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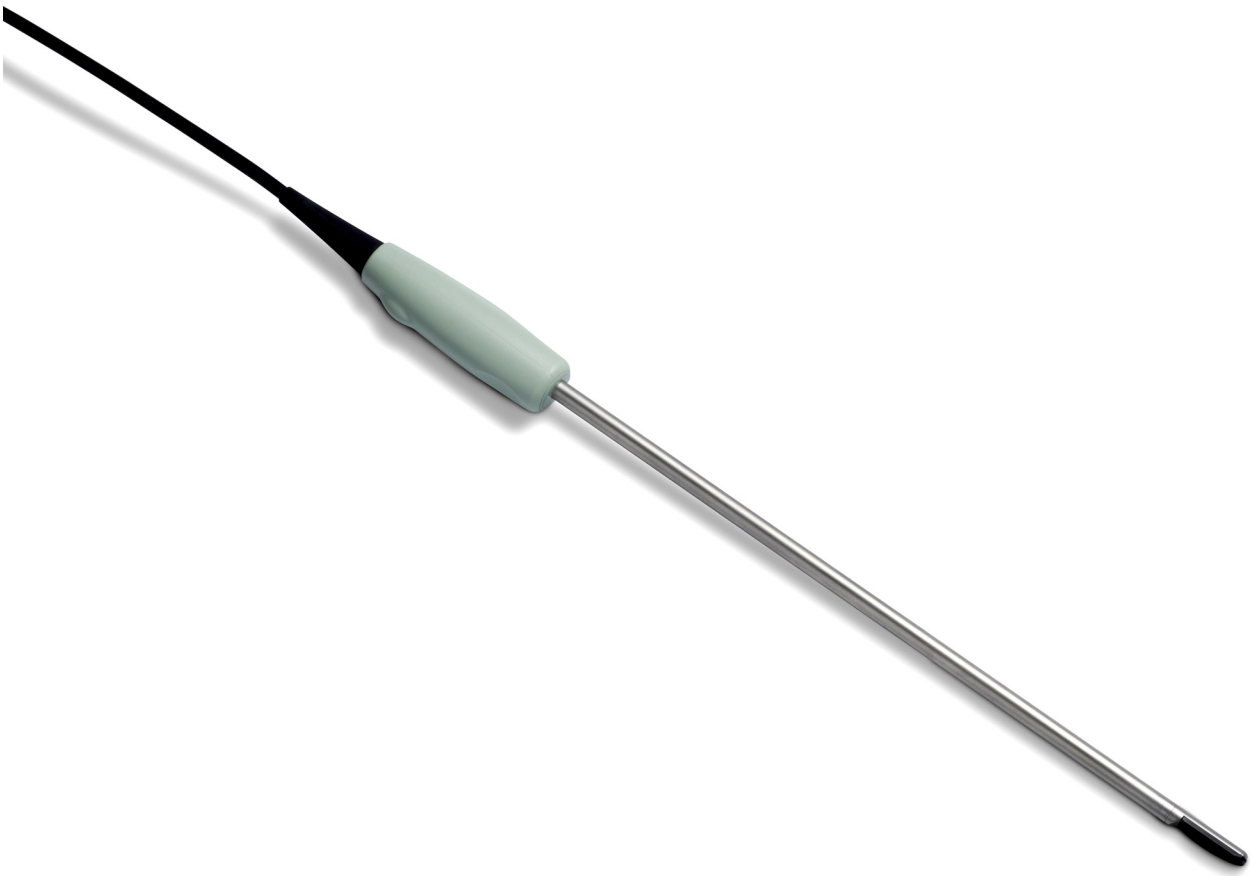
User Guide
Type 8836

Rigid Laparoscopic Transducer



English
BB2085-C
May 2016

CE 0543
For Professional Users Only

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The serial number of a BK Medical product contains information about the year of manufacture. To obtain the date of manufacture of a product, please contact your BK Medical representative or write to us at the email address above, including the product's serial number (SN number).

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 Rigid Laparoscopic Transducer Type 8836 and must be used together with your system user guide and *Care, Cleaning & Safety*, which contains important safety information.

Indications for Use

Rigid Laparoscopic Transducer Type 8836 is designed for a wide range of intraoperative procedures. Common applications are structures such as the gall bladder, uterus and liver.

Patient Population

The patient population is adults and children.

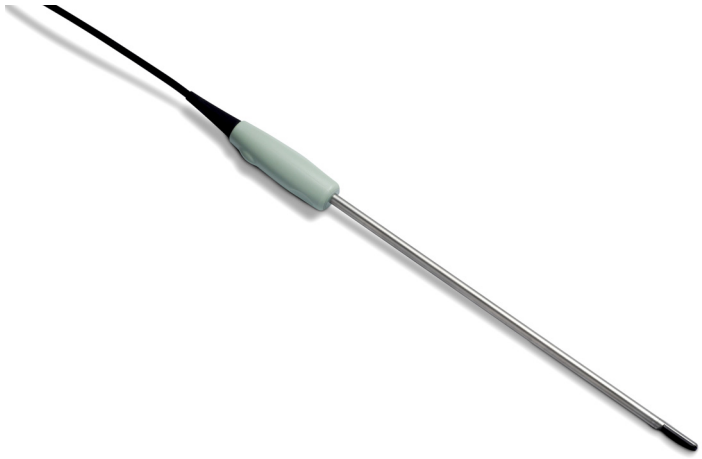

Figure 1. Rigid Laparoscopic Transducer Type 8836.

Imaging Plane

The 8836 is an intraoperative transducer designed for laparoscopic ultrasound. The transducer has a penetration depth up to 124 mm and a 9 x 33.2 mm footprint size.

Figure 2. Imaging plane for Rigid Laparoscopic Transducer Type 8836.

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 data is given in your system user guide.

WARNING

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

Always keep the exposure level (the acoustic output level and the exposure time) as low as possible.

Service and Repair

WARNING

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 electrical engineer or hospital technician should verify the safety of all equipment.

Caring for the Transducer

The transducer may be damaged during use or processing, so it must be checked before use for cracks or irregularities in the surface. It should also be checked regularly following the procedures in *Care, Cleaning & Safety*.

Cleaning and Disinfection

To ensure the best results when using BK Medical equipment, it is important to maintain a strict cleaning routine.

Full details of cleaning and disinfection procedures can be found in *Care, Cleaning & Safety* that accompanies this user guide. A list of disinfectants and disinfection 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

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.

Starting Imaging

All equipment must be cleaned and sterilized before use. If sterilization is impossible, the transducer must be processed using a high-level disinfection procedure and enclosed in a sterile transducer cover.

Connecting the Transducer

WARNING

To prevent electrical shock, keep all plugs and sockets absolutely dry at all times.

The transducer is connected to the system using the array Transducer Socket on the system. To connect, the transducer plug's locking lever should first be in a horizontal position. Align the plug to the system socket and insert securely. Turn the locking lever clockwise to lock in place.

When connected, the transducer complies with Type BF requirements of EN60601-1 (IEC 60601-1).

Changing Frequency

The Multi-Frequency Imaging (MFI) facility enables you to select the imaging frequency. The 8836 has a frequency range of 12-5 MHz on all available systems. See the applicable system user guide for instructions. The selected frequency is displayed at the top of the screen.

Using a Transducer Cover

The transducer must be sterilized before use or be processed using a high-level disinfection procedure and enclosed in a sterile transducer cover. See the Product Data sheet for a list of available transducer covers.

WARNING

Some transducer covers can contain latex. Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), 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 the screen images 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

WARNING

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

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 Type 8836

WARNING

Because of the length of the transducer shaft it is possible to apply large forces to the tip of the transducer by very small movements of the handle – if these forces are excessive they may injure the patient or cause the transducer to break.

NOTE: *Metal trocars with sharp edges are not suitable for use with 8836 as they may damage the transducer.*

Prepare the patient and insert the trocar. Hold the transducer by the handle and guide the transducer carefully into the entrance of the trocar with your other hand. Push the transducer slowly down the trocar until it is seen, using the system monitor, to touch the site of interest.

WARNING

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 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.

3D Ultrasound

The 8836 uses untracked fan for acquisition of images.

Acquiring a 3D Data Set

Before attempting to acquire a 3D data set, you must first identify the center of the sector you want to image. The default sector acquisition size is 120°.

Using the untracked fan technique, turn the transducer to one side to prepare for an acquisition covering the entire sector. Start the acquisition by rotating the transducer around its longitudial axis.

The count down clock in the right-hand corner of the monitor will time the length of the acquisition. An acqusition time of between 4 and 10 seconds is normal, depending on the maximum frame rate of the application settings that you select.

⚠ **WARNING**

Never position the transducer or start a 3D acquisition without a clear laparoscopic camera view of the transducer tip. During the 3D acquisition the camera should always be positioned for monitoring the entire movement of the transducer.

Imaging with the 8836 using untracked fan provides a 3D data set quickly and simply. However, it is important to remember that you cannot make accurate measurements on a 3D data set acquired using the untracked free hand method.

Please refer to the applicable system user guide for more information.

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. See the applicable system user guide for further details.

⚠ **WARNING**

For contaminated disposals 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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