bk medical
a GE Healthcare company

User Guide

8809 Linear Array Transducer

English
BB0911-O
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CE 2460
For Professional Users Only

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.

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Introduction

This is the user guide for Linear Array Transducer Type 8809[1], and it must be used together with the ***Care and Cleaning*** user guide, which contains important safety information.

⚠	**Caution** Rx-c1 United States Federal law restricts this equipment 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

The 8809 transducer is designed for peripheral vessel, musculoskeletal, intraoperative and small parts imaging.

⚠	**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

Patient population is adults, adolescents and children.

Figure 1. Linear Array Transducer 8809

1. Use of 8809 in the central vascular or central nervous system is not licensed by Health Canada.

Imaging Plane

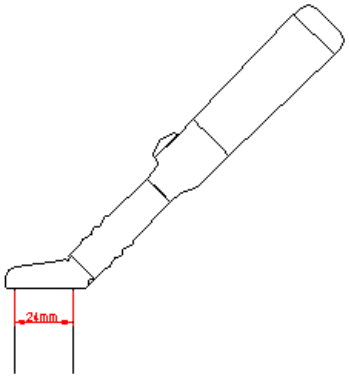

Figure 2. Imaging plane of 8809

General Information

Product specifications for this transducer can be found in the ***Product Data Sheet*** that accompanies this user guide.

Acoustic output data and data about EMC (electromagnetic compatibility) for this transducer are in ***Technical Data (BZ2100)*** that accompanies this user guide. A full explanation of acoustic output is given in your scanner user guide.

⚠	**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 Medical 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 Medical 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. It should also be checked thoroughly once a month following the procedure in ***Care and Cleaning***.

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 Medical ultrasound systems. • Do not use BK Medical transducers with other manufacturers' systems. • Do not use unauthorized combinations of transducers and puncture attachments.

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

The transducer should be enclosed in a sterile transducer cover. See the ***Product Data Sheet*** for a list of available transducer covers.

⚠	**WARNING** TC-w7 Use only approved non-pyrogenic, sterile probe sheaths (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 latex-sensitive patients and be prepared to treat allergic reactions promptly

The gel should cover the entire front end of the transducer (black part of the transducer).

For Intraoperative Applications

Apply sterile gel to the tip of the transducer or fill the transducer cover with 1 to 2 ml of sterile water.

Pull the transducer cover over the transducer. Check for air bubbles between the cover and the transducer and even out if necessary before proceeding.

This improves the screen images by preventing image artifacts caused by air bubbles.

⚠	**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 transducer has a control button that you can press to **Start** or **Stop** imaging (freeze frame). Press the button for more than one second to make a copy of the image.

Each time the button is pressed, a “beep” is emitted.

Changing Orientation

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

Operation of Type 8809

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°. See Fig. 3

Figure 3. Transducer 8809's 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 Type 8809

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

Cleaning after Use

⚠	**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.

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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