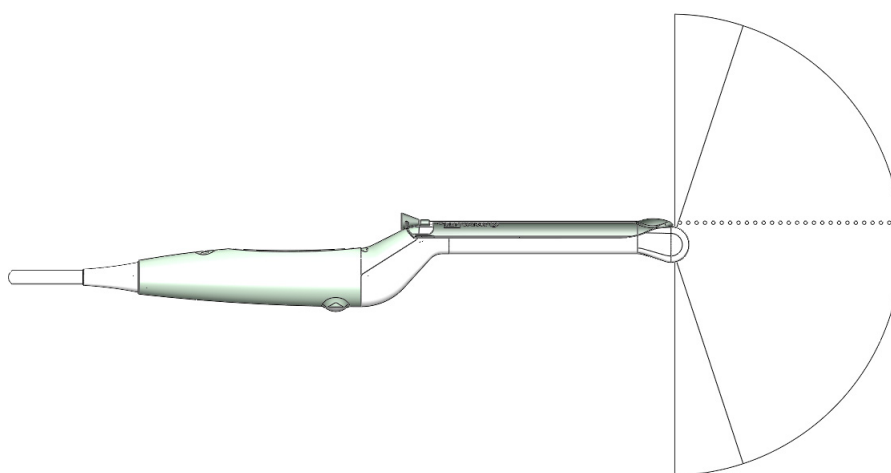



Figure 4. Illustration of the puncture line for needle guides UA1339 and UA1349.


Cleaning after Puncture and Biopsy

	<p>WARNING Reproc-w3</p> <p>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.</p>
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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.

	<p>WARNING D-w1</p> <p>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.</p>
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