



# STP 110 Precision™ Stepper

INSTRUCTIONS FOR USE



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## Introduction

**Intended Uses:** The STP 110 Precision™ Stepper (The Precision Stepper) is intended for use in prostate gland voluming and prostate brachytherapy procedures to assist the placement of the Ultrasound Transducer and Brachytherapy Needles. The Precision Stepper is not intended for direct patient contact.

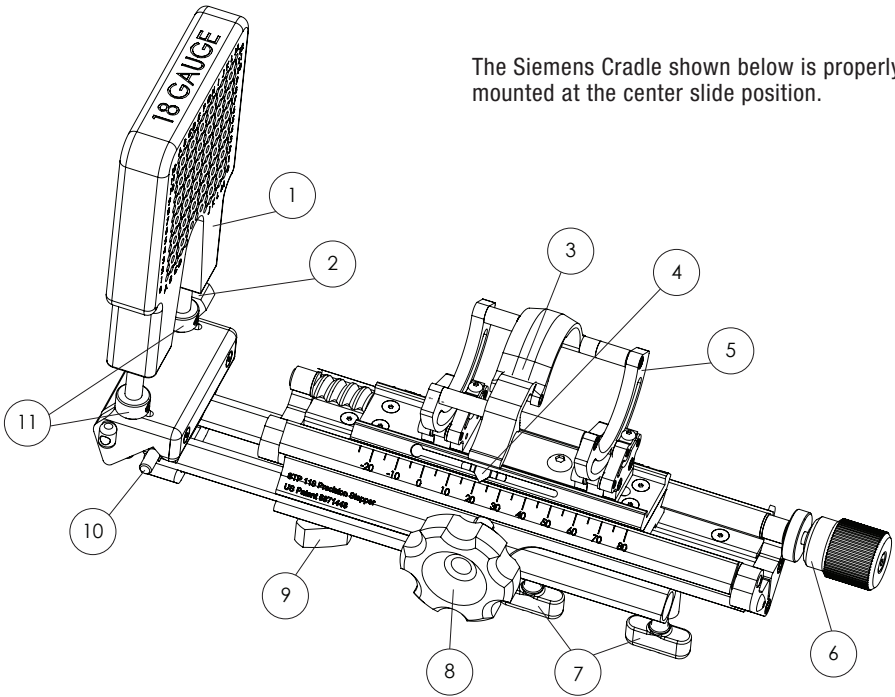
### Warnings

- > US law restricts this device to sale by or on the order of a physician.
- > The Precision Stepper should be used only AFTER reading these Instructions for Use (IFU).
- > The Precision Stepper is NOT packaged sterile. For applications requiring sterility, the Precision Stepper must be sterilized before use. Refer to the cleaning and sterilization instructions on page 11.
- > Needle path verification must be performed BEFORE the first use. Refer to the instructions on page 6.

# Major Components

The illustration below shows the major components of the Precision Stepper. This IFU will refer to these components in the instructions.

The Siemens Cradle shown below is properly mounted at the center slide position.

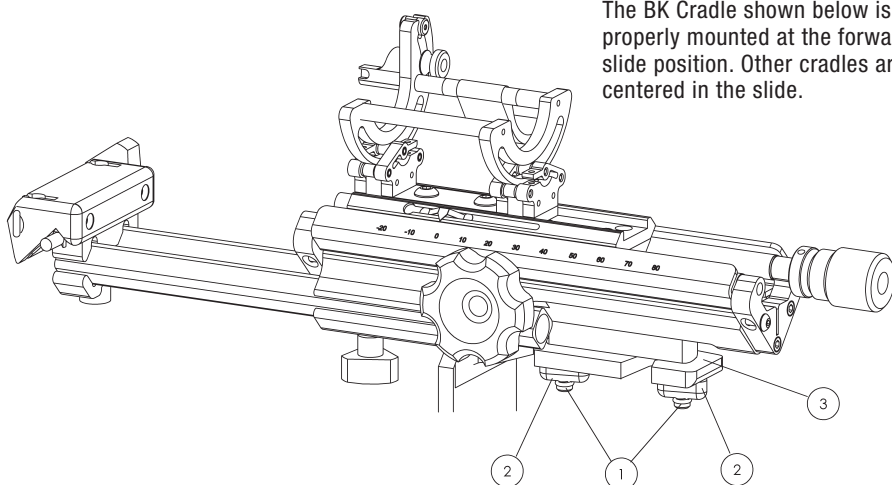


- |                             |                                 |
|-----------------------------|---------------------------------|
| 1) Needle Guide Template    | 7) Wing Nuts                    |
| 2) Template Locking Knob    | 8) 5-mm Step Knob               |
| 3) Transducer Clasp         | 9) Extension Knob               |
| 4) Baseline Marker          | 10) Horizontal Adjustment Knob  |
| 5) Transducer Cradle        | 11) Vertical Adjustment Collars |
| 6) Baseline Adjustment Knob |                                 |

# Setting Up

## Step 1: Attach the Stepper to the Stabilizer.

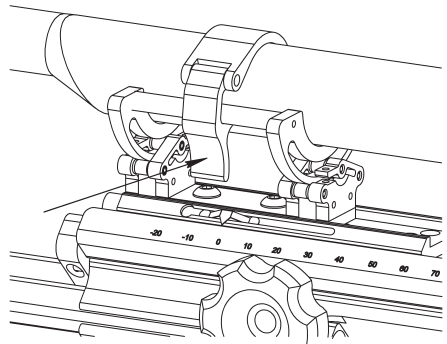
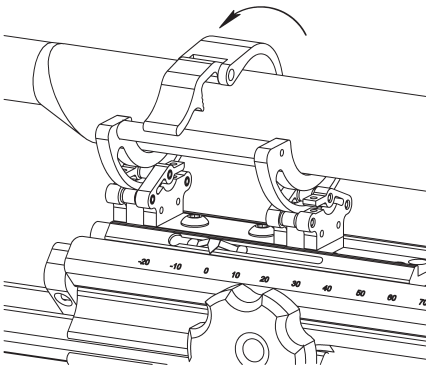
The BK Cradle shown below is properly mounted at the forward slide position. Other cradles are centered in the slide.



- 1 Loosen the Wing Nuts ② so the Mounting Screws ① can slide onto the Mounting Bracket ③ of the Stabilizer.
- 2 Locate the Precision Stepper in position by pulling backwards.
- 3 Tighten both Wing Nuts ②.

## Step 2: Lock in the Ultrasound Transducer.

**Note:** Since there are dimensional differences in Ultrasound Transducers by various manufacturers, make sure your Precision Stepper is equipped with a Transducer Cradle that fits your Ultrasound Transducer. If you use more than one brand of Ultrasound Transducer, you may need multiple Transducer Cradles. Please contact Best NOMOS for assistance.

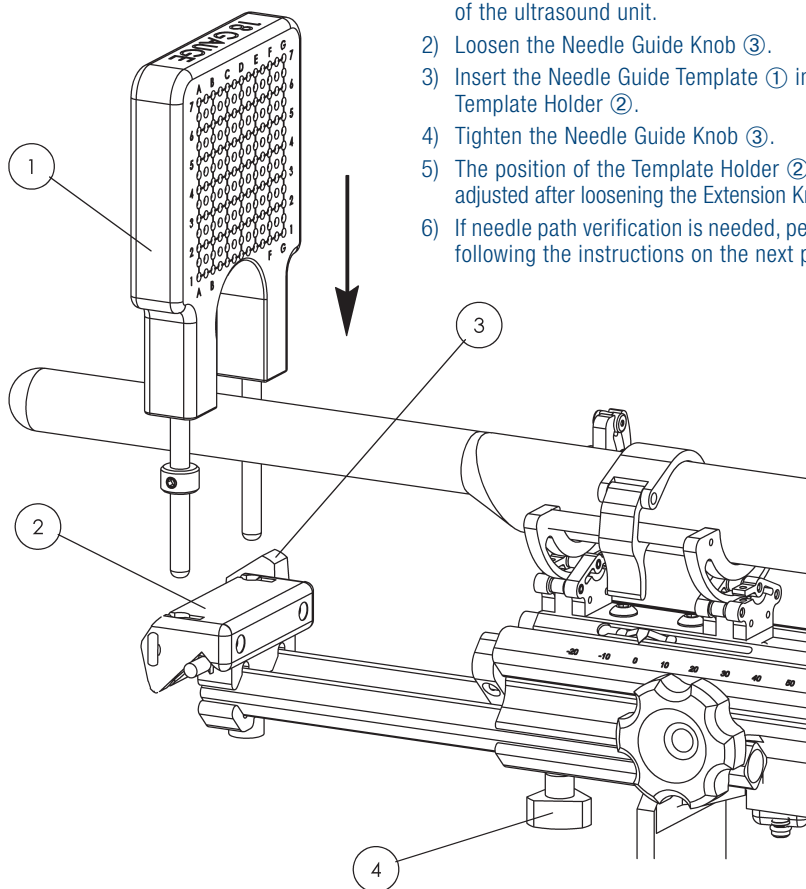


- 1) Place the Ultrasound Transducer into the Transducer Cradle.
- 2) Pull the Transducer Clasp over the Ultrasound Transducer.
  - 2.1) For Siemens Transducers, ensure that the groove at the bottom is aligned with the ridge on the Transducer Cradle, and the ridge on the top is aligned with the groove at the Transducer Clasp.
  - 2.2) For B-K Transducers, ensure that the locating pin is in the groove of the Transducer Cradle (refer to page 13 for their locations).
- 3) Push the Transducer Clasp down until it snaps closed with the Transducer Cradle.



### Step 3: Attach the Needle Guide Template.

- 1) Since the Needle Guide Template ① is reversible, verify that the template nomenclature facing the physician matches the on-screen display of the ultrasound unit.
- 2) Loosen the Needle Guide Knob ③.
- 3) Insert the Needle Guide Template ① into the Template Holder ②.
- 4) Tighten the Needle Guide Knob ③.
- 5) The position of the Template Holder ② can be adjusted after loosening the Extension Knob ④.
- 6) If needle path verification is needed, perform it by following the instructions on the next page.



#### Warning:



- > Needle Path verification must be performed BEFORE the first use of the Precision Stepper.

# Needle Path Verification

## Warning:



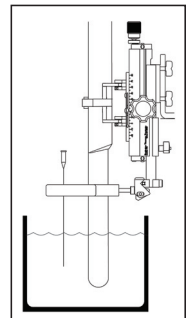
- > Needle Path verification must be performed BEFORE the first use of the Precision Stepper.

The purpose of the Needle Path verification is to verify that the path of the needle through the Needle Guide Template is accurately indicated by the on-screen grid of the ultrasound unit. Due to variances between Ultrasound Transducers, Needle Path verification should be performed with any new transducer, including those by the same manufacturer.

The Needle Path Verification test should be performed periodically, per your hospital procedures.

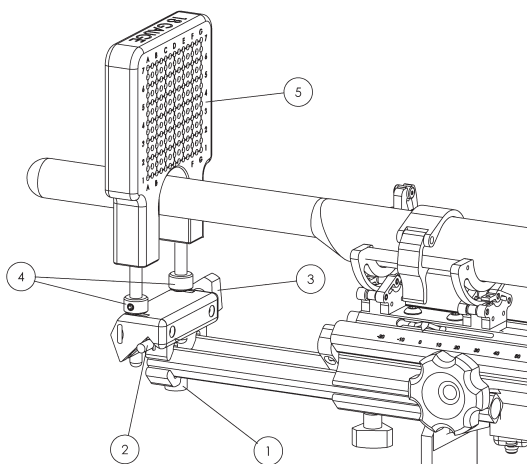
## Needle Path Verification

- 1) Ensure that the Transducer Cradle is rotated to the center position by allowing it to click into place.
- 2) Attach the Ultrasound Transducer to the Precision Stepper. Refer to page 4.
- 3) Attach the Needle Guide Template to the Precision Stepper. Refer to page 5.
- 4) Display the grid on the screen of the ultrasound unit. Ensure that the grid and the nomenclature displayed match the Needle Guide Template.
- 5) Immerse the tip of the Ultrasound Transducer in water as illustrated below.
- 6) Insert a straight needle through the Needle Guide Template at several locations, starting near the center.
- 7) Check whether the needle is displayed at the correct grid on the screen:
  - If it is, insert the needle at several different holes in the Needle Guide Template to confirm the result.
  - If it is not, follow the next instructions to adjust the needle path.



# Needle Path Adjustment

**Note:** Some ultrasound systems provide the capability to match the actual needle by adjusting the on-screen grid placement. Refer to the operating manual of your ultrasound system to see if it has this function. The Precision Stepper allows horizontal and vertical needle path adjustment by changing the needle guide template location to match the on-screen grid.



## Horizontal Adjustment

- 1) Callout ① points to a “nested” set of (2) allen-head cap screws – an inner 9/64” screw and an outer 5/16” screw. Loosen the Inner Screw ① with a 9/64” Allen Wrench by 1/4 turn. Do not loosen the outer screw or damage will occur to the template holder assembly.
- 2) Rotate the Horizontal Adjustment Knob ② to align the Needle Guide Template ⑤ horizontally with the on-screen grid.
- 3) Tighten the Inner Screw ① with an Allen Wrench.

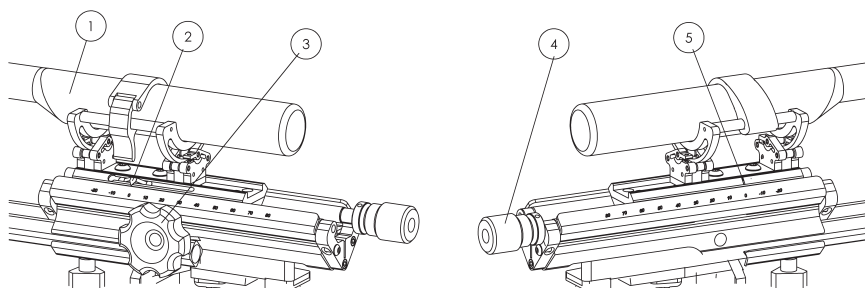
## Vertical Adjustment

- 1) Loosen the Needle Guide Knob ③.
- 2) Loosen both Vertical Adjustment Collars ④ with an Allen Wrench.
- 3) Slide the Needle Guide Template ⑤ up or down to align it vertically with the on-screen grid.
- 4) Tighten the Needle Guide Knob ③.
- 5) Tighten both Vertical Adjustment Collars ④ with an Allen Wrench.

### Warning:

The B-K Ultrasound Transducer may require rotational adjustment. See page 13 for instructions.

## Find the Prostate Baseline



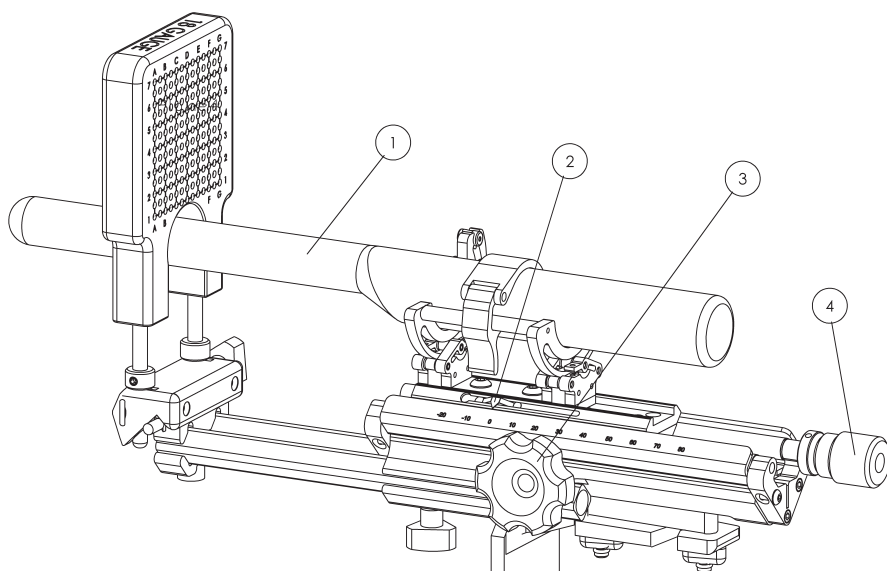
### Warning:

- > During surgery, it is possible for the prostate to swell, which may require re-setting the baseline.

- 1) Engage the Baseline Adjustment Knob ④, if needed, by pushing it forward.
- 2) Set the Fixed Marker ⑤ to zero with the 5 mm Step Knob ③ and the Baseline Adjustment Knob ④.
- 3) Use the Stabilizer control to position the Ultrasound Transducer ① in the vicinity of the prostate base.
- 4) Lock the Stabilizer in place.
- 5) Use the Baseline Knob ④ to fine-tune the location of the Ultrasound Transducer ① to the exact baseline of the prostate.
- 6) To ensure that there is ENOUGH stepper travel available to perform the surgery, the Fixed Marker ⑤ should be located between -5 and 5.
- 7) Slide the Baseline Marker ② to zero. This will allow visual verification of the Transducer location during the surgery.
- 8) To prevent accidental baseline movement, disengage the Baseline Knob ④ by pulling it back.

## 5 mm Step and 100 mm Travel

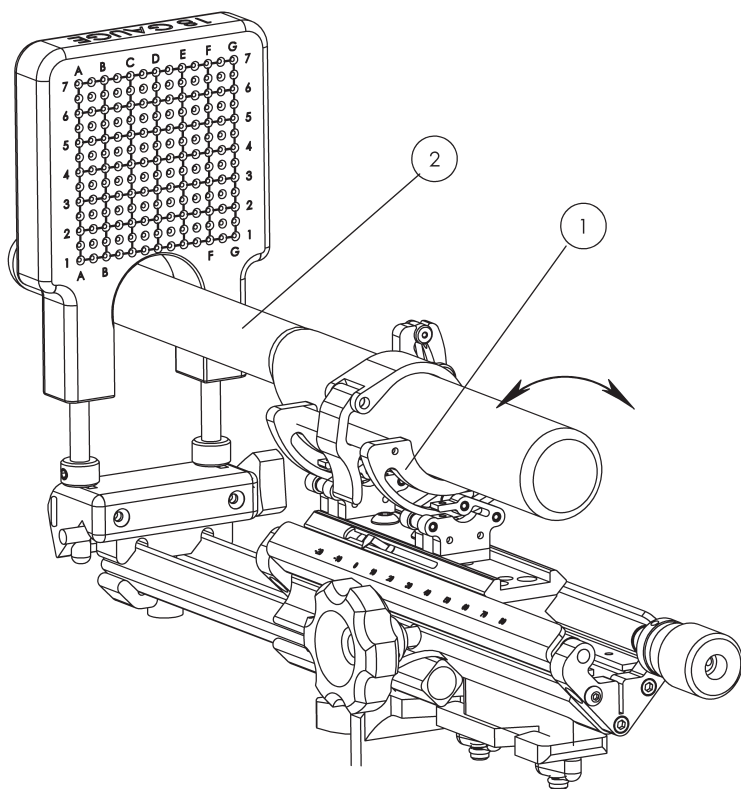
The Precision Stepper advances or retracts the Ultrasound Transducer in 5 mm steps over the 100 mm travel distance.



- 1) Rotate the 5 mm Step Knob ③ counterclockwise to advance the Ultrasound Transducer ①, and clockwise to retract it.
- 2) You will hear and feel a click each time the Ultrasound Transducer ① has traveled a 5 mm distance.
- 3) The Baseline Marker ② provides a visual verification for travel distances of the Ultrasound Transducer ①.
- 4) The Baseline Adjustment Knob ④ can be used for fine-tuning the position of the Ultrasound Transducer ① when it is required, and the 5 mm Step Knob ③ will move the Ultrasound Transducer ① in 5 mm steps starting from the adjusted location.

## Rotating the Ultrasound Transducer

The Precision Stepper allows the rotation of the Ultrasound Transducer, which is helpful to view the length of the Prostate Needle in Sagittal view.



- 1) Grasp the Transducer Cradle ① and rotate it with the Ultrasound Transducer ②.
- 2) Use the sagittal view function of the ultrasound system to view the Prostate Needle.
- 3) The Transducer Cradle ① will click into place when it is rotated back to its center position.

# Cleaning and Sterilization

## Pre-Sterilization Cleaning

**Caution:** The Needle Guide Template needs cleaning immediately following surgery so fluids do not dry.

Do NOT use peroxide, bleach, strong alkaline or acidic cleaning agents, such as automatic dishwasher detergents, on the Precision Stepper. This will damage the Precision Stepper and invalidate the warranty. Use a mild (pH 7-9) enzymatic detergent.

- 1) Scrub off debris, blood and fluids with a soft, non-metallic brush and mild (pH 7-9) detergent.
- 2) Rinse thoroughly.
- 3) Place the Needle Guide Template on a clean cloth towel and use an air gun to remove any remaining debris in the needle holes.

### Warning:



The Precision Stepper is NOT packaged sterile. For applications requiring sterility, the Precision Stepper and Needle Guide Template must be sterilized before use.

## Autoclaving

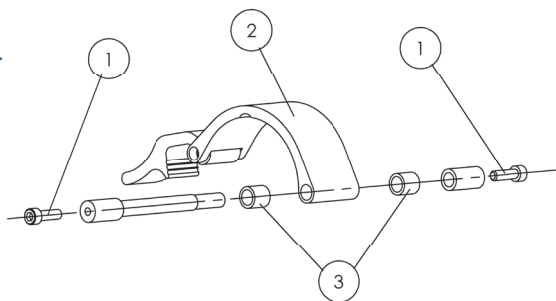
- 1) Place the Precision Stepper in an autoclave tray with the lid askew.  
Do NOT completely cover it.
- 2) Pre-vacuum autoclave at 135° C (275° F) for 10 minutes.
- 3) Allow cooling to room temperature before re-use.

# Special Adjustments for B-K Ultrasound Transducers

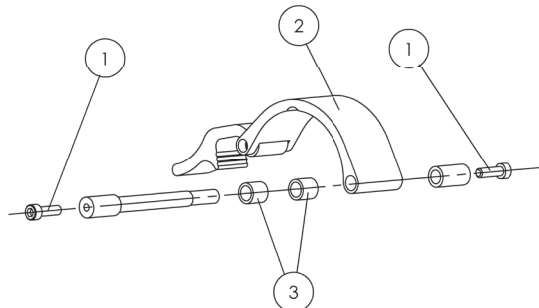
## Adjust Tightness of B-K 8808/8558/8658 Transducer Clasps

Due to variations among the B-K Ultrasound Transducers, you may find that the Transducer Clasp does not hold the Transducer with the correct tightness. Follow the steps below to adjust the Transducer Clasp.

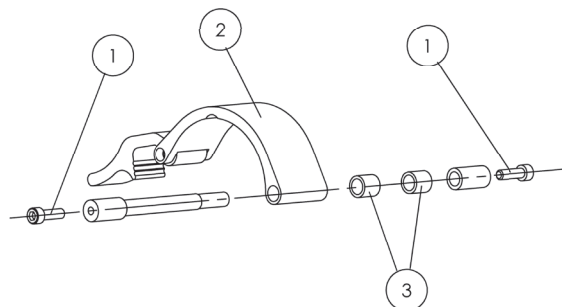
- 1) Remove Post Screws ① on both sides of the Transducer Clasp ②.



- 2a) If you need to loosen the Transducer Clasp, place both Adjustment Rings ③ behind the Transducer Clasp ②.



- 2b) If you need to tighten the Transducer Clasp, place both Adjustment Rings ③ in front of the Transducer Clasp ②.

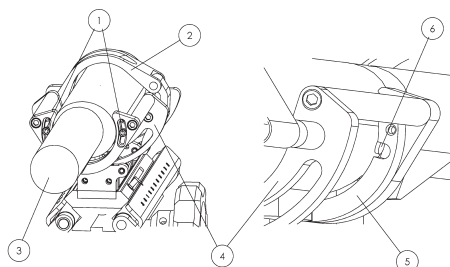


- 3) Re-attach both Post Screws ①.



## Rotate the B-K 8551 Ultrasound Transducer

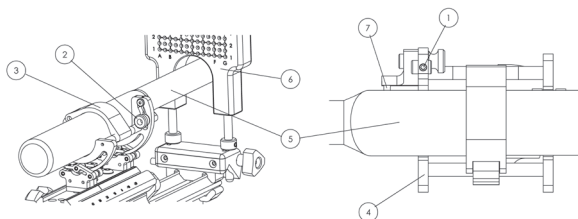
The B-K 8551 Ultrasound Transducer may require rotational adjustment to ensure the Transducer Cradle is in the upright, centered position.



- 1) Loosen both the Rotational Locator Screws ① on the front of the Transducer Cradle ④ with an Allen wrench.
- 2) Immerse the tip of the Ultrasound Transducer ③ into water, as illustrated on page 6.
- 3) Insert a straight needle into the Needle Guide Template at one of the top corners.
- 4) Release the Transducer Clasp ② while holding the Ultrasound Transducer ③ in place by hand.
- 5) Ensure the Locating Pin ⑥ is in the groove of the Rotational Locator ⑤. Rotate the Ultrasound Transducer ③ and the Rotation Locator ⑤ together until the needle path aligns with on-screen display of the ultrasound unit.
- 6) Close the Transducer Clasp.
- 7) Tighten both the Rotational Locator Screws ①.

## Rotate the B-K 8808/8558/8658/8848 Ultrasound Transducer

The B-K 8808/8558/8658/8848 Ultrasound Transducer may require rotational adjustment to ensure the Transducer Cradle is in the upright, centered position.



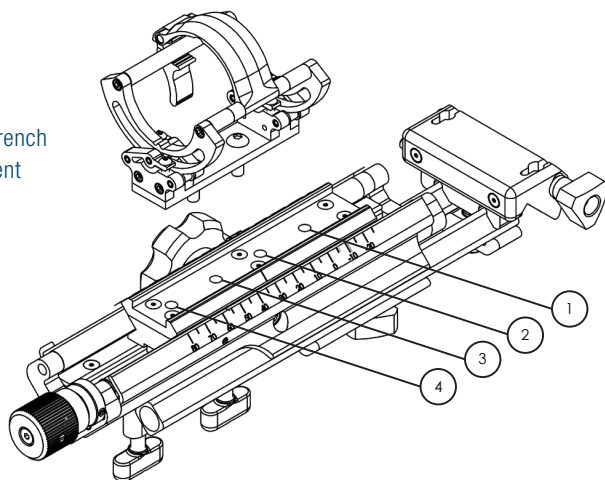
- 1) Loosen the Thumbscrew ② by rotating it counterclockwise one full turn.
- 2) Immerse the tip of the Ultrasound Transducer ⑤ into water, as illustrated on page 6.
- 3) Insert a straight needle into the Needle Guide Template ⑥ at one of the top corners.
- 4) Release the Transducer Clasp ③ while holding the Ultrasound Transducer ⑤ in place by hand.
- 5) Ensure the Locating Pin ⑦ is in the groove of the Transducer Cradle ④. Rotate the Ultrasound Transducer ⑤ by adjusting the Locator Screw ① with an Allen wrench until the needle path aligns with on-screen display of the ultrasound unit.
- 6) Close the Transducer Clasp ③.
- 7) Tighten the Thumbscrew ②.

## Cradle Replacement Instructions

The transducer cradle on the Precision Stepper can be replaced to accommodate various ultrasound probes. After cradle replacement, be certain to perform the Needle Path Verification with the corresponding needle guide before any patient procedure.

### Items Required

- > Precision Stepper
- > 1/8" Allen (hex key) wrench
- > Appropriate replacement transducer cradle



- 1) Remove the probe cradle from the Stepper. Use the 1/8" Allen wrench to remove the two screws that attach the cradle to the slide. If you are looking at the stepper from above, the screws sit right under the rotational probe cradle.
- 2) Slide the replacement cradle into place. When the cradle is replaced, hold the Stepper so that the baseline adjustment knob is closest to you. If attached correctly, the permanent hinge of the probe clasp will be on your right-hand side.
- 3) Refer to illustration above. There are four attachment holes in the slide. The cradles for the B-K probes should use attachment holes ① and ②, and the cradles for other probes should use attachment holes ② and ③.

- 4) Secure the replacement cradle to the Stepper by tightening the screws with the 1/8" Allen wrench.
- 5) Perform Needle Path Verification with correct corresponding needle guide template before performing any patient procedure (see page 6).

**Warning:**



- > Before using the Precision Stepper, you must perform a needle path verification. Failure to calibrate the needle path may result in improper needle placement.

## Troubleshooting

**Problem:** Needles do not fit through the Needle Guide Template.

- 1) Verify that the needle is the appropriate size for the Needle Guide Template. If the needle size is different from the size marked on the top of the Needle Guide Template, order the correct Needle Guide Template or needles.
- 2) Inspect the Needle Guide Template for needle hole blockage. Use a pipe cleaner or other small tool to remove any debris. Be sure to re-sterilize the Needle Guide Template after removing debris.

**Problem:** Needle Guide Template does not match the on-screen grid.

- 1) The Needle Guide Template has different nomenclature on its two faces. Make sure it is not reversed.
- 2) Some ultrasound systems allow changes of the grid display. Consult your ultrasound system's operating manual.

**Problem:** Needles are consistently going in at the wrong location.

- 1) Confirm the needle path verification was performed, and all adjustment screws were properly tightened. If any adjustment screws have become loose, repeat the needle path verification.
- 2) Make sure that the Ultrasound Transducer you are using is the same one used in the needle path verification. Due to variations in the Ultrasound Transducers, it is necessary to perform the needle path verification with any new Ultrasound Transducers, including those made by the same manufacturer.

**Problem:** Needles are consistently going in at a rotated angle.

- 1) Make sure that the Ultrasound Transducer is securely connected. For B-K Ultrasound Transducers, the locating pin should sit properly in the groove of the Transducer Cradle.
- 2) Check that the Transducer Cradle is not rotated. The Transducer Cradle should snap into its upright position.
- 3) For B-K Ultrasound Transducers, a rotational adjustment may be required. Refer to instructions on page 13.

## Warranty

The Precision Stepper is covered by a manufacturer's limited one-year warranty. If the equipment is proven to have a defect in material or workmanship that affects its operation within the warranty period, we will, without charge, either repair it or, at our option, replace it. The repair work, or the replacement, is guaranteed for one year from the service date.

When not in use, the Precision Stepper must be stored in the foam insert inside its protective "Pelican" case. Failure to do so will render the warranty void. This warranty does not cover damage caused by accident, misuse, improper storage, unauthorized repair, modification by a third party, or tampering with the equipment. A charge will apply for such repairs. Best NOMOS will examine all parts returned for warranty claims and determine whether there is a defect in material or workmanship. This warranty is not transferable and is valid only for the original purchaser.

This warranty gives you specific legal rights but excludes all incidental or consequential damages unless not allowed by the user's country.

Please do not return any equipment without first contacting Best NOMOS to obtain a Return Material Authorization RMA. Please clean (and sterilize, when appropriate) all equipment before sending units or components to Best NOMOS for repair.





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Federal law restricts this device to sale  
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