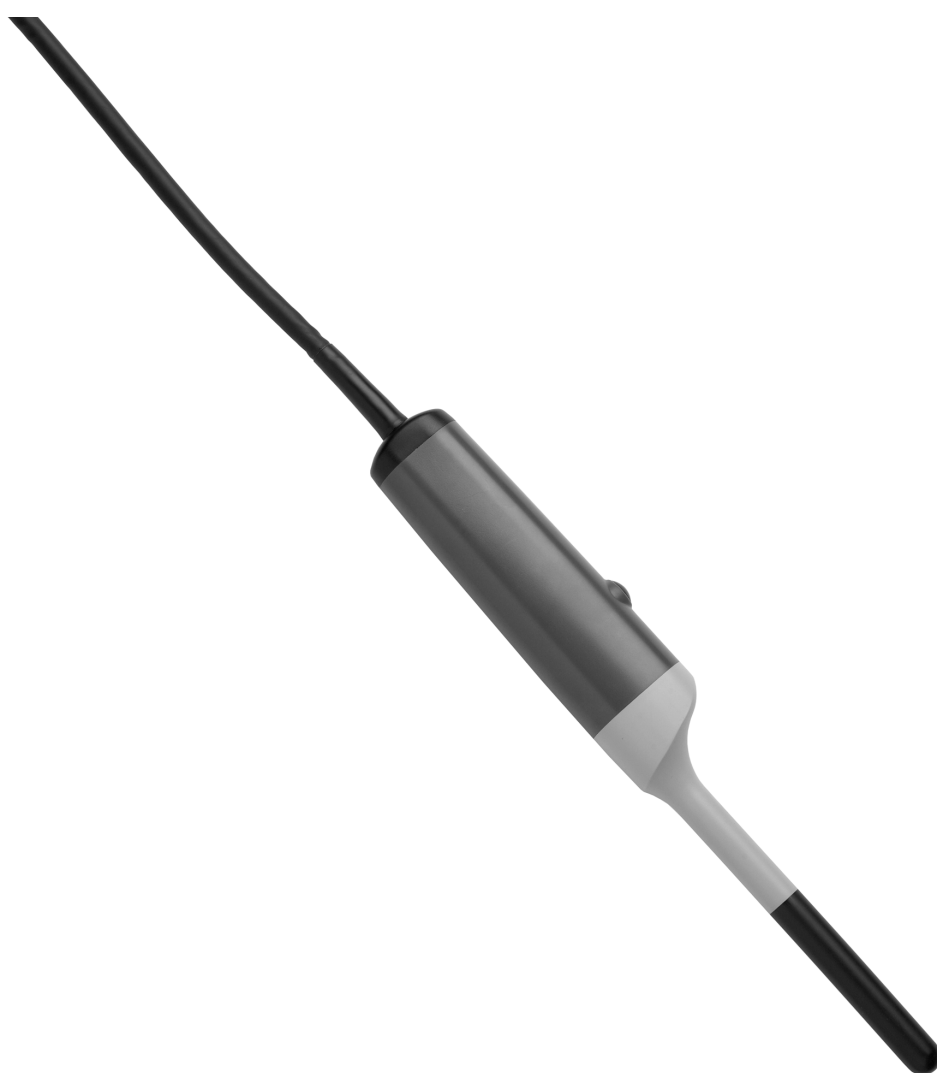


3D**ART** Transducer



BK MEDICAL
Mileparken 34
2730 Herlev
Denmark
Tel.: +45 4452 8100/Fax: +45 4452 8199
www.bkultrasound.com
Email: info@bkultrasound.com

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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BB1857-G

Introduction

This is the user guide for 3D*ART* Transducer Type 8838 and must be used together with *Care and Cleaning* which contains important safety information.

 Physicians only	Caution Rx-c1 United States Federal law restricts this device to sale by or on the order of a physician.
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Intended use

The transducer is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body.

Indications for use

8838 is suitable for 3D transrectal prostate and transvaginal imaging. It is also suitable for contrast imaging¹.

Patient Population

The patient population is adults.



Figure 1. 3D*ART* Transducer Type 8838.

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.

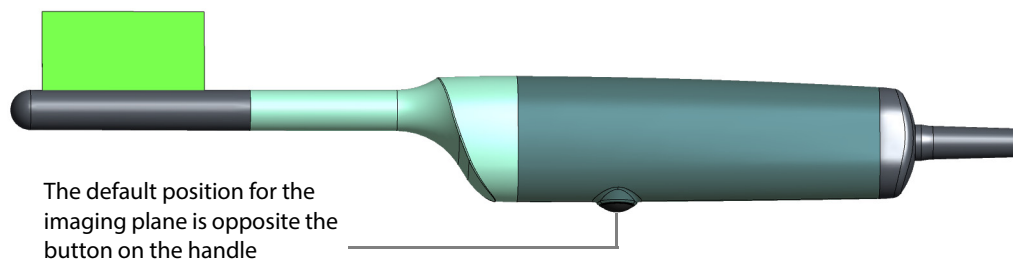


Figure 2. 2D imaging plane.

1. ProFocus only

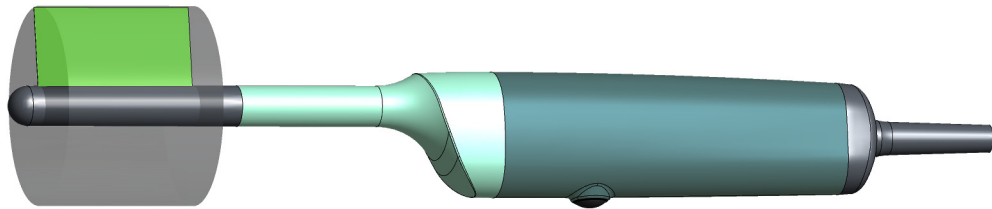


Figure 3. 3D imaging plane.

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 GS-w2 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 service representative or hospital technician.
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	WARNING AO-w1 To avoid tissue damage, always keep the exposure level (the acoustic output level and the exposure time) as low as possible.
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Service and Repair

	WARNING SR-w1 Service and repair of BK 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 electrician or hospital technician should verify the safety of all equipment.
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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 and Cleaning*.

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 and Cleaning* 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 Reproc-w2 Users of this equipment have an obligation and responsibility to provide the highest possible degree of infection control to patients, co-workers and themselves. The instructions in this book are meant as a guide. To avoid cross contamination, follow all infection control policies (including for reprocessing, packing and storage) for personnel and equipment that have been established for your office, department, or hospital.
---	---

Starting Imaging

All equipment must be cleaned and disinfected before use.

	WARNING T-w5 To prevent electrical shock and damage to the transducer, the connector pins in the transducer plug must always be completely dry before you connect to a system.
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	WARNING Pos-w1 Before starting an examination, use the ultrasound image to verify that 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 GS-w4a It is essential for the patient's safety that only the correct equipment is used. • Do not use other manufacturers' transducers with BK ultrasound systems. • Do not use BK transducers with other manufacturers' systems. • Do not use unauthorized combinations of transducers and needle guides.
---	---

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

	Caution BK-c4 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 <i>both</i> 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 BK-w13 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 TC-w1 Some transducer covers can contain latex. Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA advises 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.



Caution T-c3

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.

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 11.

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 10.

Endovaginal, Anorectal, and Transrectal Imaging with Type 8838



WARNING Colo-w1

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 Figure 2 and Figure 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

Select key

Typically, you use a 2D imaging to locate the area where you want a 3D image. 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 transducer 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.*



Rotation symbol

A rotation symbol shows the position of the array when imaging in 2D. The line inside the circle of the icon represents the position of the transducer array.

Note that the default position of the imaging plane is opposite the transducer button (see Figure 2).



Figure 4. Rotation symbol on the flex Focus 1202. Not available on the 2202 UltraView system.



You can select and drag the rotation symbol to a new position on the screen using the trackball and **Select** keys on the system keyboard. The rotation symbol disappears when you start a 3D acquisition.

There are two ways you can rotate the imaging plane:

- 1 Click the rotation symbol on the monitor with the **Select** key and press the **+/-** keys on the keyboard. You can also click +/- on the actual rotation symbol. Press or click **+** to rotate clockwise, press or click **-** to rotate anticlockwise.

NOTE: *If you want to use the +/- keys on the keyboard to rotate the imaging plane you must first click the rotation symbol (see Figure 4).*

Or:

- 2 Click the screen keys **Rotate -** or **Rotate +**.

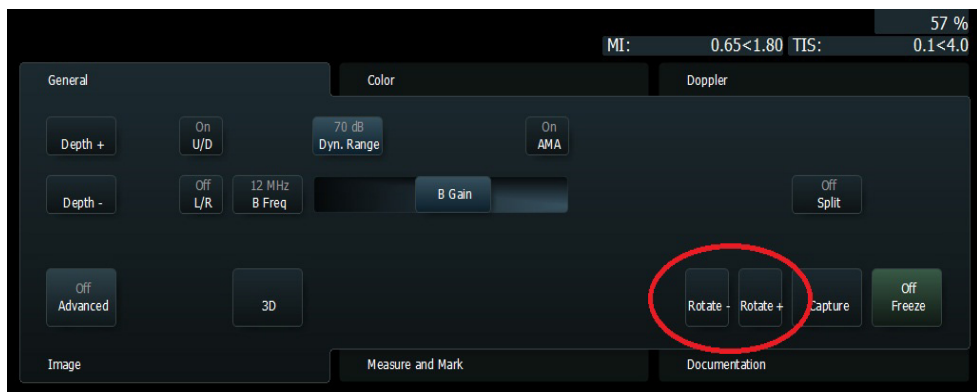


Figure 5. Rotation screen keys on the flex Focus 1202. On the 2202 UltraView system you have to assign rotation keys to the user-definable keys on the keyboard. For more information on customizing the 2202 UltraView keyboard, see the 'Setting Up and Customizing Your System' chapter in the Pro Focus 2202 Extended User Guide (BB1279).

Alternatively, you can rotate the imaging plane using the remote control. See the applicable system user guide for further information about the remote control and its functions.

Each key press/click rotates the imaging plane by 3°. Hold down the key to rotate the plane quicker. The imaging plane can be rotated 180° in either direction from the default position, see Figure 2.

When you switch to 3D, the imaging plane moves back to its default position. You should always check the position of the imaging plane to make sure that it is in the desired position.

3D Imaging

NOTE: See the advanced 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.

Note that the transducer and the patient must remain still during 3D imaging to obtain accurate images.

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.

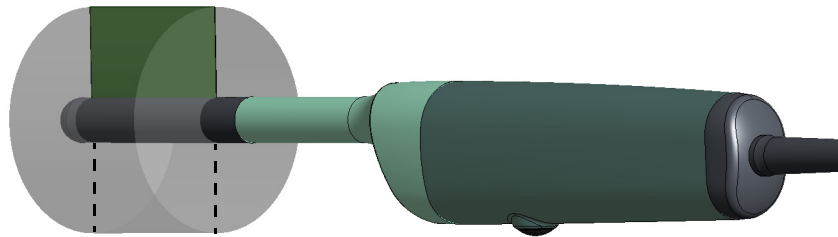
By default, the stitch line is located at the bottom of the cube, which is normally away from the area of interest; at the bottom of the cube (opposite to the default position). To make sure that the stitch line in the screen does not interfere with what you want to see, check the cube after the 3D imaging. 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** ① in the 3D General tab.

In the default center position ①, the stitch angle is opposite the array's default position; that is, towards the transducer button (see Figure 6).



The stitch angle's default center position ① is towards the transducer button

Figure 6. 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** ① in the left menu bar.

In the default center position ①, the stitch angle is opposite the array's default position; that is, towards the transducer button (see Figure 6).

- 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.

Select the **Mover** parameter on the screen. There are two options:

- **IP8838** – Moves the internal array while you hold the transducer still.
- **Untr. Fan** (Untracked Fan) – Lets you freely move the transducer to acquire images. See the system user guide for the untracked freehand warning information, as well as the extended system user guide for image issues concerning untracked freehand acquisition.

Cleaning after Use

	WARNING Reproc-w3 Immediately after use, you must pre-clean the device until visually clean (including device lumens if existing). Conduct the thorough cleaning process as soon as possible after use in order to prevent bioburden drying on the surface. Dried bioburden can lead to inefficient cleaning, disinfection and sterilization, causing a risk of cross-contamination. If pre- and thorough cleaning cannot be done immediately, keep the device moist until cleaning.
---	--

Use a suitable brush to make sure that biological material and gel are removed from all channels and grooves. See *Care and Cleaning* 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 system user guide for further details.

**WARNING** D-w1

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

 BK Medical ApS, Mileparken 34, 2730 Herlev, Denmark. T +45 4452 8100 F +45 4452 8199



powered by analogic 

BK Ultrasound
8 Centennial Drive
Peabody
MA 01960
USA
T +1 978-326-1300
bkultrasound.com

USA
Sales & Service
BK Ultrasound
8 Centennial Drive
Peabody
MA 01960
USA
T +1 978-326-1300
F +1 978-326-1399
bkultrasound.com

Europe and Rest of World
Sales, Service & Design Center
BK Ultrasound
Mileparken 34
2730 Herlev
Denmark
T +45 4452 8100
F +45 4452 8199
bkultrasound.com

Asia
Sales & Service
Analogic Medical Equipment
(Shanghai) Co., Ltd.
1377, Lan Dian Road
Pu Dong New District
Shanghai
China 201132
T +86 21 2089 0333
bkultrasound.com