

X12C4 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.


X12C4 = Ref. Type 9026

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Introduction

This is the user guide for the X12C4¹ 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

X12C4 is designed for intraoperative imaging. The transducer is ideal for ultrasound-guided robotic surgery procedures. It is also suited 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.
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Patient Population

The patient population is adults.



Figure 1. X12C4 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. X12C4 has been licensed by Health Canada for use on the bk5000 only.

**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.

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


**WARNING** Robo-w1

Transducer covers must not be used for robotic surgery because the covers may be damaged when handled by the robot tools. For use in robotic surgery, the transducer must be sterilized.

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.
- 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 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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Changing Orientation

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

Imaging with X12C4

The X12C4 and bk5000 ultrasound system can be connected to the *da Vinci* Surgical System®.



WARNING Caut-w1

When you use cautery instruments together with the transducer, you must be particularly careful. To avoid damaging the transducer and possibly the patient, keep the transducer at a safe distance from the cautery instruments. Otherwise the instruments may damage the cable shield or the acoustic surface of the transducer resulting in an electrical connection to ground. This may present an electrical hazard for the patient. There may also be a risk of contamination from damage to plastic parts.

Connecting to the Robotic Surgical System

The following step by step instruction describes how to connect the X12C4 transducer to the *da Vinci* Surgical System using a bk5000.

- 1** Connect bk5000 to the *da Vinci* Surgical Console* with a Digital Visual Interface (DVI) for integration of picture-in-picture images with TilePro™.
- 2** Connect the X12C4 transducer to the ultrasound system. Make sure the transducer is properly sterilized before use. Full details of cleaning and disinfection procedures can be found in *Care and Cleaning* that accompanies this user guide.
- 3** Gently place the X12C4 transducer in a standard 12 mm trocar before imaging.
- 4** When imaging is completed, gently remove the X12C4 transducer by pulling it back through the trocar.

* First generation *da Vinci* Surgical Systems use an analog S-Video output signal. See Technical Data (BZ2100) that accompanies this user guide for more information on the electromagnetic compatibility of the BK Medical ultrasound systems. For a list of suitable adapters, see the 'Safety Information' chapter in the bk5000 User Guide.

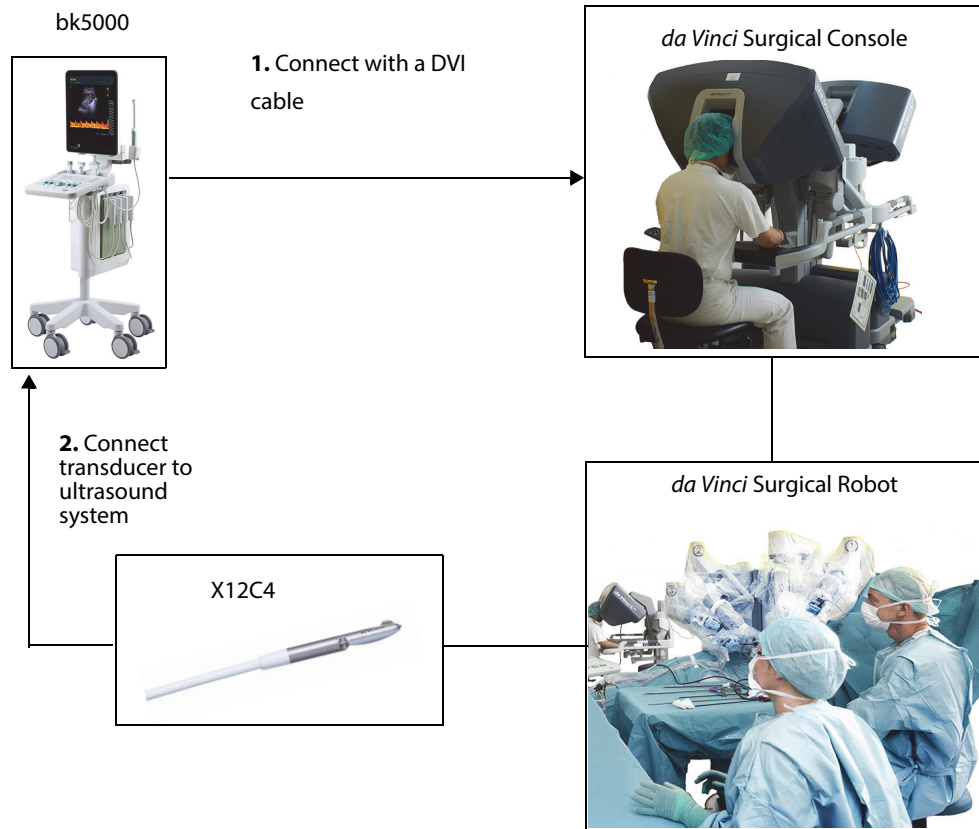



Figure 2. System overview. Numbers refer to the steps in the procedure above.

Grasping the Transducer with the Robot Tools

	<p>WARNING Robo-w2</p> <p>Check the transducer for sharp edges, especially at the grasper sites, before use.</p>
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X12C4 is designed for use with the ProGrasp Forceps™ which are manipulated from the *da Vinci* console by the surgeon.

Fig. 3 illustrates where to grab and handle the X12C4 transducer with the robot tools.

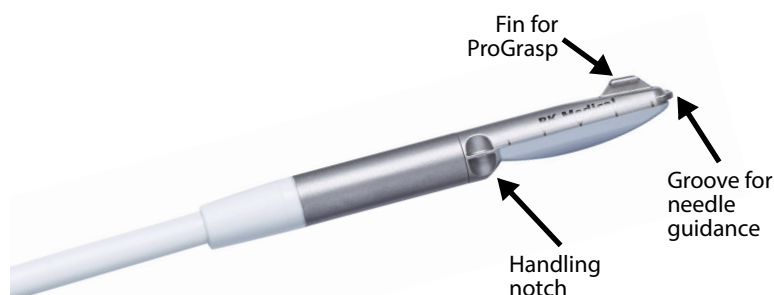


Figure 3. X12C4 transducer


When grasping the X12C4 transducer with the ProGrasp Forceps, you can use the handling notches to stabilize the transducer. The transducer fin must be grasped from the back of the transducer.

Fig. 4 illustrates how to grasp the transducer fin from the back of the transducer with the ProGrasp Forceps.



Figure 4. Grasping the transducer fin with the ProGrasp forceps


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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