

I12C5 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.


I12C5 = Ref. Type 9034

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Introduction

This is the user guide for the I12C5¹ 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.
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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

I12C5 is designed for intraoperative, musculoskeletal (superficial), and small organ (small parts) imaging. It is also suitable for contrast imaging, and elastography.


Patient Population

Patient population is adults.



Figure 1. I12C5 transducer


Contraindication


	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.
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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. I12C5 has not been licensed by Health Canada.

	<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 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.</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 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.


	<p>WARNING Reproc-w2</p> <p>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.</p>
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Starting Imaging

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

	<p>WARNING T-w5</p> <p>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.</p>
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Connecting the Transducer

	<p>WARNING GS-w4a</p> <p>It is essential for the patient's safety that only the correct equipment is used.</p> <ul style="list-style-type: none">• 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.
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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.*

	<p>WARNING TC-w7</p> <p>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.</p>
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	<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.

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.

	<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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Changing Orientation

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


Holding the Transducer for Intraoperative Scanning

Hold the transducer between two fingers and the thumb (see Fig. 2) or any position which is comfortable for your hand and move the transducer smoothly over the surface of the organ to produce the best screen image.



Figure 2. Holding 112C5 for scanning.

Intraoperative Imaging with I12C5


	<p>WARNING TC-w5</p> <p>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.</p>
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Puncture and Biopsy Facilities

The needle grooves on the I12C5 can be used for freehand puncture and biopsy. Note that the needle should be kept in the scanning plane in order for you to see the needle tip echo on the monitor.

Pressing **Biopsy** on the system will display a centerline showing the center of the plane.


Cleaning after Use

	<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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