QCKV-1 POSITIONING STAND

REF 71460
General Precautions

WARNING:
Follow manufacturer’s recommended safety procedures for radioactive sources.

CAUTION:
Do not drop or mishandle the QCkV-1 Phantom Positioning Stand.

CAUTION:
Refer all servicing to qualified individuals.

CAUTION:
Proper use of this device depends on careful reading of all instructions and labels.

Warnings and Cautions alert users to dangerous conditions that can occur if instructions in the manual are not obeyed. Warnings are conditions that can cause injury to the operator, while Cautions can cause damage to the equipment.
The Accuray Cyberknife system utilizes a pair of amorphous silicon (aSi) kilovoltage imagers for online patient positioning during treatment. The kV sources are placed at 45 degrees offset from the patient plane to generate orthogonal images. There are two configurations of this system. The G3 system utilizes imaging panels that are set at the 45 degree angle to match the source while the G4 system utilizes panels that are set flat in the floor of the treatment room.

The imaging system of the Cyberknife is an integral part of the treatment process used to continually track the tumor and/or patient and allowing the robotic delivery arm to instantly correct for any movement. Because of this it is imperative that quality control of the imaging system be performed.

The QCkV-1 phantom when utilized with the Accuray positioning stand and PIPSpro software tests spatial resolution, contrast-to-noise and overall noise of the imaging system. Results are saved to a database and powerful trending tools warn the user of issues before they become clinically significant.
The QCkV-1 Positioning Stand

Because of the 45 degree offset of the kV imagers on the Accuray Cyberknife system it is necessary to utilize a positioning stand to correctly orient the QCkV-1 phantom in the imaging beam. The stand can be positioned manually or automatically utilizing fiducial tracking and the RoboCouch® Patient Positioning System.

Step 1 – Position the Phantom

There are two options for positioning the phantom for imaging. Manual positioning allows for fast setup but may not be repeatable. Automatic positioning ensures that the phantom is positioned within a few tenths of a millimeter each time for repeatable comparable results.

Manual positioning

Align the positioning stand on the couch perpendicular to the imaging beam with the slanted face of the stand facing the imaging beam source in the ceiling. Only one of the imagers can be analyzed at a time. Repeat these steps, rotating the stand 180 degrees for analysis of the second imager.

Place the QCkV-1 phantom in the stand with the label of the phantom facing up (the phantom will need to be flipped before taking images) and place the stand on the treatment table. The rotation of the phantom is not important as you are only using the crosshair markers on the phantom for setup. Utilizing the crosshair markers on the phantom label align the phantom to isocenter based on room lasers. To ensure that the imaging beam will not be intercepted by the table place the phantom on the head support.

IMPORTANT: Be sure to turn the phantom over in the stand (label facing down with the number ‘1’ on the label facing the top of the stand) before proceeding to take images.
Step 1 – Position the Phantom continued

Automatic Positioning using fiducial markers

The QCkV-1 phantom contains 4 gold fiducial markers that are designed to be non-collinear and non-coplanar when imaged. Utilizing the fiducial tracking capabilities of the Cyberknife system can automate the placement of the phantom for quicker repeatable analyses.

1. Obtain a CT dataset of the phantom and stand - Set up the QCkV-1 positioning stand with the QCkV-1 phantom in place on the CT couch. The phantom can be placed with the label up to align to the lasers. Two scans are required, one with the phantom facing left and one with the phantom facing right. IMPORTANT: Be sure the phantom label is facing down with the number ‘1’ on the label facing the top of the stand.

During clinical testing 2 mm thick slices were utilized with settings of 120 kV and 150 mA. Export the image set to the Cyberknife planning system.

IMPORTANT: Be sure to turn the phantom over in the stand (label facing down with the number ‘1’ on the label facing the top of the stand) before proceeding to take images.

*p pictured unit is a prototype, actual appearance may vary*
2. **Create a plan in the Cyberknife planning system.** Import the CT scans into the Multi-plan software. Choose Fiducial Tracking, identify the fiducial markers in the dataset and then Align to Center.
Create a simple isocentric plan. It is advisable to set the grid size to a small area in the center of the phantom.

Save the plan as deliverable.
Step 2 – Setup phantom for imaging on Cyberknife

Place the QCkV-1 phantom in the stand in the proper orientation (label facing down with the number ‘1’ on the label facing the top of the stand) and place the stand on the treatment table. NOTE: It is necessary to repeat these steps for the second imager.

IMPORTANT: Be sure to turn the phantom over in the stand (label facing down with the number ‘1’ on the label facing the top of the stand) before proceeding to take images.

*p pictured unit is a prototype, actual appearance may vary*
1. Acquire alignment images and utilize fiducial tracking to position the phantom and stand automatically.

During testing of the phantom and stand the following settings were found to produce reliable results for fiducial tracking.

a. Imaging X-Ray Parameters
   i. KV – 120
   ii. MA – 100
   iii. EX – 100 (imager facing flat face of phantom), 125 (imager facing edge of phantom holder)

b. Imaging Parameters
   i. Rigid Body Distance Threshold – 5.0 mm
   ii. Fiducial Spacing Threshold – 50.0 mm
   iii. Collinearity Threshold – 5.0 deg
   iv. X – Axis Pairing Tolerance – 2.5 mm
   v. Confidence Threshold – 45 %
   vi. Tracking Range – 40 mm
Step 3 – Acquire Images continued

Once the fiducial markers have been found, utilize the AutoCouch function to apply the prescribed couch corrections. Re-image and verify the positioning of the phantom. NOTE: If a rotation is detected it might be necessary to manually rotate the stand on the couch to ensure the fiducials are in a non-coplanar, non-collinear setup. After the stand is positioned correctly adjust settings and acquire images for the QC test in PIPSpro.

2. Acquire images for QC testing. During testing of the phantom and stand the following settings were found to produce reliable results for images used in PIPSpro software for QC testing.

a. Imaging X-Ray Parameters
   i. KV – 125
   ii. MA – 100
   iii. EX – 35

Repeat for second imager.
It is necessary to manually retrieve the Raw QC images from the Cyberknife system in order to analyze them in PIPSpro Software.

The Raw images can be found under the path:

```
/usr/accuray/database/patients/PATIENT_ID_NAME/drr/TRACKING_MODE/PLAN_NAME/PATIENT_OR_PHANTOM/CASE_NAME/RAW_IMAGE
```

Image names will resemble the following: B_999_1172192618_PA_UP.

The ‘B’ at the beginning of the image name signifies that the image is from the B imager and the ‘UP’ at the end of the file signifies that the image is un-processed. IMPORTANT: You must utilize the un-processed image in order for the PIPSpro software to correctly analyze the image.

**NOTE:** It can be advisable to create a mapped drive to this directory for easier retrieval of images.
Step 5 – Evaluate images with PIPSpro

Please see the PIPSpro manual for instructions on performing an imager QC test and for proper set up of imager parameters, phantom parameters and baselines necessary for analysis.

1. Import the images into PIPSpro by choosing File/Import/Other…
2. Use the following settings
   a. G4 imagers
      ![G4 Import Image Format]
   b. G3 imagers
      ![G3 Import Image Format]
3. Use the Contour tool to mark the edges of the ROI area on the QCkV-1 phantom on one of the images
   ![Contour Tool]
4. Load the images into the QC module, choose the appropriate imager and phantom and perform the QC test.
Maintenance

Exterior cleaning of the device can be done with a soft brush and a cloth. Gently brush all surfaces to remove dirt and dust. Remove any remaining dirt with a cloth slightly dampened with a solution of mild detergent and water or a liquid disinfecting agent.

There are no user serviceable parts on the QCkV-1 Positioning Stand. Calibration of the QCkV-1 Positioning Stand is not required.

If assistance is desired in the proper disposal of this product (including accessories and components), after its useful life, please return to Standard Imaging.

Parts and Accessories List

<table>
<thead>
<tr>
<th>REF</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>71460</td>
<td>QCkV-1 Positioning Stand</td>
</tr>
<tr>
<td>80577</td>
<td>QCkV-1 Positioning Stand Manual</td>
</tr>
<tr>
<td>71450</td>
<td>QCkV-1 Phantom</td>
</tr>
<tr>
<td>91310</td>
<td>PIPSPro QC Software</td>
</tr>
<tr>
<td>91320</td>
<td>PIPSPro Comprehensive Software</td>
</tr>
</tbody>
</table>

Features and Specifications

Dimensions:
- Width: 19.55 cm (7.70 in)
- Length: 13.97 cm (5.50 in)
- Height: 24.00 cm (9.45 in)

Weight: 86 kg (1.90 lbs)
Customer Responsibility

This product and its components will perform properly and reliably only when operated and maintained in accordance with the instructions contained in this manual and accompanying labels. A defective device should not be used. Parts which may be broken or missing or are clearly worn, distorted or contaminated should be replaced immediately with genuine replacement parts manufactured by or made available from Standard Imaging Inc.

⚠️ CAUTION: Federal law in the U.S.A. and Canadian law restrict the sale, distribution, or use of this product to, by, or on the order of a licensed medical practitioner. The use of this product should be restricted to the supervision of a qualified medical physicist. Measurement of high activity radioactive sources is potentially hazardous and should be performed by qualified personnel.

Should repair or replacement of this product become necessary after the warranty period, the customer should seek advice from Standard Imaging Inc. prior to such repair or replacement. If this product is in need of repair, it should not be used until all repairs have been made and the product is functioning properly and ready for use. After repair, the product may need to be calibrated. The owner of this product has sole responsibility for any malfunction resulting from abuse, improper use or maintenance, or repair by anyone other than Standard Imaging Inc.

The information in this manual is subject to change without notice. No part of this manual may be copied or reproduced in any form or by any means without prior written consent of Standard Imaging Inc.

Service Policy

If service, including recalibration, is required, please contact Standard Imaging’s Customer Service department by phone or email prior to shipping the product. Standard Imaging’s Customer Service and Technical Service staff will attempt to address the product issue via phone or email. If unable to address the issue, a return material authorization (RMA) number will be issued. With the RMA number, the product can be returned to Standard Imaging. It is the responsibility of the customer to properly package, insure and ship the product, with the RMA number clearly identified on the outside of the package. The customer must immediately file a claim with their carrier for any shipping damage or lost shipments. Return shipping and insurance is to be pre-paid or billed to the customer, and the customer may request a specific shipper. Items found to be out of warranty are subject to a minimum service fee of 1 hour labor (excluding recalibrations) for diagnostic efforts and require a purchase order (PO) before service is performed. With concurrence from customer, the product may be replaced if it is unserviceable or if the required service is cost prohibitive. Products incurring service charges may be held for payment. Standard Imaging does not provide loaner products. See the Standard Imaging Warranty and Customer Responsibility for additional information.

Serialization Information

Standard Imaging products that are serialized contain coded logic in the serial number which indicates the product, day and year of manufacture, and a sequential unit number for identification:

A YY DDD X

A Unique product ID
YY Last two digits of the year
(e.g. 1999 = 99, 2000 = 00)
DDD Day of the year (1 ≤ DDD ≤ 365)
X Unique unit ID Number (1 ≤ X ≤ 9)
Warranty

Standard Imaging, Inc. sells this product under the warranty herein set forth. The warranty is extended only to the buyer purchasing the product directly from Standard Imaging, Inc. or as a new product from an authorized dealer or distributor of Standard Imaging, Inc.

For a period provided in the table below from the date of original delivery to the purchaser or a distributor, this Standard Imaging, Inc. product, provided in the table is warranted against functional defects in design, materials and workmanship, provided it is properly operated under conditions of normal use, and that repairs and replacements are made in accordance herewith. The foregoing warranty shall not apply to normal wear and tear, or if the product has been altered, disassembled or repaired other than by Standard Imaging, Inc. or if the product has been subject to abuse, misuse, negligence or accident.

<table>
<thead>
<tr>
<th>Product</th>
<th>Warranty Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Imaging Ionization Chambers</td>
<td>2 years</td>
</tr>
<tr>
<td>Standard Imaging Well Chambers</td>
<td>2 years</td>
</tr>
<tr>
<td>Standard Imaging Electrometers</td>
<td>2 years</td>
</tr>
<tr>
<td>Standard Imaging BeamChecker Products</td>
<td>2 years</td>
</tr>
<tr>
<td>Standard Imaging Software Products</td>
<td>1 year</td>
</tr>
<tr>
<td>All Other Standard Imaging Products</td>
<td>1 year</td>
</tr>
<tr>
<td>Standard Imaging Custom Products</td>
<td>1 year</td>
</tr>
<tr>
<td>Standard Imaging Remanufactured Products</td>
<td>180 days</td>
</tr>
<tr>
<td>Standard Imaging Custom Select Products</td>
<td>90 days</td>
</tr>
<tr>
<td>Consumables</td>
<td>90 days</td>
</tr>
<tr>
<td>Serviced Product</td>
<td>90 days</td>
</tr>
<tr>
<td>Resale Products</td>
<td>As defined by the Original Equipment Manufacturer</td>
</tr>
<tr>
<td>ADCL Product Calibration</td>
<td></td>
</tr>
<tr>
<td>(Standard Imaging uses the UW-ADCL for recalibrations required under warranty)</td>
<td></td>
</tr>
<tr>
<td>0 - 90 days = 100% of ADCL Calibration Costs</td>
<td></td>
</tr>
<tr>
<td>91 - 182 days = 75% of ADCL Calibration Costs</td>
<td></td>
</tr>
<tr>
<td>183 – 365 days = 50% of ADCL Calibration Costs</td>
<td></td>
</tr>
<tr>
<td>366 – 639 days = 25% of ADCL Calibration Costs</td>
<td></td>
</tr>
<tr>
<td>(days from date of shipment to customer)</td>
<td></td>
</tr>
</tbody>
</table>

Standard Imaging’s sole and exclusive obligation and the purchaser’s sole and exclusive remedy under the above warranties are, at Standard Imaging’s option, limited to repairing, replacing free of charge or revising labeling and manual content on, a product: (1) which contains a defect covered by the above warranties; (2) which are reported to Standard Imaging, Inc. not later than seven (7) days after the expiration date of the warranty period in the table; (3) which are returned to Standard Imaging, Inc. promptly after discovery of the defect; and (4) which are found to be defective upon examination by Standard Imaging Inc. Transportation related charges, (including, but not limited to shipping, customs, tariffs, taxes, and brokerage fees) to Standard Imaging are the buyer’s responsibility. This warranty extends to every part of the product except consumables (fuses, batteries, or glass breakage). Standard Imaging, Inc. shall not be otherwise liable for any damages, including but not limited to, incidental damages, consequential damages, or special damages. Repaired or replaced products are warranted for the balance of the original warranty period, or at least 90 days.

This warranty is in lieu of all other warranties, express or implied, whether statutory or otherwise, including any implied warranty of fitness for a particular purpose. In no event shall Standard Imaging, Inc. be liable for any incidental or consequential damages resulting from the use, misuse or abuse of the product or caused by any defect, failure or malfunction of the product, whether a claim of such damages is based upon the warranty, contract, negligence, or otherwise.

This warranty represents the current standard warranty of Standard Imaging, Inc. Please refer to the labeling or instruction manual of your Standard Imaging, Inc. product or the Standard Imaging, Inc. web page for any warranty conditions unique to the product.