



Endovaginal Endfire Transducer User Guide

| Types 8506-S and 8806 |



English
BB1154-E
August 2006

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Endovaginal Endfire Transducer Types 8506-S and 8806

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Introduction

This is the user guide for the Endovaginal Endfire Transducers Types 8506-S and 8806, and must be used together with *Transducer Care, Cleaning & Safety* which contains important safety information.

8506-S and 8806 are suitable for gynecological examinations.



Fig. 1. Endovaginal Endfire Transducer Types 8506-S and 8806

Scanning Plane

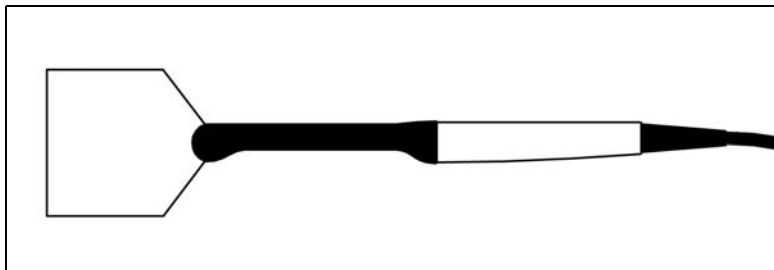


Fig. 2. Scanning plane of Types 8506-S and 8806

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 on the Technical Data CD that accompanies this user guide. A full explanation of acoustic output is given in your scanner user guide.

WARNING

If at any time the scanner malfunctions, or the image is severely distorted or degraded, or you suspect in any way that the scanner is not functioning correctly:

- *Remove all transducers from contact with the patient.*
- *Turn off the scanner. Unplug the scanner from the wall and make sure it cannot be used until it has been checked.*
- *Do not remove the scanner cover.*
- *Contact your B-K Medical representative or hospital technician.*

WARNING

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

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 thoroughly once a month following the procedure in *Transducer Care, Cleaning & Safety*.

Cleaning and Disinfection

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

Full details of cleaning and disinfection procedures can be found in the *Transducer Care, Cleaning & Safety* booklet 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 details.

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.

Caution

Keep all plugs and sockets absolutely dry at all times.

Starting Scanning

All equipment must be cleaned and disinfected before use.

Connecting the Transducer

WARNING

Keep all plugs and sockets absolutely dry at all times.

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

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

Changing Frequency

The Multi-Frequency Imaging (MFI) facility enables you to select the scanning frequency. See the applicable scanner user guide for instructions. The selected frequency is displayed at the top of the screen.

Using a Transducer Cover

The transducer should be enclosed in a transducer cover or a standard condom. See the Product Data sheet for a list of available transducer covers.

WARNING

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), FDA is advising health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly.

Apply gel to the tip of the transducer. This improves the screen images by preventing image artifacts caused by air bubbles.

Pull the transducer cover over the transducer.

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 scanning. Re-apply the gel frequently to ensure good screen images.

WARNING

Use only water-soluble agents or gels. Petroleum or mineral oil-based materials may harm the cover material.

Changing Orientation

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

Puncture Facilities

Puncture and biopsy are possible with Types 8506-S and 8806. The puncture attachment is illustrated in the following pages with a brief description of its use and operating instructions.

The use of probe sheaths during invasive applications is recommended.

For hygiene reasons, the transducer should be enclosed in a transducer cover or a standard condom. When sterile conditions are required, cover the transducer with a sterile transducer cover.

WARNING

It is essential for the patient's safety that only the correct puncture attachment is used with Types 8506-S and 8806. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers' puncture attachments.

Puncture Attachment UA1263

This metal puncture attachment (see Fig. 3.) is intended for endovaginal puncture and biopsy with Endovaginal Endfire Transducer Types 8506-S and 8806.

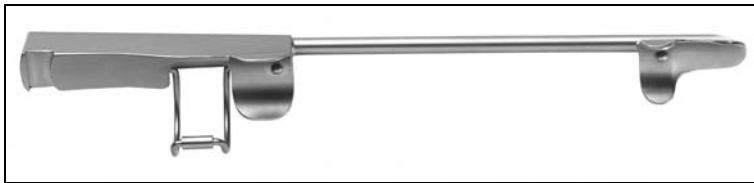


Fig. 3. Puncture attachment UA1263

The puncture attachment consists of a swinging lock-arm and a needle guide with an inner diameter of 2.1mm, suitable for up to 14 gauge needles.

The needle guide is angled 2° towards the long axis of the transducer (i.e. towards the mid-axis of the scan image). The distance from the entrance to the needle guide and the first puncture line dot on the scan image is 170mm. The dots are 5 mm apart, see Fig. 5. for details.

All parts of the puncture attachment can be autoclaved or disinfected by immersion in a suitable solution.

To mount UA1263 (as shown in Fig. 4.):



Fig. 4. Types 8506-S and 8806 with puncture attachment UA1263

1. Hold the transducer with the groove on the handle uppermost.
2. Align the two raised nodules on the underside of the attachment with the two holes on the upperside of the probe's rod.
3. Lock the swinging arm into position over the bottom of the transducer. An audible click indicates when the needle guide is securely attached.

Caution

Ensure that the tip of the needle guide lies close to the front end of the probe, if not the needle guide may be damaged and require realignment by B-K Medical technicians.

Caution

Ensure UA1263 is positioned correctly.

To remove the needle guide, unlock the swinging arm and lift the needle guide off the transducer.

Performing Puncture and Biopsy

Endovaginal Biopsy

WARNING

It is essential for the patient's safety that only the correct puncture attachments, as described in this guide, are used. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers puncture attachments.

Before beginning a puncture or biopsy procedure, always check that the type number of the transducer and the type number or description of the puncture attachment match exactly those displayed on the scanner monitor.

WARNING

The puncture line on the scan image is an indication of the expected needle path. The needle tip echo should be monitored at all times so any deviation from the desired path can be corrected.

Cover the transducer with a sterile transducer cover.

If the transducer cover is damaged when attaching the puncture attachment, replace it with a new cover.

See the Product Data sheet for a list of available transducer covers.

Press the scanner **Puncture** or **Biopsy** control button to superimpose a puncture line on the scan image.

If more than one puncture line is available, refer to the applicable scanner user guide for instructions on how to change which one appears.

Move the transducer until the puncture line transects the target. Insert the needle and monitor it as it moves along the puncture line to the target. The needle tip echo will be seen as a bright dot on the screen.

WARNING

If the needle guide is detached from the transducer during interventional procedures, cover the transducer with a new transducer cover.

To remove the puncture line from the scan image, refer to the applicable scanner user guide for instructions.

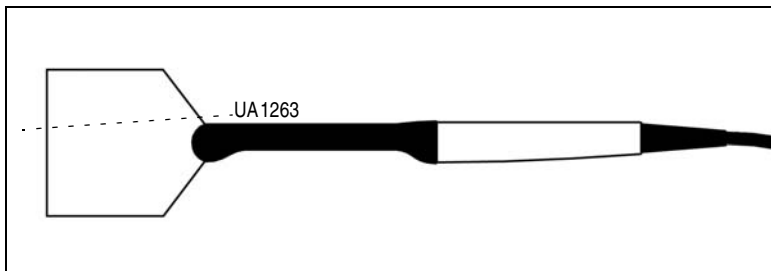


Fig. 5. Illustration of puncture line for puncture attachment UA1263

WARNING

When performing a biopsy, always make sure that the needle is fully drawn back inside the needle guide before moving the probe.

Cleaning after Puncture and Biopsy

If biological materials are allowed to dry on the transducer or puncture attachments, disinfection and sterilization processes may not be effective. Therefore, you must clean puncture attachments and transducers immediately after use.

Use a suitable brush to make sure that biological material and gel are removed from all needle guides and other channels and grooves. See *Transducer Care, Cleaning & Safety* 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. See the applicable scanner user guide for further details.

WARNING

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