

RTOG 0236 Localization Study



Status of RTOG 0236

Institution	RPC Acceptable	Letter Sent	Immobilization Acceptable	IRB	Patient Accrual
Cleveland Clinic Foundation	Yes	05/01/2006	Yes	07/01/2007	9
Duke University Medical Center	Yes	Pending			
Indiana University	Yes	12/30/2004	Yes	04/26/2007	13
Princess Margaret Hospital	Yes	12/30/2004	Yes	12/16/2007	13
Richard Roudebush VA Medical Center	Yes	Pending		05/25/2006	
Thomas Jefferson University	Yes	03/03/2005	Yes	07/19/2007	2
University of Florida	Yes	Pending		11/16/2005	
University of Rochester	Yes	11/07/2005	Took 1 st case off protocol	08/25/2007	1
University of Texas MD Anderson Cancer Center	Yes	12/23/2005	Yes	09/20/2007	1
University of Wisconsin Hospital	Yes	09/07/2005	Waiting for 1 st case	08/20/2007	
UT Southwestern Medical Center	Yes	05/20/2005	Yes	09/19/2007	5
Virginia Commonwealth University	Yes	Pending			
Wake Forest University Health Sciences	Yes	Pending			
Washington University	Yes	12/30/2004	Yes	03/22/2007	15

Total number of institutions = 14 (9 approved; 5 pending)

RTOG 0438

Phase I Trial of Highly Conformal Radiation Therapy for Patients with Liver Metastases

SCHEMA

All Patients will receive 10 fractions Monday-Friday for 2 weeks at the following levels; Dose escalation by 0.5 Gy to maximum of 50 Gy, as follows:

Dose level	<u>Level I</u>	† <u>Level II</u>	<u>Level III</u>	<u>Level IV</u>
Dose per fraction	3.5 Gy	4.0 Gy	4.5 Gy	5.0 Gy
Total dose	35 Gy	40 Gy	45 Gy	50 Gy

†Protocol Treatment Begins at Level II

SBRT Localization Study

This QA process is aimed at demonstrating that the IGRT step is successful in positioning the target(s) relative to the treatment fields

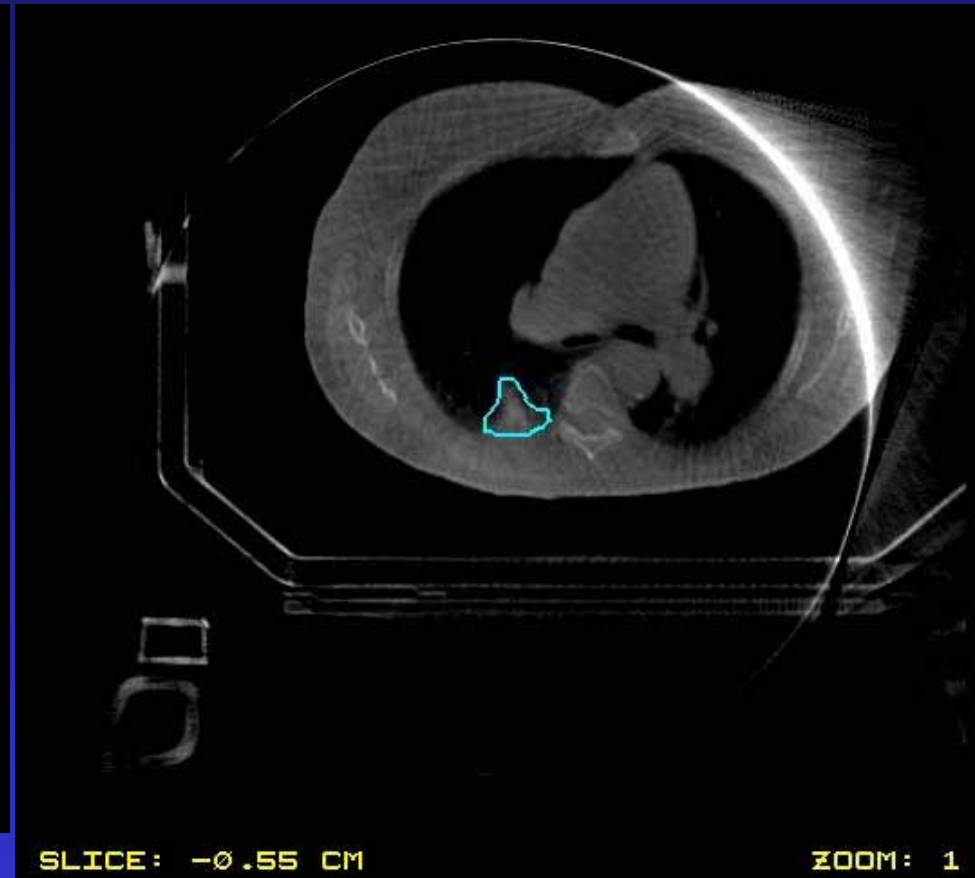
Frame Transfer



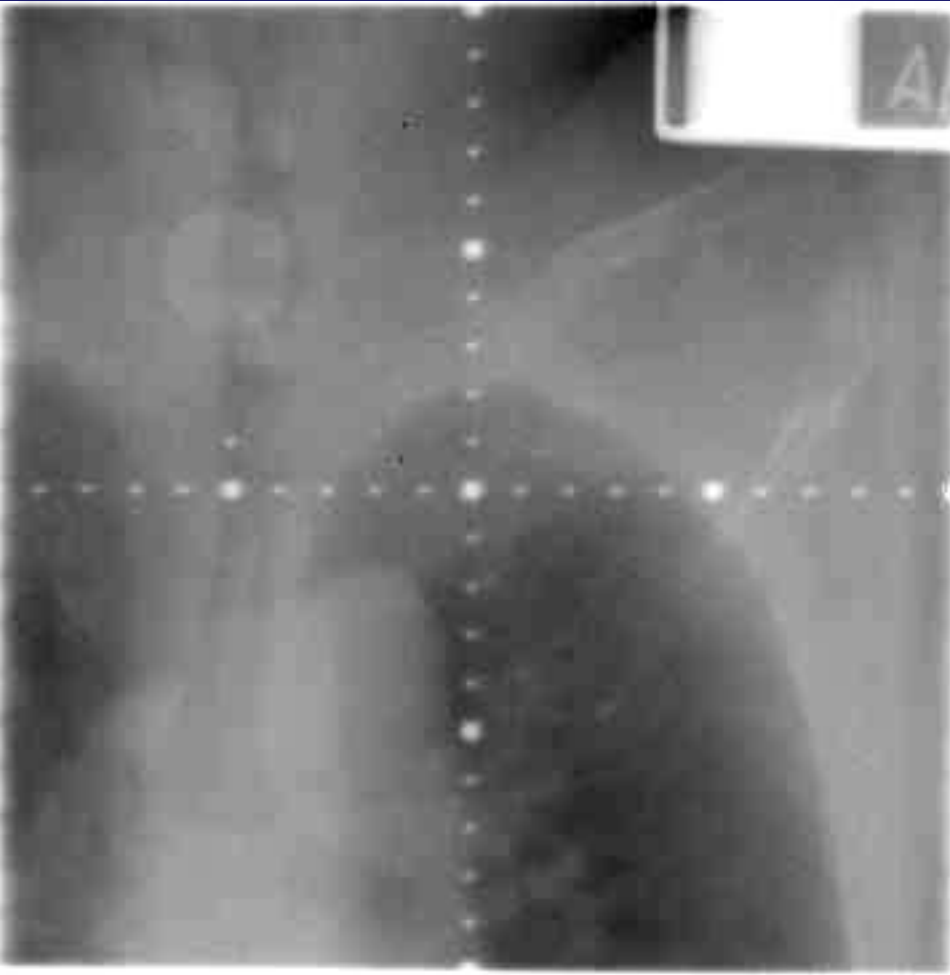
Cleveland Clinic – Abdominal Compression



ITC Remote Review Tool

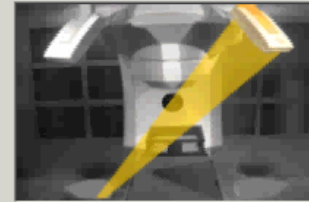
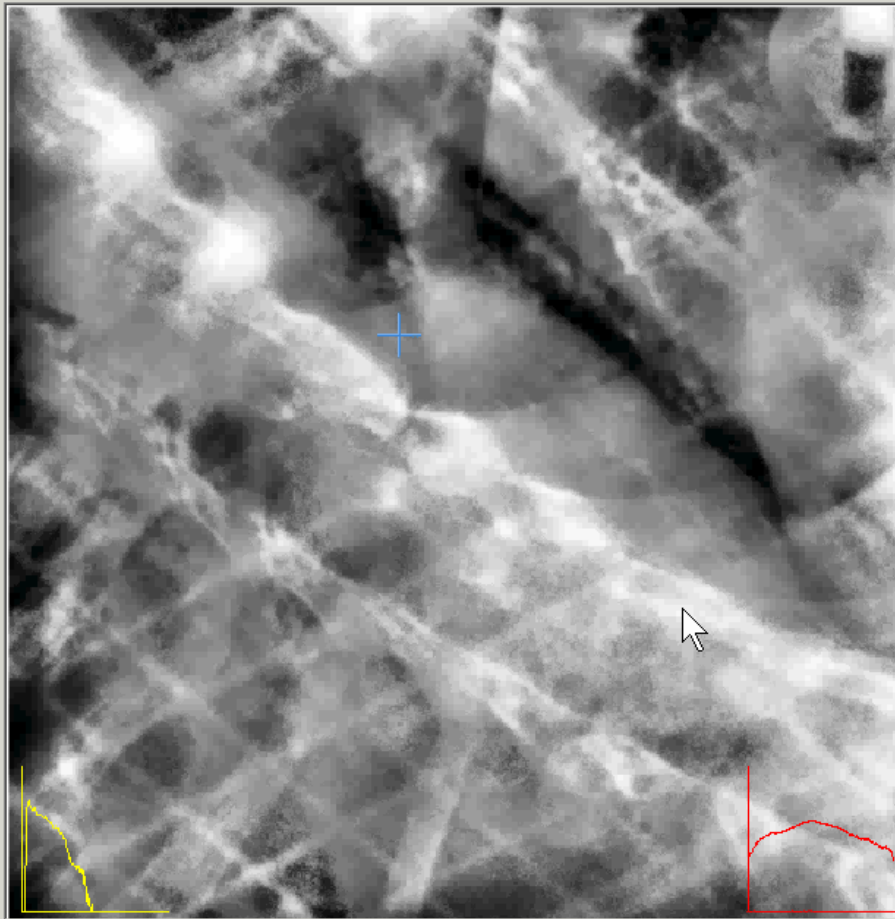


Wash. Univ. (Port Films)

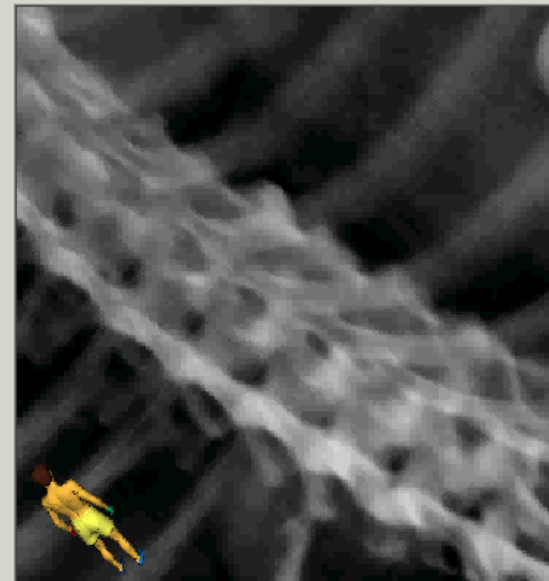


Cleveland Clinic (BrainLAB)

Unregistered HyperCam 2



DRR Preview



Contrast

Low

High



Windowing

Enable

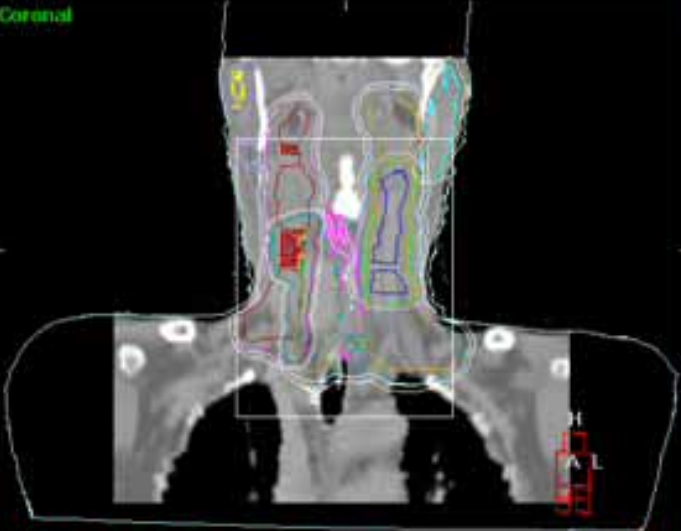


Adjust display parameters and press 'Next' to continue.

IMPAC FUSION


File Help

Coronal



Correction reference point = isocenter Slice 145 of 270

Sagittal



Slice 137 of 270

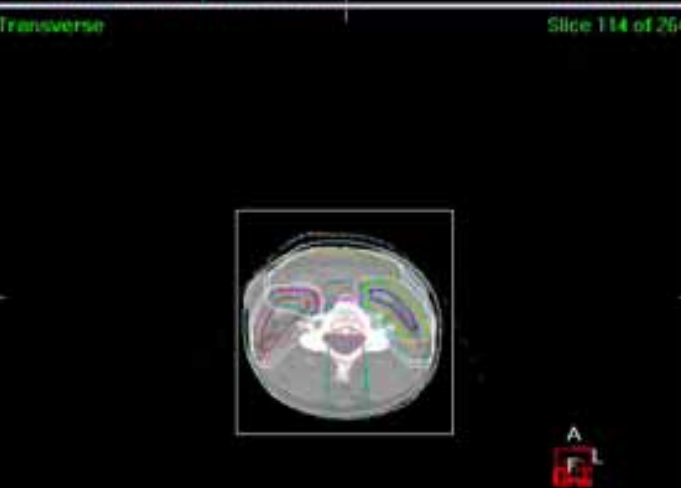
Image

Slice Averaging
none

Display Mode
Reference only

GoTo.

Transverse



Slice 114 of 264

29.01.2007 09:26:06.750 Scan Time: 7772.00:09:06.800

Reference Preset Scan Alignment Clipboard Structures

Alignment
Automatic: Bone

Position Error		Rotation (dg)		Table Correction (cm)	
Translation (cm)					
X	-0.40	X	269.3	Lateral	-
Y	-0.20	Y	355.4	Longitudinal	-
Z	-0.61	Z	1.2	Vertical	-

Treatment: 1:19779 Plan Date: 10.01.2007 15:58:33.000 Plan Description: PLAN13.PLAN13

IMPAC FUSION

File Help

Coronal

Correction reference point = isocenter Slice 145 of 270

Sagittal

Slice 137 of 270

Image

Slice Averaging: none

Display Mode: Reference only

Go To

Transverse

29.01.2007 09:26:06.750 Scan Time: 7777 00:00:00.000

Reference Preset

Scan Alignment Clipboard

Structures

Alignment

Automatic: Bone

Reset

Convert To Correlation

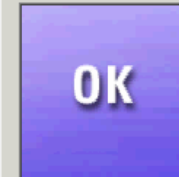
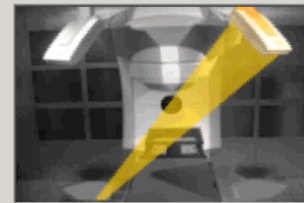
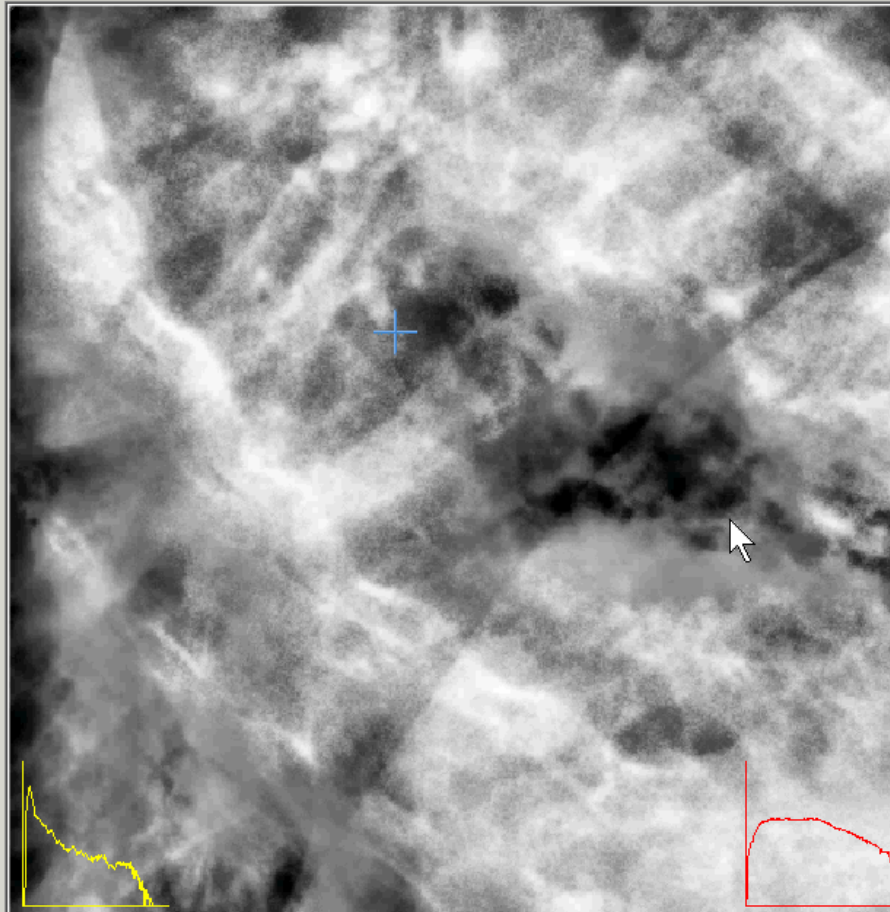
Position Error Translation (cm)		Rotation (dg)		Table Correction (cm)	
X:	-0.18	X:	355.2	Lateral	-
Y:	-0.28	Y:	0.0	Longitudinal	-
Z:	-0.70	Z:	359.0	Vertical	-

Dismiss
Accept

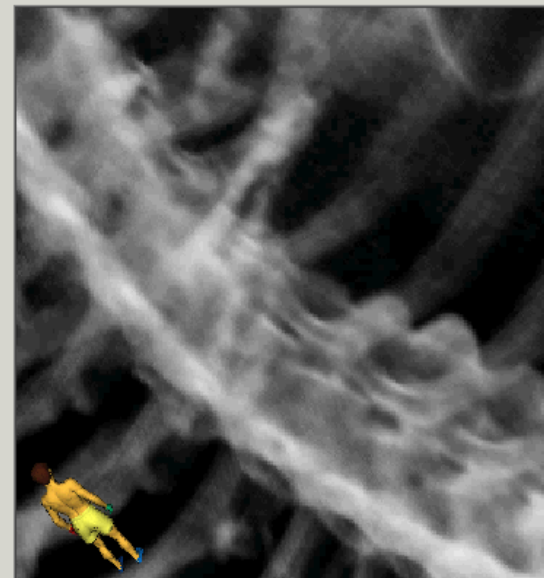
Treatment: 1:19779 Plan Date: 10.01.2007 15:58:33.000 Plan Description: PLAN13-PLAN13

Cleveland Clinic (BrainLAB)

Unregistered HyperCam 2



DRR Preview



Contrast



Windowing

Enable



Adjust display parameters and press 'Next' to continue.

Status of RTOG 0438

Institution	RPC Acceptable	ITC Acceptable	Letter Sent	Notes	IRB	Patient Accrual
University of Rochester	Yes	Pending	10/12/2006		01/04/2008	
Princess Margaret Hospital	Yes	Yes	01/30/2006	6/2/06 passed 1 st case	10/21/2007	3
Cleveland Clinic Foundation	Yes	Pending	Pending		07/12/2007	

Institution Approval Letter for RTOG – 0438

RTOG
Radiation Therapy
Oncology Group

Date

_____, M.D.
Institution – RTOG # _____ ; NCI # _____ ; RTF # _____
Department of Radiation Oncology
Address
City, State, Zip

Dear Dr. :

Your institution has successfully completed the Liver Phantom Irradiation Dosimetry Test, Facility Questionnaire, Immobilization/Localization and Respiration Control Systems Test.

You can now enter patients on to RTOG Protocol 0438.

The Dry Run / Rapid Review will be reviewed on the actual case. The dosimetry will be reviewed and the study chair will determine if this and the drawn structures are protocol compliant and sufficient for the patient to go ahead with treatment. Since this test case (Dry Run / Rapid Review) is the first case entered from your institution, the scanning parameters, the structure outline, and the dosimetry will have to be according to protocol in order to pass the Dry Run / Rapid Review **PRIOR TO DELIVERING ANY PROTOCOL TREATMENT**. The plan will be reviewed centrally at the ITC, and suggestions regarding protocol compliance will be forwarded to your institution. The treatment plan for subsequent patients enrolled from your site will not be required to be centrally reviewed prior to treatment, but will be reviewed for protocol compliance at a later date.

However, the Immobilization/Localization and Respiration Control Systems Test must be repeated for the first 2 cases submitted from your institution and the results reviewed by James Galvin, D.Sc., Medical Physics Co-Chair. The data for the first patient entered must be reviewed and approved before you enter a second patient, and the results of the Immobilization/Localization and Respiration Control Systems Study for this patient must be approved prior to entering a third patient. At this point, any additional number of patients can be entered. You will have to send forward the results of the Immobilization/Localization and Respiration Control Systems Study for the third and fourth patients entered. Please refer to the attached information.

Sincerely,

Elizabeth A. Martin
Director, R.T. Quality Assurance

cc: Physicist
Research Associate
James Galvin, D.Sc.
RTOG Randomization
ITC
RPC

a leader in defining more effective cancer therapies



RTOG Protocol 0438

Immobilization/Localization and Respiration Control Systems Study

This study must be performed on a single patient, and approval received from RTOG Headquarters, before you attempt to enter your first patient on RTOG Protocol 0438. A similar study must be performed for the first patient entered on this protocol, and approval must be received from Headquarters prior to entering a second patient. This same procedure must be followed before entering a third patient. However, once approval has been given to enter the third patient on the protocol, no additional Immobilization/Localization data needs to be gathered.