Pronumbra™ System

INSTRUCTIONS FOR USE (IFU)

CQ MEDICAL™

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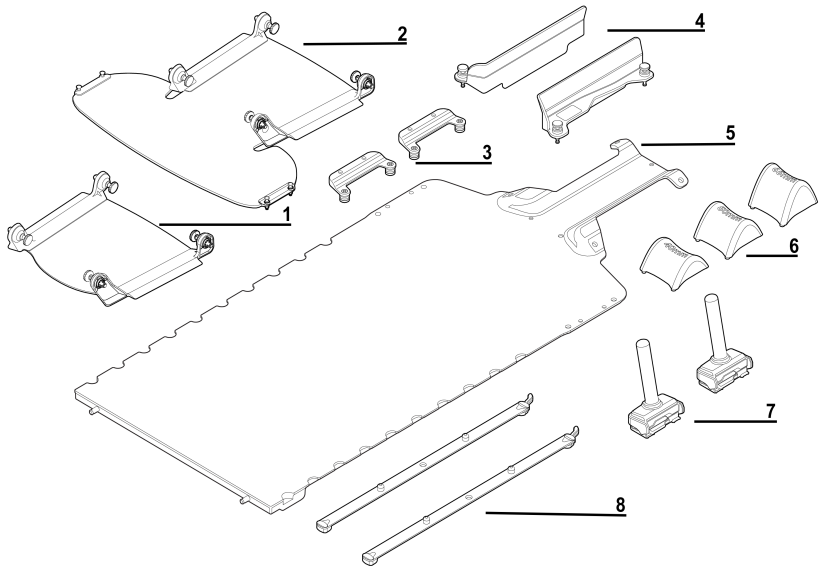
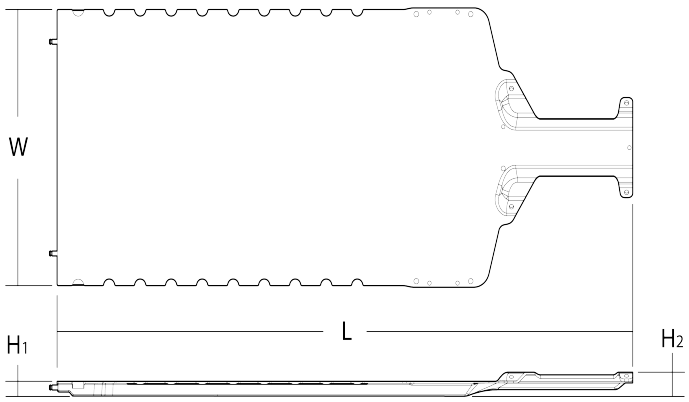
PRONUMBRA™ SYSTEM



1. Head Only Thermoplastic Mask
2. Head, Neck and Shoulder Thermoplastic Mask
3. Shoulder Adapters
4. Helping Hands™
5. Pronumbra™ Device
6. Neck Support
7. InfinityLock™ Hand Grip
8. Locking Locating Bar

SPECIFICATIONS



LENGTH (RT-4536KV-01): 130 cm (51.2 in)
WIDTH: 53 cm (20.9 in)
HEIGHT 1: 2.8 cm (1.1 in)
HEIGHT 2: 4.6 cm (1.8 in)
ALUMINUM EQUIVALENCE: ~0.7 mm @ 100 kVP
WEIGHT LIMIT: 250 kg (550 lbs) uniformly distributed load

PARTS LIST

RT-4536KV-01	kVue™ Pronumbra™ 130cm Insert
RT-C876K	Pronumbra™ Head Only Mask with Integrated Shim™, 3.2mm Microperf Fibreplast®
RT-C878K	Pronumbra™ Head, Neck and Shoulder Mask with Integrated Shim™ , 3.2mm Microperf Fibreplast®
RT-C889K	Pronumbra™ Head Only Mask with Integrated Shim™, 3.2mm Standard Perf Fibreplast®
RT-C892K	Pronumbra™ Head, Neck and Shoulder Mask with Integrated Shim™, 3.2mm Standard Perf Fibreplast®
RT-4800-04	InfinityLock™ Hand Grip
RT-4536-NS40	Pronumbra™, Neck Support, 40mm
RT-4536-NS50	Pronumbra™, Neck Support, 50mm
RT-4536-NS65	Pronumbra™, Neck Support, 65mm
RT-4536-SA01	Pronumbra™, Shoulder Adapter Assembly
RT-4536-HH01L	Pronumbra™, Helping Hands™ Assembly, Left
RT-4536-HH01R	Pronumbra™, Helping Hands™ Assembly, Right
RT-4551BAR-05	Locking Locating bar

LABEL DESCRIPTION

"NO STEP" LINE
Yellow line on kVue™ Insert represents end of support beams. Area beyond line has been designed and tested to support patient's upper torso or lower body not exceeding load rating.

Standing or sitting on the kVue™ Insert beyond the "No Step" line may damage the kVue™ insert or cause injury.

DO NOT LIFT
Never lift end of kVue™ Insert.

INTENDED USE

The Pronumbra™ device is indicated to aid in supporting, positioning, and/or immobilization of adult and pediatric patients undergoing radiation therapy of the head, brain, neck, and spine including radiosurgery, and electron, photon and proton treatments. The device is also used during image acquisition to support treatment planning.

PATIENT TARGET GROUPS

Patients undergoing radiation therapy or diagnostic imaging procedures.

INTENDED USERS

Person qualified in accordance with requirements of the regulatory region.

CAUTION

Federal (United States) law restricts this device to sale by or on the order of a physician.

⚠ WARNING

- *No modification of this equipment is allowed. If any part of this device experiences a catastrophic load, appears damaged or functions improperly, discontinue use immediately and contact CQ Medical at info@CQmedical.com.*
- *OneTouch is a precision mechanism and is only for use with approved CQ Medical kVue devices. Unapproved non- CQ Medical devices that have not been validated by CQ Medical may not be safe for use and will void warranty if used.*
- *Dose depth, deposition, and transition area effects must be evaluated during planning and treatment within a proton therapy environment.*
- *Simulation and treatment must be conducted on a Pronumbra™ Device. Other devices may be materially different and may lead to clinically inconsistent simulation to treatment plans.*
- *Verification of patient position must be completed during planning and treatment in a radiotherapy environment. Follow standardized setup verification protocols to verify patient position prior to treatment being administered.*
- *When positioning patient for first time, use setup sheet to record all adjustments. Setup sheet is available at www.CQmedical.com.*

NOTE:
- To ensure safe use of this device, it is recommended that the user is educated and trained on the safe operation of the system prior to use. To use this device accurately and safely, the user must have necessary expertise in a hospital setting. Ensure selected accessories are securely locked to patient support surface and verify setup is correct prior to initiation of treatment. Inspect device for damage prior to each use.
- If any serious incident occurs in relation to device, incident should be reported to manufacturer. If incident occurred within the European Union, also report to the competent authority of the Member State in which you are established.
- Refer to www.CQmedical.com for a listing of symbols and their definitions.

PRECAUTIONS

- Thermoplastic material may cause skin irritation in individuals with sensitive skin.
- Proceed with caution whenever treating through Fibreplast®.
- Thermoplastic masks are supplied for use on a single patient over course of treatment.
- Hand grip posts are not designed to support patient's weight. DO NOT use handles to position patient. DO NOT use handles to get on or off of device.
- Do not carry device using any accessories.

LOAD RATING

- DO NOT exceed 250 kg (550 lbs) uniformly distributed load or maximum working load of couch base, whichever is less.
- When combined with OEM couch base, load rating is the lower of the two safe working loads.kVue™ Couch Top load should NOT exceed original couch base manufacturer's specifications. Refer to product literature provided by original manufacturer.

TREATMENT BEAM ATTENUATION

Pronumbra™ Device will attenuate a radiotherapy beam. Actual attenuation based on setup should be verified with your equipment. Attenuation and increased skin dose should be taken into account during planning and treatment.

MRI SAFETY INFORMATION

Use only proven MR Safe or MR Conditional accessories, tested, and approved for your MR system. Consider MR compatibility of accessories prior to use on MR system.

⚠ WARNING

- *Use of unapproved MR accessories may result in:*
  - *Injury to Patient*
  - *Patient burns*
  - *Damage to equipment*
- *Recommended maintenance and service, as well as use of only CQ Medical-provided accessories, components, and replacement parts, are necessary to ensure safety, performance, and MRI compatibility of product(s), as well as to maintain applicable warranties.*
- *Maintenance and other services or products should never be performed in an MR environment.*

 MR Safe	Non- clinical testing has demonstrated the following components are MR Safe. • Neck Support (RT- 4536- NS40, RT- 4536- NS50, RT- 4536- NS65) • Helping Hands™ (RT- 4536- HH01L, RT- 4536- HH01R) • Hand Grip (RT- 4800- 04) • Thermoplastic Mask (RT- C876K, RT- C878K, RT- C889K, RT- C892K)
 MR Conditional	Non- clinical testing has demonstrated the following components are MR Conditional. These devices may be used with an MR system meeting the following conditions: • Shoulder Adapters (RT- 4536- SA01) • May be placed in the bore of an MR system having a static magnetic field of 3T or less.

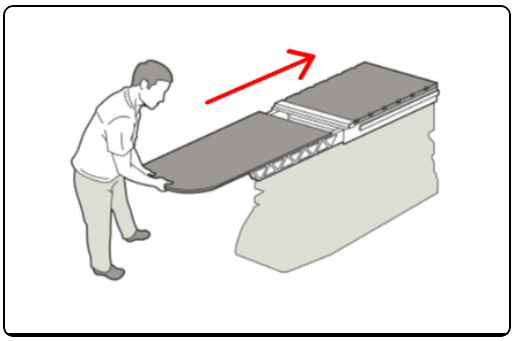
INSTALLATION

Pronumbra™ KVue™ Insert

1. Place kVue™ Insert onto kVue™ support system and align both mating pins with each receiving hole in OneTouch™ Latch.
2. From head end of kVue™, slide kVue™ Insert directly into receiving holes. You will hear a click when kVue™ Insert is locked into place. ONLY the green button surface will be visible when properly installed.

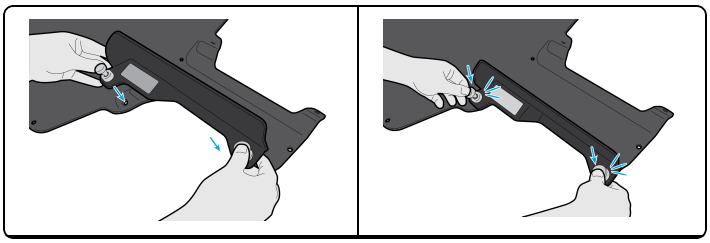
3. Verify insert is fully engaged by gently pulling it backwards, away from OneTouch Latch, to ensure it does not come out of receiving holes. Repeat this step during every patient setup, even if insert had previously been installed.

NOTE: Refer to your specific couchtop IFU for more information.



Helping Hands™

1. Align and insert pins to locating holes on Pronumbra™.
2. Push pins to attach and lock into place.
3. Ensure device is securely attached.



Neck Support

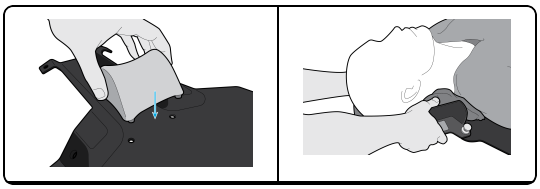
1. Align and insert pins to locating holes on Pronumbra™.
2. Ensure device is securely attached.
3. Ensure proper head and neck positioning with patient.

⚠ WARNING

- *Ensure neck is supported sufficiently to maintain patient's airway.*

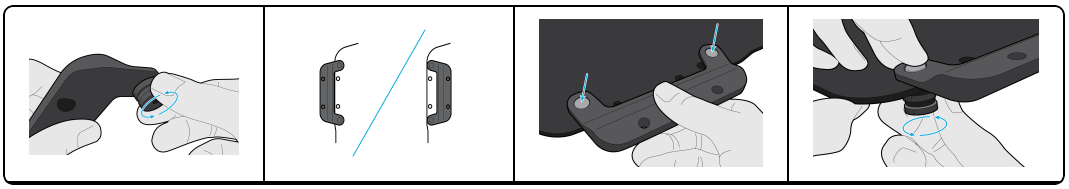
4. Form AccuForm™ using Neck Support and Helping Hands™. Allow to harden completely.

NOTE: Refer to your specific AccuForm™ Cushion IFU for more information.



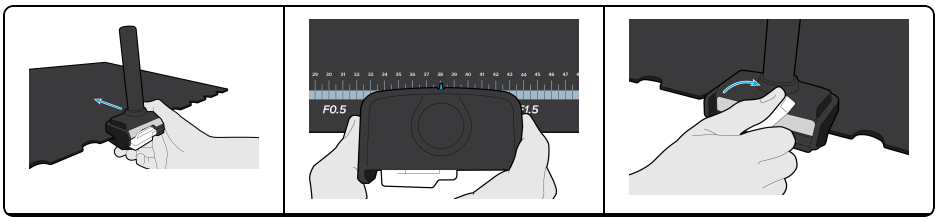
Shoulder Adapters (Optional)

1. Remove thumb nuts from Shoulder Adapter.
2. Install Shoulder Adapter as desired on top surface of Pronumbra™. Shoulder Adapters can be installed in either a wide or narrow orientation.
3. Install both thumb nuts to secure Shoulder Adapter to Pronumbra™.
4. Ensure device is securely attached.



InfinityLock™ Hand Grip

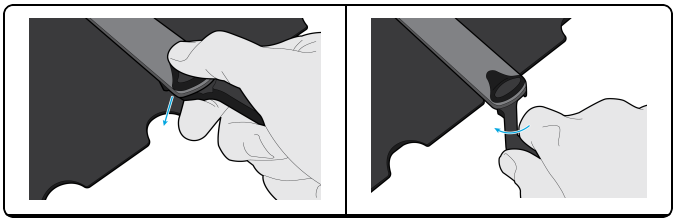
1. Ensure hand grip lever is in unlocked position.
2. Firmly slide hand grip onto InfinityEdge™ of device until hand grip is completely seated.
3. Rotate lever to lock hand grip to device.



NOTE:
- Do not rotate lever to locked position unless hand grip is fully engaged on edge of device.
- Do not store hand grip with lever in a locked position.

Locking Locating Bar

1. Place Locking Locating Bars in appropriate notches on Pronumbra™.
2. Tighten locking lever by rotating handle clockwise to lock locating bar in place.
3. To detach, loosen locking lever by rotating handle counterclockwise. Remove by pulling up on either end of locating bar.



THERMOPLASTIC MASK

Thermoplastic Type	Waterbath Temperature	Waterbath Heating Time	RapidHeat™ Oven Temperature	RapidHeat™ Oven Heating Time
Pronumbra™ Fibreplast® Mask	74°C (170°F)	2 minutes	74°C (165°F)	7- 8 minutes

⚠ WARNING
- *Frame and thermoplastic material may be hot! Handle with care. Allow to cool slightly prior to patient contact to avoid patient injury.*
- *Follow all warnings, precautions, and instructions for use contained within product guide and user manual for water bath.*
- *When positioning patient for first time, use setup sheet to record all adjustments. Setup sheet is available at www.CQmedical.com.*

NOTE:
- For RapidHeat™ Oven, refer to IFU 2007842 for RT- 2075- 110 or RT- 2075- 220.
- Ensure Helping Hands™ have been removed from device and AccuForm has completely hardened.
- For optimal immobilization, it is recommended that each patient remove facial hair prior to mask fabrication process.
- Any open wound or lesion should be covered with a dressing or plastic wrap prior to molding mask.
- Use of shoulder adapters while forming head, neck and shoulder mask should be planned in simulation prior to treatment.
- Two clinicians are required to install Head and Shoulder Thermoplastic Mask.

Integrated Shim™

NOTE: Integrated Shim™ System is built into thermoplastic mask and allows height adjustments to be made without removing mask system.

1. With pins disengaged, rotate pins clockwise to increase height and counterclockwise to decrease height.
   - Recommended starting shim height is 2 mm.
   - Shim adjustments are in increments of 0.5 mm.
   - Each shim height can be adjusted independently from one another.

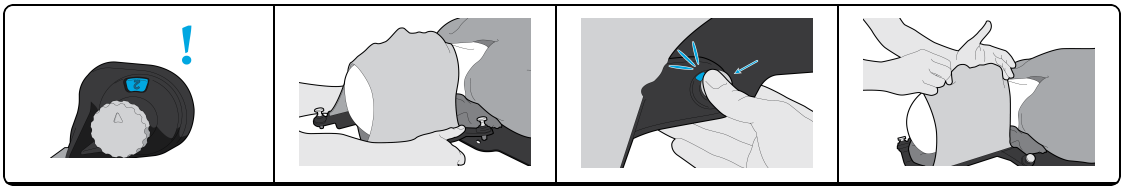
Head Only Thermoplastic Mask

1. Rotate each pin on thermoplastic mask to starting shim height.
2. Gently pre- stretch mask.
3. Install inferior Integrated Shim™ pins first, then install superior pins.

NOTE: Before securing mask, verify Integrated Shims™ are set to starting shim height.

⚠ WARNING
- *When securing mask, take care not to pinch patient or operator between mask and device.*

4. Secure mask by pressing down all Integrated Shim™ pins. You will hear an audible click. Ensure all pins are securely engaged in device.
5. Form mask around patient's face and gently contour until mask hardens.



Head, Neck And Shoulder Thermoplastic Mask

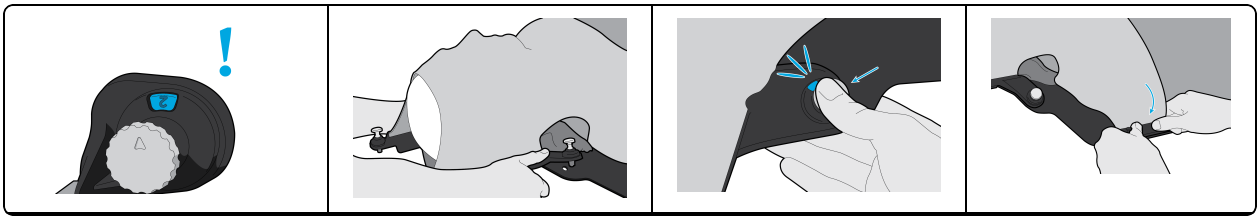
1. Rotate each pin on thermoplastic mask to starting shim height.
2. Gently pre- stretch mask.
3. Pull mask over patient's face and chest by holding shoulder pin and mask frame.
4. Install inferior Integrated Shim™ pins of head portion of mask first, then install superior pins.

NOTE: Before securing mask, verify Integrated Shims™ are set to starting shim height.

⚠ WARNING

- *When securing mask, take care not to pinch patient or operator between mask and device.*

5. Secure mask by pressing down all Integrated Shim™ pins. You will hear an audible click. Ensure all pins are securely engaged in device.
6. Gently stretch shoulder portion of mask across patient and snap pins into position into locating holes on Pronumbra Device or Shoulder Adapters. Ensure all pins are securely engaged in device or shoulder adapters.



REMOVAL

Thermoplastic Mask

1. To remove, pull frame pins until an audible click is heard, and then remove mask.

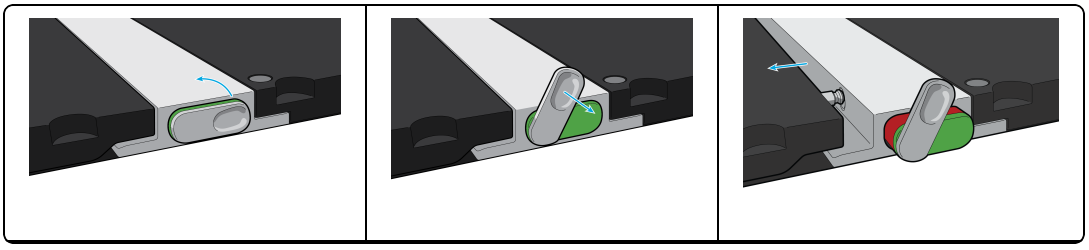
NOTE: Refer to your specific couchtop IFU for more information.

KVue™ Insert

⚠ WARNING

- *Never lift the end of kVue™ Insert! Although the mechanism is robust, the mating pins may bend or break, rendering kVue™ unusable.*

1. Rotate lever counterclockwise.
2. Pull rotated lever from one side of kVue™ until kVue™ Insert is released.
3. Remove insert.



MAINTENANCE

NOTE: Inspect device prior to use for signs of damage and general wear.

1. To disassemble Pronumbra™ Device for cleaning, remove all accessories and components from device prior to cleaning device or its accessories and components. It is not necessary to remove components in a particular order.
2. Device(s) can be cleaned with a mild, non- abrasive cleaning or disinfecting solution. To clean, apply solution to clean cloth and wipe surface. Visually inspect device, if it is not clean, repeat previous cleaning steps until visually clean. Use a clean cloth moistened with water to wipe device to remove any cleaning agent residue. To dry, wipe device with a clean, dry cloth. The following cleaning material has been tested and found to be appropriate for cleaning device.
    - Water
    - Soap and Water

Thermoplastic Mask

1. If necessary, clean surface of thermoplastic and/or frames and pins by removing gross visual contaminants with alcohol or warm soapy water. If gross visual contamination cannot be removed repeat cleaning steps and if necessary, discard device.

EC REP

CEpartner4U
Esdoornlaan 13
3951 DB Maarn, Netherlands
Ph: +31 (0) 6-516.536.26

CQ MEDICAL™

MEDTEC LLC
1401 8th Street SE
Orange City, IA 51041
United States
info@cqmedical.com

www.CQmedical.com