The Quantum Arm Positioning System

QUANTUM ARM POSITIONER IFU
(INSTRUCTIONS FOR USE)
Please read all the following instructions carefully to ensure proper functionality and to avoid injury or damage to your device.

DEVICE IS TO BE USED BY TRAINED PERSONNEL ONLY!

Throughout this manual, the ! symbol is intended to alert the user to an important instruction.

Please study and understand this user manual before using the device. Failure to do so may result in misuse of the device causing damage or injury. Only those personnel who have read and understood this user manual should be allowed to use the device.

The techniques outlined in this manual are manufacturer’s suggestions only. The attending surgeon and staff remain responsible for ensuring appropriate patient care and safety while using this device.

Service and modification to the device is to be provided by trained personnel only. This device should be inspected and proper function verified before each use. Ensure that this user manual is readily available to all personnel at all times.

Note: This document is provided as a reference for surgical staff and information within is subject to change without notice. Quantum OPS assumes no responsibility for any errors that may appear within the document. Quantum OPS will not, in any event, be liable for any damages arising from the use of this document or in connection with it.
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1. Introduction

1.1. Environmental Information

1.1.1. Packaging: Packaging is constructed of environmentally compatible materials.

1.1.2. Quantum OPS Products: Quantum OPS accepts used products or products that are no longer in service. Please contact your Quantum OPS account manager for further information.

1.1.3. Disposables: Disposable products or components must be disposed of in accordance with environmental regulations.

1.2. Use of Instructions

1.2.1. General: These instructions are intended to provide an overview of the product, its features, and use. These instructions are to be read completely and carefully before using the product.

1.2.2. Symbols and Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="DANGER!" /></td>
<td>DANGER! Indicates a risk or danger to persons or property which may result in serious or fatal injury.</td>
</tr>
<tr>
<td><img src="image" alt="LOT" /></td>
<td>Symbol for Lot Identifier</td>
</tr>
<tr>
<td><img src="image" alt="SN" /></td>
<td>Symbol for “Serial Number”</td>
</tr>
<tr>
<td><img src="image" alt="REF" /></td>
<td>Symbol for “Order Number”</td>
</tr>
<tr>
<td><img src="image" alt="Do Not Use" /></td>
<td>Symbol for “Do Not Use When Packaging is Damaged”</td>
</tr>
</tbody>
</table>
1.3. Component Identification

1.3.1. Quantum OPS Arm Positioning System

1.3.2. Arm Positioning Disposable Kit
1.4. Basic Description

1.4.1. Use in accordance with intended purpose - This product is a Class I medical device and is intended for use in human patients only. The use of this product is to be performed only under the supervision of medical personnel.

1.4.2. The Quantum OPS Arm Positioning System is used to position a patient’s arm prior to, during, and after surgery procedures. It may also be used during patient examination. The QAPS is affixed to the side rail of a surgery table and can be easily moved into various positions as needed.

1.4.3. The disposable kit for the QAPS is a single-use package of accessories to be used with each single instance of a surgery or examination on a patient.

The disposable kit includes:

1 x Disposable Camera Drape
1 x Roll of Self-adhesive Wrap
1 x Foam Hand Post Pad
1 x Formable Foam Arm Cradle
2. Safety Notices

2.1. General Safety Notes

⚠ Note the following warnings relating to the QAPS:

**Potentially Fatal:**
- The maximum patient weight for use of the product is 500 lbs.
- Vital functions may be impaired through improper use and/or positioning of the product.
- Fatalities may occur through improper use of the product.

**Warnings:**
- Improper use and positioning may lead to injury. Follow all instructions for use of the operating table system and QAPS exactly and maintain observation of patient while product is in use.

- Improperly secured products or accessories may result in patient injury. After initial positioning and after every repositioning of the product, check all fastening elements (clamps / handles...etc.) to make sure they are fully closed and secure.

- Use only approved accessories with the QAPS. All accessories must be used in accordance with instructions for use from Quantum OPS. Accessories made by other providers may be used only with written approval from Quantum OPS.

- Risk of burns may occur through contact between the QAPS and electrical equipment such as computer components and defibrillators. Contact between the patient and metallic surfaces must be avoided.

- The product can be repositioned by opening fastening elements. Prior to initially mounting or repositioning the product, hold the movable segments securely so that they do not fall or move suddenly. Also, be aware that moving the product during initial mounting or repositioning can expose personnel, patient, and other equipment to pinching or shearing. Prior to mounting or repositioning the product, be sure that the patient, all other personnel and equipment are clear of the product so pinching or shearing does not occur.

- Do not continue to use the QAPS if the product is worn, defective, or damaged in any way. Only use the product in full working condition.

- Adjustments made to the product, patient, or operating table system may result in inadvertent contact between the patient and accessories or operating table components. Make any adjustments necessary under careful observation. Make sure that no cables, sheets, or other equipment are in the way of the arm.
- Attaching the product to the operating table may affect the table’s center of gravity which may cause the operating table to tip over more easily. Make any adjustments to the operating table under careful observation.

- Do not use any oil or lubricant on the moveable parts of the QAPS. Using lubricant or oil on the product may result in damage to the product or cause the product to malfunction.

- Do not use the QAPS disposable kit if the packaging of the disposable kit is damaged or punctured. Using the disposable kit when the packaging is damaged or punctured may result in a risk of infection.
3. SETUP AND USE

3.1. Setup and Use - General warnings

⚠️ Note the following warnings and information relating to the setup and use of the Arm Positioning System.

- The QAPS is to be used only with accessories specifically designed for the product and approved by Quantum OPS.

- A sterile cover must be used on the QAPS during surgery to avoid contact with liquids and other substances used in surgery.

- The product is designed to support only the weight of the patient. Do not put any additional force on the Arm Positioning System by leaning or resting on the product.

- Avoid exposing the product to high impacts, vibrations, moisture, humidity, and radiation. The product is designed to be cleaned by wipe disinfection only.

- A risk of infection exists if the product is stored or used in a non-sterile environment. If the product is stored or used in a non-sterile environment, clean the product using the instructions given in the “Cleaning and Disinfection” section.

- The Arm Positioning System disposable kit is required for proper use of the product. The disposable kit includes one each of a formable foam arm cradle, foam hand post pad, drape, and self-adhesive wrap. The Quantum OPS disposable kit is the only disposable kit approved for use with the QAPS.

- The product is intended for use in a sterile condition only. The product should be cleaned and disinfected prior to initial use and after each use.

⚠️ Note: Ensure a sterile (autoclaved) arm tray and connector are available before beginning setup.
3.2.1 Attaching the QAPS to Surgical Table

1. Before draping the patient, attach arm positioner to the side rail of the surgical table on the operative side by loosening the 5 prong mount knob, tipping the arm forward toward the surgical table to clip the upper mount clip onto the top of the side rail, then pulling it back flush to the side rail to engage the bottom clamp.

2. Firmly tighten the 5 prong mount knob. Arm can be attached anywhere on the side rail. We recommend testing range of motion at the desired location on the side rail prior to draping to ensure satisfaction.
Arm being positioned on side rail of surgical table

Arm jaw fully seated on table rail

Arm mounted on side rail of surgical table
3.2.2. Post-draping positioning of the QAPS

- After mounting on side rail, squeeze release lever and move down and out of the way for draping, but still accessible to a non-sterile assistant after draping.

Arm positioner lever being squeezed

- After draping the patient, a non-sterile assistant should squeeze the release lever and move the arm out and up, keeping it away from the sterile drapes.

3.2.3. Attachment of connector and placement of drape

- A sterile assistant should place the connector into the provided disposable camera drape by first finding the arrows at the opening of the drape which indicate the drape opening. Insert the connector, post side first, into the opening indicated by the arrows and out the side with the blue rubber opening. Ensure that the post of the connector is sticking all the way out of the hole in the blue rubber end of the drape.
Folded disposable camera drape

Arros indicating drape opening

Arm Connector

Top

Bottom
- The arm connector should be plugged in over the receiver post in the end of the arm positioner, and the camera drape pulled all the way down and over the arm.

Correctly placed in drape

Ready for coupling to arm connector hole
3.2.4. Affixing the Foam Arm Cradle to the sterile tray
- The provided disposable blue foam arm pad should be prepped by a sterile assistant by unrolling the VelcroTM straps on the arm liner, ensuring that the soft pad side of the VelcroTM is facing up.

- Slide the round post of the arm tray through the round hole in the blue foam arm pad, ensuring that the side flap of the blue foam pad points to the right.
- Then fold the two tabs of the foam pad down and through the holes in the arm tray, curling them over so they are tight on the tray.
Arm pad tabs being folded over on reverse side

- Slide the provided hand grip pad over the round hand post of the arm tray.

Hand grip pad slides over hand post

- Plug the post at the bottom of the tray into the hole in the top of the connector, now connected to the draped arm.
3.2.5. Positioning of arm tray for patient’s forearm
- After the disposable kit has been affixed to the sterile tray, check to ensure all non-sterile areas are covered.
- Squeeze the release lever and adjust the position of the arm tray and pad so that the patient’s forearm can be easily rested on the top of the blue foam pad, with the hand gripping the hand grip post.
Arm placed on arm pad and hand gripping the hand grip post

- Bend the wrist flap of the blue pad over the wrist, shape it to grip the wrist and match its profile, then wrap the white VelcroTM strap all the way around to secure the flap and strap around the wrist.

Wrist being secured with wrist strap
3.2.6. Securing the patient’s forearm
- Wrap and secure the mid-forearm Velcro™ strap around the arm, fold the back end up around the elbow.
- Tightly wrap the provided self-adhesive wrap around the patient’s arm and arm tray, beginning at the wrist.

- Wrap the forearm with self-adhesive wrap, continuing up to the patient’s elbow. Then wrap the patient’s arm longitudinally, securing the back end of the arm pad against the patient’s elbow.
- Make a few passes longitudinally around the patient’s arm with the self-adhesive wrap and then continue wrapping self-adhesive around the wrist and forearm.

Patient’s arm further secured with longitudinal passes of self-adhesive wrap
Patient’s arm fully secured with self-adhesive wrap

Patient’s arm fully secured with self-adhesive wrap
3.3. Surgical Use

Note the following warnings and information relating to the adjustment of the QAPS product.

- When the release lever is squeezed, the moveable joints of the product are released and are free to move. The product will naturally swing downwards due to its own weight and the weight of the patient’s arm. Before squeezing the release lever, securely hold the QAPS with both hands to ensure there is no unintended movement downwards. After every adjustment process, ensure that the release lever locks into position and that no other equipment has been pinched or wrapped in the product.

- Significant force may be required to fully squeeze the release lever due to the weight of the patient’s arm. If the release lever cannot be fully squeezed, the sterile arm tray may be detached from the positioning arm to relieve the stress placed on the product. Be sure to support the patient’s arm adequately during any adjustment that requires the removal of the sterile tray and connector.

- The release lever may inadvertently catch other objects (wires, clothing, drapes...etc.). Before squeezing the release lever, ensure that no other objects are caught in the lever area.

- When adjusting the QAPS, squeeze the release lever fully. Adjusting the QAPS when the release lever is not fully squeezed may cause damage to the product.

3.3.1. Adjusting the position of the QAPS
- To adjust the position of the arm at any time, grip the release lever of the arm, and simultaneously lift up and firmly squeeze the lever.
- This will release the arm positioner and allow the arm to be moved to any desired position.
- To lock in any desired position, let go of the release lever.
- To disconnect the arm tray at any time, depress the release button at the top of the connector at the base of the tray. Pull straight up on the arm tray to pull it out of the connector.
3.4. Post-surgery tear-down
- After the case is complete, cut off the self-adhesive wrap, and remove the Velcro™ straps to free the arm. Unfold the tabs on the blue foam arm pad and slide off the hand grip pad to release and remove and discard the blue foam pad and hand grip from the arm tray.
- Depress the release button at the top of the arm and pull straight up on the arm tray/connector assembly to unplug it from the arm.

- Depress the release button on the connector to release it from the arm tray.
- Discard the used camera drape, self-adhesive wrap, blue arm pad, and hand grip.

- Loosen the black 5 prong mounting knob, and then tip the arm forward toward the surgical table to remove it from the side rail.

- Wipe down the arm with approved cleaning solution and return to storage.

- Send arm tray and connector to sterilization.

4. Cleaning and Disinfection

4.1. General Warnings

⚠️ Note the following warnings regarding the cleaning and disinfection of the QAPS.

- Use only manufacturer approved disinfectants and detergents. Follow all instructions provided by manufacturer and follow all hospital hygiene rules and policies.

- Be sure to remove all dirt and dust prior to disinfection.

- Always wear gloves when performing cleaning and disinfection of the product.

- Visually inspect the product after each cleaning and disinfection. Incorrect cleaning and disinfection procedures can damage the product.
- Do **NOT** use the following types of products when performing cleaning and disinfection:
  - Products containing alcohol
  - Products containing hydrochloric acid
  - Products containing fluoride, chlorine, bromine, and iodine
  - Scouring or scrubbing agents that may scratch the surface
  - Commercial solvents
  - Water containing metal particles of any kind
  - Sponges containing metal of any kind

- Clean the product using cloth that is soft and lint free or a soft nylon brush.

- Damage to the product can be caused by improper cleaning. Use only the amount of cleaning / disinfecting agents required. Remove any excess cleaning / disinfecting agent with a soft cloth and do not allow cleaning / disinfecting agents to dry on the product.

- Steam may damage the product. Perform a careful inspection of the product after any autoclaving activity.

- Autoclave the product by placing it in a container suited for sterilization.

### 4.2. Disinfection Instructions

![Warning](image)

Note the following information regarding approved disinfectants: Only use surface disinfectants based on Aldehydes, Quaternary compounds, or Guanidine derivatives.

- Using the disinfectant manufacturer’s instructions, spray the product with disinfectant.

- Wipe the product thoroughly with a soft cloth dampened with clean water.

- Make sure the product is free of disinfectant residue after wiping.

- Dry the product with a clean, absorbent, and lint free soft cloth.

- Inspect the product to ensure correct functionality after disinfection.
### 4.3. Cleaning and Disinfection Guide

<table>
<thead>
<tr>
<th>Components</th>
<th>Cleaning</th>
<th>Disinfection</th>
<th>Sterilization (autoclaving)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantum OPS Arm Positioning System (QAPS)</td>
<td>Clean with warm soapy water, using a soft toothbrush to remove any dirt as needed. Dry with a soft, clean cloth.</td>
<td>Spray arm with disinfectant. Wipe arm with soft, damp, and clean cloth. Dry with clean and soft cloth.</td>
<td>N/A</td>
</tr>
<tr>
<td>Sterile Arm Tray &amp; Sterile Connector</td>
<td>Clean with warm soapy water, using a soft toothbrush to remove any dirt as needed. Dry with a soft, clean cloth.</td>
<td>Immerse in disinfection solution (30 minutes) (e.g. Dr. Weigert, 2% (v/v) at 20 °C ± 2 °C in water – minimum quality of drinking water). Before immersion use a disposable syringe (60 ml syringe) to rinse every joint and movable part with 200 ml solution. To remove air bubbles move the components by hand in the solution for 10 seconds at the beginning of immersion. Immerse components in cold, demineralized water (1 minute).</td>
<td>Live steam: 121° C; 3 x fractionated prevacuum; sterilization (at least 4 minutes). Or Live steam temperature: 132 °C; 3 x fractionated prevacuum; sterilization (at least 6.5 minutes).</td>
</tr>
<tr>
<td>Disposable Set</td>
<td>N/A – Disposable set is intended for single use only</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5. Inspection of the QAPS

5.1. Visual and Functional inspection
- Visual and functional inspection of the QAPS is necessary to ensure the product is in a working condition prior to each use. The inspection must be documented and include the date, name, and signature of the person performing the inspection.

- Suggested inspection points:
  - Have specified guidelines been used to clean and disinfect the product?
  - If not, clean and disinfect the product according to guidelines before using.
  - Does the product have any damage?
  - If product has damage of any sort, or damage is suspected, do not use the product and contact your Quantum OPS representative to report the problem.

- Are all features and capabilities of the product usable?
  - If not, do not use the product and contact your Quantum OPS representative to report the problem.

5.2. Maintenance
- The QAPS product is maintenance-free. Over time, wear caused by age of the product and continued use may cause potential functional problems. Thoroughly check the product before each use. If any problems are detected or suspected, the product should not be used. All problems should be documented and the information relayed to your Quantum OPS representative.

5.3. Repair
- Do not use a defective product. If problems are identified or suspected, do not attempt to repair the product. Contact your Quantum OPS representative and provide the following information:

  Problems (confirmed or suspected):
  Product:
  Serial number:

  Contact info:
  Quantum OPS, Inc.
  1201 Riverfront Parkway Building 4
  Chattanooga, TN 37402 423-771-6367
6. Technical Specifications

6.1. Weight

<table>
<thead>
<tr>
<th>Part</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>QAPS Support Arm</td>
<td>9.4 lbs.</td>
</tr>
<tr>
<td>Sterile Connector</td>
<td>.8 lb.</td>
</tr>
<tr>
<td>Sterile Arm Tray</td>
<td>1.2 lb.</td>
</tr>
</tbody>
</table>

6.2. Temperature, Humidity, and Pressure

<table>
<thead>
<tr>
<th>Temperature</th>
<th>-4 °F to +122 °F (during shipping)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+50 °F to +104 °F (in use)</td>
</tr>
<tr>
<td></td>
<td>-4 °F to +86 °F (in storage)</td>
</tr>
<tr>
<td>Humidity</td>
<td>10 % to 95 % (during shipping)</td>
</tr>
<tr>
<td></td>
<td>30 % to 75 % (in operation)</td>
</tr>
<tr>
<td></td>
<td>30 % to 75 % (in storage)</td>
</tr>
<tr>
<td>Atmospheric Pressure</td>
<td>500 hPa to 1060 hPa (during shipping)</td>
</tr>
<tr>
<td></td>
<td>700 hPa to 1060 hPa (in operation)</td>
</tr>
<tr>
<td></td>
<td>700 hPa to 1060 hPa (in storage)</td>
</tr>
</tbody>
</table>