



3DART Transducer

User Guide

| Type 8838 |



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For Professional Users Only

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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 3D Transducer Type 8838 and must be used together with *Care, Cleaning & Safety* which contains important safety information.

The 8838 is a 3D transducer for endovaginal imaging of the pelvic floor, as well as anorectal imaging and transrectal prostate imaging.



Figure 1-1. 3D Transducer Type 8838.

Contraindications

The 8838 is not for fetal use.

Imaging Plane

The transducer contains a linear array of ultrasound elements that rotates covering an adjustable angle up to 360° to produce a 3D image, thus giving a better orientation when viewing an area of interest. No moving parts contact human tissue.

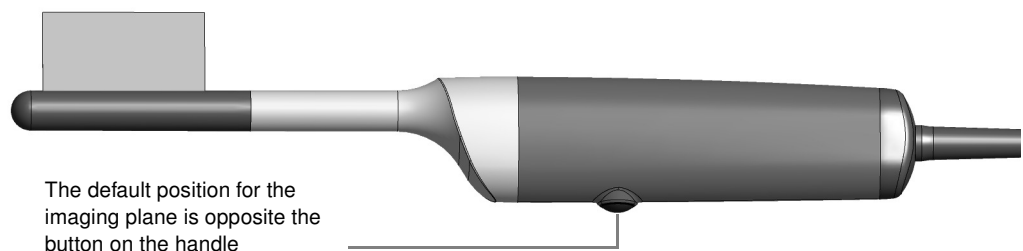


Figure 1-2. 2D imaging plane.

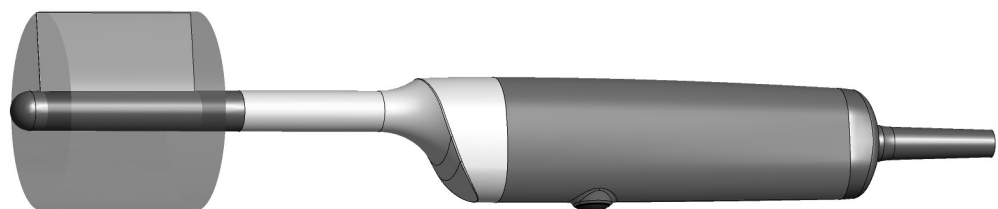


Figure 1-3. 3D imaging plane.

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 remove the system cover.
- 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 thoroughly once a month following the procedure 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 disinfected before use.



WARNING Before starting an examination, use the ultrasound image to verify the orientation of the 2D imaging plane is as indicated on the monitor. If the true imaging plane does not match the displayed orientation, images may give incorrect information about the anatomy.

Connecting the Transducer



WARNING Keep all plugs and sockets absolutely dry at all times.

The transducer is connected to the system using both the array Transducer Socket and the mechanical Transducer Socket.



Caution: The system must not be imaging when you connect the transducer. The image must be frozen or the system must be turned off. Do not unfreeze the image before you have connected the transducer to *both* sockets. Otherwise the imaging array in the transducer can be parked in an incorrect position, which can lead to incorrect 3D representations of the regions being imaged.

To connect the array Transducer Socket

- 1 Insert transducer plug into socket with locking lever in 3 o'clock position.
- 2 Turn locking lever on transducer plug clockwise to 6 o'clock position.

To connect the mechanical Transducer Socket

- 1 Align red mark on plug with red dot on transducer socket.
- 2 Insert plug in socket.



WARNING Do not connect two 8838 transducers simultaneously. The system will produce an incorrect 3D volume with only one identical image repeated throughout the entire volume.

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 imaging frequency. See the applicable system user guide for instructions. The selected frequency is displayed at the top of the screen.

Using a Transducer Cover

You must use a transducer cover. See the Product Data sheet for a list of available transducer covers, including sterile covers.

Apply imaging gel or other water-soluble agent inside and outside the cover to create good acoustic contact.



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

To put on the cover:

- 1 Apply gel to the tip of the transducer so that it covers the entire imaging surface (most of the black part of the transducer). You can also put imaging gel inside the tip of the cover before you put the cover over the transducer.
Make sure that there is enough imaging gel to cover the entire front end of the transducer (the black part of the transducer). This prevents image artifacts caused by air bubbles.
- 2 Pull the transducer cover over the transducer.
- 3 Before imaging, apply a small amount of gel to the outside of the transducer cover to create good acoustic contact between the patient and the transducer.
- 4 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 control button on the transducer controls the imaging.

Press the button to **Start** or **Stop** imaging (freeze frame).

The transducer makes a “beep” sound each time you press the button.

The button function can be customized. For more information, see the user guide for the system and “3D Imaging” on page 9.

Changing Orientation

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

To change the angle of the 2D imaging plane, see “Rotating the 2D Imaging Plane” on page 9.

Endovaginal, Anorectal, and Transrectal Imaging with Type 8838



WARNING Do not use excessive force during insertion. 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.

Both 2D and 3D imaging in Type 8838 is on the sagittal plane as shown in Fig 1-2 and Fig 1-3.

NOTE: *The default position for the imaging plane is opposite the button on the handle. All linear images start with the linear array in this default position where it can display live, 2D images.*

Rotating the 2D Imaging Plane

You can rotate the 2D imaging plane from the system or the remote control. This allows you to locate the area where you want to image without moving the probe inside the patient.

Rotating the 2D imaging plane does not change the default start position for 3D imaging or the chosen angle or extent of 3D imaging.

NOTE: *You cannot rotate the 2D imaging plane if the image is frozen or in split screen mode.*

You must assign user-definable keys on the screen, the keyboard or the remote control to rotate the imaging plane (see the applicable system user guide for further details). Choose **Rotate +** to rotate clockwise and **Rotate -** to rotate counterclockwise.

Each key press rotates the imaging plane by 1°. Hold down the key to rotate the plane quicker. The imaging plane can be rotated 180° in either direction from the default position, see Fig 1-2.

When you switch to 3D, the imaging plane moves back to its default position.

3D Imaging

NOTE: *See the extended system user guide for more information about 3D imaging.*

Typically, you use the 2D imaging to locate the area where you want a 3D image. When the transducer is in the desired location, begin the 3D imaging by pressing the 3D button on the system. From the system, you can also customize the transducer control button.

When you begin the 3D imaging, you define the area for your image on a scale of 10° to 360° in the **Extent** parameter on the system screen. When you choose an imaging angle, the image is centered on the default position such that each half of the image sector is on either side.

During an imaging, the images are captured at the angle and frame rate defined by the user on the system. When the desired imaging is completed, the array moves back to the default position.

360° Images and the Stitch Angle

If you set the **Extent** parameter for a 3D image to 360°, a stitch angle appears on the image. (The stitch angle parameter is only active when **Extent** is set to 360°.)


Stitch angle vs stitch line


The stitch *angle* is a parameter that you set on the screen. The stitch *line* is the line that is in the 3D image, reflecting the setting of the stitch angle parameter.

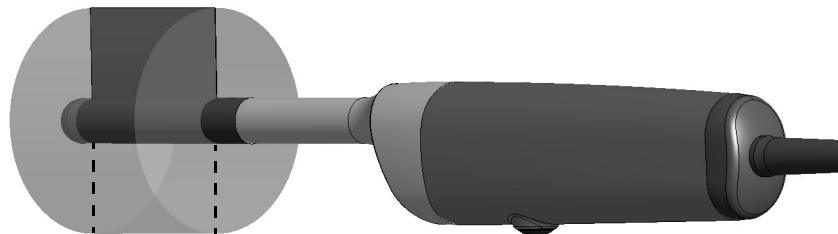
By default, the stitch line is located at the bottom of the cube, which is normally away from the area of interest; at the bottom of the cube (opposite to the default position). To make sure that the stitch line in the screen does not interfere with what you want to see, check the cube after the 3D imaging. If necessary, rotate the stitch line to a new position.

Adjusting the stitch angle

To adjust the stitch angle – on Flex Focus 1202:

- 1 Select the appropriate pro package for your imaging session and click **Stitch**  in the 3D General tab.

In the default center position , the stitch angle is opposite the array's default position; that is, towards the transducer button (see Fig 1-4).




The stitch angle's default center position  is towards the transducer button


Figure 1-4. The stitch angle's default position.


- 2 Select the position you want by choosing the icon that indicates the desired position – away from the area of interest.

A stitch angle setting applies only for a particular imaging session.

When you start the imaging, the control panel is locked to avoid accidental interruption of the imaging process. A progress bar is displayed at the top of the image as a graphic image and as the number of seconds remaining to show how much time is left to complete the image.

To adjust the stitch angle – on Pro Focus 2202 UltraView:

- 1 Select the appropriate pro package for your imaging session and click **Stitch**  in the left menu bar.

In the default center position , the stitch angle is opposite the array's default position; that is, towards the transducer button (see Fig 1-4).

- 2 Select the position you want by adjusting the slider bar that indicates the desired position – away from the area of interest.

A stitch angle setting applies only for a particular imaging session.

When you start the imaging, the control panel is locked to avoid accidental interruption of the imaging process. A progress bar is displayed at the top of the image as a graphic image and as the number of seconds remaining to show how much time is left to complete the image.

The Stitch Line

The 3D imaging must be completed before you can begin to analyze the resulting data in any direction. The stitch line is only shown in the final 3D image result.

Hide or show
stitch line

To hide the stitch line – on Flex Focus 1202:

- 1 On the 3D General tab, click **Stitch line** to hide or show the stitch line.
See the *Flex Focus Advanced User Guide* for more information about how to assign screen keys.

To hide the stitch line – on Pro Focus 2202 UltraView:

- 1 On the right side, click **Layout**.
- 2 In the drop-down menu, click **Stitch line** to hide or show the stitch line.

3D Mover

The 3D mover is automatically selected, so you cannot change this parameter on the system. Untracked 3D acquisition, available with some transducers, is not an option for this transducer.



Caution: The transducer and the patient must remain still during 3D imaging to obtain accurate images.

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, follow disposal control policies established for your office, department or hospital.