BK Medical

Endosonic Multiplane Transducer

User Guide

Type 8551

English
BB0100-M
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we specialize because you do

WORLD HEADQUARTERS
Mileparken 34
DK-2730 Herlev
Denmark
Tel.:+45 4452 8100 / Fax:+45 4452 8199
www.bkmed.com
Email: info@bkmed.dk

B-K 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 B-K Medical representative or by contacting us directly.

Trademark:

Luer Lock is a trademark of Abbott Laboratories.

Endosonic Multiplane Transducer Type 8551

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Introduction

This is the user guide for Endosonic Multiplane Transducer Type 8551 and must be used together with *Transducer Care, Cleaning & Safety* which contains important safety information.

8551 is a mechanical (single-element) multiplane transducer for transrectal scanning.

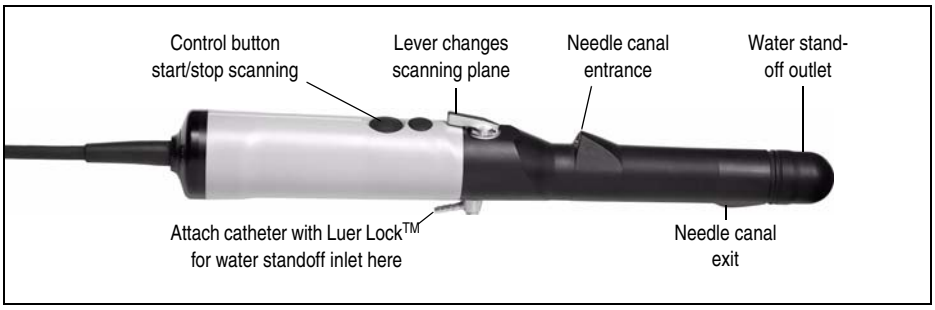

Fig. 1. Endosonic Multiplane Transducer Type 8551

Scanning Plane

The scanning plane rotation axis is perpendicular to the transducer's longitudinal axis. The scanning plane rotation axis is angled 16° to the sector mid-line to ensure the optimal view of the prostate gland and the biopsy needle (see Fig. 2).

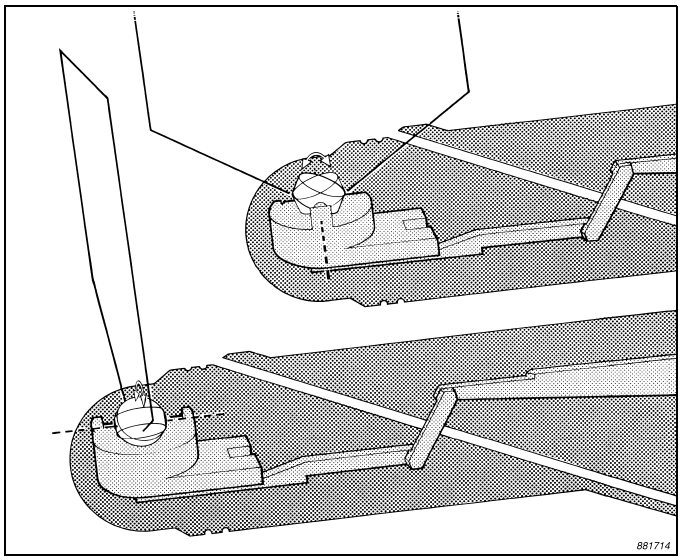

Fig. 2. A single crystal is rotated to produce both longitudinal and transverse images.

The scanning plane can be rotated 90° using the lever on the transducer housing. Longitudinal images are produced when the lever points to 0° (Fig. 3); transverse images are produced when the lever points to 90° (Fig. 4). Scanning in intermediate (oblique) planes is also possible.

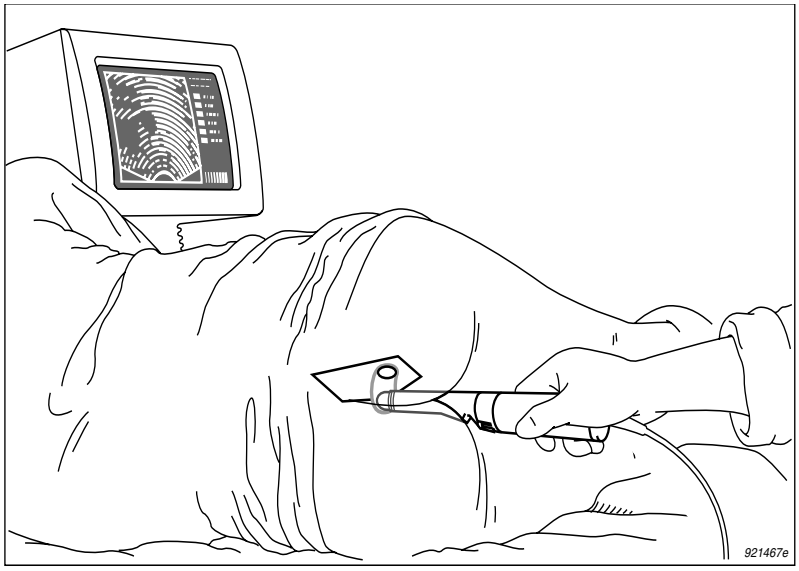

Fig. 3. Longitudinal scanning. The lever on the transducer's housing should be pointing at 0°

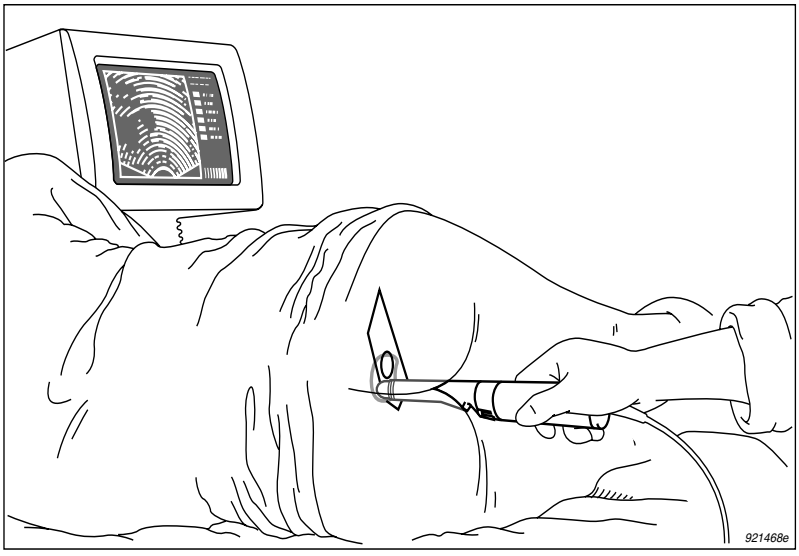

Fig. 4. Transverse scanning. The lever on the transducer's housing should be pointing at 90°

Scanning plane orientation is shown on the monitor. The scanning plane rotation axis may also be displayed.

If the patient is placed in the left lateral position, as is often recommended, image orientation requirements can still be met. See Fig. 3 and Fig. 4

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

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 *Transducer 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 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

Do not stick anything into the water inlet to clean it. Poking something into this hole can damage the water channel inside the transducer. You can clean the water channel by flushing it with water soon after use, before any foreign matter such as scanning gel has a chance to harden.

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.

1. Unscrew the connector plug cover on the transducer (if attached).
2. On the connector plug, make sure that the red arrow is aligned with the red dot on the transducer socket.
3. Pull back the outer locking mechanism and insert the plug in the socket.
4. Release the locking mechanism to secure 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.

1. Apply gel to the tip of the transducer. This improves the screen images by preventing image artifacts caused by air bubbles.
2. Pull the transducer cover over the transducer.
3. 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 instructions.

Assembling the 8551 for Transrectal Use

The 8551 may be equipped with a water standoff facility to improve focusing during transrectal scanning of the prostate. A rubber sheath is mounted on the end of the transducer and filled with water to ensure good acoustic contact with the rectal wall. By varying the amount of water in the sheath it is possible to alter the position of the transducer's focal zone in the tissue.

If the water standoff facility is required, follow the steps below to assemble it. Fig. 5 illustrates each step.

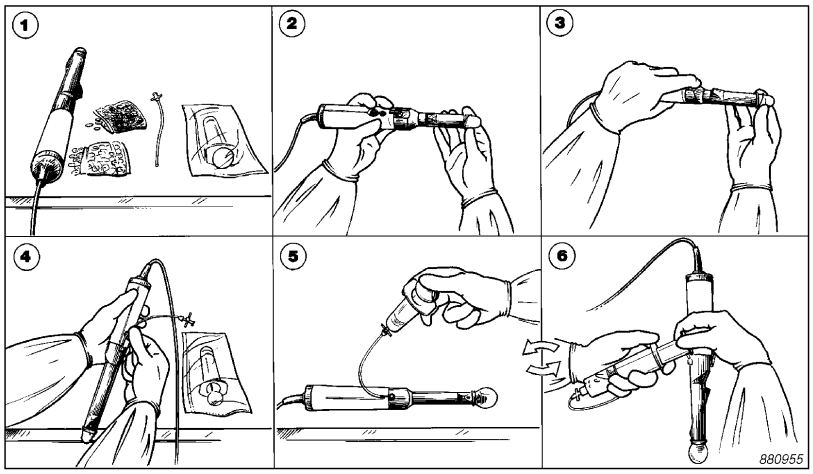

Fig. 5. Assembly of the water standoff facility (pictures 1 through 6)

1. Mount the rubber sheath UA0799 on the transducer and roll it down until it covers the groove *furthest* away from the tip of the transducer (see Picture 2 above).
2. Pull "O" ring QA0185 over the rubber sheath and position it in the groove *nearest* the tip of the transducer (Picture 3). The "O" ring holds the rubber sheath securely in place.
3. Attach a catheter with a Luer Lock to the water standoff inlet (Picture 4) and fill the rubber sheath with water using a standard disposable syringe (Picture 5).

Caution

Use a catheter with soft tubing. Tubing with hard plastic ends can damage the transducer's metal water port.

Air bubbles may appear in the rubber sheath, which will disrupt the path of the ultrasound beam and cause image artifacts. They must be removed.

4. To remove all air from the rubber sheath, hold the transducer with the rubber sheath pointing downwards. Then, using the syringe, draw off as much air as possible (Picture 6).
5. Refill the sheath with water. Continue to draw off as much air as possible and refill the sheath with water until you are sure that there is no air left in either the sheath or the water outlet.
6. Now that you have removed air bubbles that could interfere with the scanning image, draw all the water out of the rubber sheath. (The transducer will be inserted into the patient without water in the sheath. After the transducer is inserted, water can be introduced again into the sheath.)
7. Cover the probe with a standard condom containing a small amount of scanning gel.

Note: Before you start scanning, the patient may require a small enema to clean the rectum as fecal material may disturb the ultrasound image.

WARNING
Do not use excessive force during insertion. Do not over-inflate the balloon. Do not make excessive lateral movements during or after insertion. Risk of injury or tissue damage to the patient could occur under certain circumstances. A digital palpation of the rectum may need to be carried out by a clinician prior to insertion or use of the probe as a precautionary measure.

Puncture Facilities

Transrectal puncture and biopsy are possible with the 8551 using the built-in canal. The puncture equipment 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 needle guide is used with the 8551. Never use unauthorized combinations of transducers and needle guides or other manufacturers' puncture attachments.

Built-in Transrectal Puncture Canal

The 8551 has a built-in needle canal for transrectal puncture and biopsy. The needle canal has an inner diameter of 2.1mm. The guide canal is angled at 21° to the transducer's longitudinal axis.

An additional needle guide fits into the built-in guide canal for transrectal puncture. This guide, UC 5299, has an internal diameter of 1.7mm and is also available in an extended version (UC5299-E). Fig. 6 shows the transducer assembled for transrectal puncture.

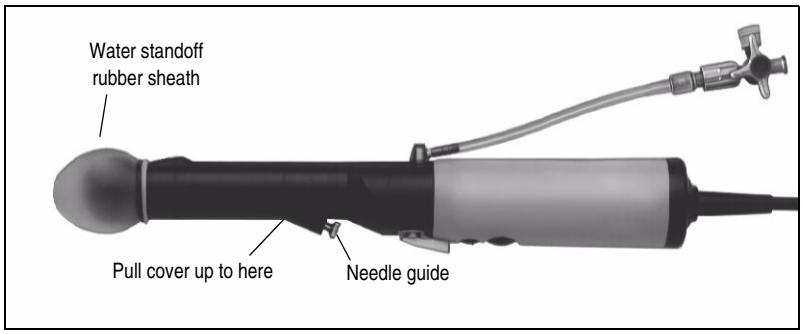

Fig. 6. 8551 assembled for transrectal puncture (here shown without cover)

Both needle guides (UC5299 and UC5299-E) 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.

1. Draw all water out of the rubber sheath.
2. Remove transducer from patient.
3. Remove any standard condom.
4. Carefully insert needle guide (UC5299 or UC5299-E) into the built-in needle canal.

WARNING

Do not use excessive force during insertion. Ensure that the needle guide is correctly positioned.

Never insert the needle guide while the transducer is inside the patient.

5. Cover the probe with a sterile condom containing a small amount of sterile scanning gel. The condom should not cover the entrance of the needle canal, see Fig. 6.

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

6. 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.

7. Insert the transducer in the patient.
8. 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.

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

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

Transrectal Biopsy

Transrectal puncture and biopsy are possible in all planes. B-K Medical recommends that transrectal biopsies are taken while scanning in the longitudinal plane.

The puncture line will differ depending on the scanning plane orientation.

In the longitudinal plane the puncture path is indicated by a line of dots. The distance between each puncture dot is 5mm.

In oblique and transverse planes, a single dot indicates the point at which the needle will transect the scanning plane image rotation axis.

The distance from the entrance of the built-in needle guide to the puncture dot on the scanning plane rotation axis is 107.5mm in all planes, see Fig. 7.

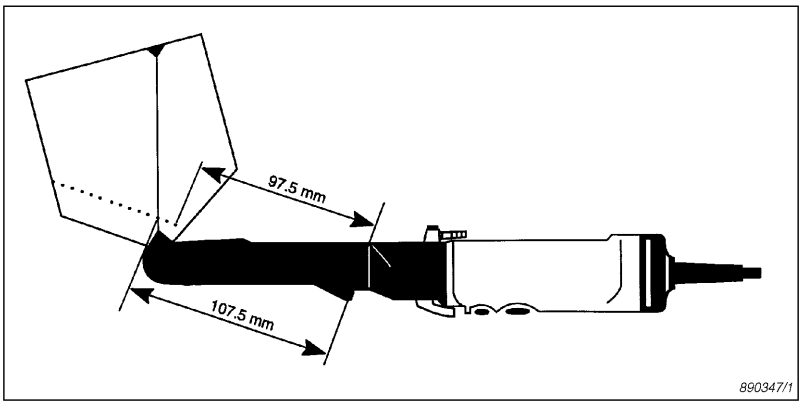

Fig. 7. Transrectal puncture with 8551

Cleaning after Puncture and Biopsy

If biological materials are allowed to dry on the transducer or needle guide, disinfection and sterilization processes may not be effective. Therefore, you must clean needle guides 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.

Caution

Do not stick anything into the water inlet to clean it. Poking something into this hole can damage the water channel inside the transducer. You can clean the water channel by flushing it with water soon after use, before any foreign matter such as scanning gel has a chance to harden.

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.