X12C4 Transducer
The serial number label 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.
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Introduction

This is the user guide for the X12C4\textsuperscript{1} transducer, and it must be used together with the Care and Cleaning user guide which contains important safety information.

\begin{itemize}
  \item [\textbf{Caution Rx-c1}] Federal law in North America restricts this device to sale to, or on the order of, a physician.
\end{itemize}

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\textsuperscript{2} and elastography\textsuperscript{3}.

\begin{itemize}
  \item [\textbf{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.
\end{itemize}

Patient Population

The patient population is adults, adolescents and children.

![Figure 1. X12C4 transducer](image)

General Information

Product specifications, acoustic output data and data about EMC (electromagnetic compatibility) for this transducer can be found in the \textit{Product Data Sheet} and the \textit{Technical Data (BZ2100)} that accompany this user guide.

1. X12C4 has not been market cleared by Health Canada
2. In the USA, contrast-enhanced ultrasound has not been market cleared by the FDA, with the exception of only select cardiac imaging applications
3. Elastography on the bk5000 has not been licensed by Health Canada.
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.
Starting Imaging

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

Connecting the Transducer

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.

WARNING Reproc-w2
Users of this equipment have an obligation and responsibility to provide the highest degree of infection control possible to patients, co-workers and themselves. To avoid cross contamination, follow all infection control policies for personnel and equipment established for your office, department, or hospital.

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.

WARNING GS-w4b
It is essential for the patient’s safety that only the correct equipment is used.
- Do not use other manufacturers’ transducers with BK Medical ultrasound systems.
- Do not use BK Medical transducers with other manufacturers’ systems.

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.
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 non-pyrogenic, sterile transducer sheaths (transducer covers) that are approved for intraoperative use. 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.
• 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 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.

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 adaptors, see the ‘Safety Information’ chapter in the bk5000 User Guide.
Figure 2. System overview. Numbers refer to the steps in the procedure above.

1. Connect with a DVI cable

2. Connect transducer to ultrasound system
Grasping the Transducer with the Robot Tools

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

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 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.

**WARNING D-w1**

For contaminated disposals such as transducer covers or needle guides, follow disposal control policies established for your office, department, or hospital.