

| Types 8570 and 8670 |



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Linear Array Transducer Types 8570 and 8670

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Introduction

This is the user guide for Linear Array Transducer Types 8570 and 8670 and must be used together with *Transducer Care, Cleaning & Safety* which contains important safety information.

8570/8670 is suitable for breast, testis, penile Doppler, vascular and musculoskeletal applications.

FDA WARNING for the United States of America

*Types 8570 and 8670 are **not** for fetal use.*

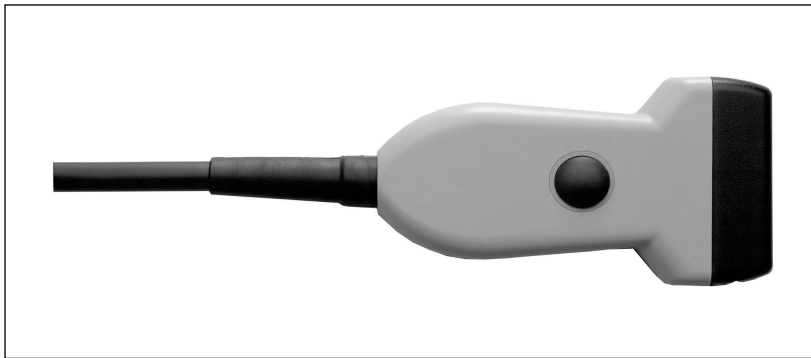


Fig. 1. Linear Array Transducer Types 8570 and 8670

Scanning Plane

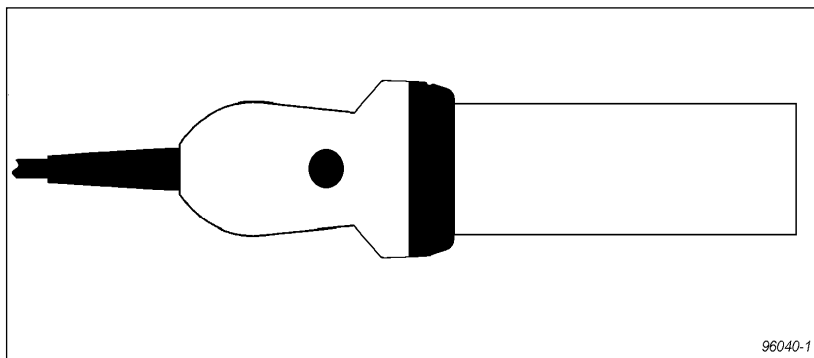


Fig. 2. Scanning plane of 8570

8570 and 8670 • General Information

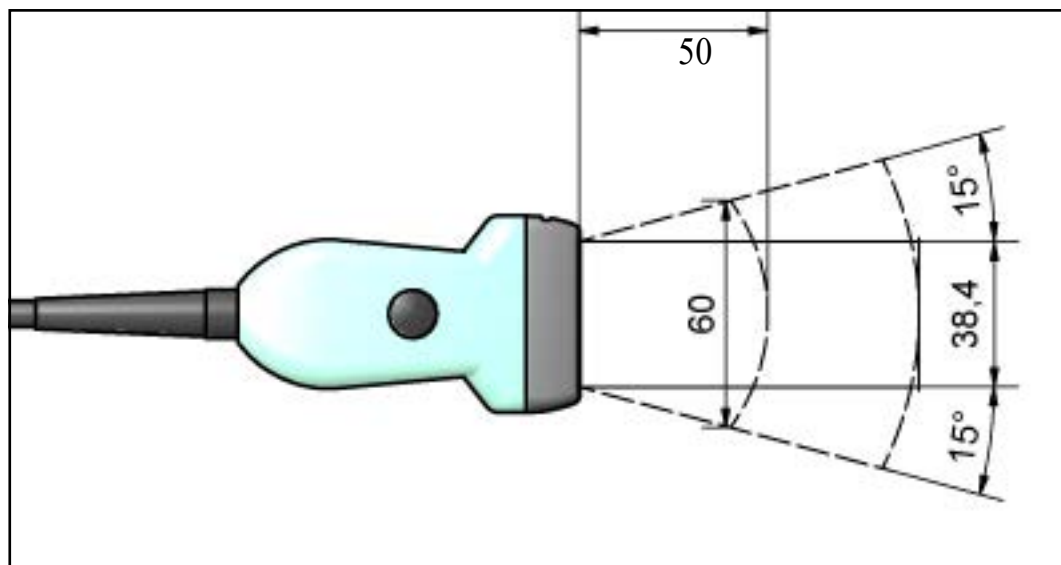


Fig. 3. Scanning plane of 8670 with expanded sector (with the Pro Focus 2202 ultrasound scanner)

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.*
- *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.

Service and Repair

WARNING

Service and repair of B-K Medical electromedical equipment must be carried out only by the manufacturer or its authorized representatives. B-K Medical reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties. After 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 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 front panel. 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 scanning 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.

Scanning 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.

Using the Transducer Control Button

The transducer has a control button that you can press to **Start** or **Stop** scanning (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 scanner user guide for detailed instructions.

Puncture Facilities

Puncture and biopsy is possible with Types 8570 and 8670. The puncture attachment is illustrated in the following pages with a brief description of its use and operating instructions..

WARNING

It is essential for the patient's safety that only the correct puncture attachment is used with Types 8570 and 8670. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers' puncture attachments

UA1269 - with 8670 on the Pro Focus 2202 ultrasound scanner

Puncture guide attachment UA1269 is designed for interventional procedures. It consists of a mounting bracket, which secures the puncture attachment to the transducer, and a needle guide. There are two screws, marked A and B in Fig. 4. A holds the needle in place and B allows the needle guide to be adjusted to three different angles of insertion.

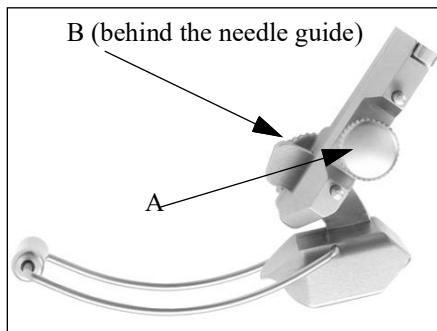


Fig. 4. Puncture guide attachment UA1269

To mount UA1269:

1. Fit the metal mounting bracket on to the transducer.

The metal ridge on the inside of the bracket fits into the indentation on the transducer.

2. Lock the swing arm into position. An audible “click” indicates the needle guide is securely attached (see Fig. 5.).

The needle guide is specifically designed to accept needles with an internal bore diameter of 0.6 - 2.4 mm.

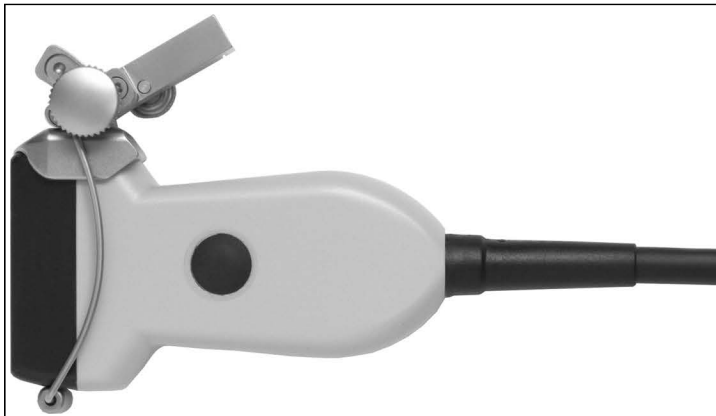


Fig. 5. Puncture guide UA1269 mounted on 8670

There are three different angles of insertion available; 30°, 45° and 60°. To help you estimate the depth of needle penetration, the puncture line pattern is shown on the scanner (see Fig. 9.) the distance between each dot is 5 mm.

To alter the angle of the needle guide:

1. Loosen screw B by turning it 90° counterclockwise.

The needle guide can move backwards and forwards.

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Caution

Loosening screw B further than 90° will release the needle guide from the puncture attachment.

2. Move the needle guide into place in one of the three indentations on the mounting bracket.
3. Tighten screw B until the needle guide is in place.

To insert a needle into the needle guide:

1. Loosen screw A.
2. Insert needle and tighten screw A.

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

UA1246

The needle puncture guide attachment (see Fig. 6.) is made of stainless steel and is designed for interventional procedures. It consists of three parts - the head which houses a plastic needle cartridge (UA0028) and two curved bars that are connected by a rolling cylinder.



Fig. 6. Puncture guide UA1246

The needle guide is specifically designed to accept needles with an internal bore diameter of 0.7 - 2.7 mm.

The needle guide has an angle of insertion of 45° to the image axis and this is shown on the image as a line of dots.

To help you estimate the depth of needle penetration, the puncture line pattern is shown on the scanner (see Fig. 8.) the distance between each dot is 5 mm.

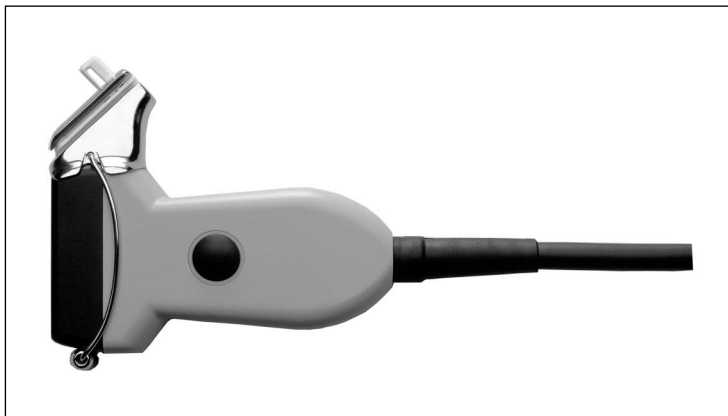


Fig. 7. Puncture Guide UA1246 mounted on the 8570

To mount the needle puncture guide attachment:

1. Hold the transducer so that the vertical grooved edge is facing to the right and the cable is facing down.

8570 and 8670 • Performing Puncture and Biopsy

2. Hold the puncture attachment so that the curved bars and the rolling cylinder are pointing up.
3. Position the needle guide head so that it fits snugly onto the side of the transducer that has the vertical groove. The two grooved bars will “hug” both sides of the transducer head. Hold the puncture attachment in place while the bars are being secured.
4. Press the rolling cylinder down into the recessed horizontal groove until it “clicks” into place.

Caution

Ensure the puncture attachment is securely in place.

To insert a needle:

1. Select the desired needle size and the corresponding disposable needle cartridge (UA0028).
2. Place the cartridge into the slot located in the head of the needle guide.
3. Turn the cartridge handle until it “clicks” into place.
4. Slide the desired needle into the cartridge.

The puncture guide allows the user to remove the transducer without having to remove the needle.

5. To detach the needle during intraoperative use, turn the cartridge handle towards you. Slide the transducer away from the needle.

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

Performing Puncture and 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.

8570 and 8670 • Performing Puncture and Biopsy

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.

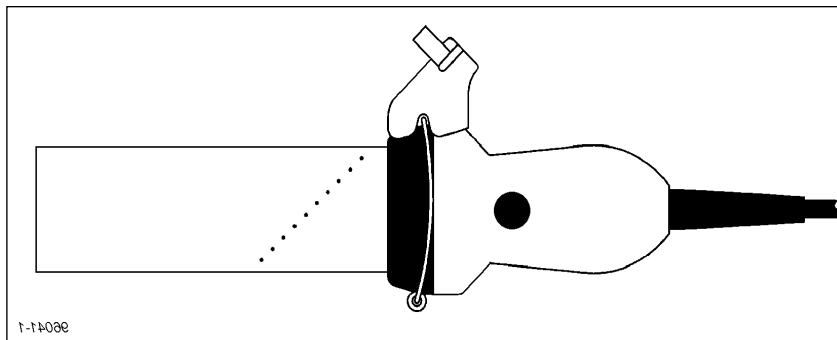


Fig. 8. Puncture line for UA1246 on Types 8570 and 8670

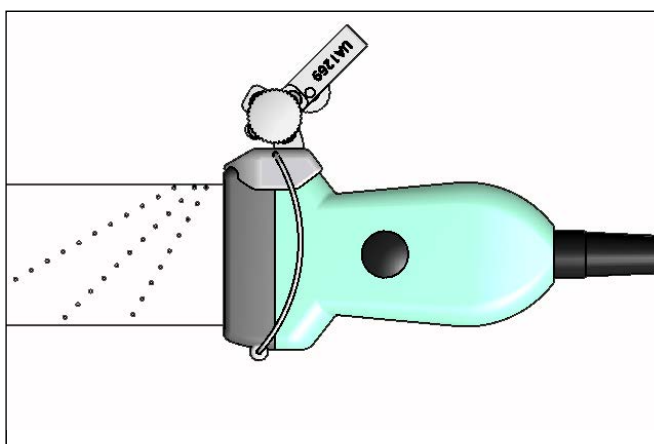


Fig. 9. Puncture lines for UA1249 with 8670

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.

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