bk medical

User Guide

E10C4 Transducer

16-01266-EN-05
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CE 0543

For Professional Users Only

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.

E10C4 = Ref. Type 9019

Contents

English source version
16-01266-EN-05

Introduction

This is the user guide for the E10C4[1] transducer, and it 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.

Intended use

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

Indications for Use

E10C4 is an endovaginal transducer suitable for gynecological examinations, transvaginal imaging, transrectal imaging, fetal studies in early pregnancy and for ultrasound-guided interventional procedures. It is also suitable for elastography.

Needle guides UA1282 and UA1350 provide guidance for needles or other interventional devices during an ultrasound-guided procedure. UA1282/UA1350 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.

Patient Population

The patient population is adults.

Fig. 1. E10C4 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.

1. E10C4 has not been licensed by Health Canada for use on the bkSpecto.

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 AO-w1

To avoid tissue damage, always keep the exposure level (the acoustic output level and the exposure time) as low as possible.

Fetal Imaging

When you use the transducer for fetal imaging, it is important to make sure that the default settings are appropriate and to reset to the default setting before imaging a new patient. A full explanation of acoustic output is given in your system user guide.

Service and Repair

WARNING SR-w1

Service and repair of BK 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 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. • Do not use other manufacturers' needle guides with BK Medical transducers.

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.

⚠	**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.

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 E10C4. The puncture attachment is illustrated in the following pages with a brief description of its use and operating instructions.

The use of probe sheaths during invasive applications is recommended.

For hygiene reasons, the transducer should be enclosed in a transducer cover or a standard condom. When sterile conditions are required, cover the transducer with a sterile transducer cover.

Puncture Attachment UA1282

This metal puncture attachment (see Fig. 2) is intended for transvaginal puncture and biopsy with E10C4.

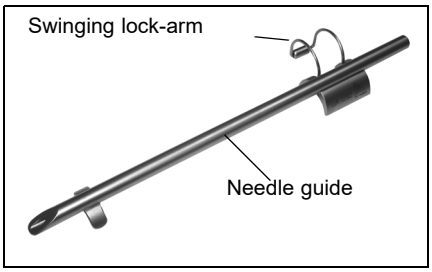

Fig. 2. Puncture attachment UA1282

The puncture attachment consists of a swinging lock-arm and a needle guide with an inner diameter of 1.8 mm, suitable for up to 14 gauge needles.

The needle guide is angled 0.9° towards the long axis of the transducer (i.e. towards the mid-axis of the scan image). The distance from the entrance to the needle guide and the first puncture line dot on the scan image is 173 mm. The dots are 5 mm apart, see Fig. 5 for details.

All parts of the puncture attachment can be autoclaved or disinfected by immersion in a suitable solution. See the ***Product Data Sheet*** for more information.

To mount UA1282:

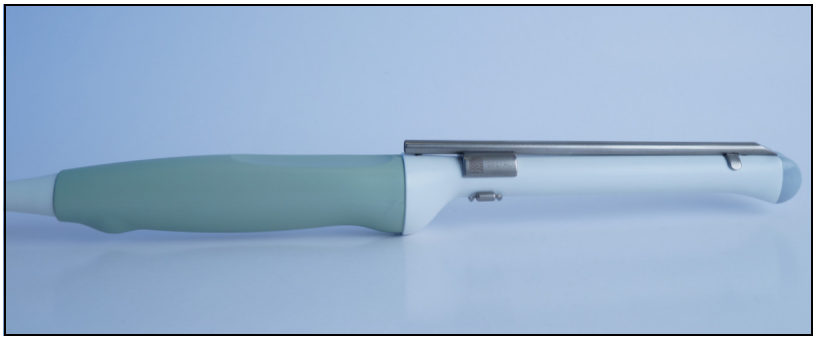

Fig. 3. E10C4 with puncture attachment UA1282

1. Hold the transducer with the groove on the handle uppermost.
2. Align the two raised nodules on the underside of the attachment with the two holes on the upperside of the probe's rod.
3. Lock the swinging arm into position over the bottom of the transducer. An audible click indicates when the needle guide is securely attached.

To remove the needle guide, unlock the swinging arm and lift the needle guide off the transducer.

Single-Use Sterile Needle Guide UA1350

Needle guide UA1350 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.

⚠	**WARNING** Sterile-w1 Single-use 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 needle guides must be stored at a temperature range from +5ºC (+41ºF) to +25ºC (+77ºF) and a storage humidity of 0% to 80%.

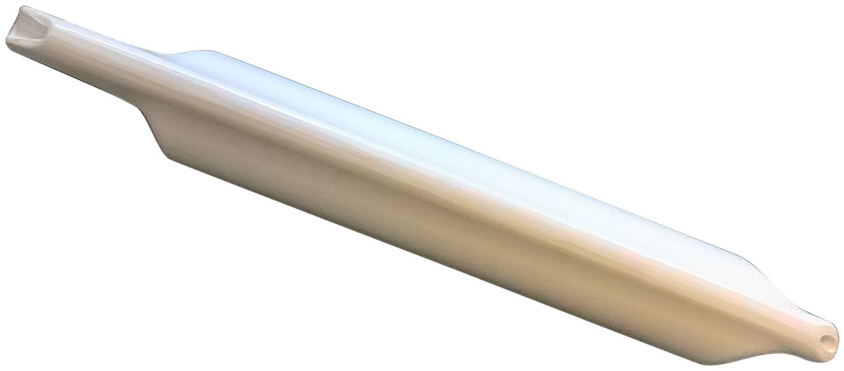

Fig. 4. Single-use needle guide UA1350.

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.

Performing Puncture and Biopsy

NOTE:

When using the UA1350, the needle guide number on the monitor will be ***610-958****.*

⚠	**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 is not sterilized, cover it with a sterile transducer cover.

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.

Press the **Puncture** or **Biopsy** control 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.

⚠	**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.

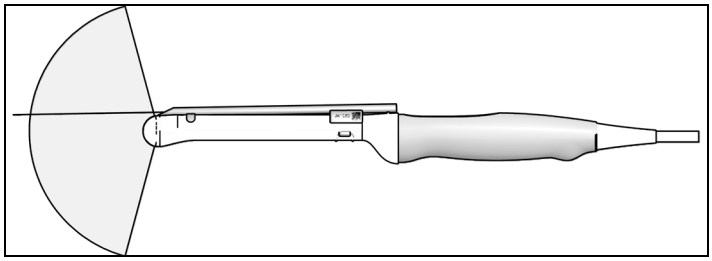

Fig. 5. Illustration of puncture line for puncture attachment UA1282

⚠	**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.

⚠	**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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