

Anorectal 3D Transducer



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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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General Information



Figure 1. Anorectal 3D transducers type 2052.

This is the user guide for Anorectal 3D Transducer Type 2052. It contains a description of the transducer, a list of the intended applications, and information about operating this particular transducer. You must use this guide together with other documents that contain important information, including vital safety information.

Information not in this user guide	Where to find it
How to use the transducer with your system, including setting up user-defined functions	System User Guide
Safety information and caring for the transducer	<i>Care, Cleaning & Safety</i>
Cleaning and disinfection	<i>Care, Cleaning & Safety</i>
Disinfectants and disinfection methods	Product Data Sheet and <i>Care, Cleaning & Safety</i>
Disposal	<i>Care, Cleaning & Safety</i>
Product specifications	Product Data Sheet (BP0133)
Available accessories, including sterile covers	Product Data Sheet (BP0133)
Acoustic output data	Technical Data, User Documentation CD
Explanation of acoustic output	System User Guide
EMC (electromagnetic compatibility) data	Technical Data, User Documentation CD

Table 1-1. Where to find additional information essential to the operation of this transducer.

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

About the Transducer

Applications

The transducer is suitable for the following types of examinations.

Colorectal Imaging

- endoanal imaging
- endorectal imaging

Pelvic Floor Imaging

- endoanal imaging
- endovaginal imaging of the pelvic floor

Crystals

The transducer is a mechanical (single-element) multifrequency transducer with a built-in 3D mover. Inside the transducer head is a double crystal assembly where 2 crystals sit back to back. The assembly can rotate inside the transducer to give a 360° field of view. No moving parts contact human tissue.

H or L The selected crystal is indicated after the transducer number at the top of the screen: **H** (high-frequency) or **L** (low-frequency).

The crystal assembly can be positioned manually or – if you have a 3D option installed (see “3D Imaging” on page 25) – by the system.

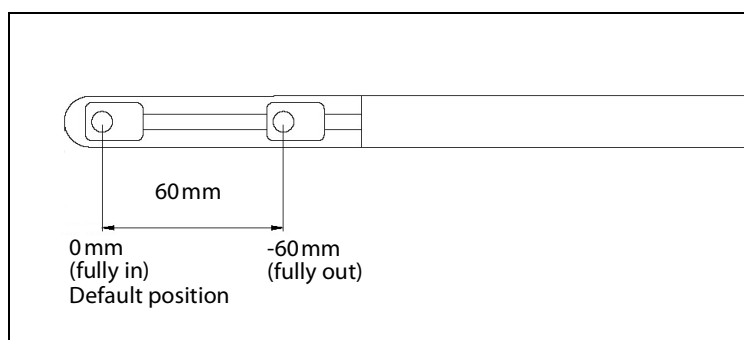


Figure 2. Movement of the crystal assembly inside the transducer head.

Imaging Plane

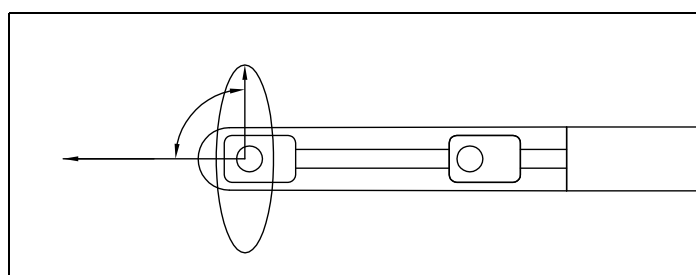


Figure 3. Imaging plane for the anorectal transducer. The extreme positions of the crystal assembly are shown.

Imaging Frequencies

Each crystal has 3 imaging frequencies. On the system, the imaging frequency is displayed on the screen.

Control Buttons

The transducer has 3 control buttons on the handle.

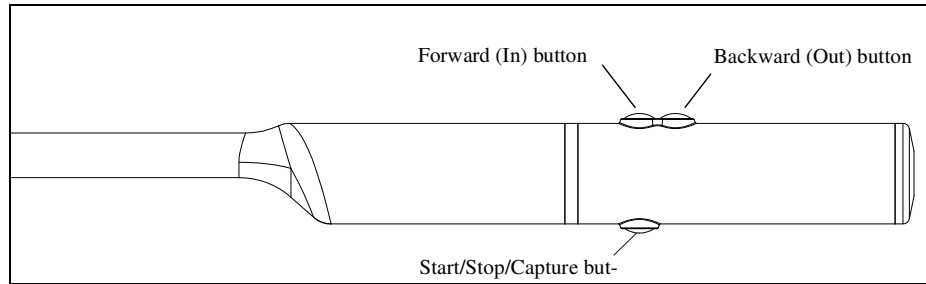


Figure 4. Transducer control buttons.

The **Start/Stop/Capture** button on the underside of the handle is used to start or stop imaging. You can specify a user-defined function for a long press (at least one second) on the button: by default, a long press captures the current image.

The **Crystal Position** buttons (**Forward** and **Backward**) on the upper side move the crystal assembly.

Beeps

The system emits “beeps” when:

- The **Start/Stop/Capture** button on the transducer is pressed.
- The crystal arrives at its default position (0mm – see Fig. 2).

Safety Information



WARNING To avoid tissue damage, always keep the exposure level (the acoustic output level and the exposure time) as low as possible.



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.

Contact your BK Medical representative if you believe the correct functioning of any BK Medical equipment is impaired in any way.

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.

Cleaning and Disinfection

A transducer used for endocavity procedures with no puncture must be cleaned immediately after use and disinfected before it is used. You must use a transducer cover. See *Care, Cleaning & Safety*.



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.

A list of disinfectants and disinfection methods that the transducer can withstand are listed in the Product Data sheet and *Care, Cleaning & Safety*.

Preparing the Transducer for Imaging

All equipment must be cleaned and disinfected before use.

Checking Before Use

The transducer may be damaged during use or processing, so it must be checked before use. Check the transducer more thoroughly once a month. See *Care, Cleaning & Safety*. Contact your BK Medical service representative if you detect any signs of damage or of oil leaking from the transducer.



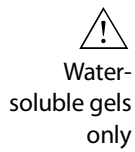
WARNING To avoid harming the patient, do not use the transducer if you detect any signs of damage.

Using a Transducer Cover

Endoanal or Transvaginal Imaging

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 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.



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.

Endorectal Imaging

You must use a water-standoff system (with a water standoff condom) to image the rectum from the anorectal junction and further into the rectum. See page 13.

Connecting the Transducer



WARNING To prevent electrical shock, keep all plugs and sockets absolutely dry at all times.

To connect the transducer:

- 1 If the connector plug cover (used to protect the plug during cleaning and disinfection) is screwed on, unscrew it to remove it.
- 2 Align the red arrow on the connector plug with the red dot on the transducer socket.
- 3 Insert the plug in the socket.

NOTE: *To disconnect the transducer, you must pull back the outer locking mechanism on the plug before you remove the plug from the socket.*

Selecting the Crystal and Imaging Frequency

To select the other crystal or change the imaging frequency, please refer to your system user guide.

The 2052 Crystal Position Imaging With Pro Focus UltraView 2202

This section **only** applies to Anorectal Transducer Type 2052 when used with the Pro Focus UltraView 2202 system.

The 2052 Crystal Position Displayed on the Pro Focus UltraView 2202 Screen

The system tracks the crystal position and displays it in cm on the left side of the screen next to **Crystal Pos**.



Figure 5. Position of the 2052 transducer crystal.

Default position

The crystal position is 0 when the crystal is at the tip of the transducer (farthest into the patient). This is the default position.

The following actions cause the crystal to move to the default position:

- Connecting the transducer to the system.
- Selecting a new preset.
- Pressing the **Forward** button until the system beeps.
- Entering a new patient ID on the screen.

Other positions

All other crystal positions are expressed as negative numbers (see Fig. 5 for an example). -6.0 (cm) is the crystal position closest to the transducer handle.

Changing the 2052 Crystal Position on the Pro Focus UltraView 2202

You can use the **Forward** and **Backward** buttons on the transducer handle to move the crystal.

You can also use the on-screen control to change the crystal position.

To move the crystal in the 2052 transducer:

Transducer control button

- Press one of the control buttons on the upper side of the transducer handle (see Fig. 4) until the crystal is where you want it.

A short press moves the crystal. As you hold the button down, the crystal moves faster.

or

On-screen control

- Click **Crystal Pos** under **General** on the left side of the screen and drag the slider (or point at **Crystal Pos** and press $[+/-]$).

The value you set is displayed in italic font to indicate that it is the desired (destination) position rather than the actual position (see Fig. 5)

When the crystal reaches the position you have set, the font changes to normal.

Insertion Depth of the 2052 Transducer and Anatomic Position of the Crystal

When imaging with the 2052, you can specify the transducer insertion depth (how far the transducer is inserted into the rectum). The system then calculates the anatomic position (depth in the body) of the crystal and displays that, too, in cm on the left side of the screen next to **Anat. Pos.** (See Fig. 5 to see the format of the display.)

NOTE: *If the combination of insertion depth and crystal position results in an impossible anatomic position, the displayed value next to **Anat. Pos.** is NA/y, where y is the insertion depth.*

To set the insertion depth:

- 1 Find the actual insertion depth by reading the scale on the transducer.
- 2 Click **Anat. Pos** under **General** on the left side of the screen and drag the slider to the actual insertion depth (or point at **Anat. Pos** and press $[+/-]$).

The system calculates the anatomic position based on the insertion depth and the crystal position (note that crystal position is a negative number):
Anatomic Position=Insertion Depth+Crystal Position.

Insertion Depth Not Set If you do not set an insertion depth, the system cannot calculate the anatomic position. There may be cases, however, where you set an insertion depth and then do not want to use it.

To remove the insertion depth setting:

- Drag the **Anat. Pos.** (insertion depth) slider to 0.

or

- Make sure the image is frozen, and press the **Start/Stop/Capture** to move the insertion depth to zero.

If the insertion depth is not set, or is zero, the displayed value next to **Anat. Pos.** is NA.

Imaging

Image Orientation

The 12 o'clock position on the displayed image is identified by the two control buttons on the transducer handle pointing to the anterior 12 o'clock position.



WARNING To avoid misinterpreting structures in the ultrasound image, verify the orientation of both crystals in the transducer before you start imaging.

To verify crystal orientation:

- 1 Hold the transducer in the 12 o'clock position, that is, with the 2 control buttons on the handle pointing to the anterior 12 o'clock position.
- 2 Touch the tip of the transducer with your finger.
- 3 Verify that the image of your finger is displayed at the top of the image displayed on the screen

Changing the Image Orientation

See the system user guide.

Imaging, Freezing and Capturing an Image

To start or stop imaging (freeze the image):

- Press the **Start/Stop/Capture** button (see Fig. 4) briefly.

To copy the image:

- Press the **Start/Stop/Capture** button for more than one second.

NOTE: *Your system may be set up so that a long press on the button has a different function.*

Endoanal or Transvaginal Imaging

Preparing the Transducer

You must use a transducer cover. (See "Using a Transducer Cover" on page 8.)

Endorectal Imaging

Water Standoff Systems

You must use a water standoff system to image the rectum from the anorectal junction and beyond.

BK Medical offers reusable water standoff systems and single-use water standoff systems. When using a water standoff system, you should always follow policies established by your office, hospital or institution when you are performing endorectal imaging.

Reusable Water Standoff

You can use a reusable water standoff system with the following components:

Reusable
water
standoff
system

- Water standoff collar UA0671 with O-ring UA0674
- Plastic extension tube UA0676
- 2-way stopcock UA0677
- Plastic syringe UA0678
- Light cable adaptor UA0682, reusable (for UA0683)
- Non-sterile water standoff condoms UA0037

and one of the following rectosigmoidoscopes:

- Rectosigmoidoscope kit UA0672 (DO0164 compatible with Welch Allyn® light source, with obturator DO0163)
- Rectosigmoidoscope kit UA0673 (DO0165 compatible with Storz® light source, with obturator DO0163)
- Single-use, sterile Rectosigmoidoscope kit UA0683

Single-Use Water Standoff

You can also use a single-use water standoff system UA0048 with the following components:

Single-use
water
standoff
system

- Inner cover [A]
- Outer cover [B]
- Tape [C]
- Plastic syringe e.g. UA0678.

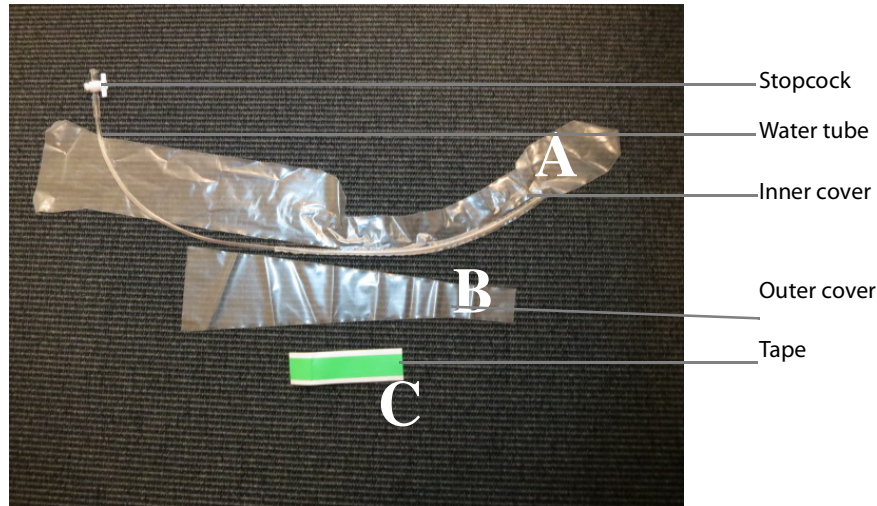


Figure 6. UA0048 water standoff system components.

NOTE: See the Product Data sheet for ordering information.

Preparing the Patient

- 1 Always perform a digital palpation before you insert a rectosigmoidoscope or endo transducer into the rectum.
- 2 Give the patient an enema – liquid should be held retained as long as possible before being expelled.

Preparing the Reusable Water Standoff System

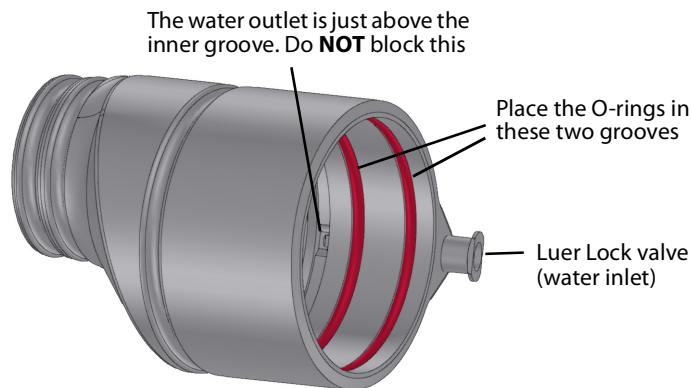
Disinfect
before using

The transducer, water standoff collar, O-ring, rectosigmoidoscope and obturator must be cleaned and disinfected before use. The water standoff collar, O-ring, rectosigmoidoscope and obturator can be autoclaved.

NOTE: For best results, separate the O-ring from the water standoff collar before autoclaving. O-rings that are no longer watertight should be replaced.

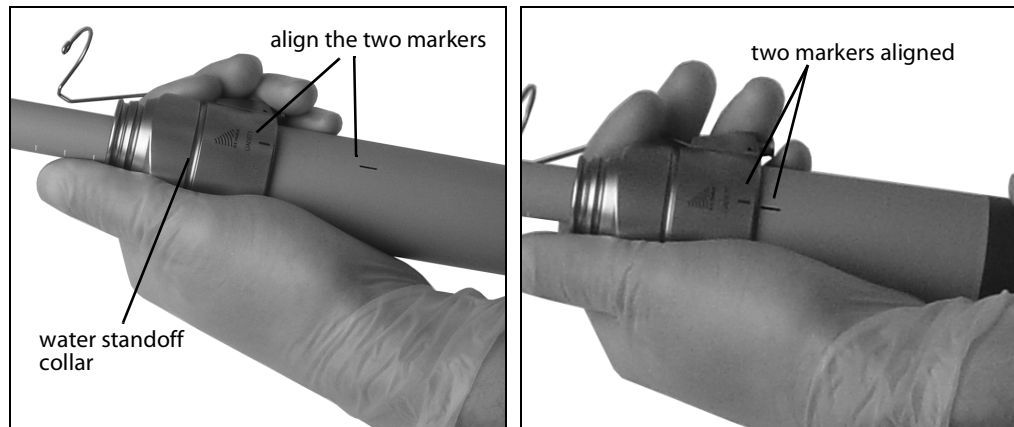
To prepare the reusable water standoff system:

- 1 Place the two O-rings in the outer grooves as shown in this picture.

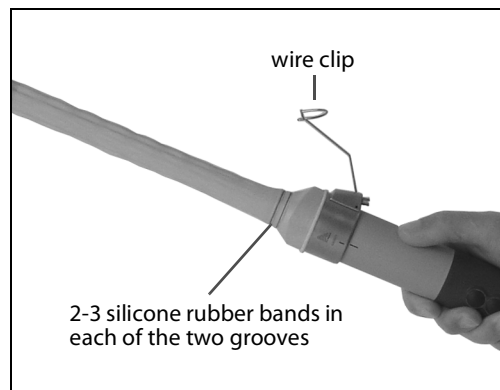


- 2 Use a little water to moisten the silicone O-rings inside the water standoff collar.
- 3 Gently slide the water standoff collar over the transducer.

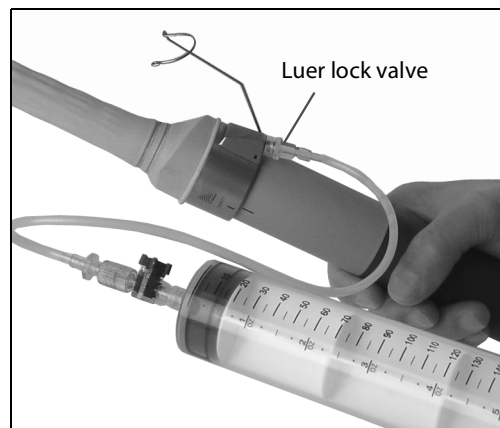
Make sure that the marker on the water standoff collar is aligned with the marker on the transducer.



- 4 Pull a water standoff condom over the transducer, attaching it to the groove on the water standoff collar. Check the water standoff condom for tears.



- 5 Secure the water standoff condom in place with 2 or more silicone rubber bands in each groove (silicone rubber bands are supplied with water standoff condoms UA0037).
- 6 Fill the syringe with degassed water. Use the 2-way stopcock and plastic extension tube to attach the syringe to the Luer lock valve on the water standoff collar.



- 7 Fill the water standoff condom with approximately 50ml of degassed water.

Air bubbles may appear in the water standoff condom. You must remove the air bubbles to avoid artifacts on the ultrasound image.

- 8 Hold the transducer with the water standoff condom pointing downwards and use the syringe to aspirate as much air as possible.



- 9 Refill the water standoff condom with degassed water. Repeat this procedure until there is no air left in the water standoff condom.
- 10 Remove enough water from the water standoff condom to allow the system to pass through the BK Medical rectosigmoidoscope.
- 11 Lubricate the entire outer surface of the water standoff condom with a glycerine-based lubricant.



Caution: You must lubricate the condom before you insert the system into the rectosigmoidoscope. The lubricant must be glycerine-based.

The transducer is designed to pass through Rectosigmoidoscope UA0672, Rectosigmoidoscope UA0673 or single-use Rectosigmoidoscope UA0683.



Caution: If you use a rectosigmoidoscope that you do not purchase from BK Medical, it must be fully cylindrical and have an inner diameter of at least 21 mm.

The transducer is now prepared for an endorectal examination.



Caution: You **MUST** lubricate the outer surface of the water standoff condom before you introduce the transducer with a water standoff system into a rectosigmoidoscope. Without lubrication you may not be able to retract the transducer from the rectosigmoidoscope. This can damage the transducer.



Caution: If the transducer cannot be withdrawn from the rectosigmoidoscope, contact your BK Medical representative immediately.

Preparing the UA0048 Single-Use Water Standoff System

Before you start, see Fig. 6 to familiarize yourself with the parts of the single-use water standoff system.

To prepare the single-use water standoff system:

- 1 Place the transducer in an upright and stable position, for example, in the system's transducer holder.



Figure 7. Transducer held in a stable position.

- 2 Apply water to moisten the transducer.



Figure 8. Moistening the transducer with water.

- 3 Pull the inner cover (A in Fig. 6) over the transducer. (See Fig. 9.) Check the inner cover for damage (tears).



Inner cover on correctly

Figure 9. Putting on the inner cover.

- 4 Create a tape handle: Partly remove the protective strip from the tape so only the first cm of the tape is exposed. Then bend the first (sticky) cm in half and tape the sides together to create a 0.5 cm “handle”. (See Fig. 10.)

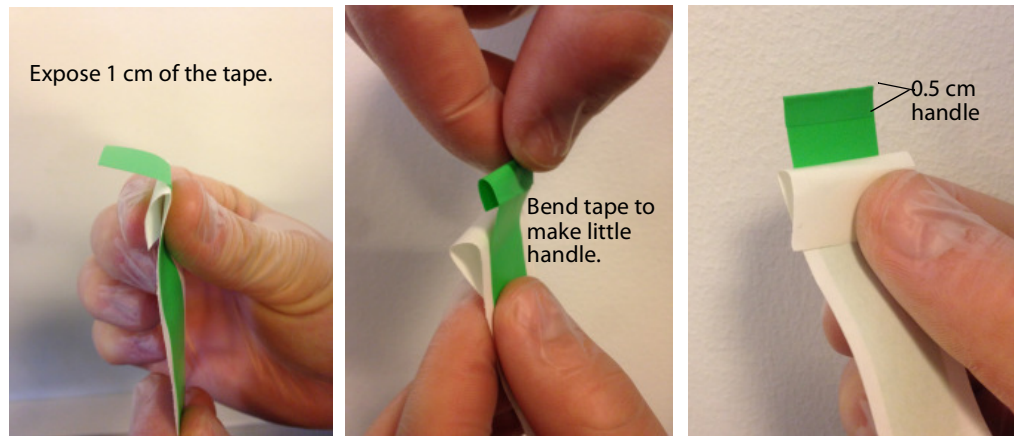


Figure 10. Creating a tape “handle”.

NOTE: Make sure you do not tape more than the first cm together. The tape will be too short to fit around the transducer.

- 5 Push the non-handle end of the tape through the opening in the inner cover and wind the tape tightly around the cover and then around the water tube that forms the opening.

Make sure that when you wind the tape around, it covers the top of the water tube on the inner cover by 1-2 mm.

Follow the steps shown in Fig. 11. The tape must be tight so that when you put water in the standoff, it doesn’t run out under the tape.

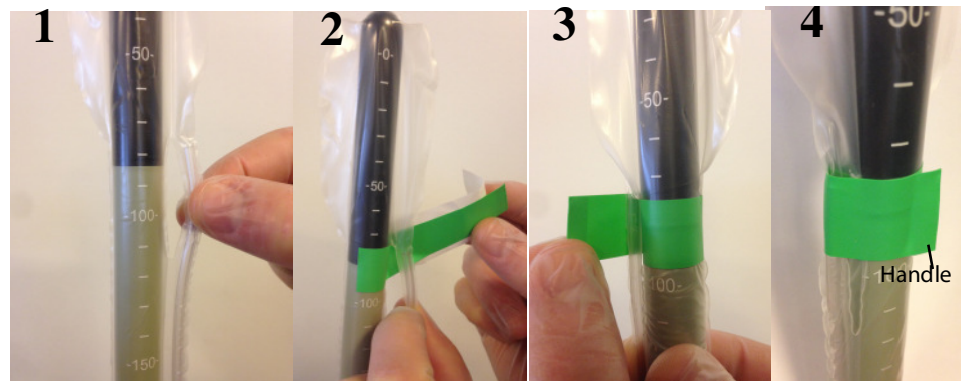


Figure 11. How to place the tape around the water standoff condom. The tape should cover the bottom of the black part of the transducer.

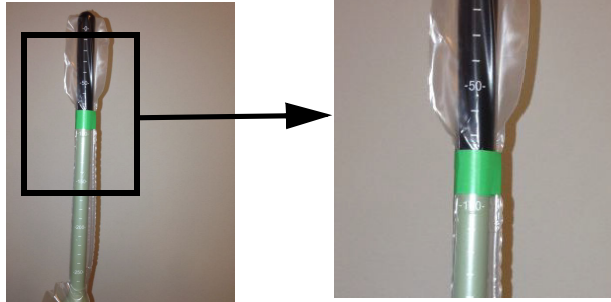


Figure 12. Inner cover correctly taped.

- 6 Pull the outer cover (B in Fig. 6) over the transducer and inner cover. Make sure that it completely covers the tape, as shown in Fig. 13.



Figure 13. Pulling the outer cover on to cover the tape completely.

- 7 Using a standard syringe, fill the water standoff system slowly with degassed water (max 200 ml).

NOTE: Make sure that the stopcock on the water tube is positioned correctly to allow water to pass through the tube. (See Fig. 14.)

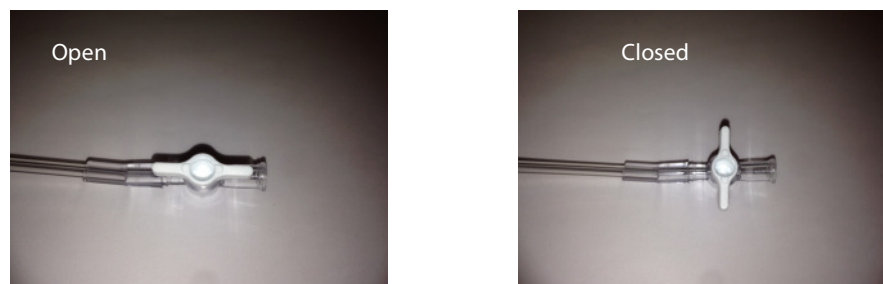


Figure 14. Open and closed positions of stopcock.

Remove air bubbles

Air bubbles may appear in the inner cover. You must remove the air bubbles to avoid artifacts on the ultrasound image

- 8 Hold the transducer with the tip pointing downwards and use the syringe to aspirate as much air as possible.
- 9 Close the stopcock to seal the system and unscrew the syringe so you can push the air out of it.
- 10 Screw the syringe back on, open the stopcock and repeat this procedure until there is no air left in the inner cover.

Lubricate the entire outer surface of the standoff that will enter the patient. Aspirate enough water from the standoff to allow for easy insertion.

The transducer is now prepared for an endorectal examination.

Performing a Rectoscopy Using a Reusable Water Standoff System



WARNING To avoid tissue damage, always perform a thorough rectoscopy before doing an endorectal imaging.

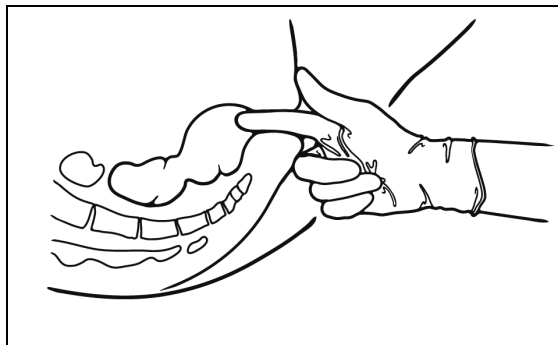
The patient is examined in the left lateral decubitus or the dorsal lithotomy position.

Follow policies established for your office, department or hospital for the use of a rectosigmoidoscope.

To perform an endorectal examination:

Prepare the water standoff system before you start. (See “Preparing the Patient” on page 14.)

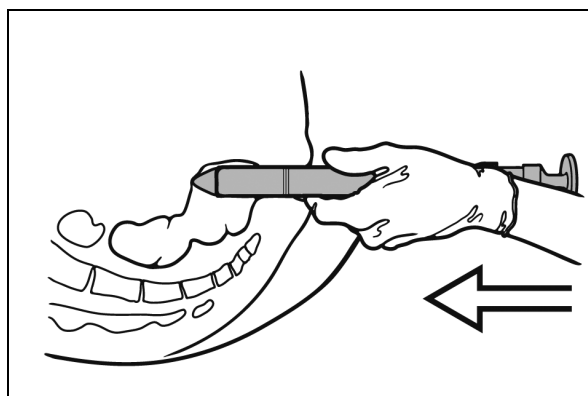
Always perform a digital palpation before you insert a rectosigmoidoscope or endo transducer into the rectum.



Using a Rectosigmoidoscope

Insert the obturator fully into the rectosigmoidoscope and apply gel to the outside tip.

Introduce the rectosigmoidoscope as far as the beginning of the rectal ampulla (4–5 cm).





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.

Slowly remove the obturator.

Use the light source and visually inspect the rectum. If necessary, empty the rectum.

Using visual guidance, advance the rectosigmoidoscope to the level of interest – so that it just covers the area you want to image.



WARNING To avoid harming the patient if you advance the rectosigmoidoscope further into the rectum, you must use visual guidance under conventional techniques that are approved at your hospital.

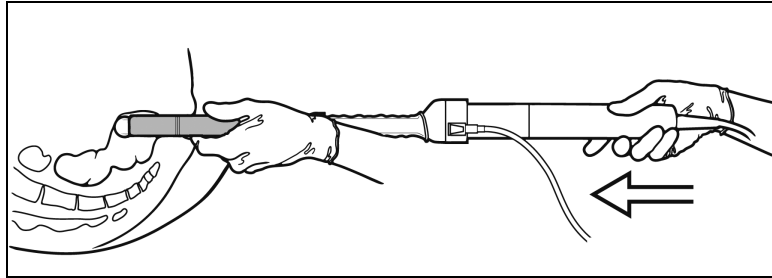
Inserting the transducer and reusable water standoff system

Reusable
water
standoff
system

Make sure that the entire outer surface of the water standoff condom is thoroughly lubricated with a glycerine-based lubricant.

Insert the transducer just until the tip of the transducer is at the far end of the rectosigmoidoscope.

The end of the rectosigmoidoscope nearest you will be at the 200 mm mark on the transducer if you are using either the UA0672 or UA0673 rectosigmoidoscope. If you are using the single-use rectosigmoidoscope UA0683 then it will be at the 190 mm mark.

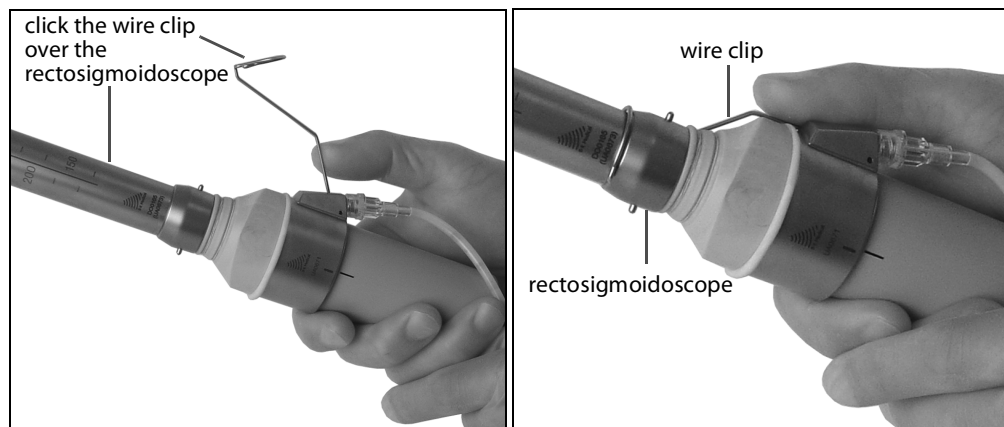


WARNING To avoid harming the patient, never advance the transducer/rectosigmoidoscope combination beyond the level identified by introducing the rectosigmoidoscope under visual guidance.

Hold the transducer in position and pull the rectosigmoidoscope slowly back toward yourself until the rim touches the water standoff collar UA0671.

NOTE: *It is important to hold collar and rectoscope tight together.*

Click the wire clip over the rectosigmoidoscope to hold it in place with the water standoff collar. Do not reposition the transducer relative to the patient while you are doing this.



Inserting the Transducer and Single-Use Water Standoff System

Do not use together with a rectosigmoidoscope



NOTE: *The single-use water standoff system is not designed for use with a rectosigmoidoscope.*

WARNING To avoid tissue damage, always perform a thorough rectoscopy before doing an endorectal imaging.

Single-use water standoff system

Aspirate enough water from the water standoff system to allow for easy insertion of the transducer. Re-apply gel to the outside of the water standoff system before you insert the transducer in the cavity. This ensures optimal contact between the transducer and the rectal wall. Insert the transducer in the cavity and refill the water standoff system slowly with water.

Before imaging, make sure the knob on the water dispense tube is locked to avoid water leakage.

Imaging

To start imaging, press the **Start/Stop/Capture** button on the underside of the transducer handle. Image the exposed area. (For a 3D image, see “3D Imaging” on page 25.)

If you have not imaged the entire object of interest in the first pass, pull the transducer *together with the rectosigmoidoscope (if you are using one)* back another 4–6 cm, and image again.



WARNING To avoid misinterpreting structures in the ultrasound image, you must identify possible artifacts in the ultrasound image created by the seams on the UA0048 single-use water standoff system.

Removing the Reusable Water Standoff System from the Patient

Reusable water standoff system

When you have completed the examination, empty the water from the water standoff condom, using a syringe.

Release the wire clip from the rectosigmoidoscope. Withdraw the transducer.

Then withdraw the rectosigmoidoscope.

Removing the Single-Use Water Standoff System from the Patient

Single-use water standoff system

To remove the water standoff system:

- 1 When you have completed the examination, empty the water from the water standoff condom, using a syringe.
- 2 Withdraw the transducer and remove the outer cover by pulling it inside out up over the transducer tip.



Figure 15. Removing the outer cover.

- 3 Remove the tape from the inner cover.



Figure 16. Removing the tape.

- 4 Remove the inner cover by pulling it inside out up over the transducer tip.



Figure 17. Removing the inner cover.

Clean Immediately after Use

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

Use a suitable brush to make sure that biological material and gel are removed from all channels and grooves, when using reusable water standoff system (including the collar and wire clip attachment). See *Care, Cleaning & Safety* for cleaning and disinfection instructions.

3D Imaging

To acquire a 3D dataset, you must have the 3D option installed on your system: this includes the necessary software and hardware as well as a 3D license.

To acquire a 3D dataset:

- See the system user guide for instructions.

NOTE: The maximum length of a dataset acquired using this transducer is 60mm. The resolution of the dataset is never worse than 0.5mm (i.e. 2 images per 1mm of movement). The default resolution is 0.25mm.

Transducer Support Collar UA0679

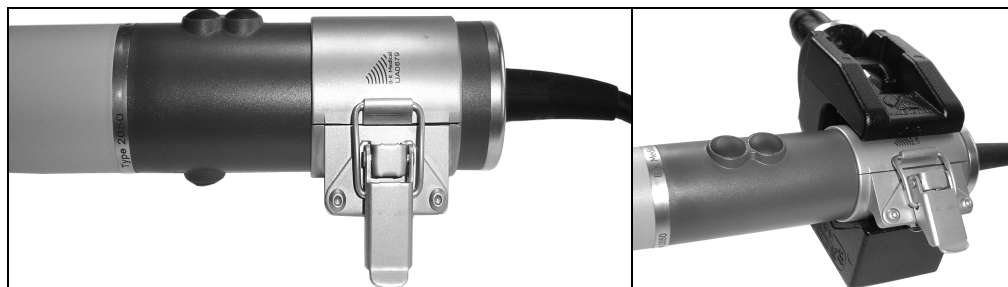


Figure 18. The support collar on the transducer without and with a fixation clamp.



Caution: It is strongly recommended that you use the transducer support collar to reinforce the transducer handle when you use a fixation device (such as the variable friction support arm UA0553) to hold the transducer in place.

Slide the collar over the handle of the transducer and clamp it in place.

Then with the variable friction support arm, you can either:

- Clamp the instrument fixation clamp to the support collar.
- or
- Remove the fixation clamp from a support arm and screw the support collar directly to the arm, using the threaded hole at the end of the steel ball joint piece.

Disinfection and Sterilization

The transducer support collar can be autoclaved.

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.

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Innovative Solutions for Life

Analogic Corporation creates innovative technology to improve the health and enhance the safety of people around the world. We are committed to providing ultrasound solutions under the BK Medical brand name that advance medicine and save lives.



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