

X18L5s (9009) Transducer



LEGAL MANUFACTURER

BK Medical Aps
Mileparken 34
2730 Herlev
Denmark
Tel.:+45 44528100 / Fax:+45 44528199
www.bkmedical.com
Email: info@bkmedical.com

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.


X18L5s = Ref. Type 9009

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Introduction

This is the user guide for the X18L5s 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

The X18L5s transducer is designed for peripheral vessel (peripheral vascular), musculoskeletal (conventional/superficial), intraoperative^{1,2}, intraoperative (neuro)^{1,3} and small organ (small parts) imaging. X18L5s is also suitable for elastography^{3,4}.

	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


Patient population is infants⁵, children, adolescents and adults.



Figure 1. X18L5s transducer


1. bk5000 only.
2. Use of the X18L5s for intraoperative has not been cleared by Health Canada for use on common carotid arteries.
3. Use of X18L5s for neuro and elastography has not been CE-marked.
4. Imaging mode not available on the bkSpecto in Japan
5. Surface use only.


Contraindications

	<p>WARNING T-w6</p> <p>To avoid causing injury to the eye, do not use this transducer for ophthalmic use, or any application that causes the acoustic beam to pass through the eye.</p>
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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.

	<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>
	<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>
	<p>WARNING TC-w2</p> <p>For neurosurgical applications, use only non-pyrogenic, sterile transducer covers that are approved for neurosurgical 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.</p>

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.

For Intraoperative Applications:

- Irrigate the organ to be imaged with 0.9% sterile physiological saline solution while imaging.

For Surface Use:

- 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 reapply 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.

Using the Transducer Control Button

The control button on the transducer controls the imaging.

Press the button to **Start** or **Stop** imaging (freeze frame). Press the button for more than one second to make a copy of the image.

Changing Orientation

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

Operation of X18L5s

Adjustment of Flexible Tip

The transducer has a flexible tip. The tip can be adjusted through an angle of up to 90° in four steps: 0°, 30°, 60° and 90°:

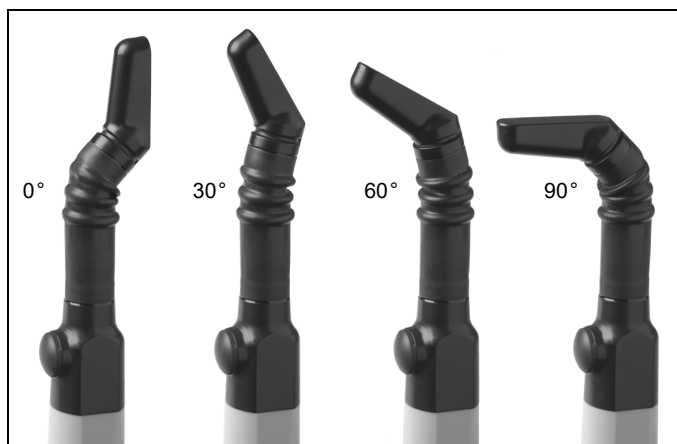



Figure 2. X18L5s' flexible tip


The transducer should be checked before use for cracks or irregularities in the surface. It is important to check the black rubber cover on the transducer handle and the articulation joint on the flexible tip of the transducer to ensure that there are no defects in these areas. It should also be checked thoroughly once a month following the procedure in *Care and Cleaning*.

Intraoperative Imaging with X18L5s


Before intraoperative imaging, refer to *Care and Cleaning* for disinfection and sterilization instructions.

Intraoperative (neuro) Imaging with X18L5s


	<p>WARNING C-J-w1</p> <p>Do not use this transducer for neurosurgical applications if the patient is suspected of having Creutzfeldt-Jakob disease. If a neurosurgical transducer has been used on a patient suspected of or diagnosed as being Creutzfeldt-Jakob positive, the transducer must be destroyed, following approved procedures for your hospital.</p>
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	<p>WARNING TC-w10</p> <p>Avoid scraping the transducer against any raw bone edges along the drill hole. This could damage the transducer cover and increase the risk of contamination.</p>
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NOTE: *Ensure that the transducer cable is secured so that it cannot move and pull the transducer out of position.*

	<p>WARNING Exam-w7</p> <p>To avoid patient injury, do not lean on, bend or apply excessive force when using the transducer. Remain aware of the location of the tip of the transducer at all times.</p>
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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 contaminated disposals such as transducer covers or needle guides, follow disposal control policies established for your office, department, or hospital.</p>
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 BK Medical ApS, Mileparken 34, 2730 Herlev, Denmark. T +45 4452 8100 F +45 4452 8199



BK Medical
8 Centennial Drive
Peabody
MA01960
USA
T + 1 978-326-1300
bkmedical.com

USA
Sales & Service
BK Medical
8 Centennial Drive
Peabody
MA01960
USA
T + 1 978-326-1300
F + 1 978-326-1399
bkmedical.com

Europe and Rest of World
Sales, Service & Design Center
BK Medical
Mileparken 34
2730 Herlev
Denmark
T +45 4452 8100
F +45 4452 8199
bkmedical.com