

Radionics® CRW®

Stereotactic System



Operator's Manual

TITLE AND PUBLICATION NUMBER

CRW Stereotactic System User's Guide
15960003 Rev. G (1/2010)

COPYRIGHT INFORMATION

©2010 Integra Radionics, Inc.
All rights reserved.

CAUTION

U.S. Federal law restricts this device to sale by, or on the order of, a physician.

NOTICES

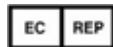
No part of this document may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means — electronic, mechanical, photocopying, recording, or otherwise — without the expressed, written consent of Integra Radionics. Additional copies of this document may be ordered from Integra Radionics.

TRADEMARKS

CRW, Luminant, Radionics, NeuroSight, and Integra NeuroSciences are trademarks of Integra LifeSciences Corporation or its subsidiaries in the United States and/or other countries. MAYFIELD is a registered trademark of SM USA, Inc. and is used by Integra LifeSciences Corporation under license. The Integra wave logo and StereoCalc are trademarks of Integra LifeSciences Corporation or its subsidiaries. Clorox is a registered trademark of the Clorox Company. Cidex and Sterrad are registered trademarks of Johnson and Johnson.



Integra Radionics, Inc.
22 Terry Avenue
Burlington, MA 01803 USA
Tel: 781-272-1233
800-466-6814 (toll-free in U.S. only)
Fax: 781-272-2428



Integra NeuroSciences, Ltd.
Newbury Road
Andover
Hampshire SP10 4DR England
Tel: +44 (0) 1264 345 700
Fax: +44 (0) 1264 332 113

Internet Address: <http://www.radionics.com>
Made in USA Printed in USA

WARRANTY

Integra Radionics, Inc. (“Integra Radionics”) warrants to the original purchaser only that each new Integra Radionics product is free from manufacturing defects in material and workmanship under normal use and service for a period of one year from the date of delivery by Integra Radionics to the first purchaser, but in no event beyond the expiration date stated on any product labeling.

- Surgical instruments are guaranteed to be free from defects in material and workmanship when maintained and cleaned properly and used normally for their intended purpose.
- Any covered product that is placed by Integra Radionics under a lease, rental or installment purchase agreement and that requires repair service during the term of such placement agreement shall be repaired in accordance with the terms of such agreement.

If any covered defect occurs during the warranty period or term of such placement agreement, the purchaser should communicate directly with Integra Radionics’ home office. If purchaser seeks to invoke the terms of this warranty, the product must be returned to Integra Radionics at its home office. The defective product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to Integra Radionics shall be at Customer’s risk. Integra Radionics’ sole responsibility under this warranty shall be repair or replacement, at the sole discretion and expense of Integra Radionics, subject to the terms of this warranty and applicable agreements.

IN NO EVENT SHALL INTEGRA RADIONICS BE LIABLE FOR ANY INCIDENTAL, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY INTEGRA RADIONICS PRODUCT. Further, this warranty shall not apply to, and Integra Radionics shall not be responsible for, any loss arising in connection with the purchase or use of any Integra Radionics product that has been repaired by anyone other than an authorized Integra Radionics service representative or altered in any way so as, in Integra Radionics’ judgment, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with the instructions furnished by INTEGRA RADIONICS. THIS LIMITED WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF INTEGRA RADIONICS, AND INTEGRA RADIONICS NEITHER ASSUMES NOR AUTHORIZES ANY REPRESENTATIVE OR OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH INTEGRA RADIONICS PRODUCTS.

INTEGRA RADIONICS DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY AS WELL AS ANY EXPRESS OR IMPLIED WARRANTY TO PATIENTS. No warranty or guarantee may be created by any act or statement nor may this Standard Warranty be modified in any way, except as a result of a writing signed by an officer of Integra Radionics. These limitations on the creation or modification of this warranty may not be waived or modified orally or by any conduct.

Definitions of Alerts Used in this Manual



Warning: An operation or maintenance procedure, practice, condition, statement, etc. which, if not strictly adhered to, could result in injury, long term health hazard, or death of a patient or personnel.

Caution *An operation or maintenance procedure, practice, condition, statement, etc. which, if not strictly adhered to, could result in damage to or destruction of part or all of the device, or could result in displaying erroneous information.*

Note An important point of interest or instruction which may simplify a procedure or prevent unnecessary labor.

TABLE OF CONTENTS

Chapter 1: About the CRW® Stereotactic System

About this User's Manual	1
About CRW® Compatibility	1
Indications for Using the CRW	1
Standard Stereotactic Procedures.....	1
Contraindications for Using the CRW	2
Single Use Precautions	2
Accuracy of the CRW.....	3
Using the CRW with Electrosurgical Devices.....	3
List of CRW Arc System Components	4

Chapter 2: Assembling and Configuring the CRW® Stereotactic System

Assembling the UCHRA.....	13
Attaching the Head Ring Screw Cross Bar (Optional).....	14
Installing the Head Ring	15
Assembling the HRAIM	19
Assembling the Localizer Frames	23
Assembling the BRWLF on the UCHRA or on the HRAIM.....	23
Assembling the Luminant® on the UCHRA	25
Assembling the CRW Arc System.....	26
Setting the Fixed Radial Distance for the Arc System Pointer	33
Setting the Fixed Radial Distance for an Instrument.	35
Selecting the Guide Tube and Reducing Tube/Bushing Combinations.....	36
Assembling the Arc System to the Phantom Base	37
Assembling the Arc to the Head Rings	39
Attaching the Head Ring to the Operating Table	41
Attaching the UCHRA or the HRAIM to the Operating Table	41
Creating a Sterile Field	42

Chapter 3: Scanning with the CRW® Stereotactic System

Scanning the Luminant® Localizer Frame	45
Manually Calculating the Luminant Target Positions	45
Calculating Target Positions for Axial Scans.....	46
Calculating Target Positions for Coronal Scans	47
Calculating Target Positions for Sagittal Scans.....	49
Scanning the BRW Localizer Frame	50

Collecting CT Scan Rod Position Data	50
--	----

Chapter 4: Setting Targets on the CRW® Arc

About the Arc System	51
About the Arc System Coordinates	52
Measuring Arc System Coordinates with the Vernier Scale	54
Setting the Coordinates with a Vernier Scale	55
Setting the Guide Block Holder Approach Angle	56
Setting the Trunion Ring Approach Angle.....	57
Transposing the Arc Rings.....	57
Using Parallel Trajectories	58
Entering Multiple Targets Through a Single Burr Hole	58
Examples of Different Arc Orientations.....	59

Chapter 5: Using the CRW® Accessories

Tools for Calibration Guidance	61
Using the Micro Slide	61
Using the MicroDrive.....	62
Visualizing Lateral Trajectories with the Trunion Reticles	63
Visualizing Anterior-Posterior Trajectories with the AP Reticles	63
Clamping Patients to the CT Table.....	64
Using the Geometric Phantom for Qualifying Transfer Accuracy	64

Chapter 6: Cleaning, Sterilizing, and Maintaining the CRW®

Cleaning the CRW® Components	65
Cleaning the HRAIM and UCHR Components	65
Cleaning the BRWLF and Luminant® Localizer Frames.....	65
Cleaning the CRW Arc System.....	66
Cleaning Miscellaneous CRW Parts	66
Disassembling the CRW Components	66
Packing the CRW Components.....	67
Sterilizing the CRW Components	68
Parameters for Sterilizing the CRW Components.....	68
Summary of CRW Sterilization Procedures	69
Maintaining the CRW System.....	70
Preventing Equipment Loss	70
Calibrating the CRW System	70

Index	71
--------------------	-----------

CHAPTER 1 ABOUT THE CRW[®] STEREOTACTIC SYSTEM

About this User's Manual	1
About CRW [®] Compatibility	1
Indications for Using the CRW	1
Contraindications for Using the CRW	2
Single Use Precautions	2
Using the CRW with Electrosurgical Devices	3
List of CRW Arc System Components	4

About this User's Manual

This manual supports the CRW[®] (Cosman, Roberts, and Wells) Stereotactic System, and is not intended to be a clinical medical document. This publication details the mechanical/functional features of the System and describes how to properly assemble, use, sterilize and maintain the equipment in the System. Read and become familiar with these instructions before using the System in surgery.

About CRW[®] Compatibility

The CRW Stereotactic System is a target-centered system that can be configured to be CT-only or CT/MR compatible.

Indications for Using the CRW

Standard Stereotactic Procedures

The CRW Stereotactic System is a multi-purpose system used for localizing intercranial targets for precisely directing instruments such as:

- Biopsy forceps
- RF lesioning electrodes
- Deep brain electrodes
- Recording and stimulating electrodes
- Hematoma evacuators
- Endoscopes

Note Localization is performed using CT or MR imaging.

Contraindications for Using the CRW

- The Head Ring is contraindicated for infants whose coronal sutures have not yet closed.
- The CRW System is contraindicated for patients with Creutzfeldt–Jakob disease.

Single Use Precautions

Single use devices are used with the CRW Stereotactic System. The following precautions should be taken:



For single patient use only. The Disposable Head Ring Screws, Long and Short (DHRSS5, DHRSL5) are designed as single-use, disposable products and should not be re-sterilized or reused.

Re-sterilization and reuse may result in dullness of the screw, leading to potential head ring movement, and cross contamination. Any Disposable Head Ring Screw, once used, should be discarded according to hospital policy.



For single patient use only. The Apuzzo Stereotactic Drapes (ASD1 and ASD1B) are designed as single-use, disposable products and should not be re-sterilized or reused.

Reuse of this device may result in cross contamination or compromised sterility of the drape and sterile field. Any drape, once used, should be discarded according to hospital policy.



For single patient use only. The Nashhold Biopsy Needle (NBND) is designed as a single-use, disposable product and should not be re-sterilized or reused.

Re-sterilization may result in impaired function (e.g. dulling of the cutting window, loss of vacuum) and cross contamination. Any needle, once used, should be discarded according to hospital policy.



For single patient use only. The CRW BiopsyPlus Kit (CRWBP) is designed as a single-use, disposable product and should not be re-sterilized or reused.

Re-sterilization may result in impaired function (e.g. dullness of cutting window, loss of vacuum, inaccuracy of bushing) and cross contamination. Once used, the kit should be discarded according to hospital policy.

Accuracy of the CRW

User error in the cursor placement and slice positioning contribute to the total application error. The accuracy in the lateral and AP dimension is ± 2 mm. Error in the vertical direction may be as large as the thickness of the scan slice (2 or 4 mm). The intrinsic mechanical accuracy of the arc is better than 0.5 mm, as determined in bench testing.

Using the CRW with Electrosurgical Devices



If the CRW System is to be used with a ground-referenced electrosurgical device (monopolar or bipolar electrode), the Head Ring should not contact the patient. Maintain a gap (at least 1/4 inch) between the Head Ring and the patient's body.

- **Follow safety procedures consistent with the use of anesthetizing gases when using the Arc System with electrosurgical equipment.**
- **Review the system and its accessories prior to surgery to ensure that all items are available and functional.**

List of CRW Arc System Components

CRW Arc

System

CRW Lightweight Arc System

Catalog #







CRWASL





This system includes:

- Lightweight Arc (not sold separately)
- Probe Holder (not sold separately)
- Guide Block (CRWASGB)
- Keller Depth Gauge (KDG)
- Stainless Steel Ruler (SR)
- Arc System Wrench (SWTS)
- Storage and Sterilization Case (CRWCASE)
- MAYFIELD® Adapter (CRWMA)
- Drill Assembly, 2.7 mm (DA27)
- Guide Tube, 2.7 mm I.D. x 116 mm length (GT27116)
- Guide Tube, 2.7 mm I.D. x 76 mm length (GT2776)
- Reducing Bushing, 2.7 mm I.D. (RB27)
- Reducing Tube, NBND I.D. x 76 mm length (RTNBND76)
- User's Manual







System Accessories and Components




<u>Accessories and Components</u>	<u>Catalog #</u>	
Keller Depth Gauge	KDG	
Guide Block	CRWASGB	
Stainless Steel Ruler	SR	
Arc System Wrench	SWTS	
MAYFIELD Adapters	CRWMA	
	CRWFMA	

<u>Accessories and Components</u>	<u>Catalog #</u>	
Guide Tubes	<ul style="list-style-type: none"> • GT27116: 2.7 mm I.D. x 116 mm working length • GT27116: 2.7 mm I.D. x 116 mm working length • GT2776: 2.7 mm I.D. x 76 mm working length • GT32116: 3.2 mm I.D. x 116 mm working length • GT32160: 3.2 mm I.D. x 160 mm working length • GT3276: 3.2 mm I.D. x 76 mm working length • GT46116: 4.6 mm I.D. x 116 mm total length 	
Reducing Bushings	<ul style="list-style-type: none"> • RB27: 2.7 mm I.D. • RB32: 3.2 mm I.D. 	
Reducing Tubes	<ul style="list-style-type: none"> • RT11116: 1.1 mm I.D. x 116 mm length • RT1176: 1.1 mm I.D. x 76 mm length • RT16116: 1.6 mm I.D. x 116 mm length • RT1676: 1.8 mm I.D. x 76 mm length • RT1876: 1.8 mm I.D. x 116 mm length • RT18116: 2.0 mm I.D. x 116 mm length • RT20116: 2.0 mm I.D. x 76 mm length • RT20160: 2.1 mm I.D. x 160 mm length • RT21116: 2.1 mm I.D. x 116 mm length • RT2176: 2.1 mm I.D. x 76 mm length • RTNBND160: NBND I.D. x 160 mm length • RTNBND116 : NBND I.D. x 116 mm length • RTNBND76 : NBND I.D. x 76 mm length 	
Probe Holder (30 Degree Offset)	CRWMCPH30	



Head Rings and Accessories

<u>Head Rings and Accessories</u>	<u>Catalog #</u>
UCHRA (Universal Compact Head Ring)	UCHRA 
UCHR (Universal Compact Head Ring Sub Assembly)	UCHR 
UCHRAP (Adapter Plate)	UCHRAP 
UCHRP (Composite Post & Cross Bar Kit)	UCHRP 
UCHREBA (Head Ring Ear Bar Kit)	UCHREBA 


<u>Head Rings and Accessories</u>	<u>Catalog #</u>
HRW (Head Ring Wrench)	HRW 
HRAIM (Intubation Head Ring Assembly)	HRAIM 
HRD (Head Ring Drive)	HRD 
HRDXS (Head Ring Drive Extender / Shortener)	HRDXS 
HRP (Head Ring Post)	HRP 
TAP (Cleaning Tap for HRP and UCHRP)	TAP 




<u>Head Rings and Accessories</u>	<u>Catalog #</u>
HRKTP (Head Ring Positioner)	HRKTP 
Conical T-Bolt Screws	CSS 
HREBA (Intubation Head Ring Ear Bar Kit)	HREBA 

Imaging Localizers




<u>Localizer</u>	<u>Catalog #</u>	
BRWLF (CT Localizer Frame)	BRWLF	
Luminant® (MR/CT Localizer)	LL01	

Quality Assurance Components

<u>QA Component</u>	<u>Catalog #</u>	
Phantom Base System	CRWPBS	

<u>QA Component</u>	<u>Catalog #</u>
CRW Arc System Pointer	CRWASP 
Reticles	<ul style="list-style-type: none"> <li data-bbox="636 514 885 556">• CRWTBSS (Trunion)  <li data-bbox="636 756 1003 798">• CRWAPBS (Anterior / Posterior) 

Sterile Devices (Single Use Only)

<u>Sterile Device</u>	<u>Catalog #</u>	
Apuzzo Stereotactic Drape	<ul style="list-style-type: none">• ASD1 (Sterile drape)• ASD1B (10 sterile drapes)	 A photograph showing a large, dark-colored sterile drape with a central opening and a smaller square opening, and two smaller, rectangular sterile drapes in their packaging.
Disposable Head Ring Screws	<ul style="list-style-type: none">• DHRSL5 (box of long screws)• DHRSS5 (box of short screws)	 Four individual disposable head ring screws are shown, arranged vertically. They have a textured, cylindrical body and a pointed tip.
NBND Nashold Biopsy Needle, Disposable	<ul style="list-style-type: none">• NBND (single)• NBND5 (box of 5)	 A single Nashold Biopsy Needle (NBND) is shown, consisting of a long, thin needle with a handle and a small circular component near the tip.

CHAPTER 2 ASSEMBLING AND CONFIGURING THE CRW[®] STEREOTACTIC SYSTEM

Assembling the UCHRA	13
Assembling the HRAIM	19
Assembling the CRW Arc System	26
Attaching the Head Ring to the Operating Table	41

Assembling the UCHRA

1. Attach the 4 Head Ring Posts onto the head ring. Use the Head Ring Wrench to tighten the head post attachment screws.

Note The anterior Head Ring Posts are longer than the posterior Posts, and are angled rather than straight.

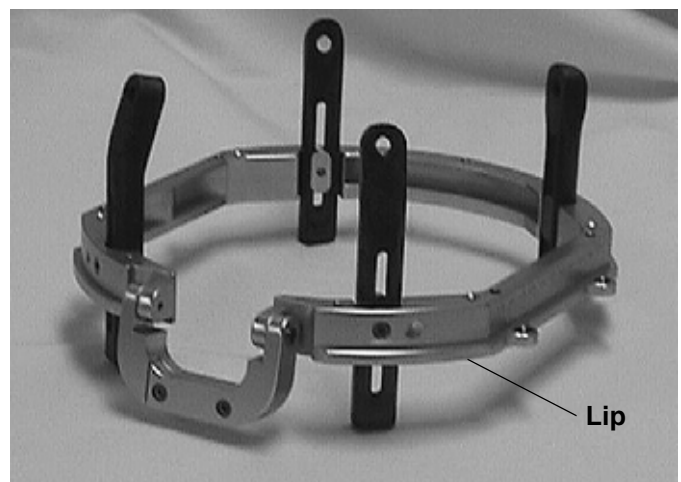
Caution *Assemble the Head Ring Posts onto the Head Ring prior to installing the Head Ring Screws. Failure to do so could potentially place increased stress on the Head Ring Post Assembly.*



2. See the picture to the right for a sample of a properly assembled Head Ring.

Note The "lip" that goes around the head ring should be on the bottom.

Note To prevent breaking the head post attachment screws, ensure that the post screws are tightened so that the post is flush with the head ring before tightening the disposable head ring screws.



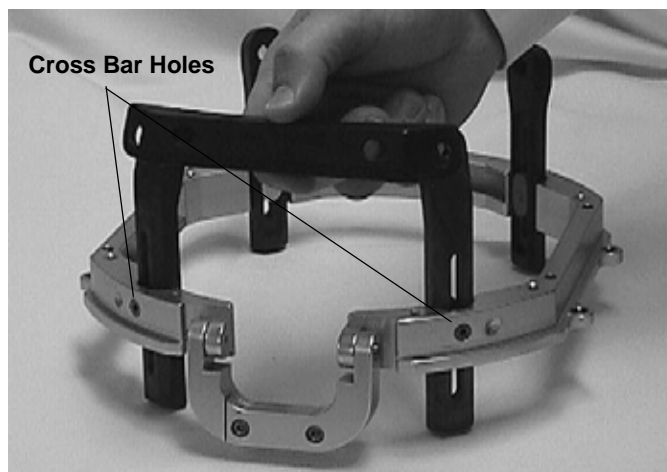
Attaching the Head Ring Screw Cross Bar (Optional)

Note If you are not using the optional Head Ring Screw Cross Bar, proceed to "Installing the Head Ring," on page 15).

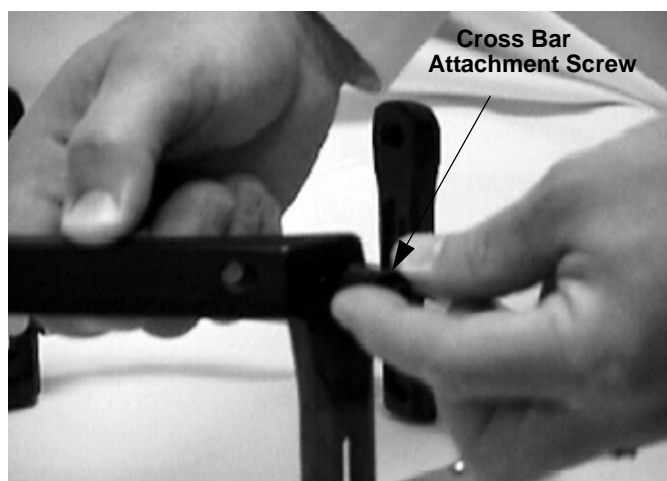


To avoid placement of the Head Ring screws into the temporalis muscle, use the Head Ring Cross Bar.

1. Align the Cross Bar holes with the Head Ring screw holes of the anterior Head Ring Posts.



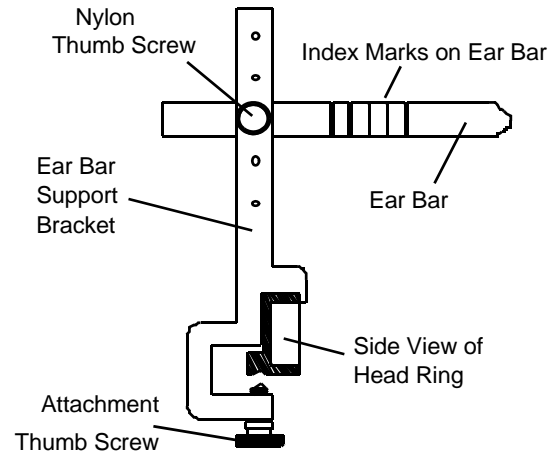
2. Attach the Cross Bar with the Cross Bar attachment screws.



Installing the Head Ring

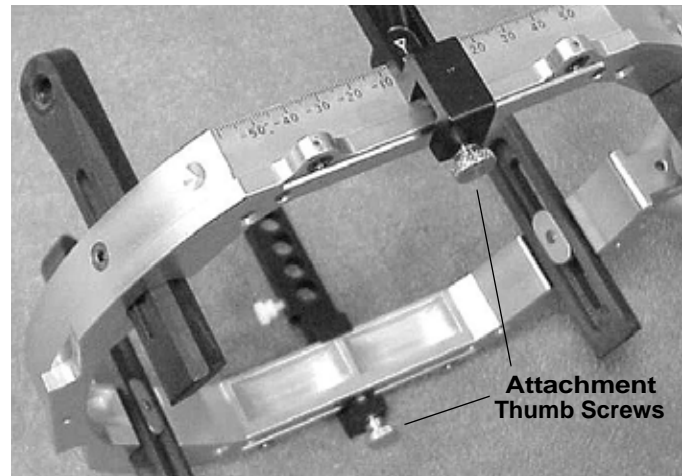
Assembling the Ear Bar

1. Loosen the nylon thumb screw on the Ear Bar support bracket to place the Ear Bar in the bracket.



2. Fit the Support Brackets on opposite sides of the Head Ring, then finger tighten the Attachment Thumb Screws.

Note The scales on the sides of the Head Ring are for reference only and allow for alignment of the Head Ring to the patient.



Placing the Head Ring Assembly on the Patient

Note Placing the Head Ring assembly is easier if two people perform the procedure.

1. Have the first person hold the Head Ring in the desired position over the patient's head.
2. Have the second person arrange the Ear Bars so that the rounded end of each Bar rests comfortably in the patient's outer ear

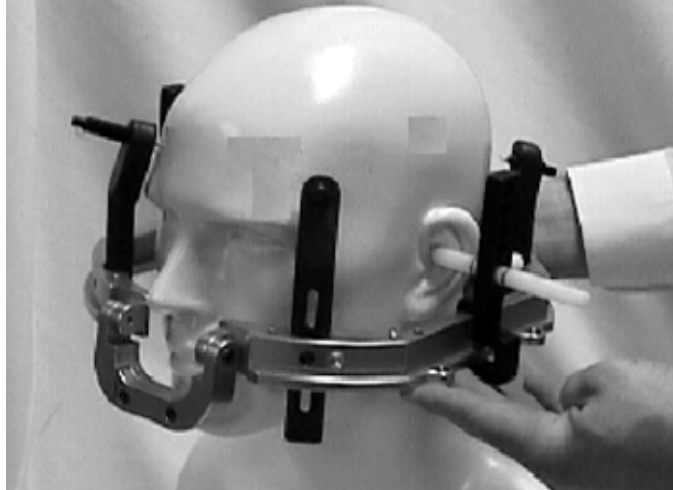
Note Use the index marks on each Ear Bar to help center the assembly.

Note Fit the Head Ring to the patient's skull while the patient is in a sitting position.

Caution *To reduce patient discomfort, do not allow the weight of the Head Ring Assembly to rest on the Ear Bars.*

Caution *Use of the Velcro strap (GTCSVS) helps position the Head Ring assembly and take the weight off the Ear Bars. For more information on this strap, see page 20.*

3. Finger-tighten the Nylon Thumb Screws on each Support Bracket to secure the Ear Bars.



Installing the Head Ring Screw



When installing the Head Ring Screws:

- Only use Radionics disposable Head Ring Screws.
- Select the appropriate Head Ring screw length so that the screws protrude at least 13 mm from the outside surface of the Head Ring posts.
- Use all four (4) Head Ring screws to attach the Head Ring.

1. Cleanse the patient's scalp and apply local anesthesia through the Head Ring Post openings (or Cross Bar openings, if applicable).
2. Allow the local anesthetic to take effect.
3. Use the Head Ring Wrench to drive the Head Ring Screws into the patient's skull.

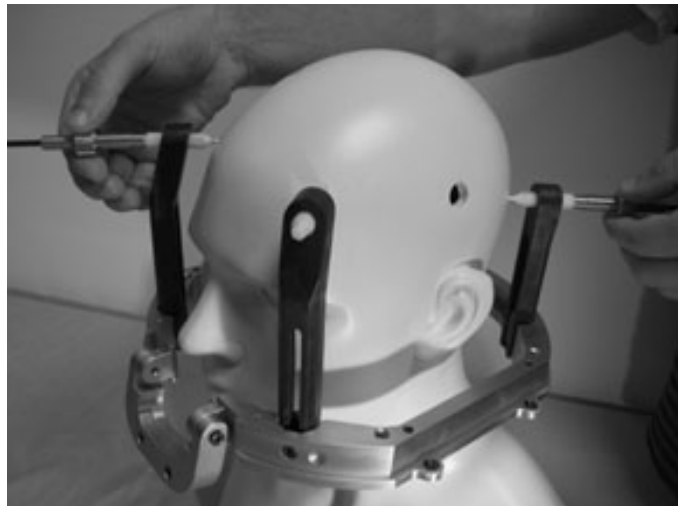
Note Integra Radionics recommends the use of an antibacterial ointment on the tips of the screws to help avoid infection.



4. Insert and tighten two diagonally-opposed Head Ring Screws at a time.

Note Using the Head Ring Wrench, hand-tighten each screw equally and alternately.

5. After securing the first pair of screws, install the second pair.
6. Be sure that the Head Ring Assembly is securely in place, then remove the two ear bars from the Support Brackets.
7. Loosen the thumb screws and remove the ear bar Support Brackets from the Head Ring Assembly.
8. Remove the Velcro strap, if used.



Caution *Overtightening of the Head Ring screws can cause premature failure of the Head Ring posts and/or the Head Ring screws.*

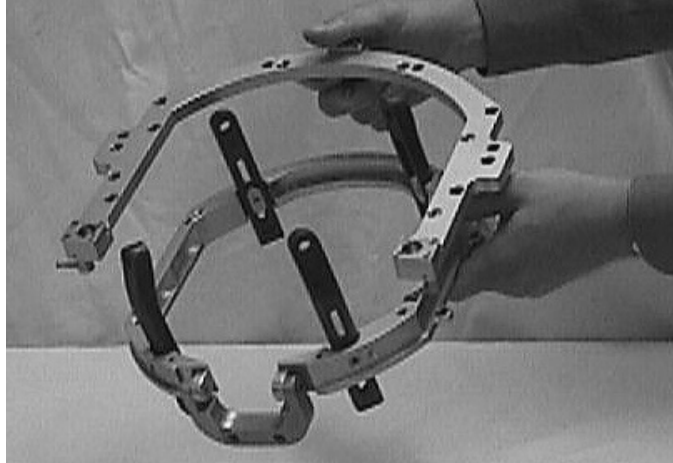
The head ring is now ready for Luminant® localizer attachment. If attaching the BRWLF to the head ring, proceed to the next page for further assembly instructions.

Attaching the Arc Adapter Plate to the UCHRA

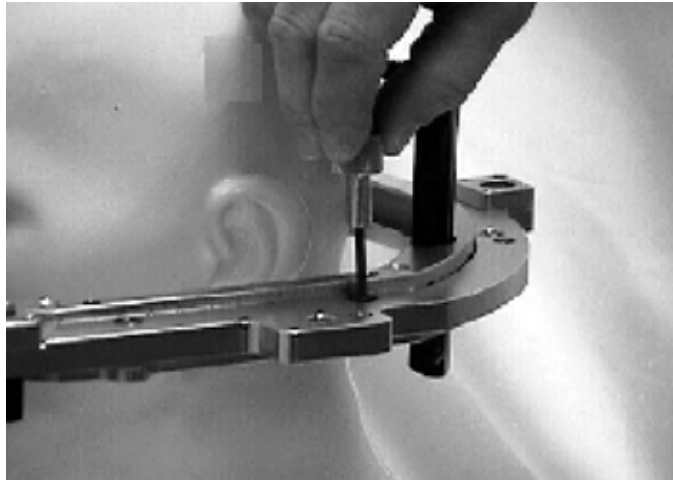
Note You must attach the Arc Adapter Plate to the UCHRA before you can place the BRWLF on the UCHRA.

1. Position the Arc Adapter Plate so that the open end faces the UCHRA Assembly anterior.

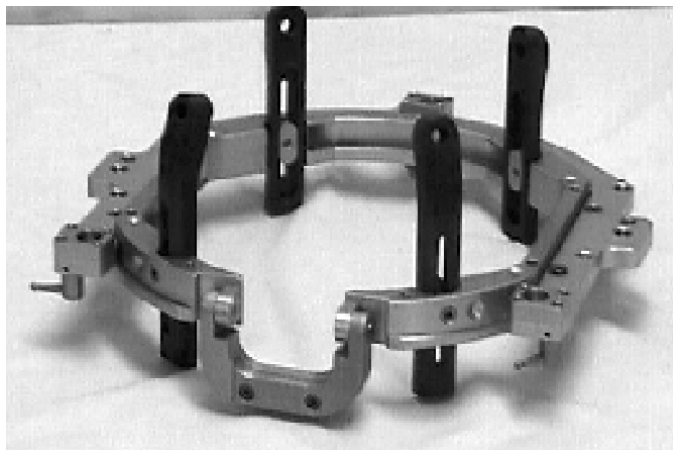
Note The Arc Adapter is used to attach the BRWLF to the UCHRA for CT scanning, and also attach the CRWASL to the UCHRA.



2. Use the Head Ring Wrench to tighten the Attachment Screws, securing the Arc Adapter Plate to the Head Ring Assembly.

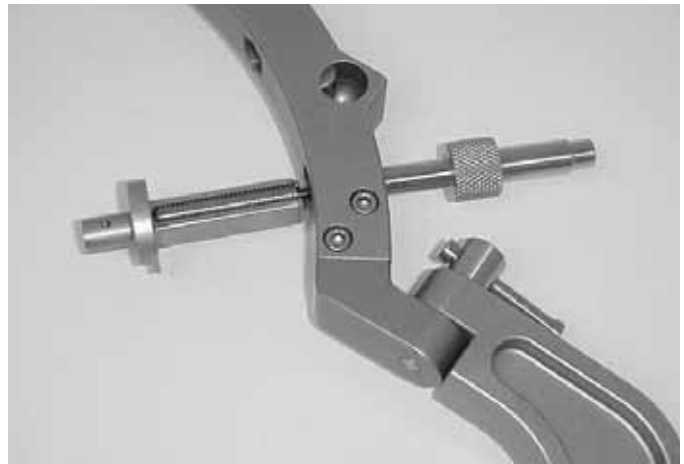


3. The UCHRA with the Arc Adapter Plate in place:

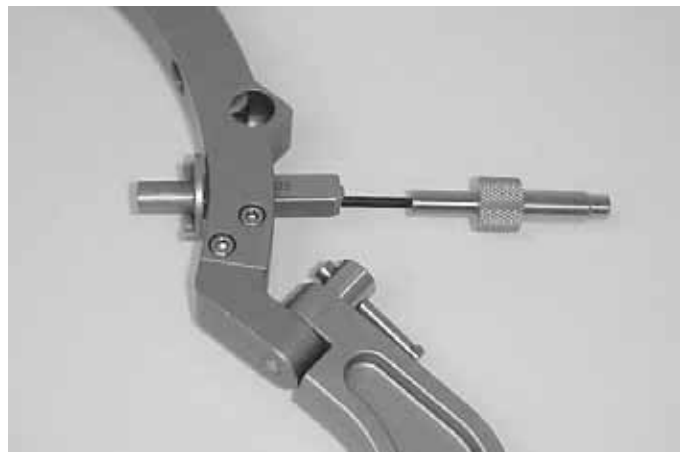


Assembling the HRAIM

1. Use the Head Ring Wrench to back the Head Ring Drives (HRD) into the Head Ring.



2. The HRDs fully seated in the Head Ring.

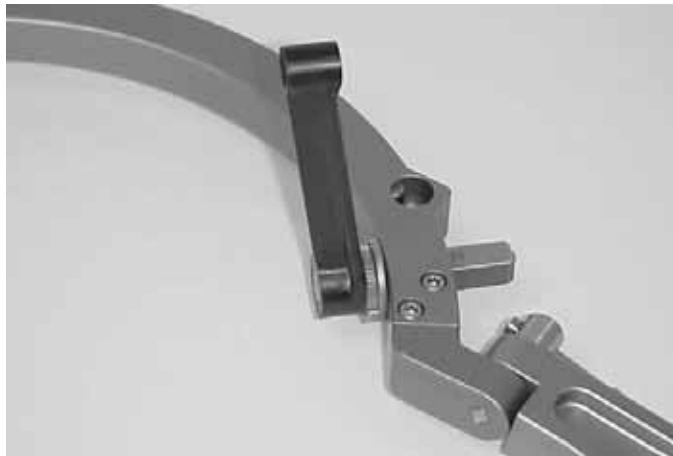


3. Position the Head Ring Posts (HRP) onto the Head Ring Drives.



-
4. Secure the Head Ring Posts onto the Head Ring Drives.

Note Ensure that the Head Ring Posts are fully seated against the Head Ring Drives (see the illustration at right).



5. Place the HRKTP Head Ring positioner onto the Head Ring.

Note Using the Head Ring Positioner helps support the weight of the Head Ring Assembly during placement on the patient.



Head Ring Positioner (HRKTP)



-
6. Place the Head Ring over the patient's head.
 7. Rotate the posts to achieve good skull pin placement.

Note The Head Ring can be placed in any orientation on the patient's head; targeting is not affected.

Caution *Avoid the temporalis muscle.*

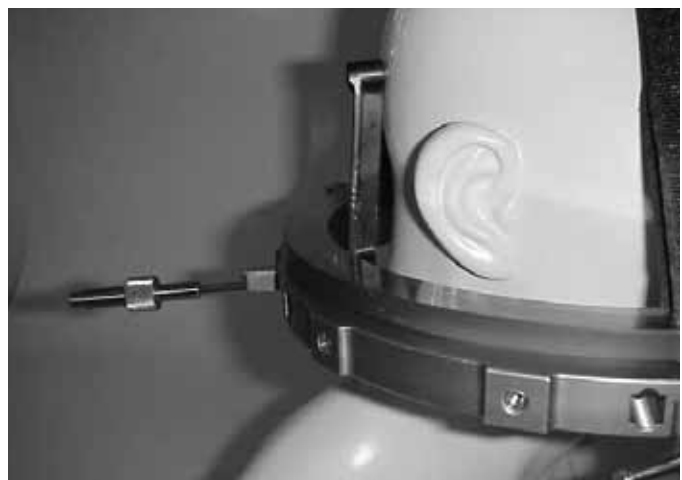


8. Clean and anesthetize the skull pin sites.
9. Allow the local anesthetic to take effect.

Note Integra Radionics recommends the use of an antibacterial ointment on the tips of the screws to help avoid infection.



10. Using the Head Ring Wrench, move the Head Ring Drives to position the Head Ring Posts to firmly touch the patient's scalp.



11. Using the Head Ring Wrench, insert and tighten two diagonally-opposed Head Ring screws.



When installing the Head Ring Screws:

- Only use Radionics disposable Head Ring Screws.
- Select the appropriate Head Ring screw length so that the screws protrude at least 13 mm from the outside surface of the Head Ring posts.
- Use all four (4) Head Ring screws to attach the Head Ring.

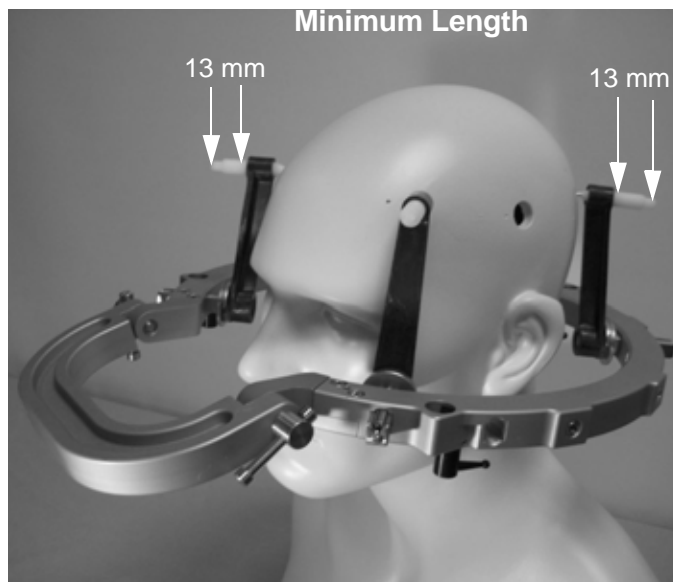
Caution *To prevent torque of the head ring, tighten the intubation cam locks prior to driving the head ring screws.*

12. After securing the first pair of Head Ring screws, install the second pair.

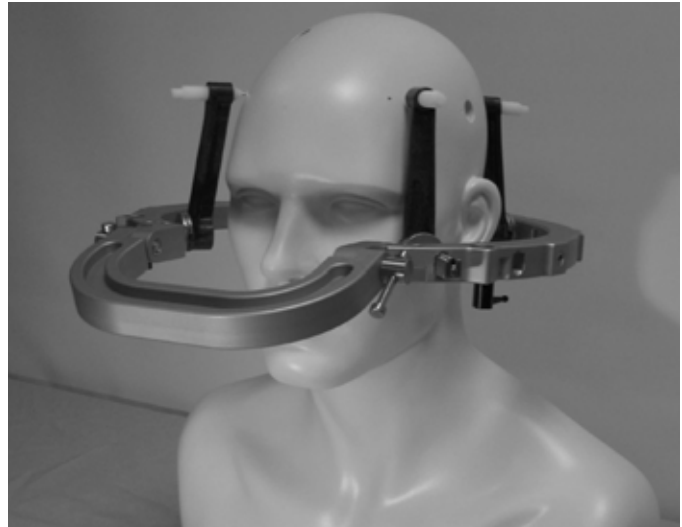
Note Hand-tighten all screws with the Head Ring Wrench.

Caution *Overtightening the Head Ring screws can cause premature failure of the Head Ring Posts and/or Head Ring screws.*

Note Be sure that the spine of the posts do not press against the skin for patient comfort.



13. Remove the Head Ring Positioner.

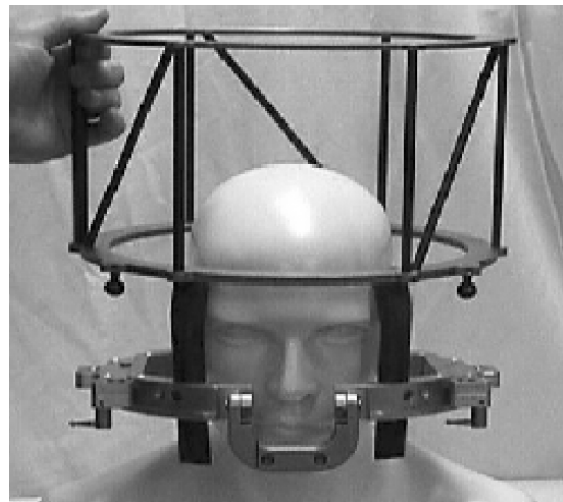


Assembling the Localizer Frames

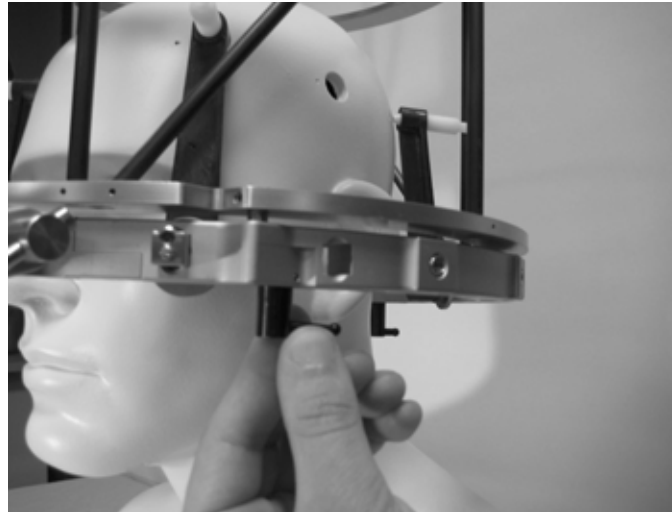
The CRW supports the BRWLF and Luminant™ localizer frames.

Assembling the BRWLF on the UCHRA or on the HRAIM

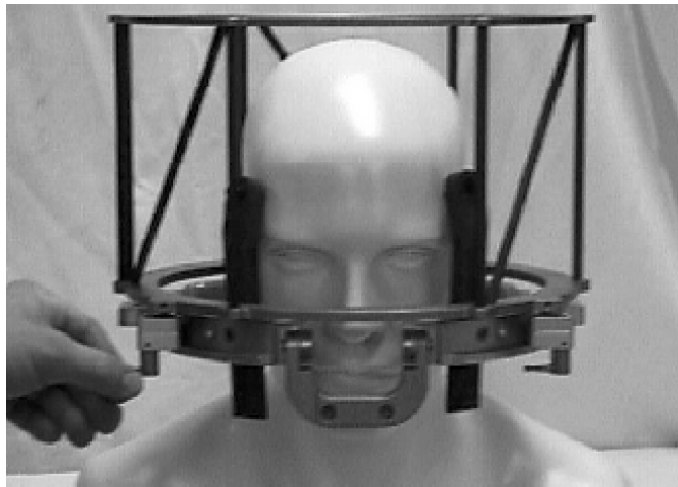
1. Place the BRW localizer frame (**BRWLF**) onto either the UCHRA (with the Arc Adapter installed) or the HRAIM:
 - The BRWLF on the UCHRA is shown:



-
- The BRWLF on the HRAIM is shown:



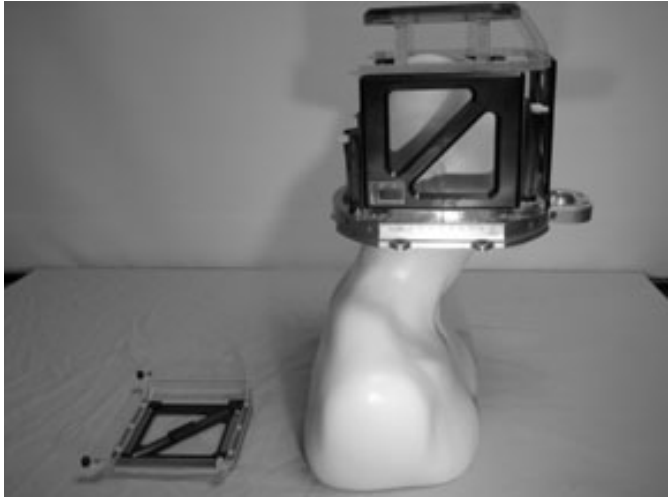
2. Lock the cams to fasten the localizer frame to the Adapter Plate of the UCHRA or HRAIM.



Assembling the Luminant® on the UCHRA

Note For MR setup, do not attach the Arc Adapter to the UCHRA.

1. Remove the Luminant® localizer Posterior Panel and position the localizer so that the Anterior Panel is above the Intubation Hoop on the Head Ring Assembly (without the Arc Adapter installed).

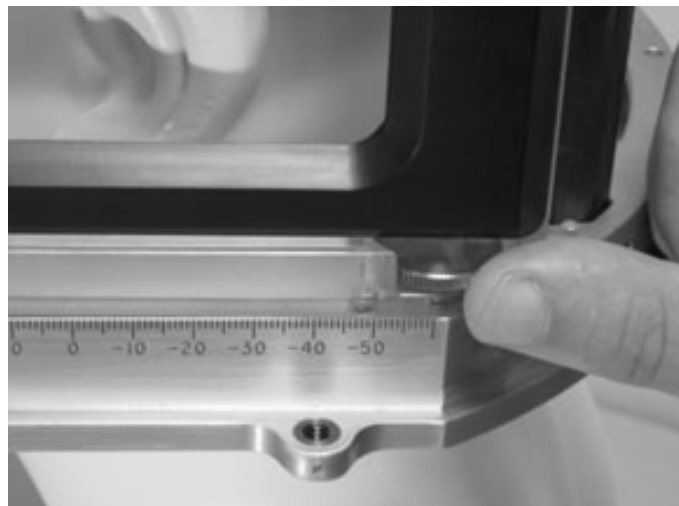


Note The UCHRA Intubation Hoop must be in the down position to fit into the MR scanner head coil - - the illustration at the right displays the hoop in the **Up** position. Use the head wring wrench (HRW) to loosen/tighten the intubation hoop for positioning.



2. Secure the Luminant localizer by thumb-tightening the four Attachment Screws into the four threaded holes on the top of the head ring.

Note The Luminant localizer and UCHRA fit together in one orientation only - - all four screws will align properly. Do not attempt to assemble these parts in another orientation.



Assembling the CRW Arc System

Step 1

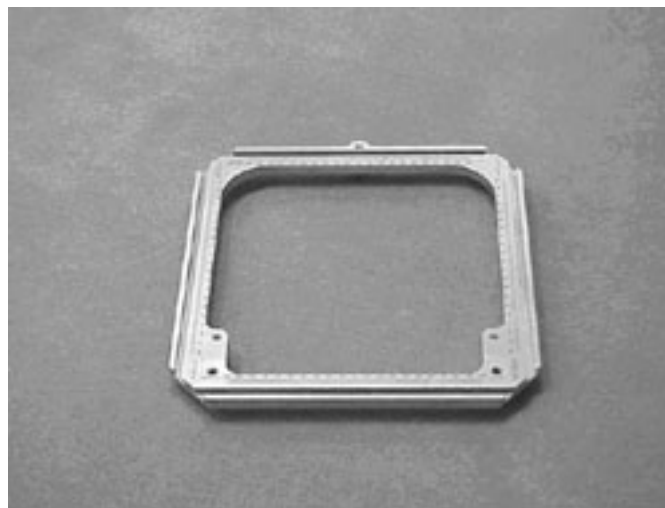
A. Remove Arc base plate from sterilization tray.

B. Do one of the following:

- Place Arc base plate on sterile table.

OR

- Place Arc base plate on sterile or sterile draped Phantom Base.



Step 2

A. Remove Arc assembly from sterilization tray.

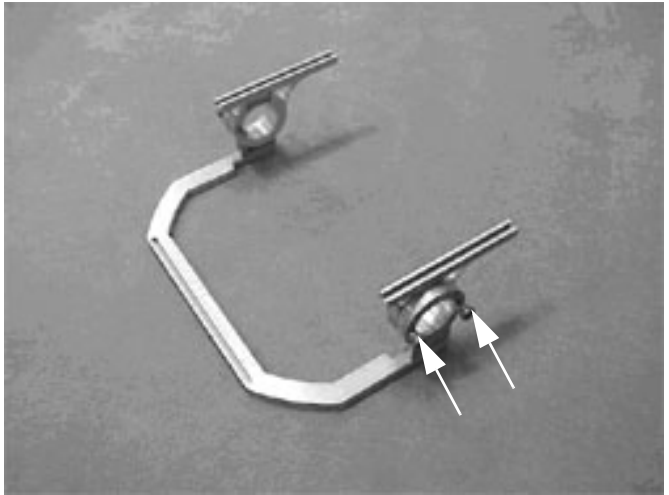
B. Verify Trunion Rings are fully assembled.

C. Loosen Trunion Ring locking screws.



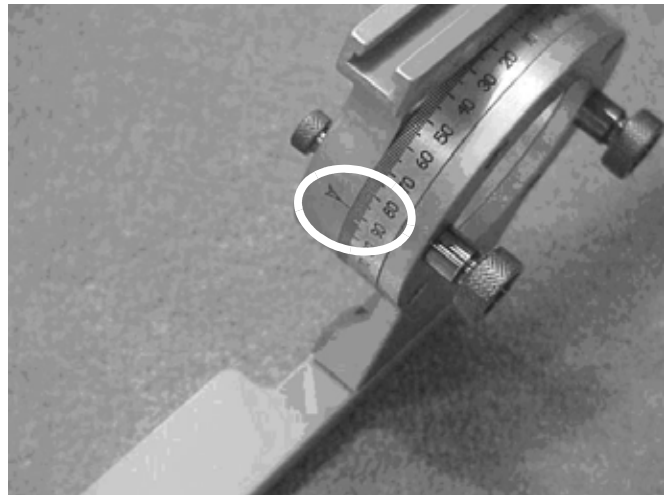
Step 3

- A. Position Trunion Rings at 90°.
- B. Tighten Trunion Ring locking screws.



Step 4.

Verify both Trunion Rings are set to 90°



Step 5

- A. Remove Trunion Supports from tray.
- B. Verify Trunion Rings are fully assembled with locking screws and slider bars.



Step 6

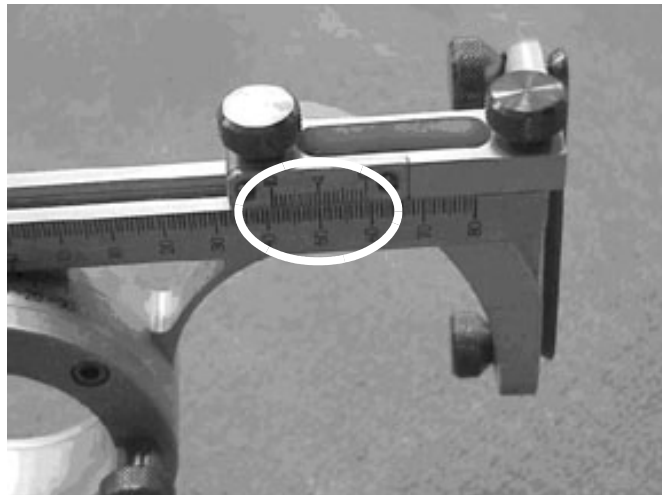
Slide Trunion Supports onto Trunion Ring Posts from bottom (see picture). Note that the shorter leg attaches to the Trunion Ring posts, while the longer side of trunion supports faces inward



Step 7

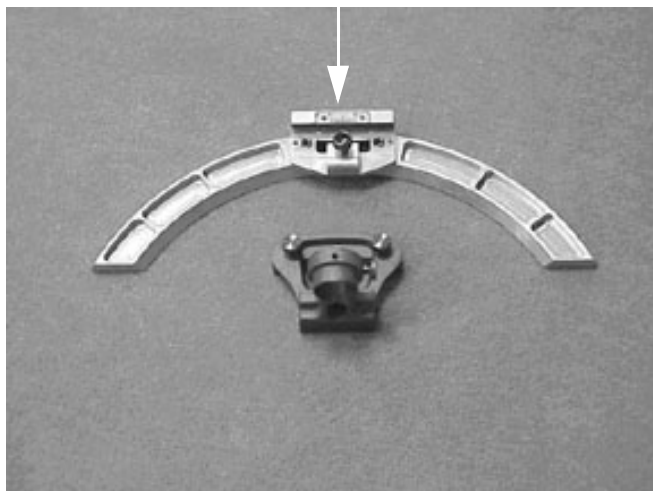
Do one of the following:

- Lock both Trunion Supports at 50 mm for easier assembly; or
- Set to calculated VERT stereotactic coordinate.



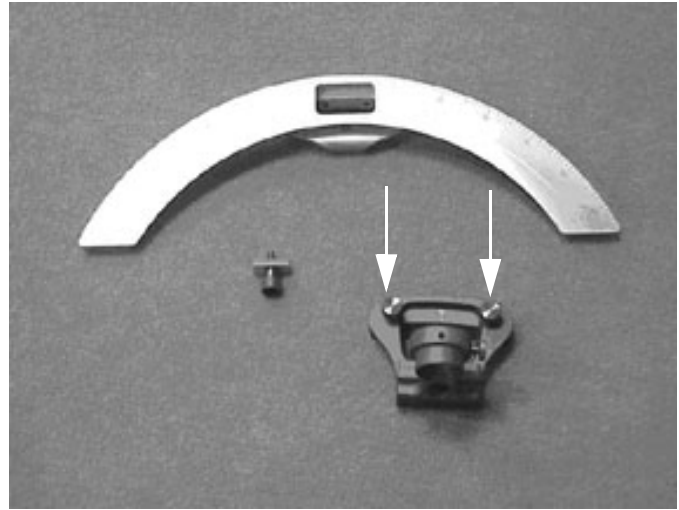
Step 8

3. Remove Lateral Arc Slide and Guide Block Holder from the sterilization tray.
4. Remove Lateral Slide Screw and Lock Nut from the arc.



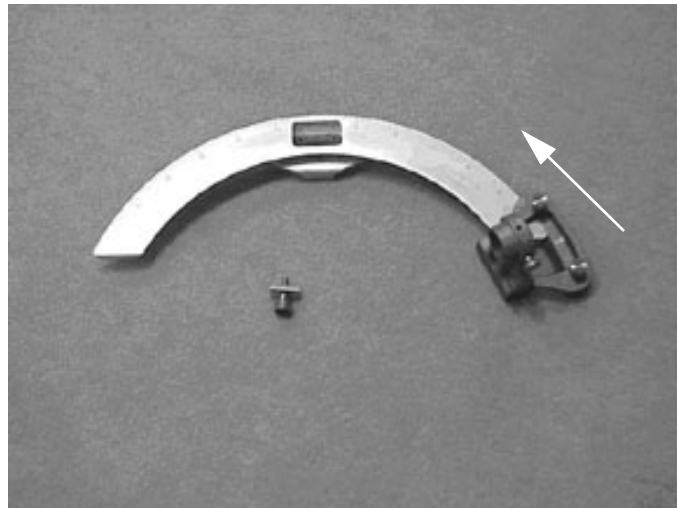
Step 9

- A. Turn the lateral arc slide over.
- B. Loosen the screws on the guide block holder.



Step 10

Slide Guide Block Holder onto Lateral Arc Slide.



Step 11

Do one of the following:

- Set Guide Block Holder to 0°; or
- Set to desired slide angle



Step 12

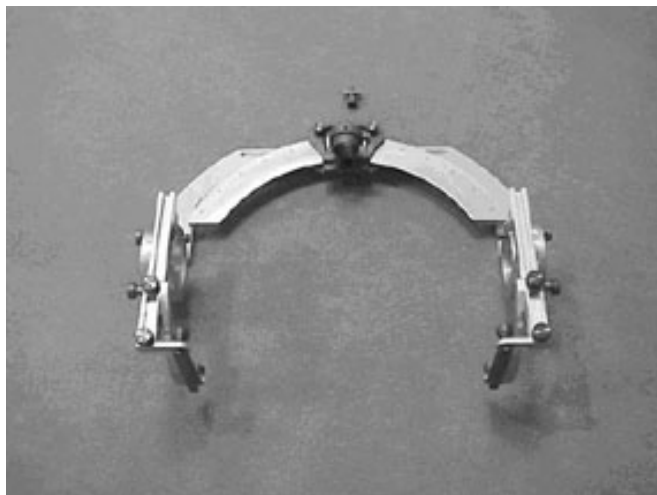
Place the Arc assembly and Lateral Arc Slide together.



Step 13

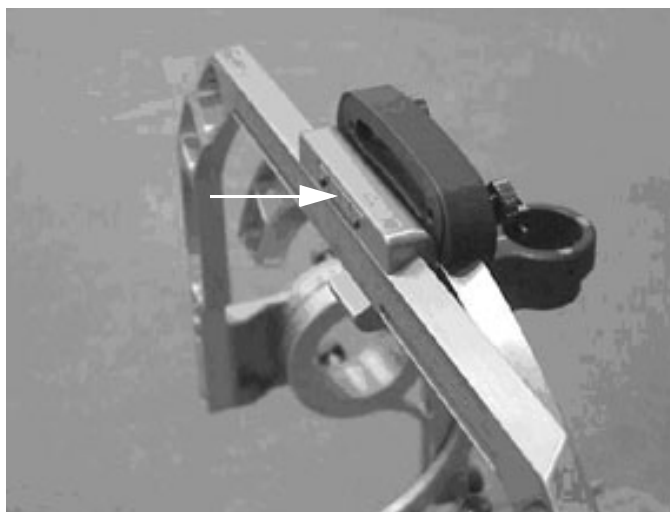
A. Attach Lateral Arc Slide to main Arc assembly.

B. Place Lateral Arc Slide over top of bridge.



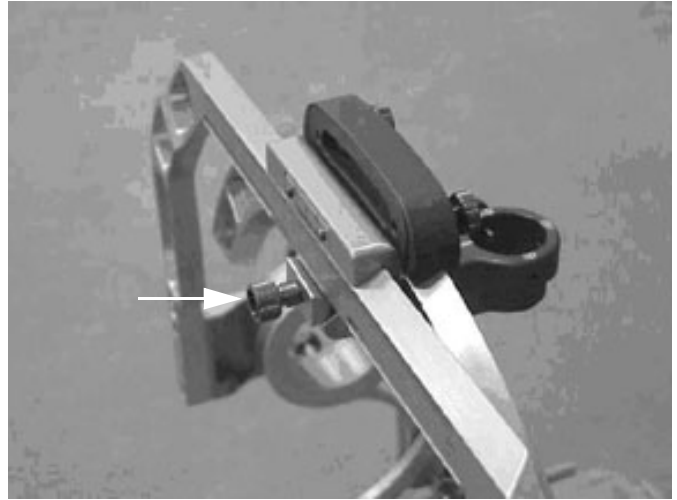
Step 14

The Lateral Arc Slide hooks over the top of the main Arc assembly



Step 15

- A. Insert the Lateral Arc Slide Locking Screw and Nut Set.
- B. Set the Lateral Arc Slide at the appropriate LAT stereotactic coordinate, tighten screw.



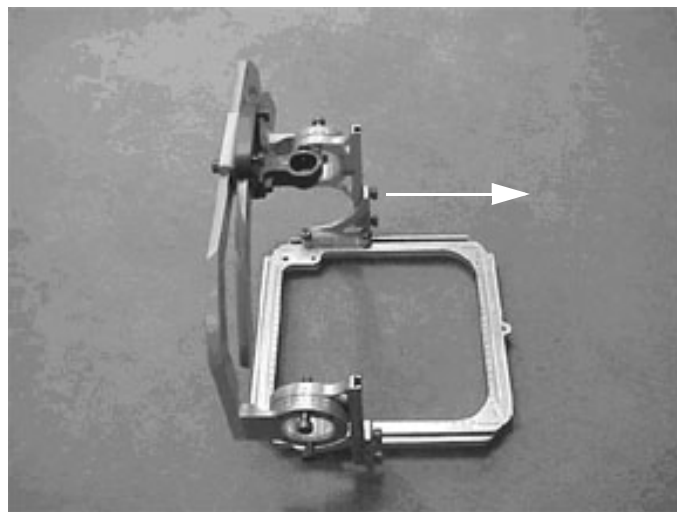
Step 16

- A. Place Arc assembly with the Base Plate
- B. Loosen all four base screws on the Trunion Supports.



Step 17

- A. Slide Arc assembly onto Base Plate.
- B. Typical clinical setup (shown) has the Guide Block Holder pointing to the Posterior.



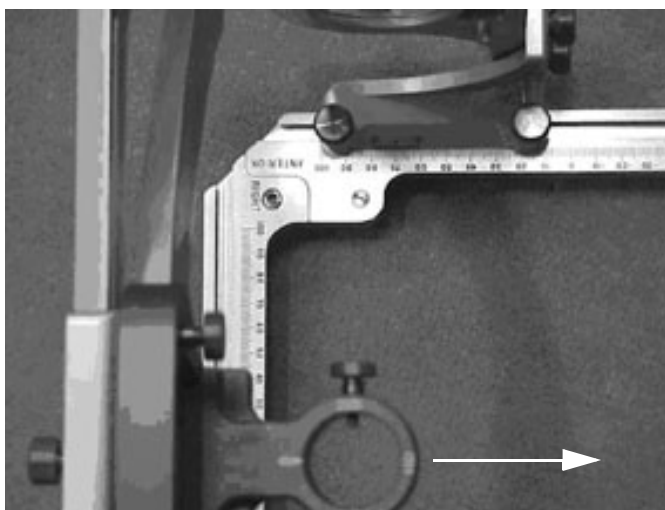
Step 18

- A. Slide Arc assembly to calculated AP stereotactic coordinate.
- B. Tighten and lock the trunion slide base screws.



Step 19

Note the Guide Block Holder is opposite the anterior side of the frame (pointing to the posterior)



Step 20

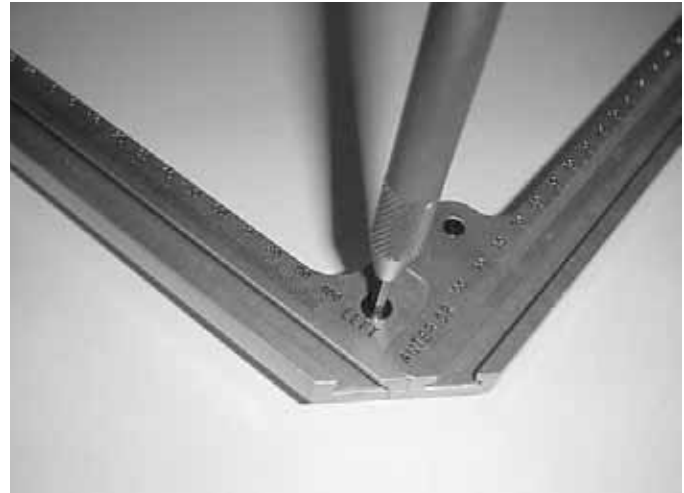
Fully assembled CRW Arc System.



Step 21 (Optional)

Remove the anterior base plate of the CRW using the arc system wrench (SWTS).

Note This will not compromise the rigidity or accuracy of the system.

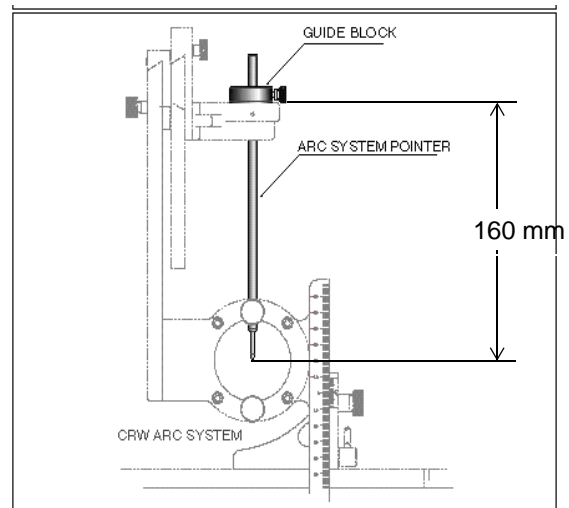


Setting the Fixed Radial Distance for the Arc System Pointer

Note The CRW Arc has a fixed radial distance of 160 mm from the resting surface on the Guide Block holder to the target.

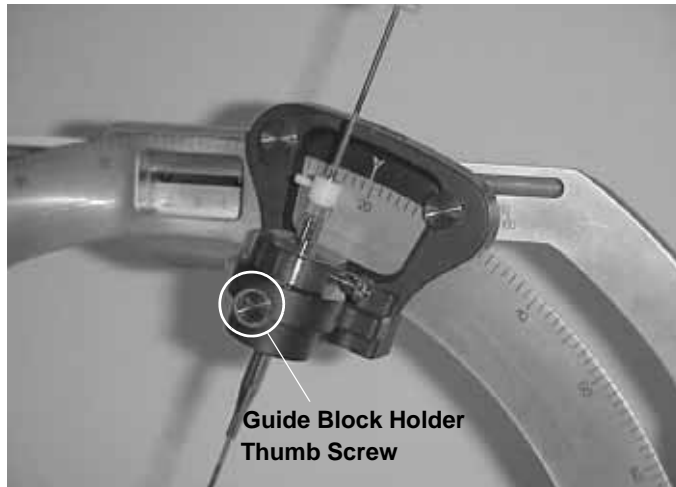
1. Place the Arc System Pointer in the Guide Block, and align the edge of a millimeter scale with the resting surface of the Guide Block.
2. Slide the Pointer in the Guide Block so that the tip of the Pointer is at **160 mm**.
3. Use the Set Screw to secure the Pointer in the Guide Block.

Note When this Pointer assembly is put into the Guide Block, the distance from the top surface of the Probe Holder to the tip of the Pointer will be 160 mm.



-
4. Place the Guide Block and Arc System Pointer assembly into the Guide Block Holder.
 5. Secure the Pointer assembly with the Guide Block Holder Thumb Screw.

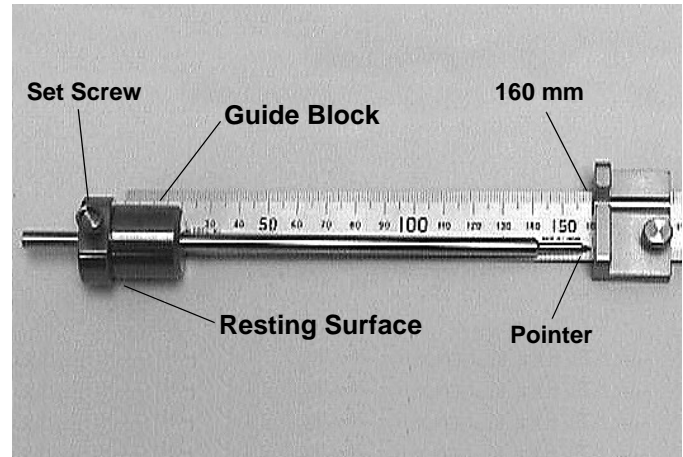
Note This prepares the setup of the Arc and instrument length for testing on the Phantom Base.



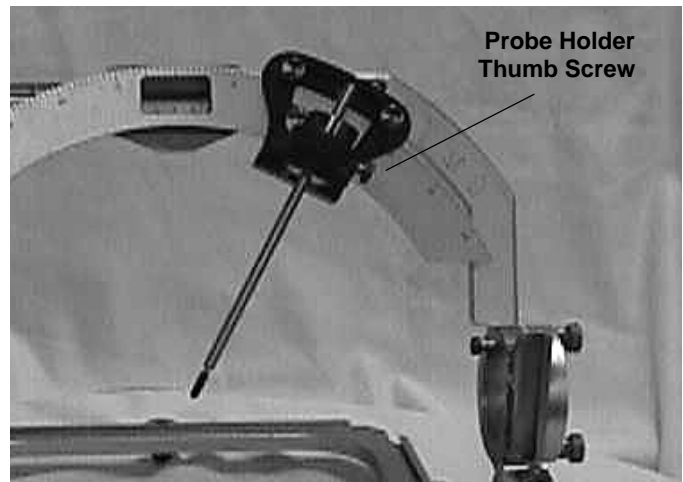
Setting the Fixed Radial Distance for an Instrument.

With the Arc System Pointer or instrument set to 160mm, and the Arc set onto the CRW-PBS Phantom Base System, the Arc System Pointer or instrument and Phantom Base Pointer will meet, if these devices have been set to the proper target coordinates

1. Put the Instrument with Depth Stop into an appropriate Guide Tube, and slide this assembly into the Guide Block.
2. Place the 0 mm edge of a millimeter scale against the resting surface of the Guide Block.
3. Loosen the Depth Stop Set Screw so that the Instrument slides freely in the Guide Block.
4. Adjust the length of the instrument in the Guide Tube so that its point is at **160 mm**, and tighten the Set Screw.



5. Place the Guide Block, Guide Tube, and Instrument into the Guide Block Holder and secure with the Guide Block Holder Thumb Screw.



Selecting the Guide Tube and Reducing Tube/Bushing Combinations

Guide Tubes

Guide Tubes fit directly into the Guide Block and have a 6.35 mm outer diameter. They are specified by **GT** followed by inner diameter and length in mm. Guide Tubes with 2.7 I.D. must be used with Reducing Bushing RB27 or with a compatible length reducing tube. Guide Tubes with 3.2 mm I.D. must be used with RB32 to guide 3.2 mm O.D. drills. Guide Tube GT46116 is used with 4.6 mm O.D. drills and does not require a Reducing Bushing or a Reducing Tube.

Reducing Tubes and Reducing Bushings

Reducing Tubes and Reducing Bushings are screwed into Guide Tubes so that the combination has a proper inner diameter for stereotactic guidance of various electrodes, cannulae, and needles.

Reducing Tubes are specified as **RT** followed by the nominal outer diameter of the instrument to be guided and the length of the Reducing Tube in mm. All Reducing Tubes are only compatible with Guide Tubes with 2.7 mm I.D. and matching length. For example, RT20(X) Reducing Tubes screws into GT27(X), where X=76, 116 or 160 mm, and guide 2.0 mm O.D. probes.

RB27 and RB32 Reducing Bushings also screw into the GT27(X) and GT32(X) Guide Tubes, respectively, to provide proper guidance of 2.5 to 2.7 mm probes and 3.0 to 3.2 mm probes, respectively. Reducing Bushings are commonly used with Drill Assemblies.

Nashold Biopsy Needle (NBND)

To use the NBND needle:

RTNBND76 and GT2776

-or- RTNBND116 and GT27116

-or- RTNBND160 and GT27160

Drill Assemblies

DA27 is a 2.7 mm diameter twist drill that can make a skull hole through the standard GT27(X) Guide Tubes. (X = 76, 116, 160). The drill is fitted with a depth stop and knurled knob. The knob facilitates gripping and twisting the drill by hand.

To use the Drill Assemblies:

DA27 Drill Assembly: RB27 and GT27(X) (X = 76, 116, or 160)

DA32 Drill Assembly: RB32 and GT32(X) (X = 76, 116, or 160)

DA46 Drill Assembly: GT46116

DA63 Drill Assembly: DA63GS and DA63GB

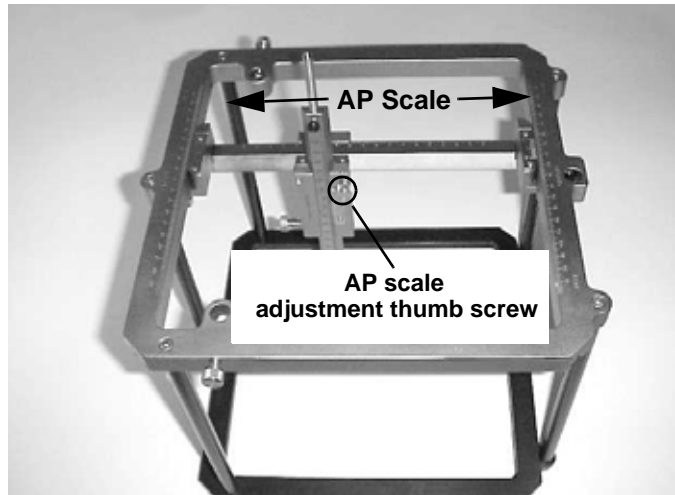
Assembling the Arc System to the Phantom Base

The Phantom Base Assembly:



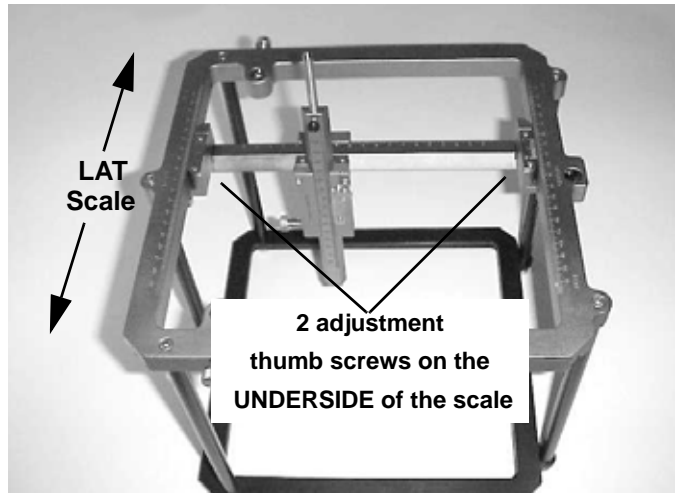
1. Adjust the AP, Lat, and Vert of the target on the Phantom Base scales

A. AP Scale adjustment thumb screw:

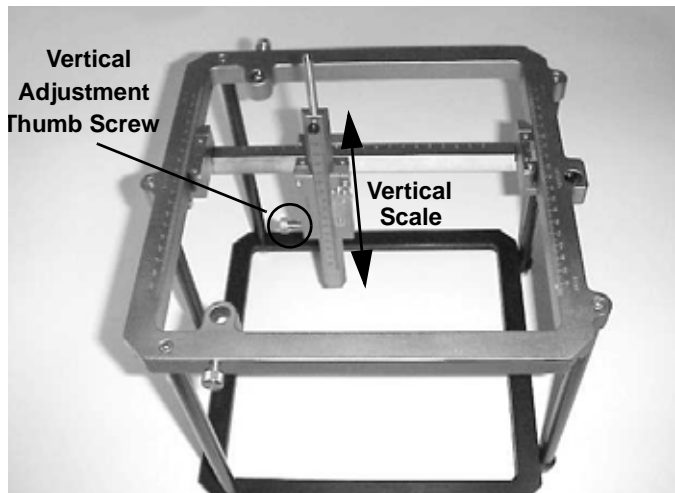


B. Lateral Scale adjustment thumb screws:

Caution *The Lateral Scale adjustment screws are located on the underside of the scale. Do not remove the screws on the top of the scale; this will result in disassembly of the Scale and cause the Scale to be inaccurate.*



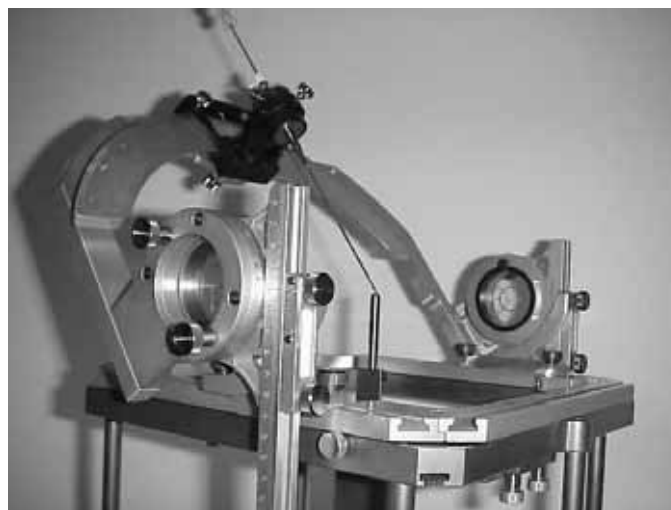
C. Vertical Scale adjustment thumb screw:



-
2. After setting both the Phantom Base Target and the Arc System Target coordinates (see Chapter 4), place the Arc System on the Phantom Base so that the Arc System Pointer and the Phantom Pointer are in alignment.

Note Use the Phantom Base to check the Probe depth before surgery, whenever possible.

Note To further check the accuracy of the coordinate settings, loosen and rotate the upright Arc to verify that the tips of the pointer and probe do not move away from each other.

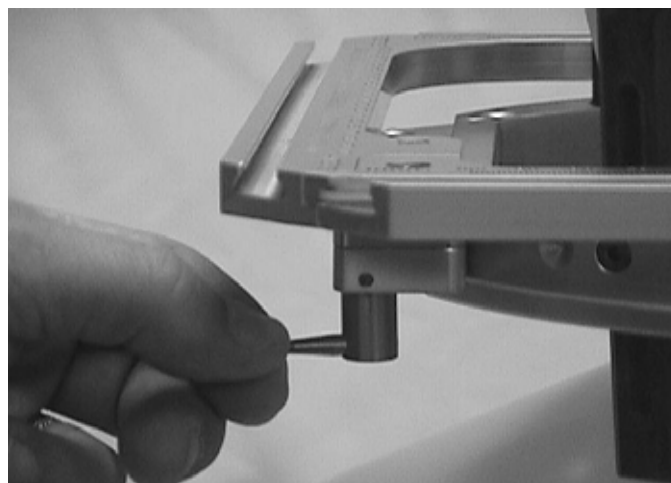


Assembling the Arc to the Head Rings

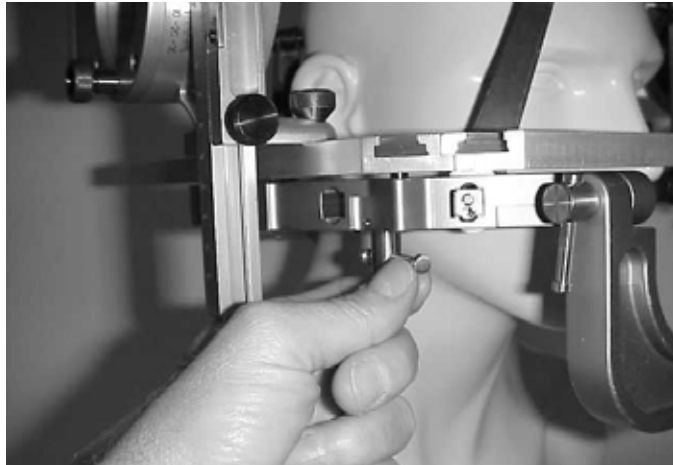
Note The Arc System attaches to both the HRAIM and the UCHRA in only one orientation.

Note Before attaching the CRW Arc to the UCHRA, make sure to assemble the UCHRA with the Adapter Plate.

1. Fit the three fixation ball feet on the bottom of the Arc Base into the ball sockets of the UCHRA Arc Adapter, or into the ball sockets of the HRAIM.
2. Secure the cam locks.



-
- The assembled Arc and HRAIM:



Attaching the Head Ring to the Operating Table

This procedure requires the MAYFIELD® Adapter and the CSS bolts.

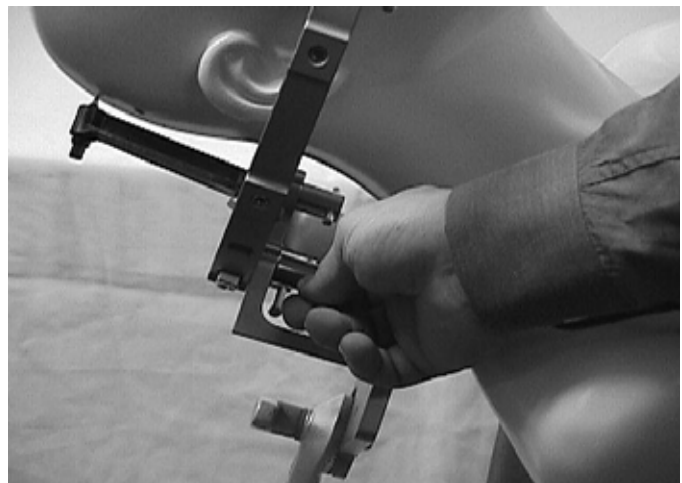
Attaching the UCHRA or the HRAIM to the Operating Table

1. Clamp the MAYFIELD® Adapter to the operating table as shown.



2. Attach the UCHRA or HRAIM to the MAYFIELD Adapter using the short T-Bolts.

Note Place the CSS T-Bolts onto the frame and guide the patient onto the CRWMA Mayfield Adapter to ease locking of the frame to the MAYFIELD Adapter.



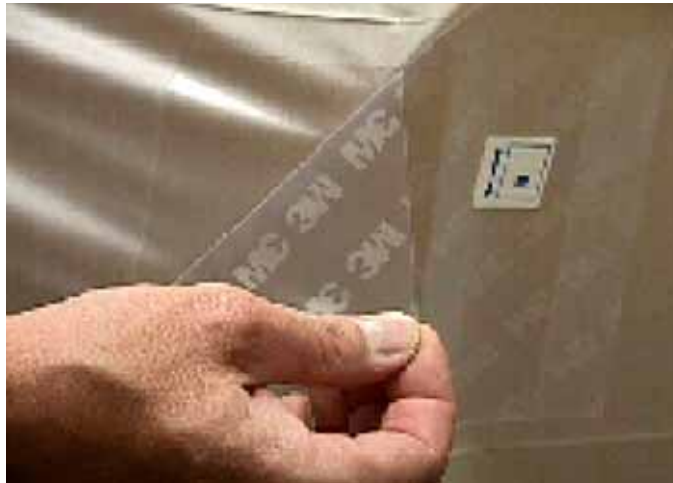
Creating a Sterile Field

1. After the patient is secured to the OR table, place an Apuzzo Sterile Drape over the Head Ring. The Drape has a centered adhesive patch for the patient's head and holes with adhesive that align with the sphere sockets on the Arc Adapter or the HRAIM.

Note Shave and prep the surgery area. Coat hair with lubricant to prevent the Drape from sticking to the hair.



2. Remove the backing of the center adhesive area.



3. Place the Drape firmly over the patient's head at the area where the entry point will be.



-
4. Remove the adhesive backing from the hole areas.



5. Secure the Drape to the Arc Adapter or HRAIM.



6. The following illustration shows the Arc System being placed over the Sterile Drape.



CHAPTER 3 SCANNING WITH THE CRW[®] STEREOTACTIC SYSTEM

Scanning the Luminant [®] Localizer Frame	45
Manually Calculating the Luminant Target Positions	45
Scanning the BRW Localizer Frame	50

Scanning the Luminant[®] Localizer Frame

The Luminant[®] MR/CT localizer frame (**LL01**) is a universal localizer designed for use in both MR and CT imaging. The frame is designed to fit the Universal Compact Head Ring (UCHRA) during standard MR or CT imaging. The Luminant localizer can be used with StereoCalc[™], NeuroSight[®] Arc, or other appropriate target/trajectory–calculation applications. For complete instructions on scanning the Luminant localizer, see the *Luminant Localizer Instructions for Use*.

Manually Calculating the Luminant Target Positions

After scanning the patient in the Luminant localizer, you can manually calculate the positions of targets for axial, coronal, and sagittal scans.

Note These calculations are performed directly on the CT or MR console.

Note There is no difference between CT and MR regarding the actual calculations.



It is critical to understand which side of the scan corresponds to patient–right and patient–posterior. Pay close attention to the orientations of the images shown in the scanner; the geometry may be reversed.

Be extremely careful with negative numbers when performing hand calculations. Not all scanners discriminate between positive and negative directions.

Scans must be acquired orthogonal to the localizer for manual calculations.

The distances and coordinates correspond as follows:

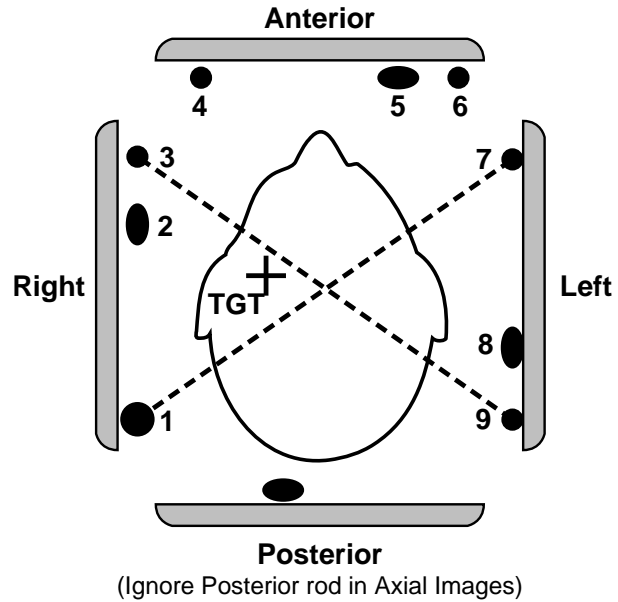
- LAT = X
- AP = Y
- VERT = Z

Calculating Target Positions for Axial Scans

Find The Center of the AP-LAT Plane

1. Select an axial slice that best shows the desired target.
2. Locate Rod 1, on the patient's Right-Posterior, and Rod 7, on the patient's Left-Anterior. Draw a line connecting the centers of those two rods.
3. Locate Rod 3, on the patient's Right-Anterior, and Rod 9, on the patient's Left-Posterior. Draw a line connecting the centers of those two rods.

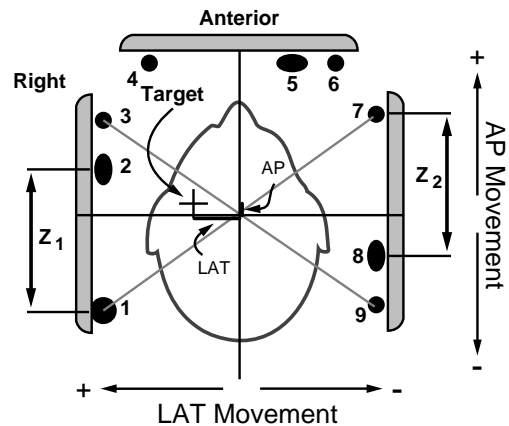
Note The intersection of these two lines marks the center point **(0,0)** of the **AP-LAT** plane.



Find the AP and LAT Distances to the Target

1. Use a scanner function to place a grid or set of axes on the screen. A point of this grid must be at the center **(0,0)** of **AP-LAT** plane.
2. Measure the **AP** and **LAT** distances from the center point **(0,0)** of the **AP-LAT** plane to the target.

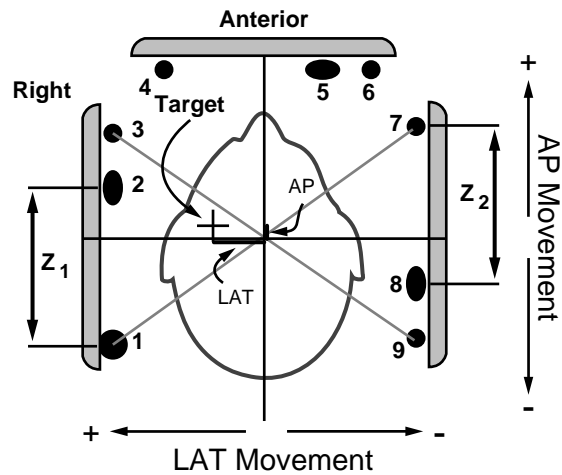
Note The position of the target is relative to the origin of the **AP-LAT** plane. Movements from patient Left-to-Right or patient Posterior-to-Anterior produce positive numeric values, while movements from patient Right-to-Left or patient Anterior-to-Posterior produce negative numeric values.



Find the VERT Coordinates to the Target

1. Measure the distance from the center of Rod 1 to the center of Rod 2. Record this value as Z_1 .
2. Measure the center-to-center distance between rods 7 and 8. Record this value as Z_2 .
3. Calculate Z , where $Z = [Z_1 + Z_2]/2$.
4. Calculate the VERT coordinate:
 - $VERT = Z - 60\text{mm}$

Note A positive value is above the center of localizer frame (Superior); a negative value is below center (Inferior).

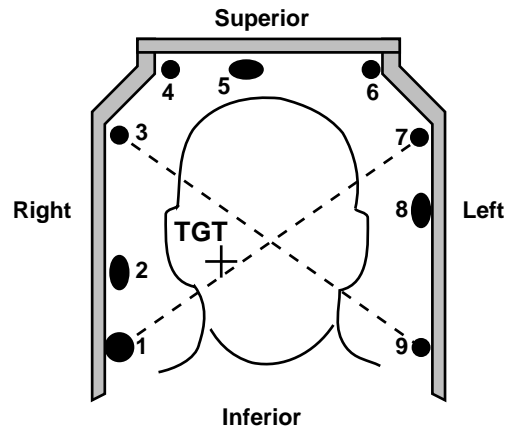


Calculating Target Positions for Coronal Scans

Find the Center of the LAT-VERT Plane

1. Select a coronal slice that best shows the desired target.
2. Locate Rod 1, on the patient's Right-Inferior, and Rod 7, on the patient's Left-Superior. Draw a line intersecting the centers of those two rods.
3. Locate Rod 3, on the patient's Right-Superior, and Rod 9, on the patient's Left-Inferior. Draw a line connecting the centers of those two rods.

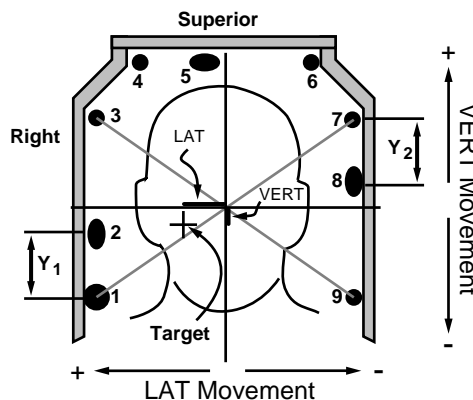
Note The intersection of these two lines marks the center point (0,0) of the LAT-VERT plane.



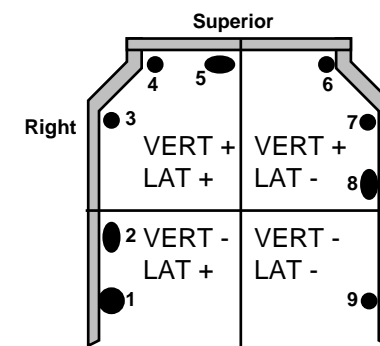
Find the LAT and VERT Distances to the Target

Note Make sure that the image is not skewed or tilted.

1. Use a scanner function to place a grid or set of axes on the screen. A point of this grid must be at the center **(0,0)** of **LAT-VERT** plane.
2. Measure the **LAT** and **VERT** distances from the center point **(0,0)** of the **LAT-VERT** plane to the target. The scanner may perform a distance function from **(0,0)** to the target and provide **x** and **y** ordinates automatically.



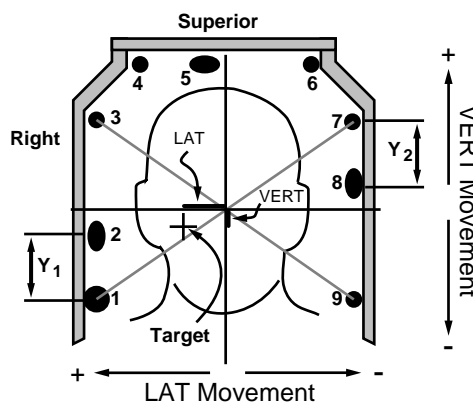
Note The position of the target is relative to the origin of the **LAT-VERT** plane. Movements from patient Left-to-Right or patient Inferior-to-Superior produce positive numeric values, while movements from patient Right-to-Left or patient Superior-to-Inferior produce negative numeric values.



Find the AP Coordinates

1. Measure the distance from the center of Rod 1 to the center of Rod 2. Record this value as Y_1 .
2. Measure the center-to-center distance between rods 7 and 8, and record this as Y_2 .
3. Calculate Y , where $Y = [Y_1 + Y_2]/2$.
4. Calculate the AP coordinate:
 - $AP = Y - 60\text{mm}$

Note A positive value is in the anterior direction; a negative value is in the posterior direction.



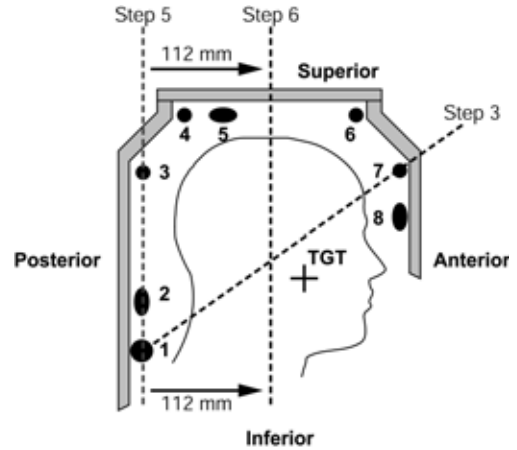
Calculating Target Positions for Sagittal Scans

Find the Center of the AP-VERT Plane

1. Select a sagittal slice that best shows the desired target.
2. Locate Rod 1, on the patient's Posterior-Inferior, and Rod 7, on the patient's Anterior-Superior. Draw a line intersecting the centers of those two rods.
3. Draw a straight line through the centers of Rods 1, 2 and 3.
4. Draw a parallel line, **112 mm** towards the Anterior.

The intersection point of the two lines marks the center **(0,0)** of the **AP-VERT** plane.

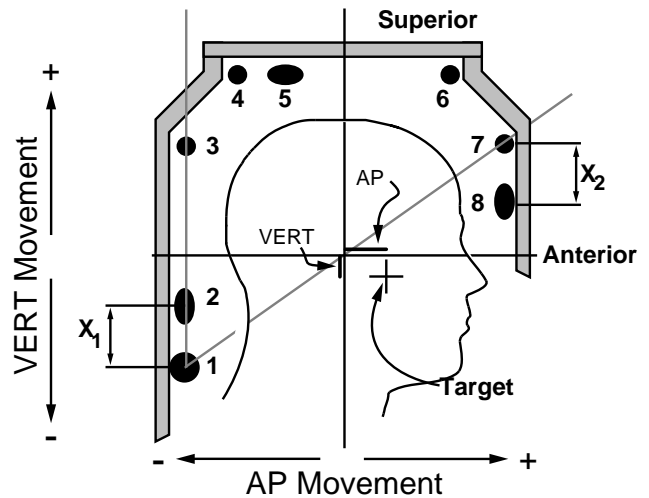
Note The origin is 112 mm from Posterior, but 105 mm from Anterior.



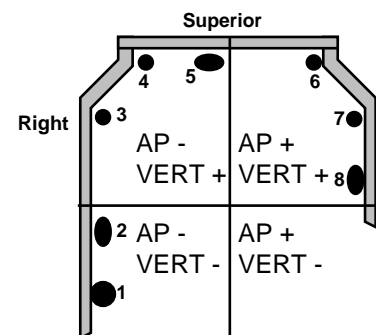
Find the AP and VERT Distances to the Target

Note Make sure that the image is not skewed or tilted.

1. Use a scanner function to place a grid or set of axes on the screen. A point of this grid must be at the center **(0,0)** of **AP-VERT** plane.
2. Measure the **AP** and **VERT** distances from the center point **(0,0)** of the **AP-VERT** plane to the target. The scanner may perform a distance function from **(0,0)** to the target and provide **x** and **y** coordinates automatically.



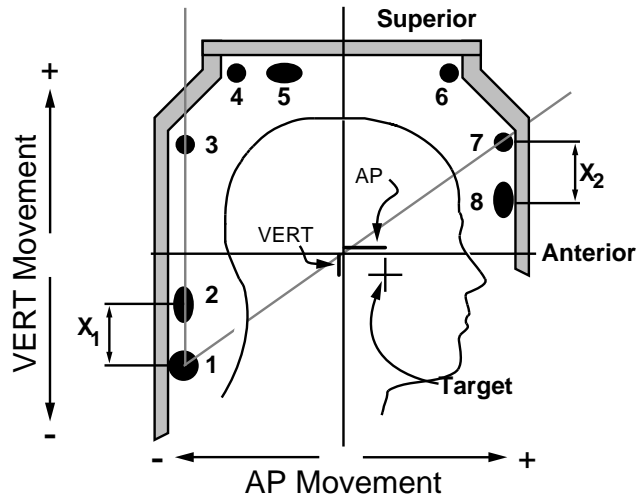
Note The position of the target is relative to the origin of the AP-VERT plane. Movements from patient Posterior-to-Anterior or patient Inferior-to-Superior produce positive numeric values, while movements from patient Anterior-to-Posterior or patient Superior-to-Inferior produce negative numeric values.



Find the LAT Coordinate

1. Measure the distance from the center of Rod 1 to the center of Rod 2. Record this value as X_1 .
2. Measure the center-to-center distance between rods 7 and 8. Record this as X_2 .
3. Calculate X , where $X = [X_1 + X_2]/2$.
4. Calculate the LAT coordinate:
 - $LAT = X - 60\text{mm}$

Note A positive value is to the patient's right; a negative value is to the patient's left.



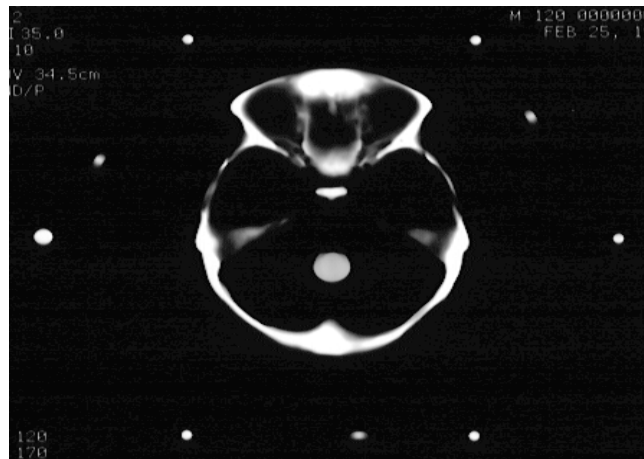
Scanning the BRW Localizer Frame

The Brown, Roberts, and Wells Localizer Frame (**BRWLF**) is used for spatial localization of target coordinates for targets seen in a CT image. The localizer enables calculation of stereotactic targets and trajectories relative to the head ring assembly, using data taken from a scan slice. The BRW frame can be used with the StereoCalc™, NeuroSight Arc, or other appropriate target approach calculation applications.

Note Refer to the appropriate User's Manual for complete instructions on data collection and use.

Collecting CT Scan Rod Position Data

1. Collect CT data after the patient scan.
2. Use a scanner function to determine each of the rod position coordinates on the BRW localizer frame. Note that the number 1 rod is the largest, while the number 2 rod appears closest to the number 1 rod.
3. Record these coordinates.



CHAPTER 4 SETTING TARGETS ON THE CRW[®] ARC

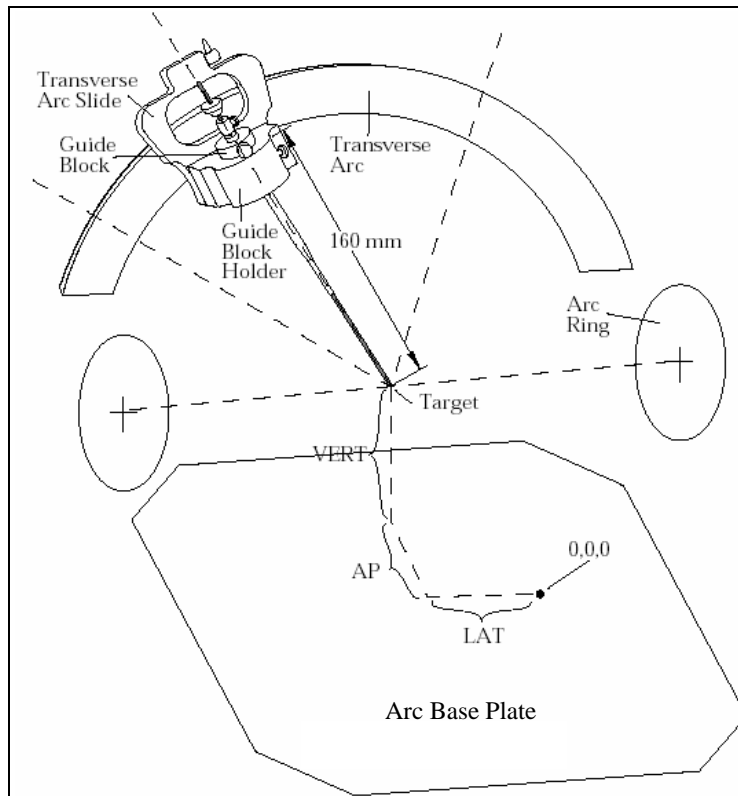
About the Arc System 51

Measuring Arc System Coordinates with the Vernier Scale 54

About the Arc System

The coordinate scales on the CRW[®] Arc System directly correspond to target positions relative to the Head Ring Assembly. The Arc is a target-centered system: the probe path, relative to the Transverse Arc, is a radius for that Arc. Therefore, for any position of the Guide Block Holder, any radius corresponding to that position will pass through the target. Similarly, for any rotation angles of the Arc Trunion Rings, the corresponding probe path will pass through the target.

The target lies on the center of the Transverse Arc circle and on the center line between the Trunion Rings



Target Position as Center of Arc

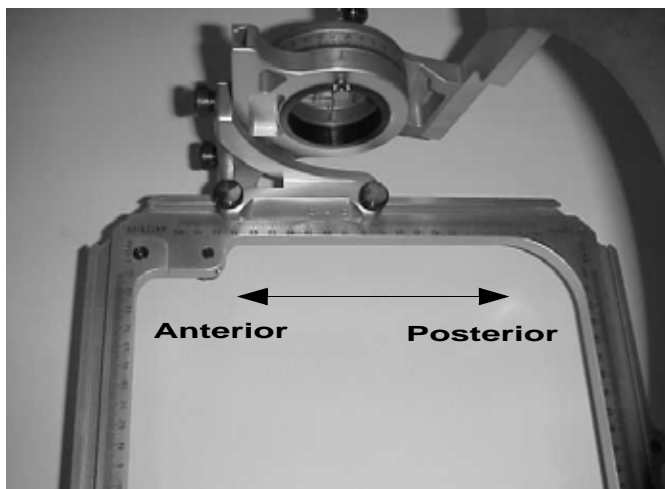
All radii of the Transverse Arc always pass through the target, and the target position equals the center of the Transverse Arc for all Arc Slide and Ring angles.

About the Arc System Coordinates

AP (Anterior–Posterior) Scales

The **AP** scales of the Arc Base are ruled in increments from **0** to **100** mm in both the anterior and posterior directions. A negative sign (–) is stamped next to posterior numbers.

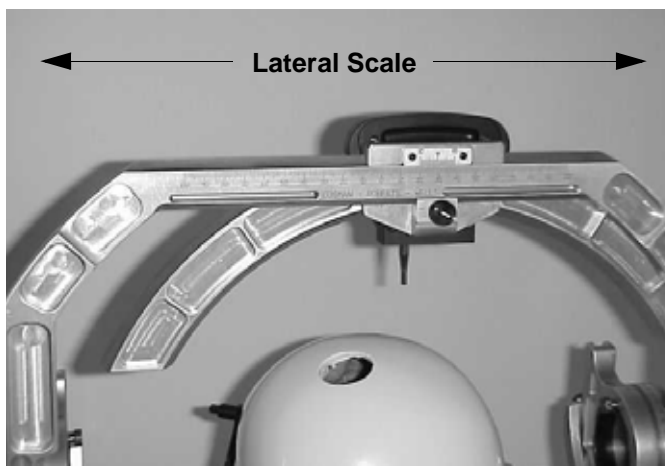
Note The words **Anterior** and **Posterior** are engraved on the corresponding ends of the Base.



LAT (Lateral) Scales

The **LAT** scales are at the front and rear of the upright Arc assembly.

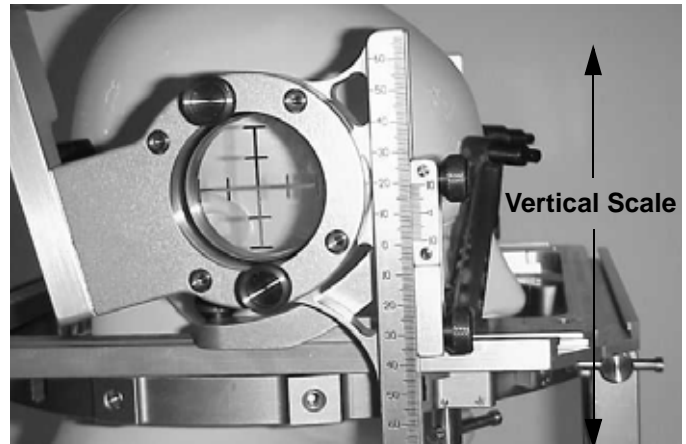
- The scales runs from **0** to **100** mm to the right and left sides of center.
- Negative numbers have a negative symbol (–), and are shown on the corresponding base plate scale.
- The words **Right** and **Left** are stamped on the corresponding ends on the corresponding base plate of the scale.



Vert (Vertical) Scales

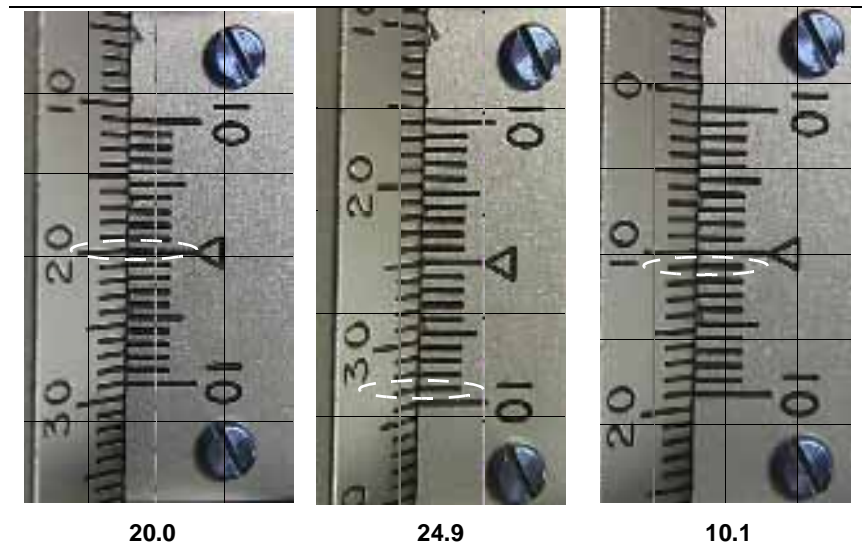
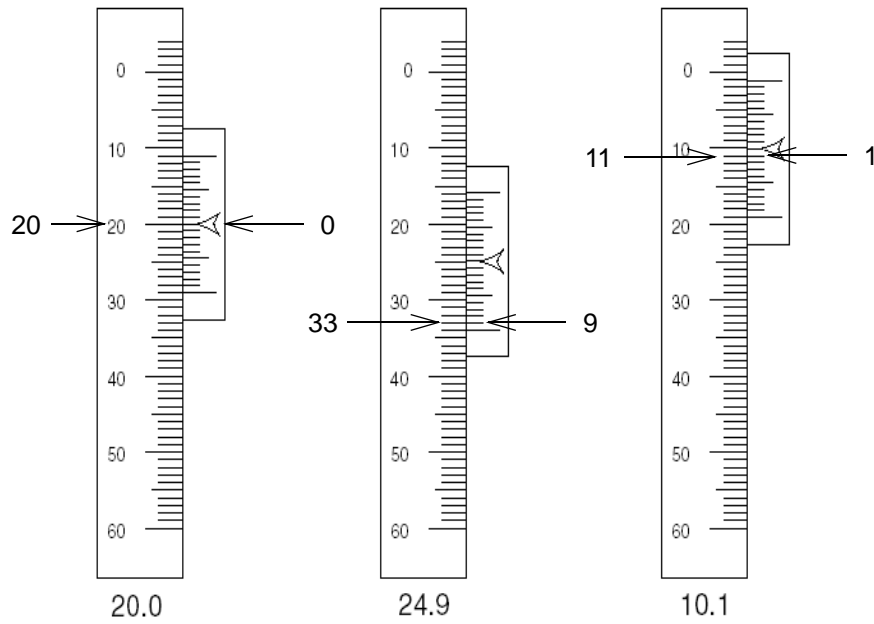
VERT scales are engraved on the Trunion Slides.

- The scale ranges from **0** to **80** mm as the Trunion Rings are lifted, and **0** to **-60** mm as the Trunion Rings are lowered.



Measuring Arc System Coordinates with the Vernier Scale

This topic describes how to set coordinates using a vernier scale. The following illustrations show sample vernier settings for **20.0**, **24.9**, and **10.0**:



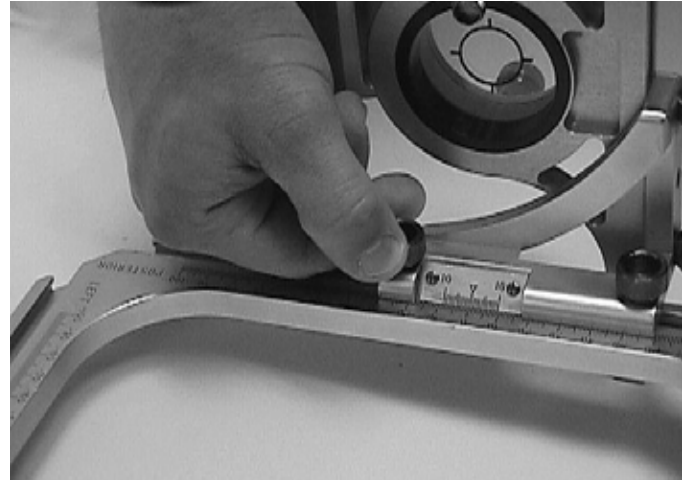
A simple method of setting the vernier scale:

1. To set 24.9, add $24+9=33$.
2. Move the #9 mark on the vernier scale to line up with the “33” on the whole scale.

Setting the Coordinates with a Vernier Scale

Setting the AP (Anterior–Posterior) Coordinates

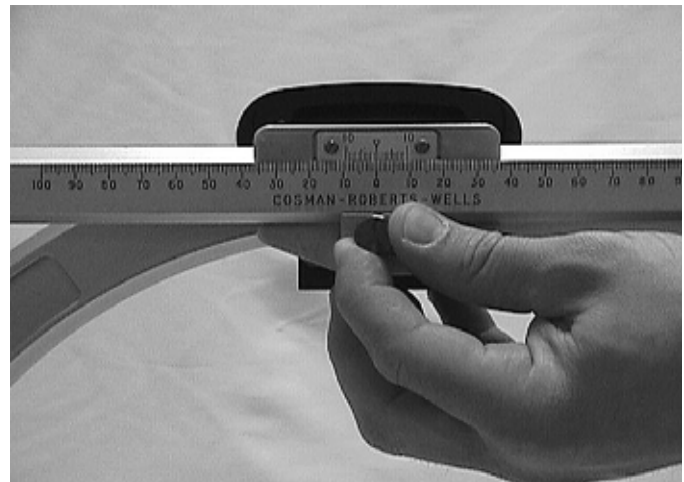
Loosen thumb screws and align the Trunion Slide scale with the appropriate **AP** target value on the Arc Base, then tighten the thumb screws.



Setting the LAT (Lateral) Coordinates

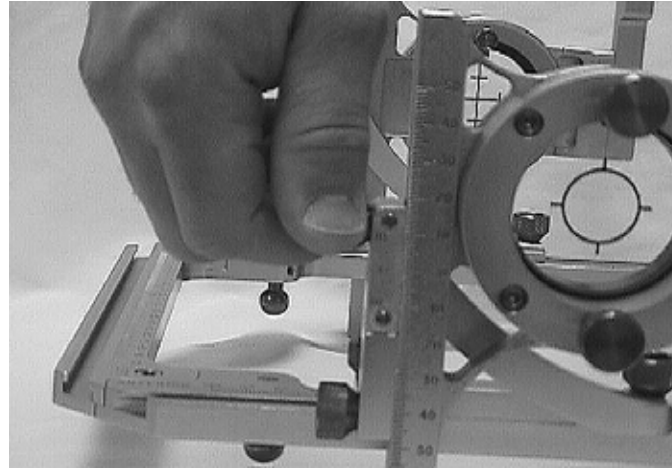
1. Loosen the Lateral Slide Lock Screw on the back of the Arc Slide, and align the Arc Slide scale with the appropriate value on the Arc Frame.
2. Tighten the Lateral Slide Lock Screw.

Caution *The Upright Arc Assembly scale is not stamped with positive (+) or negative (-) symbols. Use the corresponding Arc Base scale to set the appropriate positive or negative value on the Arc Slide.*



Setting the VERT (Vertical) Coordinates

While supporting the Arc Frame, loosen the Trunion Slide Screws and set the **VERT** coordinate on each vertical scale.

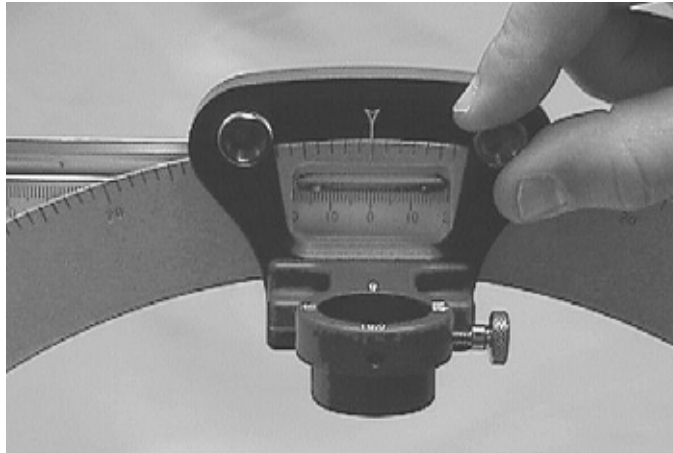


Setting the Guide Block Holder Approach Angle

Once the **AP**, **LAT**, and **VERT** coordinate settings are secure, adjust the Guide Block Holder angle.

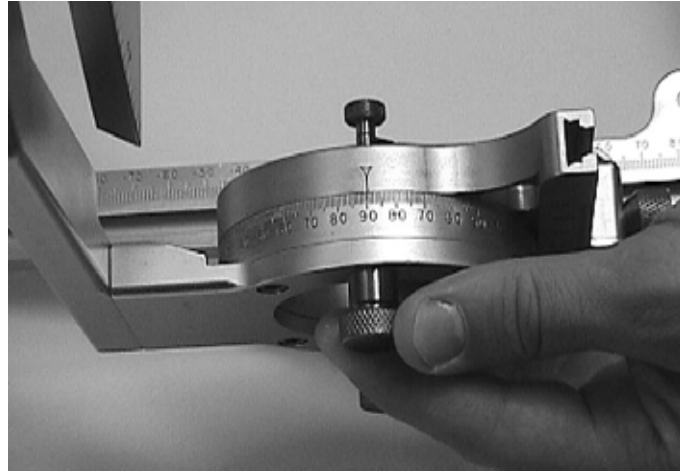
1. Loosen Guide Block Holder Thumb Screws and slide the Holder to the appropriate angle.
2. Tighten the Thumb Screws simultaneously:

Note To avoid torque on the Guide Block holder, tighten both the screws at the same time.



Setting the Trunion Ring Approach Angle

Loosen the Trunion Ring Thumb Screw and set the Ring scale.



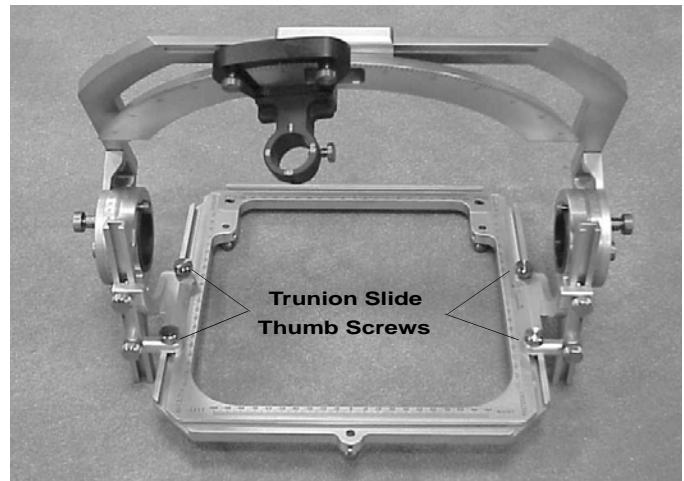
Transposing the Arc Rings

Trunion Rings can be transposed from a **left-to-right** to an **anterior-posterior** orientation on the Arc Base.

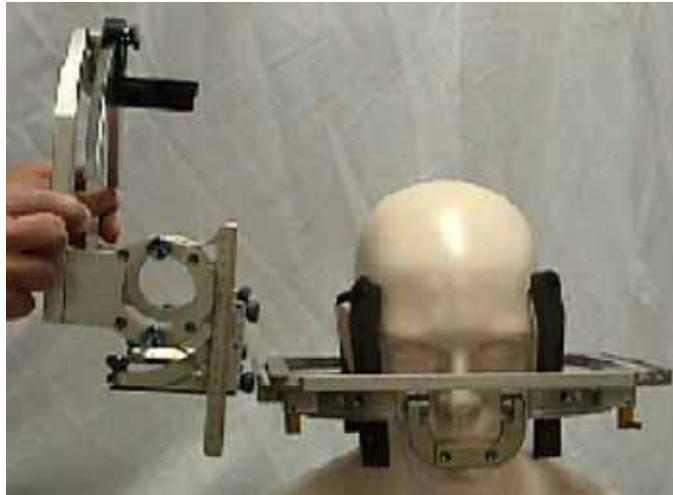
Note Before transposing the Trunion Rings, confirm that both Trunion Slide **vertical** scales are set to the same coordinate and that there is no tension or torque between the two Trunion Rings. This check will ensure that the Arc Assembly slides off and on the Base easily

Transpose the Trunion Rings

1. Loosen the Trunion Slide Thumb Screws and slide the Arc Assembly off the Base.



-
2. Rotate the Assembly 90° degrees, slide it onto the Base, and tighten the Thumb Screws.



With the Arc trunion rings set along the anterior-posterior axis of the arc base, the trunion slides will move along the LAT tracks of the base plate. In this orientation, the A-P target coordinate is set on the transverse arc coordinate scale, and the LAT target coordinate is set with the trunion slide.

Note that LAT and AP target coordinates, and their positive/negative values, are always derived from the base plate no matter what the orientation of the arc.

Using Parallel Trajectories

To approach several targets via parallel tracts:

1. Set the **AP**, **LAT**, and **VERT** slides and arc angle slides for the first target coordinates.
2. Keeping the Arc angles constant, set each additional target.

Entering Multiple Targets Through a Single Burr Hole

To approach several targets through a single burr hole:

1. Set the **AP**, **LAT**, and **VERT** coordinates on the Arc for the first target.
2. Position the two Arc angles so that the probe passes through the single burr hole.
3. Set the **AP**, **LAT**, and **VERT** coordinates for the next target on the Arc Base. The probe can then be passed through the same burr hole by adjusting the two arc angles (the Transverse Arc and the Trunion Rings).

This procedure is repeated for multiple targets.

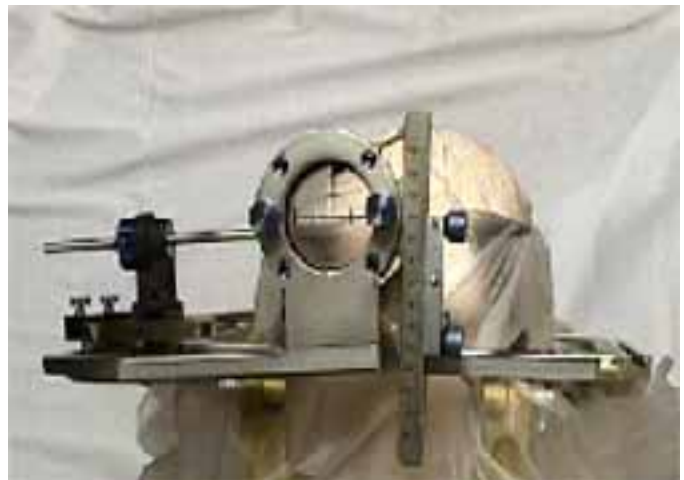
Examples of Different Arc Orientations

Lateral Approach

A lateral approach is shown with the Arc System rotated on the Arc Base.

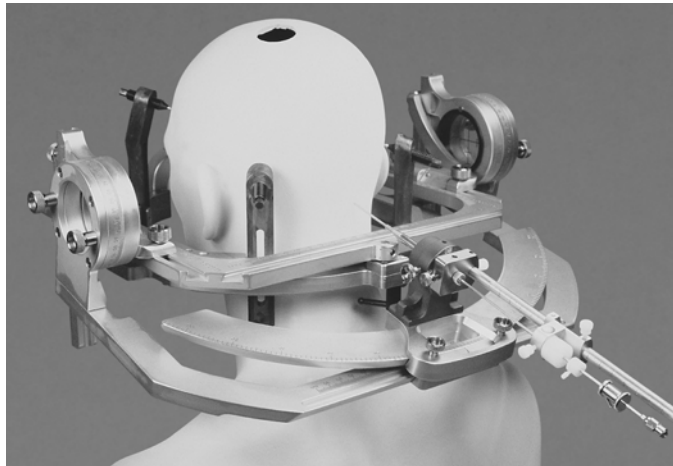


A front view of a lateral approach is shown with the Arc System rotated on the Arc Base over the Sterile Drape.

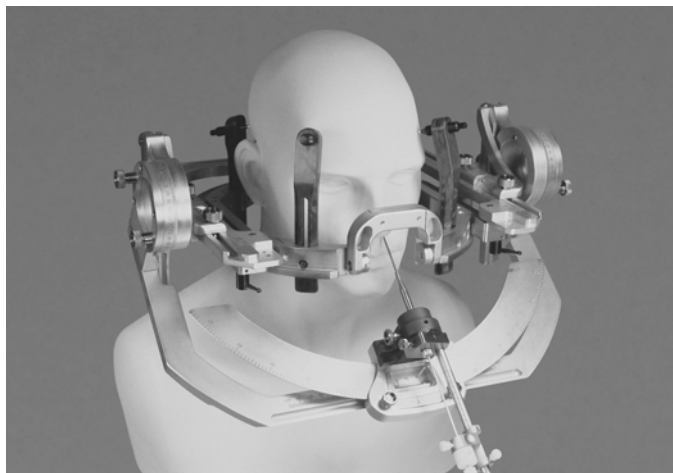


Posterior Fossa Approach

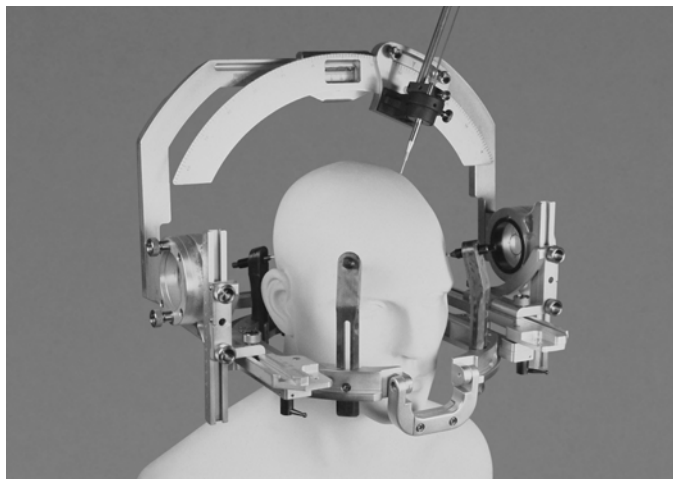
A posterior fossa approach is shown with the Arc System rotated on the Arc Base.



Transphenoidal approach shown with the Anterior Plate removed:



Standard Approach:



CHAPTER 5 USING THE CRW[®] ACCESSORIES

Tools for Calibration Guidance	61
Visualizing Lateral Trajectories with the Trunion Reticles	63
Visualizing Anterior-Posterior Trajectories with the AP Reticles	63
Clamping Patients to the CT Table.....	64
Using the Geometric Phantom for Qualifying Transfer Accuracy	64

Tools for Calibration Guidance

The Micro Slide (**CRWMS**) and Probe MicroDrive (**CRWPMDD**) enable smooth and calibrated guidance for any fine instrument or electrode. The Micro Slide and Probe MicroDrive have a scale for measuring how far a probe is inserted in the patient.

Using the Micro Slide

1. Insert the appropriate plastic bushing into slide.
2. Insert the appropriate Guide tube into the Guide Block portion of the Micro Slide.
3. Set slide to zero.
4. Insert instrument through the plastic bushing on the slide, then through the guide tube.
5. Measure the instrument to be 160 mm from the bottom lip of the Guide Block.
6. Tighten the depth stop.
7. Instrument can now be placed at any depth along the CRW[™] trajectory.



Using the MicroDrive



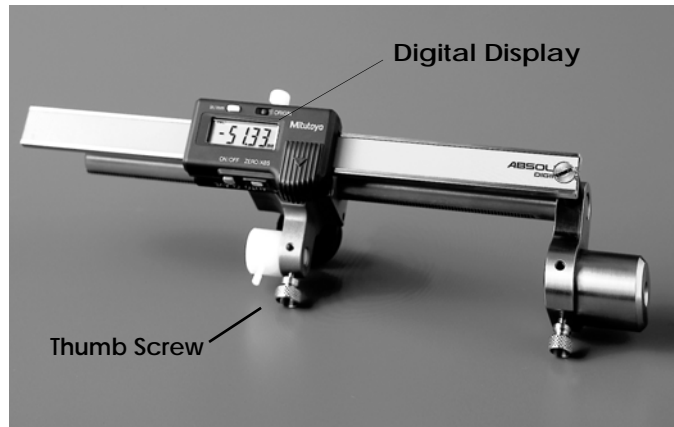
Never use the inch setting of the Digital Probe MicroDrive because all of the CRW Arc System settings are in mm.

1. Set the Digital Probe MicroDrive to millimeters by pressing the **in/mm** button on the digital display.

Note The Digital Probe MicroDrive uses both a digital readout and a verniated scale.

Caution *The digital readout will change sign when the carrier passes zero. Pay careful attention to the sign; this will identify whether the probe is above or below the target.*

2. Calibrate the digital display to zero with the verniated scale set to zero.



Measuring a Relative Distance

1. Set the digital display to show absolute distances using the **ZERO/ABS** button.

Note When the **ZERO/ABS** button is pressed in firmly, the display will turn to zero and show “**INC**” on the display.

2. Position the instrument so that the display reads the desired value.
3. Press the **ZERO/ABS** button again, and the display will reset to zero. Measure the next absolute distance.

Note The Digital Probe MicroDrive must be shut off to change from **Absolute** measurements. When turned back on, the MicroDrive will display in **Zero** mode again.

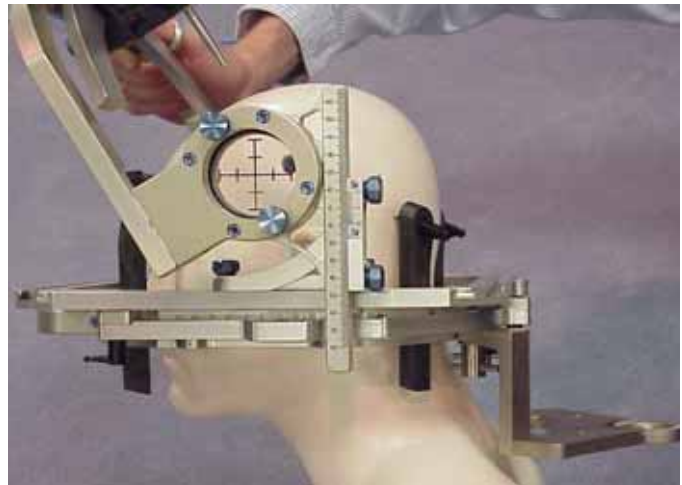
4. Recalibrate zero by pressing and holding the **ORIGIN** button until the display changes to zero.



Be sure to recalibrate the Digital Probe MicroDrive back to the zero point of the verniated scale after completing the operation.

Visualizing Lateral Trajectories with the Trunion Reticles

The Trunion Reticles (**CRWTBSS**) accommodate alignment for a lateral x-ray of the target.



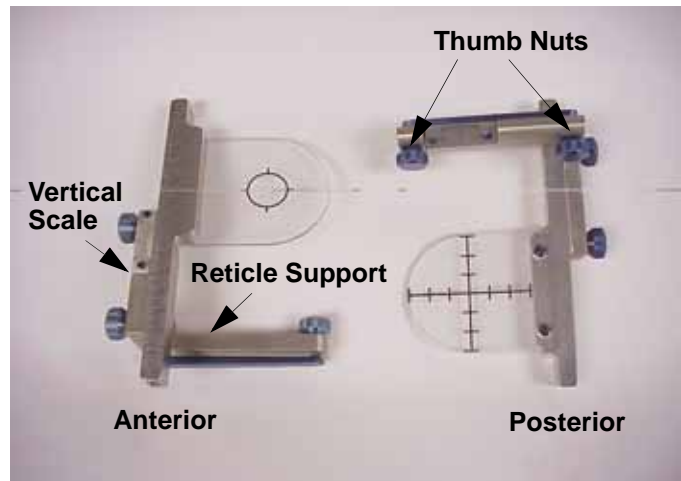
Visualizing Anterior-Posterior Trajectories with the AP Reticles

The Anterior-Posterior Reticles (**CRWAPBS**) align with the Arc to visualize the trajectory in AP view. The A-P Reticles accommodate alignment of an x-ray camera for an AP x-ray of the target.

1. Loosen the thumb nuts so that the sight support is loose, and slide the sight into the left/right track of the Arc Base.

Note Use the scale on the Base to set the Reticle lateral coordinate.

2. Tighten the thumb nuts when the reticle is in place.



-
3. Use the vertical scale on each reticle for vertical alignment.



Clamping Patients to the CT Table

Clamping Plates for CT Scanners are used when there is a need to clamp the patient to the CT table in order to hold the patient's head still. For more information, contact Integra Radionics technical support for specific information.

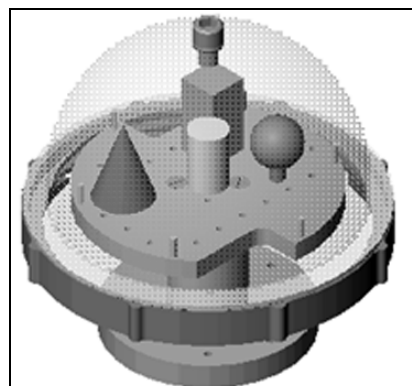
Using the Geometric Phantom for Qualifying Transfer Accuracy

The Geometric Phantom qualifies the transfer accuracy between the scanner and specific Integra Radionics software. It provides a full independent check that the Head Ring, Localizer, CT or MR scan images and software all give accurate volumetric target localization.

About the Geometric Phantom

The Geometric Phantom is a plastic globe with a removable top and precisely located structures inside the globe. The GEO-Phantom attaches to various stereotactic Head Ring Assemblies.

GEOPH1:	Phantom for HRAIM
GEOPH3:	Phantom for UCHRA



CHAPTER 6 **CLEANING, STERILIZING, AND MAINTAINING THE CRW®**

Cleaning the CRW® Components	65
Disassembling the CRW Components	66
Packing the CRW Components	67
Sterilizing the CRW Components	68
Maintaining the CRW System	70

Cleaning the CRW® Components

Note The use of Betadine and other related fluids containing iodine may stain the surface of the stereotactic system. To minimize discolorization, wipe off any traces of Betadine and similar solutions as soon as a possible during or following the surgery.

Cleaning the HRAIM and UCHR Components

Use the following guidelines when cleaning the Universal Compact Head Ring (UCHR) components (Head Ring, Posts, Screws, and CT Intubation Head Ring):

Caution *Do not use saline, as it will attack the metal surface. Do not use corrosive agents, such as Clorox® or Cidex®. Do not use alcohol or hydrogen peroxide on any black composite materials.*

- After each procedure, clean components with de-ionized distilled water to remove any residue of Betadine, blood, CSF or other debris.
- Thoroughly dry and wrap components for sterilization.
- Remove any liquids from components as soon as possible after surgery to prevent corrosion or tarnishing of the surfaces.
- The cleaning tap (TAP) may be used to remove debris from inside the head ring post threads. Insert fully and remove the tap to cleanse the thread.

Cleaning the BRWLF and Luminant® Localizer Frames

The localizer frames are not exposed to the surgical environment and should not be sterilized. However, if grease or other dirt accumulates on the Frame, wipe it down with distilled water and promptly dry.

Cleaning the CRW Arc System



If the Arc system is soaked in bleach, disassemble the Guide Block, Guide Tube, and other removable parts to ensure that the bleach is thoroughly rinsed off.

Because the CRW Arc System is exposed to blood, CSF, Betadine, and other solutions, it is mandatory to adhere to the following procedures:

- Wash the Arc System with distilled, de-ionized water and mild hand cleaner after surgery to remove all traces of potentially corrosive fluids.
- Examine the T-slots on the base of the arc and wipe off any solution residue with a cloth or Q-tip.
- Remove the Guide Block from the Guide Block Holder while still wet. If either component is exposed to ionic solutions and remains wet, galvanic action may occur.
- Dry the Arc System promptly after washing.
- Wrap the arc in Sterile Drapes during storage to protect it from physical damage.

Note Moving parts of the Arc System may be lubricated with a medical silicone spray lubricant.

Note Use of alcohol may remove the black on the CRW system scales.

Cleaning Miscellaneous CRW Parts



If instruments are exposed to highly caustic solutions such as bleach solutions, immediately rinse the instruments with de-ionized distilled water to prevent corrosive damage to surfaces and moving parts.

Clean the CRW Mayfield Adaptor, CT Clamping Plate, T-Handle Adaptor Screws, Head Ring Wrenches, Tap, and Drill Assemblies as described above for the CRW Arc System.

Disassembling the CRW Components

The CRW Stereotactic System should be disassembled prior to sterilization to the point that the components fit into the CRW sterilization case. Further disassembly is **not** required for sterilization. Any disassembly that requires a hex wrench is not required to prepare the CRW for sterilization. Disassembly that requires a hex wrench may compromise the calibration of the CRW system. Specifically, the CRW trunion rings and vernier scales should never be fully disassembled.

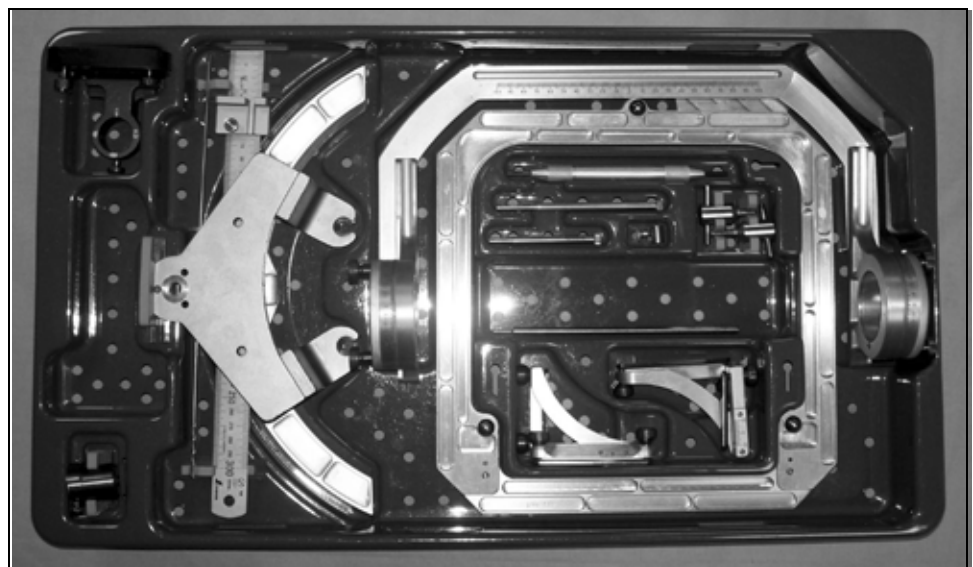
Packing the CRW Components

Pack the CRW components into the sterilization trays after cleaning and before sterilization

Placing the UCHRA in the Sterilization Case



Placing the CRW Arc in the Sterilization Tray



Sterilizing the CRW Components



Whenever virus–contact with the instrumentation is possible, proper sterilizing measures must be followed. It is the responsibility of hospital personnel to review sterilization procedures for susceptible components and to implement procedures addressing such hazards.

Caution *Do not sterilize the localizer frame. Sterilization will destroy this component.*

Parameters for Sterilizing the CRW Components

The following tables provide recommended sterilization parameters for the CRW Stereotactic System. Due to variations in sterilization chambers and load configurations, it is the responsibility of the facility to determine a sterilization protocol that ensures sterility of the device.

EtO (100% EtO)		
Parameters:	Option 1	Option 2
Concentration:	≥ 725 mg/L	≥ 600 mg/L
Temperature:	≥ 130° F	≥ 130° F
Exposure Time:	≥ 60 minutes	≥ 120 minutes
Humidity:	30-80% RH	30-80% RH

Steam AutoClave (Gravity)		
Parameters:	Option 1	Option 2
Temperature:	250°F / 121° C	270°F / 132° C
Exposure Time:	20 minutes	10 minutes
Dry Time:	20 minutes	10 minutes

Sterrad®	
Parameters:	Option 1
System:	100S
Temperature:	45°C to 55°C (113°F to 131°F)
Exposure Time:	20 minutes
Cycle Time:	~55 minutes (short cycle)

Summary of CRW Sterilization Procedures

Component	Description	EtO	Steam Autoclave	Sterrad
UCHRA	Universal Compact head ring	Yes	Yes	No
UCHRPA, UCHRPP	composite head ring posts, cross bar & attach screws	Yes	No	Yes
HRAIM	Intubation head ring	Yes	Yes	No
HRP	Head ring posts	Yes	No	Yes
HRKTP	Head ring positioner	Not Necessary	Not Necessary	No
TAP	Post tap	Yes	Yes	No
HREBA	Ear bar assembly	Yes	Yes	No
HRW	Head ring wrench	Yes	Yes	No
BRWLF	CT localizer	No	No	No
Luminant® (LLO1)	MR / CT localizer	No	No	No
CRWASL	CRW stereotactic system	Yes	Yes	No
CTCP	Clamping plate	Not Necessary	Not Necessary	No
CRWWMA & CRWFMA	Mayfield adapter	Not Necessary	Not Necessary	No
CSS	Conical t-bolt screw	Not Necessary	Not Necessary	No
CRWPBS	Phantom Base Assembly	Yes	Yes	No
CRWASP	Arc System Pointer	Yes	Yes	No
CRWTBSS	Trunion Ring Reticles	Yes	No	Yes
CRWAPBS	Anterior / Posterior Reticles	Yes	No	No
DAxx & SDK	Drill Assemblies	Yes	Yes	No
SDK	Salcman Drill Kit	Yes	Yes	No
GTxxxx	Guide Tube	Yes	Yes	No
RBxx	Reducing Bushing	Yes	Yes	No
RTxx	Reducing Tube	Yes	Yes	No
CRWMCPH30	30° Offset Probe Holder	Yes	Yes	No
CRWMS	Probe MicroSlide	Yes	Yes	No
CRWPMDD	Digital Probe Microdrive	Yes	No	No
DSxx	Depth Stop, plastic	Option 2	Yes	No

Maintaining the CRW System

Preventing Equipment Loss

Be sure to gather the small, miscellaneous parts (such as bushings, screws, and nuts) following surgery to prevent loss.

Calibrating the CRW System

Return the CRW Arc System and Phantom Base to Integra Radionics for calibration once each year.

INDEX

A

accessories, list of CRW 5
accuracy
 checking with Phantom Base 39
 mechanical 3
accuracy, CRW 3
adapter plates, UCHRAP
 attaching the 18
 picture of 7
AP reticles, visualizing AP trajectories 63
approved uses for, CRW 1
Apuzzo sterile drapes 42
arc adapter
 attaching to the UCHRA 18
arc orientations, CRW 59–60
arc system
 about the CRW 51
 assembling the 26–33
 cleaning the 66
 disassembling the 66
arc system pointer, setting the 33
assembly
 arc 26–33
 BRW localizer 23
 HRAIM 19–23
 Luminant localizer 25
 phantom base 37–39
 UCHRA 13–18
autoclaving
 parameters for 68

B

base plates, CRW arc 26, 31
biopsy forceps, support for 1
Brown, Roberts, Wells (see BRW localizer frames)
BRW localizer frames
 assembling the 23
 cleaning the 65
 scanning the 50
burr hole, entering multiple targets through 58
bushings, selecting tubes and reducing 36

C

calibrations
 annual CRW 70
 MicroSlides and MicroDrives 61–62
clamping plates, CT table 64
cleaning instructions, CRW 65–66
clinical use, CRW 1
compatibility, CT and MR 1
components, list of CRW 4–12
contraindications, CRW 1
coordinates, measuring with Vernier scales 54–56
creutzfeldt-jakob, contraindications for 2
cross bars, attaching head ring 14
CRWAPBS and CRWTBSS (see reticles, trunion and AP)
CSS bolts (see T-bolt screws)
CT and MR, CRW support for 1
CT localizers (see BRW localizer)

CT/MR localizer (see Luminant localizer)

D

depth gauges, Keller 5
depth stops, sterilizing 69
depth, setting instrument and probe 33–35
disassembly, CRW 66
distances, measuring radial 35
drapes, Apuzzo sterile 42
drill assemblies, using the 37
drives, head ring 19

E

ear bars, assembling the UCHRA 15
electrosurgical devices, warnings for 3
endoscopes, support for 1
errors, total application 3
EtO sterilization, parameters for 68

G

geometric phantom, qualifying scanners with 64
guide block holder angles, adjusting 56
guide blocks and guide tubes, using 33–36

H

hair, preparing patient's 42
head ring accessories, UCHRA
 drives 19
 ear bars 15
 positioner 20
 posts 13–14, 19
 screws 17
 wrench 8, 13–18
head rings
 accessories list 7
 assembling the HRAIM 19–23
 assembling the UCHRA 13–18
 attaching arc to 39
 attaching to table 41
 positioning patients in 20–22
head rings, Radionics
 sterilizing the radiosurgery 68
hematoma evacuators, support for 1
HRAIM, assembling the 19–23
HRD (head ring drives) 19
HRKTP (head ring positioner) 20
HRP (head ring posts) 13–14, 19
HRW (head ring wrenches) 8

I

indications for use 1
infants, contraindications for 2
instruments, supported 1
intubation head ring (see HRAIM, assembling the)

K

Keller depth gauge 5

L

- lateral approach, arc orientation for 59
- localization, CT and MR 1
- localizer frames
 - assembling the BRW and Luminant 23–25
- Luminant localizer
 - assembling the 25
 - cleaning the 65
 - manually calculating targets 45–50
 - picture of 10
 - scanning the 45

M

- MicroSlide and MicroDrive, calibration tools 61–62
- MR and CT, CRW support for 1
- MR/CT localizer (see Luminant localizer)
- multiple targets, locating 58

N

- NBND needle, using the 36

P

- packing, CRW components 67
- parallel trajectories, setting 58
- parts, list of CRW 4–12
- phantom base
 - assembling the 37–39
- phantom, qualifying scanners with geometric 64
- pins, skull 21
- pointer, CRW arc
 - picture of 11
 - setting the 33
- pointer, setting the CRW arc 33
- positioner, head ring 20
- posterior fossa approach, arc orientation 60
- posts, head ring 13–14, 19
- probe holder
 - picture of 6

Q

- Quality Assurance (QA) components 10

R

- radial distances, measuring 35
- radiosurgery head rings
 - sterilizing 68
- reducing bushings and tubes
 - picture of 6
- reducing bushings and tubes, selecting 36
- reticles, trunion and AP 63
- rulers, probe depth 5

S

- scales
 - AP, LAT and VERT 52
 - Vernier 54–56
- scanning
 - BRW localizer 50
 - Luminant localizer 45
 - qualifying with geometric phantom 64
 - verifying orientations 45
- screws, head ring 17
- single use devices, warnings about 2
- skull pins, placing 21
- standard approach, arc orientation 60

- steam autoclaving
 - parameters for 68
- stereotactic procedures, supported 1
- sterile devices, list of 12
- sterile fields, creating 42
- sterilization tray 67
- sterilizing radiosurgery head rings (HRAIM) 68
- sterilizing, CRW components 68–69
- Sterrad sterilization, head ring posts only 68
- storing, CRW components 67

T

- tables, attaching head ring to 41
- tap, cleaning 65
- targets
 - about AP, LAT and VERT 55
 - calculating Luminant coordinates 45–50
 - locating multiple 58
 - Vernier scales 54–56
- T-bolt screws 9, 41
- temporalis muscles, avoiding the 21
- transphenoidal approaches, arc orientation 60
- transverse arcs, radii of 52
- trunion reticles, visualizing LAT trajectories 63
- trunion ring, setting 57–58

U

- UCHRA
 - assembling the 13–18
 - cleaning the 65
- UCHRAP (see adapter plates, UCHRAP)
- universal compact head ring assembly (see UCHRA)
- uses for CRW, approved 1

V

- Vernier scales 54–56

W

- warnings
 - anesthetizing gases 3
 - cleaning with bleach 66
 - deriving LAT and AP targets 58
 - electrosurgical equipment 3
 - ground-referenced electrosurgical device 3
 - head ring screws, selecting 17, 22
 - Luminant localizer targets 45
 - monopolar or bipolar electrode 3
 - recalibrating the digital probe microdrive 62
 - reviewing sterilization procedures 68
 - scan orientations 45
 - setting the digital probe microdrive 62
 - single use devices 2
 - temporalis muscles 14
- wrenches
 - arc system, picture of 5
 - cleaning head ring and arc system 66
 - head ring, picture of 8
 - hex, cautions for using 66

www.radionics.com

Integra Radionics, Inc.
22 Terry Avenue
Burlington, MA 01803 USA

15960003 Rev. G

