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User Guide

I12C4f Transducer

CE 0543
For Professional Users Only

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LEGAL MANUFACTURER

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The serial number on a BK Medical product contains information about the year of manufacture.

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.

If you have comments about the user documentation, please write to us at the email address above. We would like to hear from you.

I12C4f = Ref. Type 9066

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Introduction

This is the user guide for the I12C4f transducer[1], 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

I12C4f is designed for laparoscopic[2] intraoperative imaging and is suitable for contrast imaging and elastography.

⚠	**WARNING** Cardio-w1 To avoid patient injury, do not use the transducer for applications where it may come in direct conductive contact with the patient's heart.

Patient Population

The patient population is adults and adolescents.

Figure 1. I12C4f 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. I12C4f has not been licensed by Health Canada

2. The laparoscopic application has only been market cleared by the FDA

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.

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.

Caution Check-c1

It is particularly important to check the rubber cover over the 2 rocker switches on the transducer handle and the articulation joint on the flexible tip of the transducer to make sure that there are no defects in these areas.

If the transducer needs a small readjustment or tightening of the flexible tip, BK Medical can carry out the readjustment. Contact your local service center for details about this service.

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 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-w7 Use only approved non-pyrogenic, sterile transducer covers. This means that in the USA they must be market cleared by the FDA and in Europe they must be CE-marked. In Canada, they must be licensed by Health Canada.

⚠	**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.

Pull the transducer cover over the transducer. Check for air bubbles between the cover and the transducer and even out if necessary before proceeding. Irrigate the organ to be imaged with 0.9% sterile physiological saline solution while imaging.

Follow these precautions when putting sterile covers on a transducer:

- Wear sterile gloves.

Note: The trocar used with I12C4f must have a minimum inner diameter of 10mm. When using a laparoscopic cover, the trocar must have an inner diameter of 12mm.

⚠	**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.

Changing Orientation

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

Operation of the Flexible Tip

Transducer Controls

The flexible tip is controlled by:

- 2 levers for the orientation of the flexible tip, one on either side of the transducer handle.
- 2 rocker switches to control the action of the adjustment levers. These 2 switches are located under a black rubber cover on the underside of the transducer handle.

Lever Action

The action of the levers can be switched between an incremental ratchet action (where the tip will be locked between movements of the lever) and a smooth continuous action, where the tip automatically returns to the zero position when you let go of the lever. Each lever has a separate rocker switch that controls its action, and these switches can be used independently.

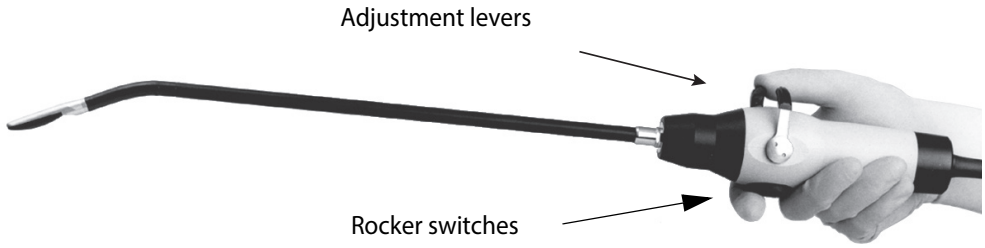

Figure 2. Transducer I12C4f when held in the upright position

Adjustment of the Flexible Tip

The flexible tip of the transducer can be adjusted through an angle of up to 90° in 4 planes, up, down, left and right. See Fig. 3 and Fig. 4

The position of the tip is adjusted by the 2 levers, one on either side of the transducer handle. As an extra guide, there are direction arrows on the handle, beside each lever. These give an indication of the direction of movement of the flexible tip when the corresponding lever is adjusted.

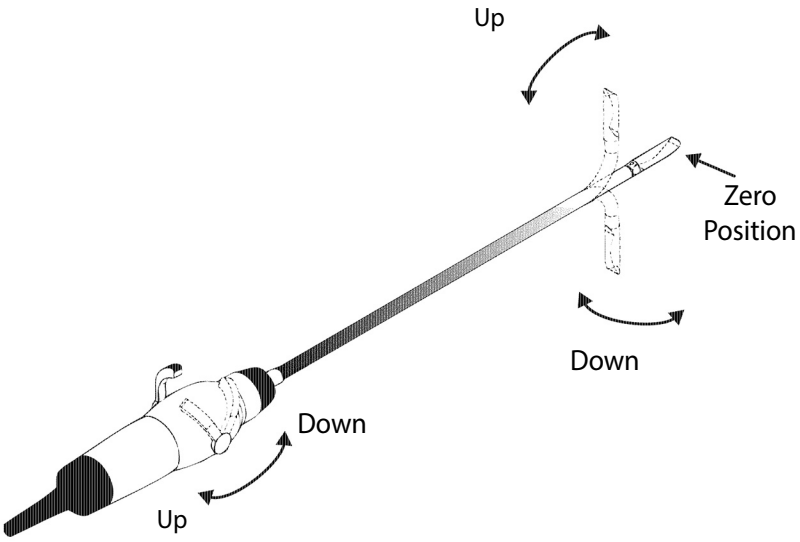

Figure 3. Movement of the I12C4f's flexible tip. Up and down

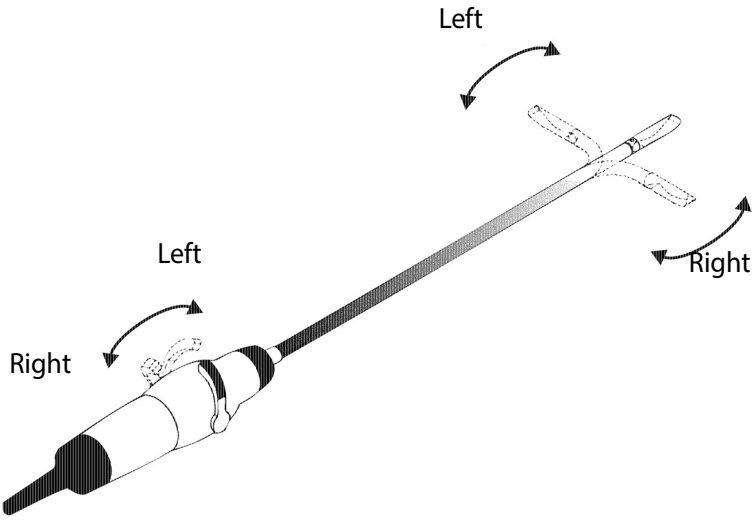

Figure 4. Movement of the I12C4f's flexible tip. Right and left

Zero Position

Both levers have a zero position. This position is indicated by a line on the transducer's handle, between the 2 levers. When both the levers are adjusted to the zero position then the tip of the transducer will be in the straight, non-adjusted, zero position. See Fig. 3

Before You Start Imaging

Check the proper mechanical operation of the transducer. Move the transducer tip up and down, right and left, and try out the rocker switches. Make sure that movement operates smoothly when the incremental ratchet action is not activated and that you are familiar with the operation of the flexible tip before you use it on a patient.

Intraoperative Imaging with I12C4f

⚠	**WARNING** T-w7 The length of the transducer shaft means that you can apply large amounts of pressure by very small movements of the handles. To avoid patient injury, do not apply excessive force when operating the handles of the transducer.

⚠	**WARNING** TC-w5 If the transducer cover is damaged during interventional procedures, follow the policies of the hospital or clinic for treatment of the patient under such circumstances.

⚠	**Caution** T-c6 BK recommends using a disposable plastic trocar to minimize the risk of scratching the transducer array. Metal trocars with sharp edges are not suitable as they may damage the transducer.

Prepare the patient and insert the trocar:

1. Make sure that the flexible tip is in the zero position before starting to insert the transducer into the trocar.
2. Hold the transducer by the handle and guide the transducer carefully into the entrance of the trocar.
3. Push the transducer slowly down the trocar until it is seen, using the video monitor, to touch the site of interest.

⚠	**Caution** T-c7 The transducer must be in the zero position when it is removed from the trocar. Failure to do this may result in damage to the transducer's rubber sleeve.

⚠	**Caution** T-c8 The transducer is typically moved back and forth and around within the trocar, and the tip of the transducer is flexed. Keep the transducer's flexible tip as far from the trocar edge as possible. The trocar edge can damage the rubber sleeve of the flexible tip.

3D Ultrasound

I12C4f uses the untracked freehand method for 3D imaging.

⚠	**WARNING** 3D-w2 You cannot make accurate measurements on a 3D data set acquired using the untracked freehand method.

Acquiring a 3D dataset

- Before attempting to acquire a 3D data set, you must first identify the center of the sector to be imaged. The default sector acquisition size is 120°.
- Using the freehand technique, turn the transducer to one side to prepare for an acquisition of the full sector. Start the acquisition by rotating the transducer around its longitudinal axis.
- The count down clock on the monitor will time the length of the acquisition. An acquisition time between 4 and 10 seconds is normal, depending on the maximum frame rate of the application settings you select.

Note: If you are not sure of the absolute contour of the surface over which you intend to acquire a 3D data set, make sure that the two transducer handles are set to the unlocked position. This allows the transducer to follow the surfaces more smoothly.

⚠	**WARNING** 3D-w3 The accuracy of the 3D dataset will be compromised if the transducer is not completely straight when imaging.

⚠	**WARNING** 3D-w4 To avoid patient injury, never position the transducer or start a 3D acquisition without a clear laparoscopic camera view of the transducer tip.

See the appropriate system user guide for more information.

Puncture and Biopsy Facilities

Figure 5. The needle channel in the tip of I12C4f.

The needle channel in the tip of I12C4f can be used for puncture and biopsy.

⚠	**WARNING** Lap-w1 To avoid patient injury, always make sure that the needle angulation is optimal when you insert a biopsy needle. This is particularly important with obese patients, as it is difficult to change the angle of the needle to connect with the transducer needle channel/notch once you have penetrated the abdominal wall.

⚠	**WARNING** TC-w8 Do not use sterile transducer covers with this transducer during interventional procedures. Needles will puncture the transducer cover causing a risk of cross-contamination.

Performing Puncture and Biopsy

⚠	**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.

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.

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

⚠	**WARNING** P-w12 You must have a clear laparoscopic view of the transducer tip at all times, to ensure that the tip of the biopsy needle is not exposed beyond the end of the transducer. If the tip of the needle is seen to be exposed, then it should be withdrawn immediately to avoid the risk of damaging any tissue or organs.

⚠	**WARNING** Lap-w2 Always make sure that the angulation of the transducer tip matches the inserted needle. The needle must pass easily through the needle channel/notch in the transducer. Keep this angle of the transducer tip when you retract the needle, otherwise the needle might stick in the needle channel/notch. This is especially important when you use large-diameter needles.

Ablation

When performing ablation, you must always follow the instructions provided by the manufacturer of the ablation equipment. Be sure to pay attention to all warnings.

Large-diameter needles that are stiff (for example, some ablation needles) can seem to "stick" when you retract them. This is especially true if the needle is coated. The needle is not really stuck, but if it is not perfectly aligned with the axis of the needle channel, there can be friction between the needle and the edges of the channel. The friction can make the needle "stick" and it can also pull the transducer tip back slightly when you pull on the needle.

Therefore, you should practice inserting and retracting the needle before you use it to perform a procedure on a patient.

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⚠	**WARNING** RF-w1 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.

⚠	**WARNING** RF-w2 When using the transducer for ablation, be sure to burn off tissue that might stick to the needle and retract the tines fully (while flushing with water as the manufacturer recommends) before you retract an ablation needle.

⚠	**Caution** RF-c1 Avoid possibly overheating the transducer when you burn a tumor close to the surface of an organ: pull the transducer back from the organ surface while you ablate. Make sure that you keep the transducer tip in the same angle, otherwise the needle might stick when you retract it.

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. If pre- and thorough cleaning cannot be done immediately, keep the device moist until cleaning.

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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