Multivendor SBRT/IGRT
The Calypso 4D Localization and Tracking System / Elekta Synergy-S

Toufik Djemil, Ph.D.
Cleveland Clinic

Practical Medical Physics Symposium

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Objectives

- Understand operational and quality assurance aspects of Calypso combined with Synergy-S and Pinnacle TPS
- Understand the technical limitations of the hybrid system
- Describe clinical implementation of the system and typical cases treated

Objectives

- Understand the clinical rationale for localization and tracking
- Understand the necessity of hybrid technologies and systems
- Understand the physics behind the Calypso localization mechanism and its principles of operation

Introduction

- Dose escalation to the prostate increases local control
- Image guidance for accurate treatment delivery and intra-fraction motion monitoring is critical in this environment of dose escalation and hypo fractionation

Real Time Tracking

Prostate Motion During Treatment

C.A. Enke[1], T. Solberg[1], A. Mahadevan[2], T. Djemil[2] , P. Kupelian[3],
T. Willoughby[3], G. Weinstein[4], S. Jani[4], N. Flores[5], D. Liu[5],

[1]Nebraska Medical Center, Omaha, NE, [2]Cleveland Clinic, Cleveland, OH,
[3]M. D. Anderson Cancer Center Orlando, Orlando, FL, [4]Sharp Memorial Hospital, San Diego, CA,
[5]Scottsdale Healthcare/Arizona Oncology Services, Scottsdale, AZ.

Patient ID	# Fractions Analyzed	Fractions with > 3mm excursion for >30 seconds cumulative		Fractions with > 5mm excursion for >30 seconds cumulative	
		#	%	#	%
All (N=35)	1157	473	40.88	179	15.47

Percent of Fractions for All Patients			
Patients	No. fractions analyzed	Fractions with ≥3mm excursion	Fractions with ≥5mm excursion
35	1157	Study average: 41% Individual: up to 87%	Study average: 15% Individual: up to 56%

IGRT

- **Transabdominal ultrasound, KV X-rays, and KV/MV CBCT**
- **Disavantages:**
  - **Snapshots of the prostate position**
  - **Not available during radiation delivery**
  - **Additional ionizing radiation exposure**
  - **May be subjective and operator dependent in acquisition and interpretation**
- **Option: Hybrid system used for prostate EBRT (IMRT/SBRT)**

Synergy-S/Calypso

The Calypso 4D Localization System

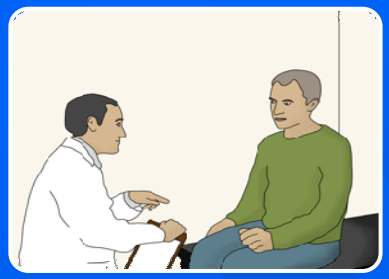
- New technology using non ionizing AC electromagnetic (EM) field for locating and tracking patient tumors: the Calypso system.
- An intermitent EM pulse excite implanted wireless circuits called Beacon transponders
- The Beacons echo a distinct signal determining their coordinates

The Calypso 4D Localization System

- The Beacons' coordinates are used to determine the translational shifts in the X, Y, Z directions to register the target to linac isocenter.
- Rotation of the target around the three directions is also determined.
- After patient setup, the system continously tracks the position of the target in real time.

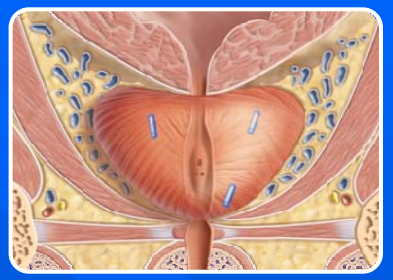
Calypso System Workflow

Referral and Implant Procedure Phase



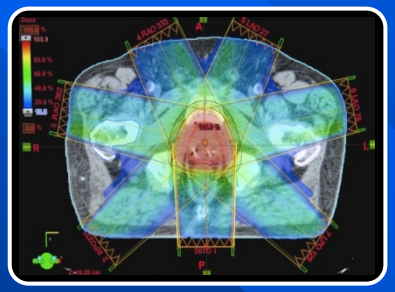
Urologists consults the patient on treatment options

Decision to use EBRT and Implant Beacon® Transponders



Implant procedure

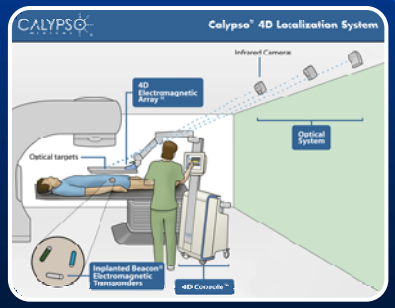
Treatment Planning Phase



Identify Beacon transponders in treatment planning 4—14 Days post implant

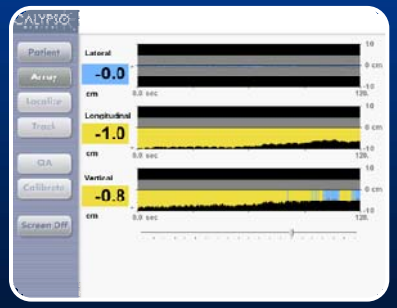
Enter treatment planning data into Calypso 4D Tracking Station

Treatment Delivery Phase



Plan check on Calypso 4D Console

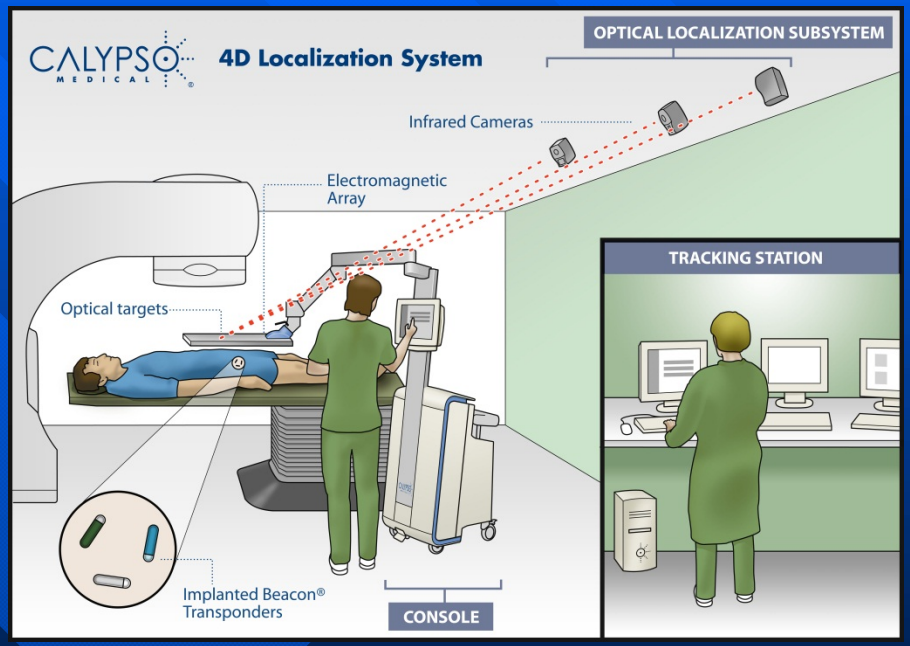
Real-Time Setup with Calypso 4D Console



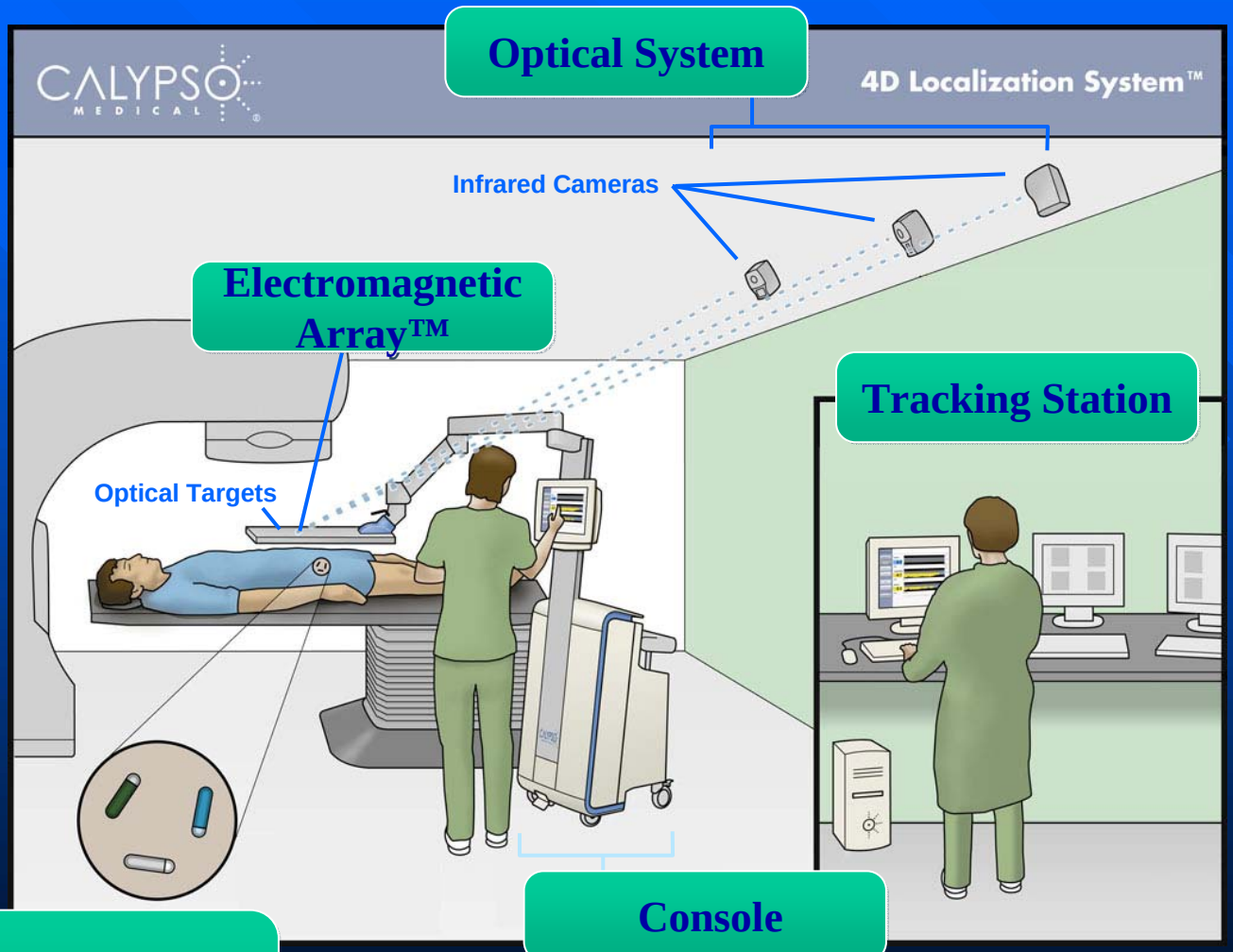
Objective, continuous monitoring during treatment

The Calypso 4D Localization System

- It consists of:
  - Beacon transponders
  - Console
  - Array
  - Optical cameras
  - Tracking station

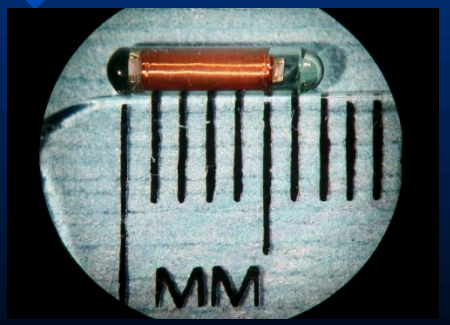


Platform Overview

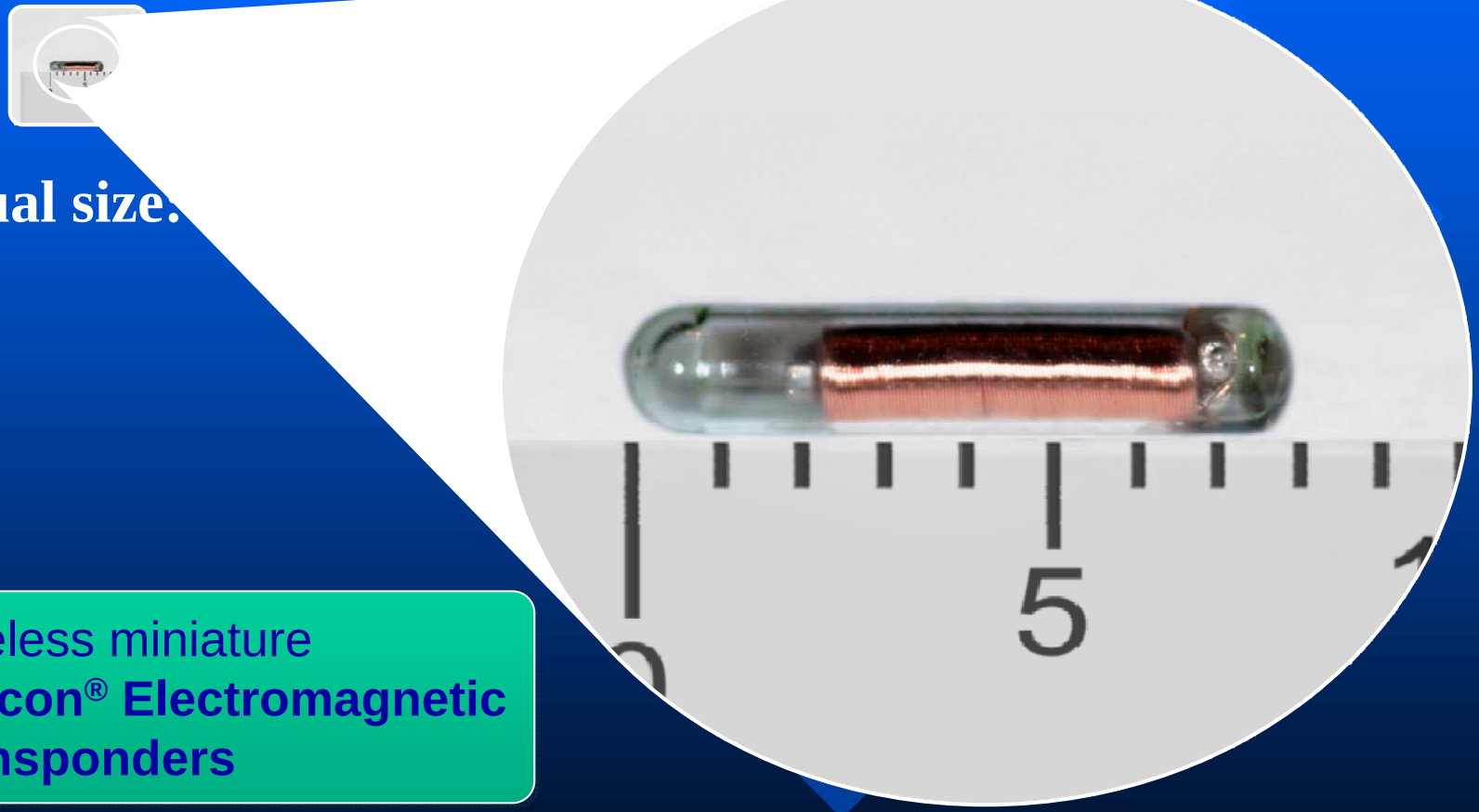


Beacon Transponders

- Three Transponders Beacons are implanted under Ultrasound guidance
- 1.8mm x 8.5 mm (14 Gauge needle)
- When Excited with an EM pulse, they echo distinct signals used to determine their coordinates
- Coordinates used to locate target with respect to machine isocenter



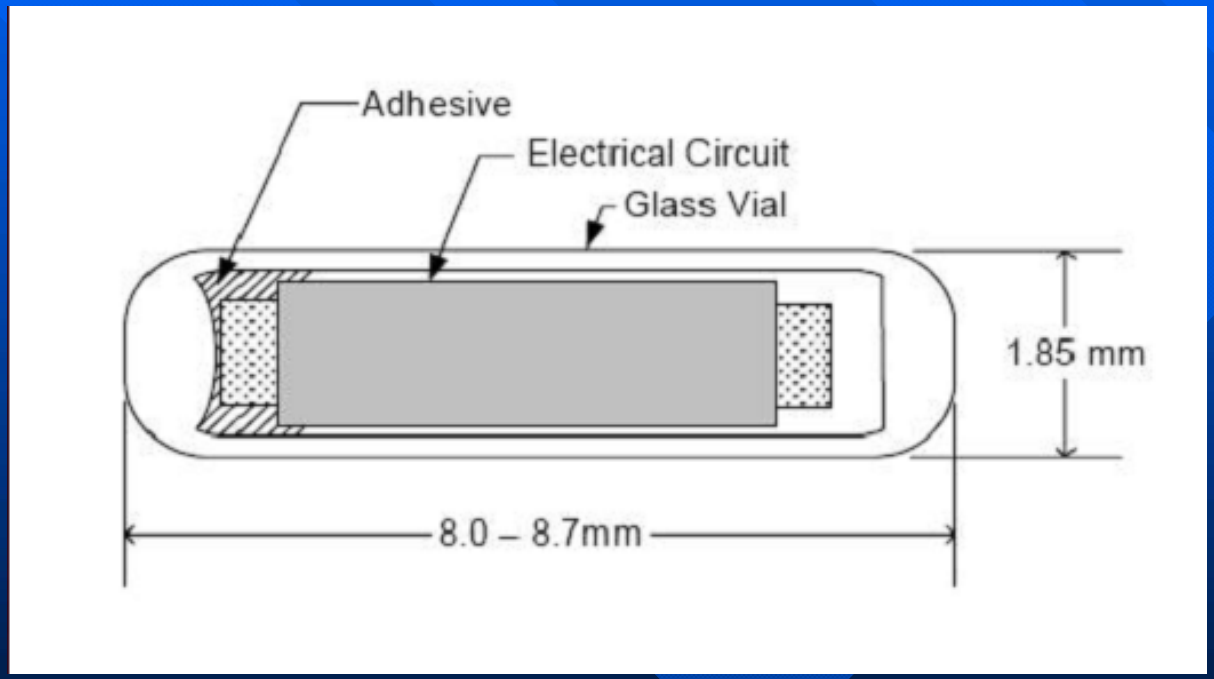
The Calypso System - Beacon® Transponder



Actual size.

Wireless miniature
Beacon® Electromagnetic Transponders

The Calypso System - Beacon® Transponder

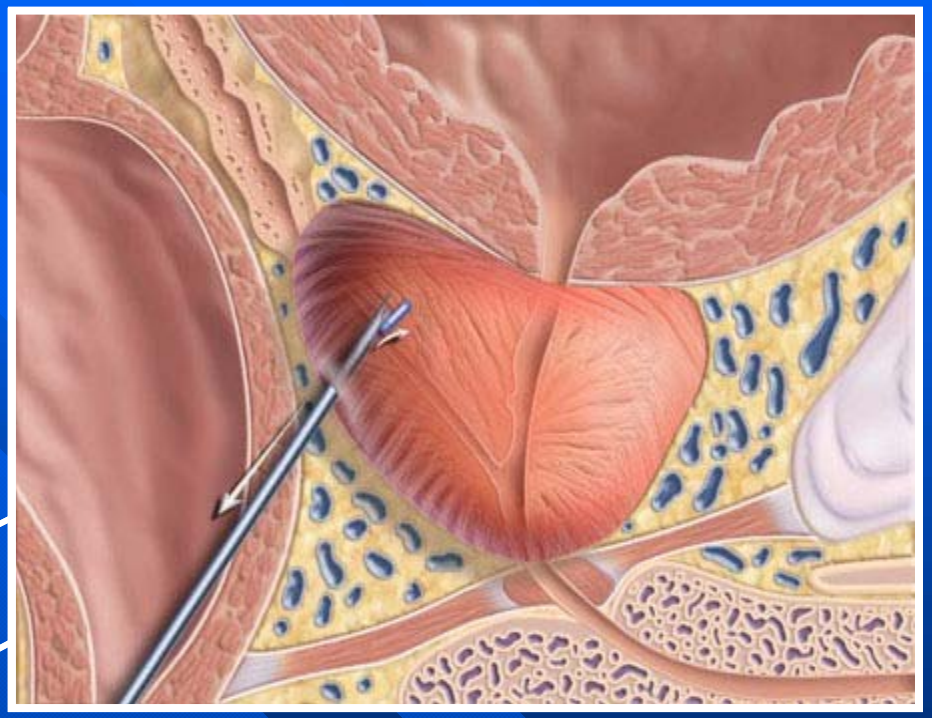


Implantation Procedure

- **Outpatient procedure — prep w antibiotics and same day enema**
- **Transrectal US and transperineal implantation by urology or radiation oncology**
- **Typically done w local anesthesia, @ 10 minutes**

Standard ultrasound probe

Needle guide and introducer assembly



Transrectal ultrasound probe, needle guide and introducer for Beacon® electromagnetic transponder implant into prostate

Contraindications

- Anticoagulation/Antiplatelet (Implantation)
- Allergy to local anesthetics (Implantation)
- Implanted signaling devices (Pacemaker, neurostimulator, certain infusion devices) - Interaction with electromagnetic signal unknown
- Prosthetic hip or large metal implantation (Vascular grafts) near transponders
- AP diameter restrictions

Implantation

- In pilot study with prototype system 58 of 60 implanted transponders were usable (1 voided, 1 unresponsive), a 3rd transponder moved 3cm from apex to superior SV (in venous plexus?) but was usable

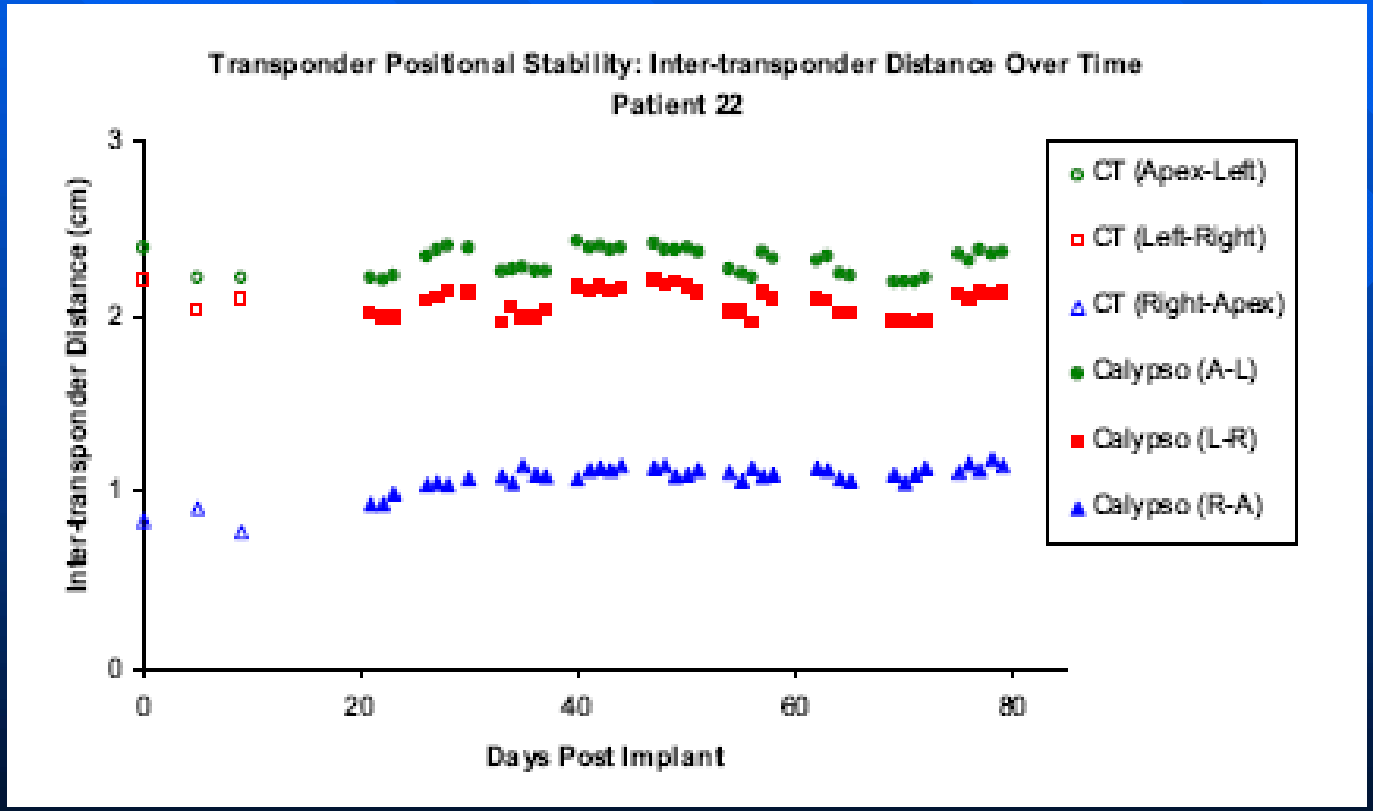
Willoughby et al., IJROBP 2006;65(2):528-534

- Follow-up study 125 of 126 transponders usable (1 voided), one placed on prostate/rectal interface but usable

Kupelian et al., IJROBP 2007;67(4):1088-1098

Stability

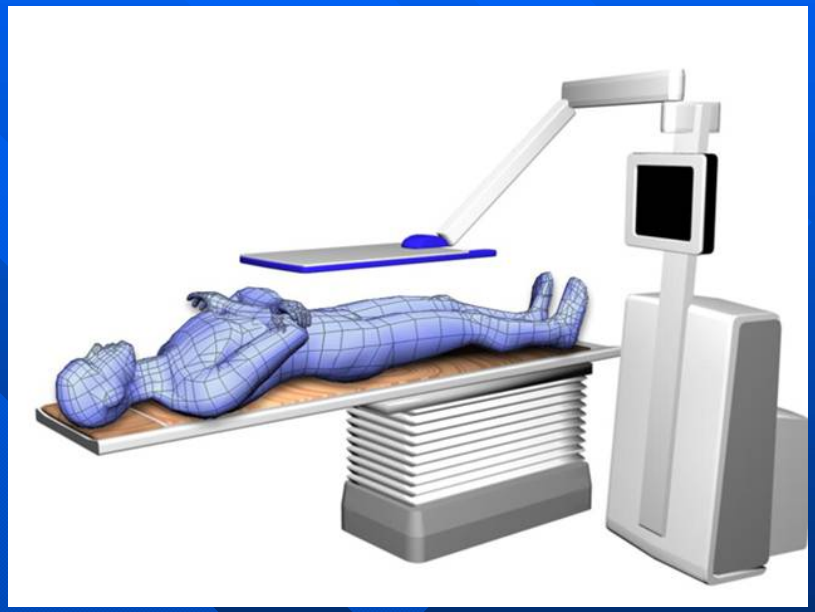
- On second study of 42 patients (125 transponders) mean SD of intratransponder distances was 0.8 mm from day 4 to 80.



Kupelian et al., IJROBP 2007;67(4):1088-1098

The Flat Panel Array

- The array is an extendible flat panel
- Contains the source coils that generate the EM signal
- Source coils emit frequencies between 275 and 550 kHz
- 1 to 2% attenuation

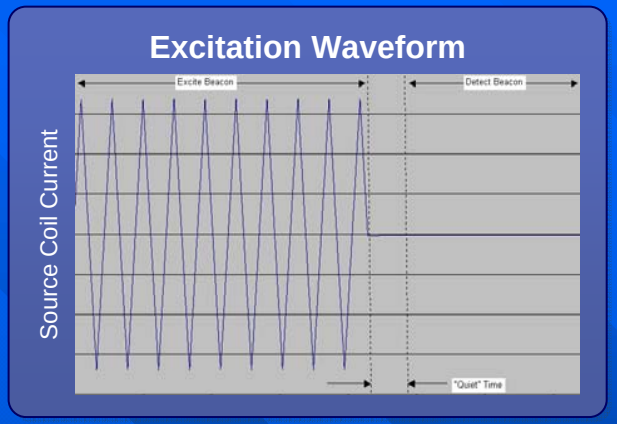


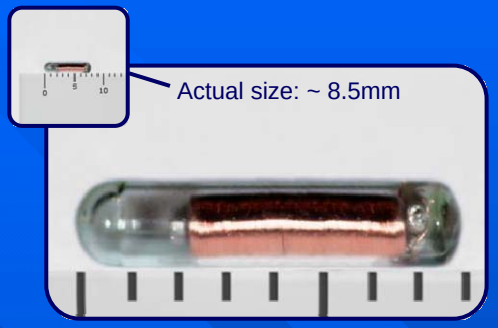
Flat Panel Array

- Continuous, real-time monitoring of the prostate
- Objective guidance enables clinician to manage organ motion
- Accurate localization for maximum confidence
- Non-ionizing technology for quick patient setup

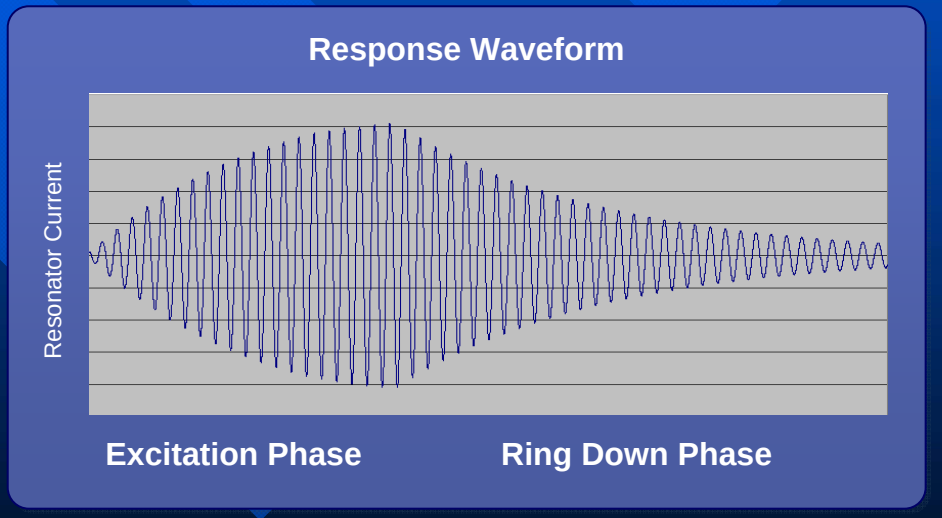
Transponder Signals

- Transponders excited sequentially at each of three unique resonant frequencies
- Each transponder subsequently responds with a decaying magnetic field
- Process of excitation and sensing is repeated several hundred times to improve signal/noise for each transponder localization



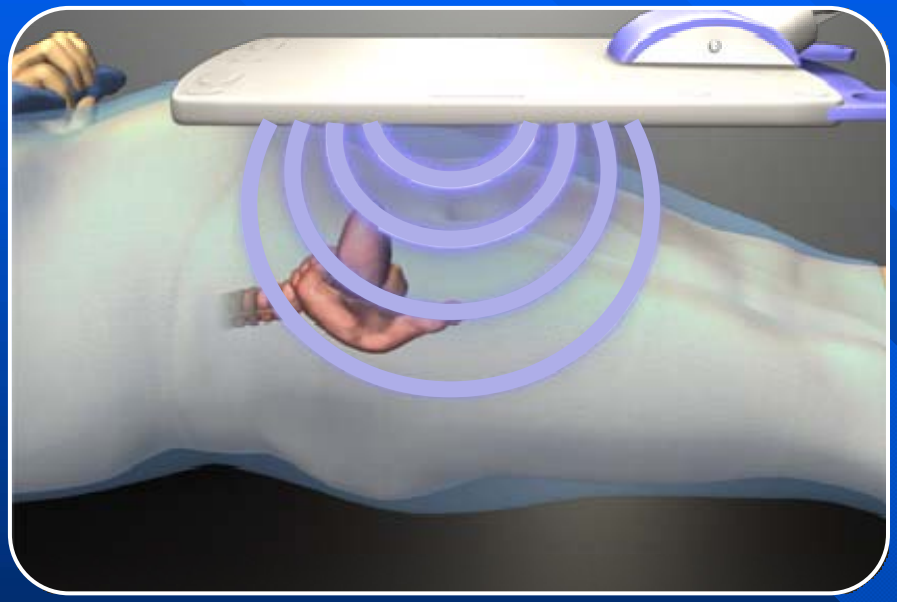


Beacon® Electromagnetic Transponder



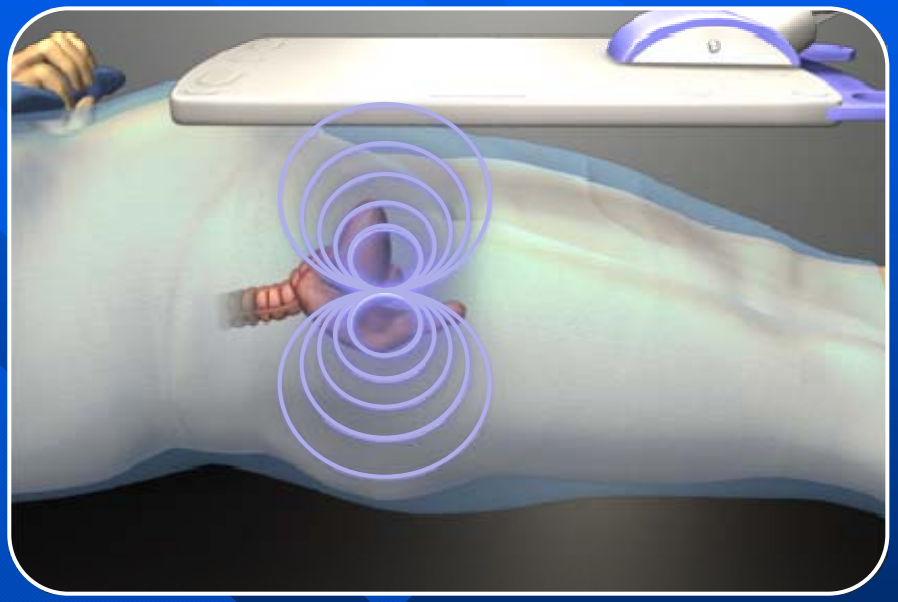
Locate and Track Continuously

GPS for the Body®



Step 1

Beacon® Electromagnetic Transponders are excited by a pulse of electromagnetic energy



Step 2

The Beacon transponders respond with an identifiable signature allowing the clinician to determine tumor location and motion (10 Hz update rate)

Unique Frequencies Identify Location

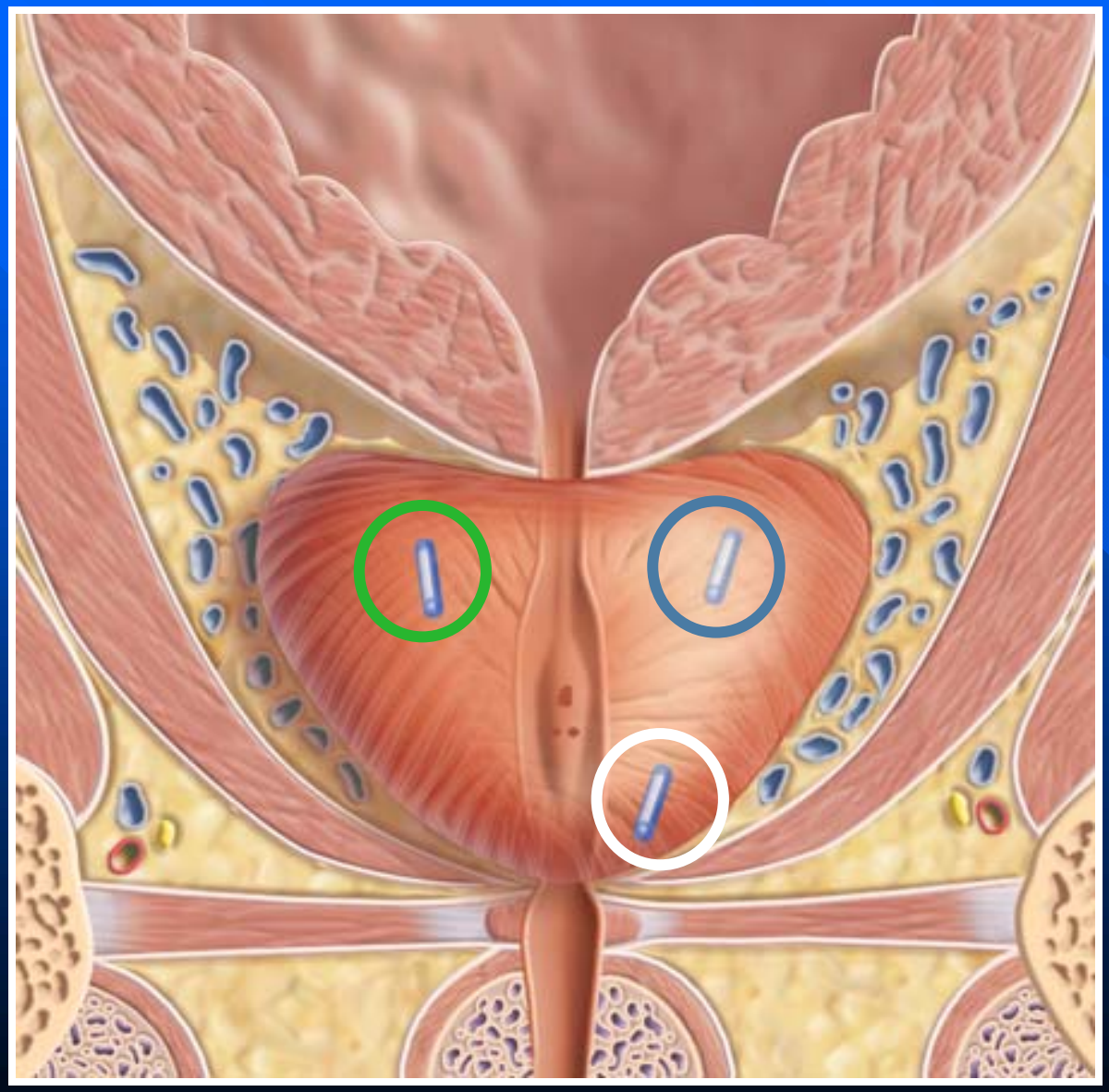
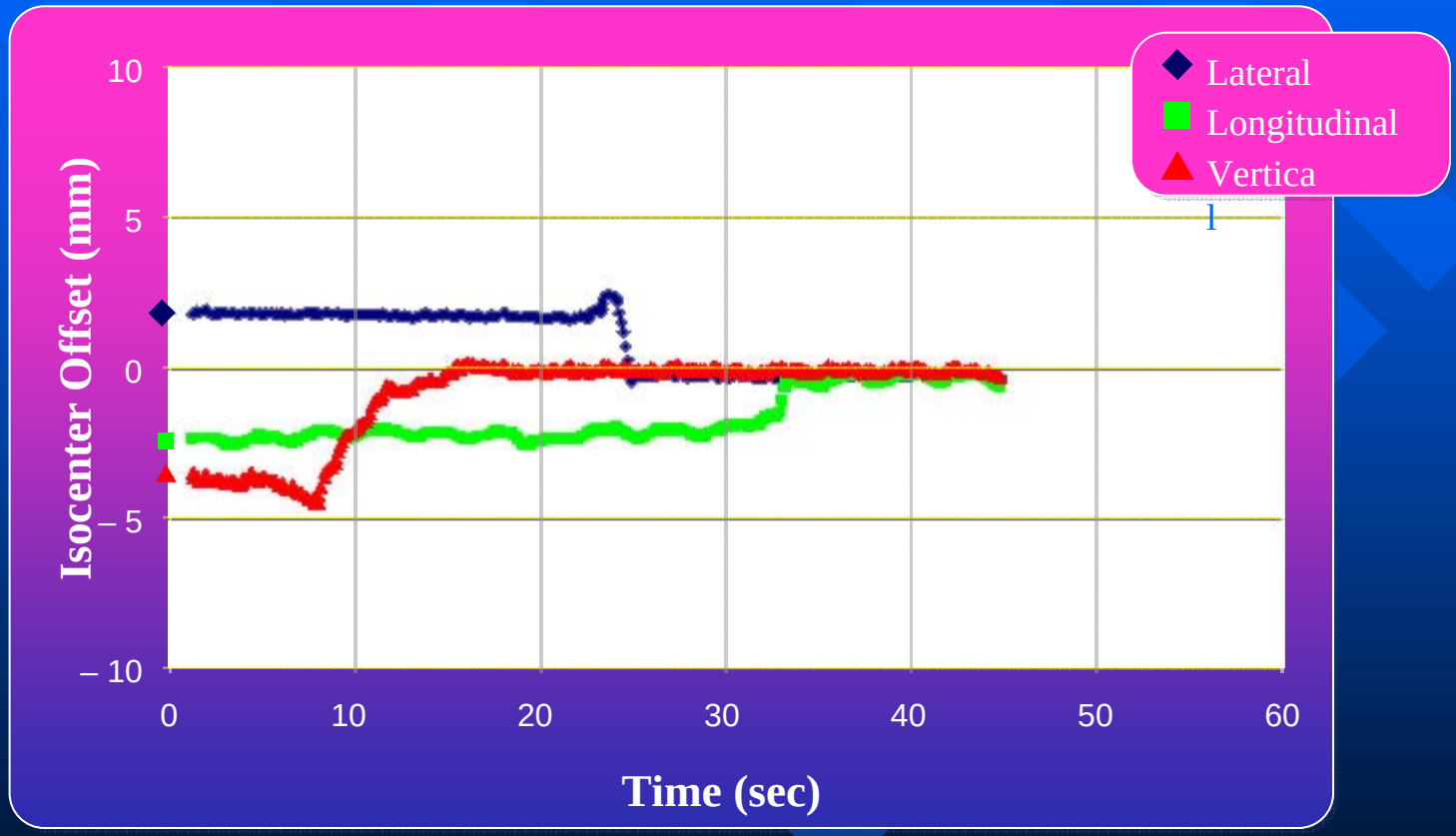


Table Overlay

- 3-Piece Kevlar Overlay
- No Standard couch, carbon fiber, tennis-racquet due to interference

Efficient Setup — Precise Positioning

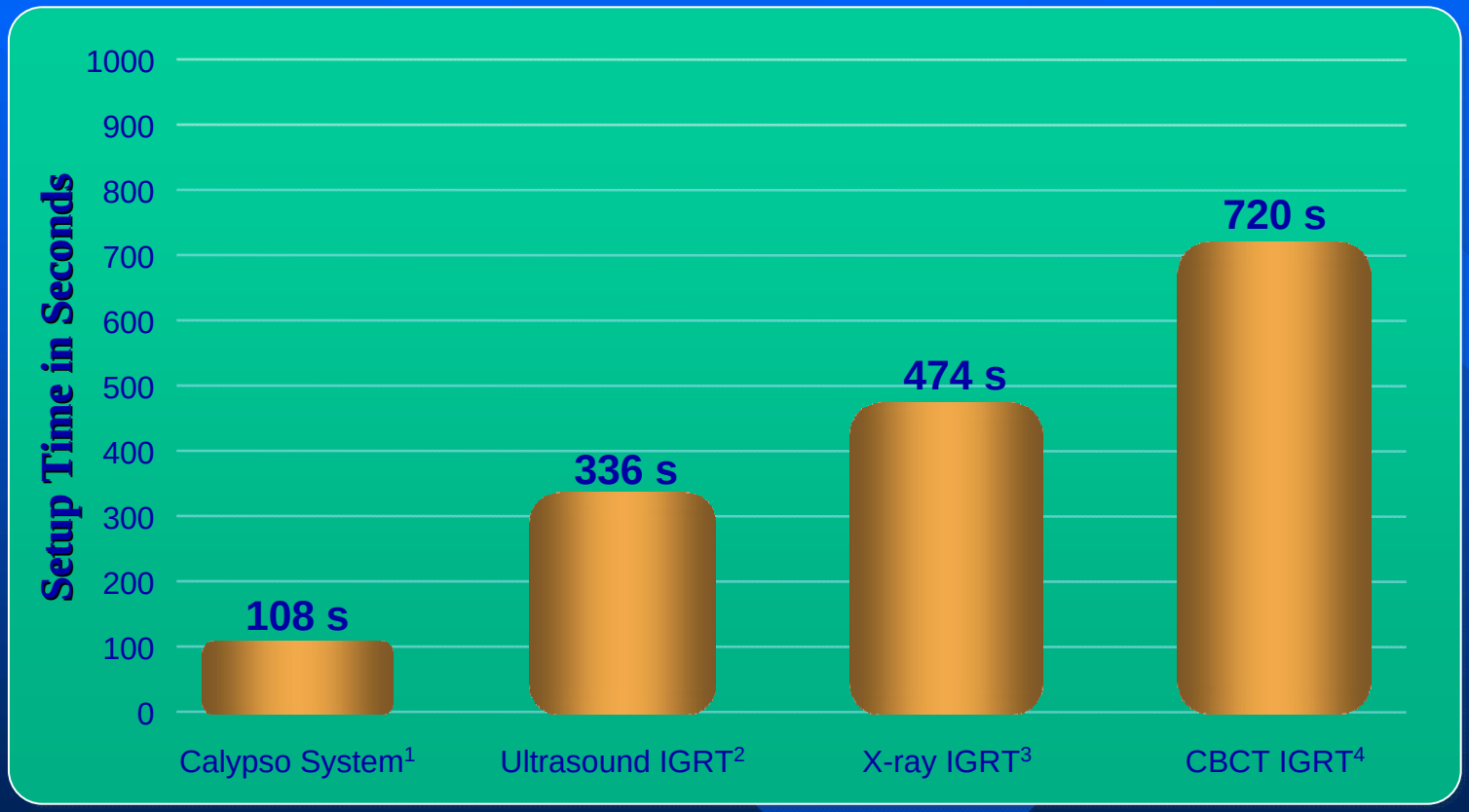
Patient Alignment



Rapid shift to isocenter <35 seconds

Efficient Setup

Setup Time (seconds)

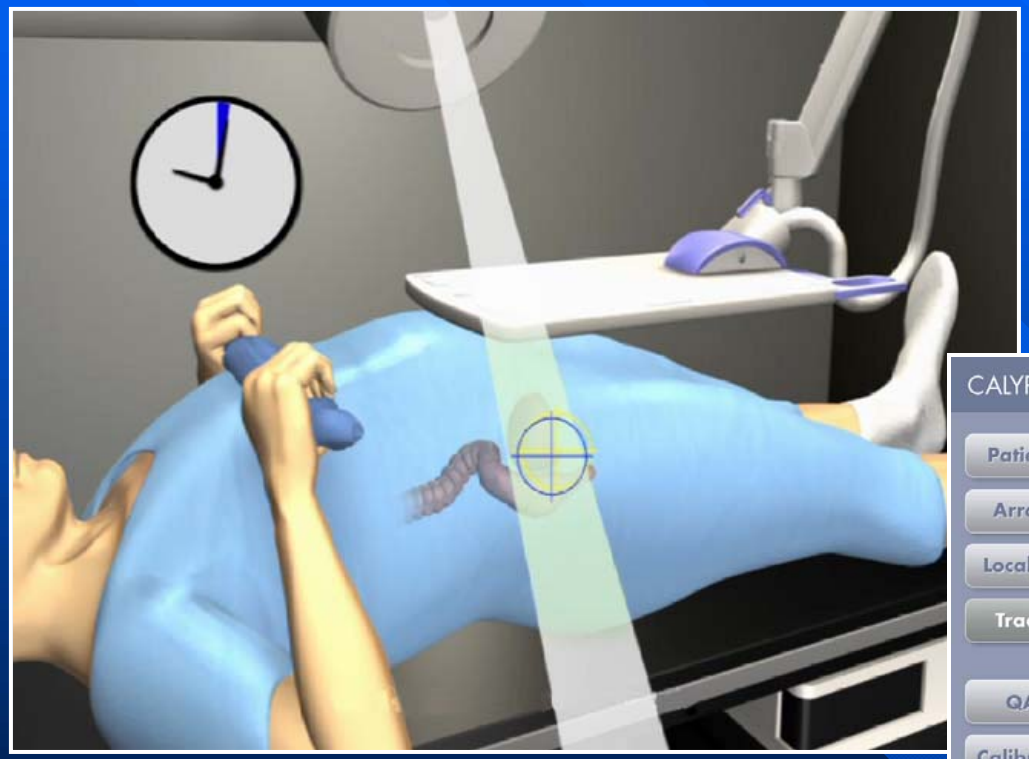


Sources:
[1]Calypso Medical Pivotal Study; [2]Chandra et al, Int. J. Radiation Oncology Biol. Phys. Vol 56, No. 2, pp 436-447, 2003; [3]Fox et al, J. Am Coll Radiol 2006;3:38-44; [4]Ghilezan et al, Int. J. Radiation Oncology Biol. Phys. Vol 60, No. 5, pp 1602-1610, 2004

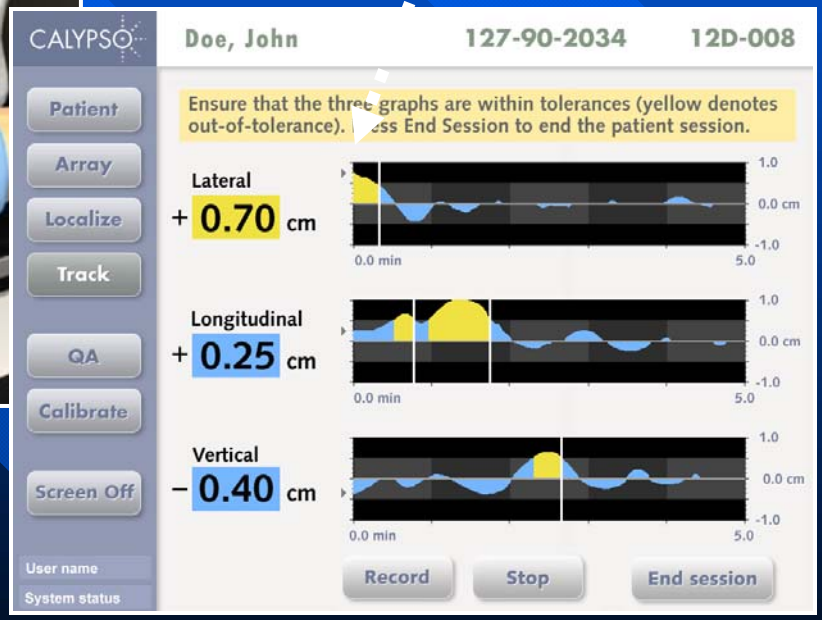
Disclaimer: This content is informational only and represents no promise or guarantee by Calypso® Medical regarding coverage, coding, billing and payment levels.

Calypso v US 1.6 v 3.7 min @ CCF, Warman et al., IJROBP 2007

During Radiation Prostate is Constantly Monitored



From outside the treatment room, RTT can watch for “Out Of Tolerance” indicator



Cleveland Clinic Prostate EBRT

- **Dose**:

  -Low-risk 76 Gy, 2 Gy per fraction

  -Int & High-risk 78 Gy (66 Gy to proximal SV)

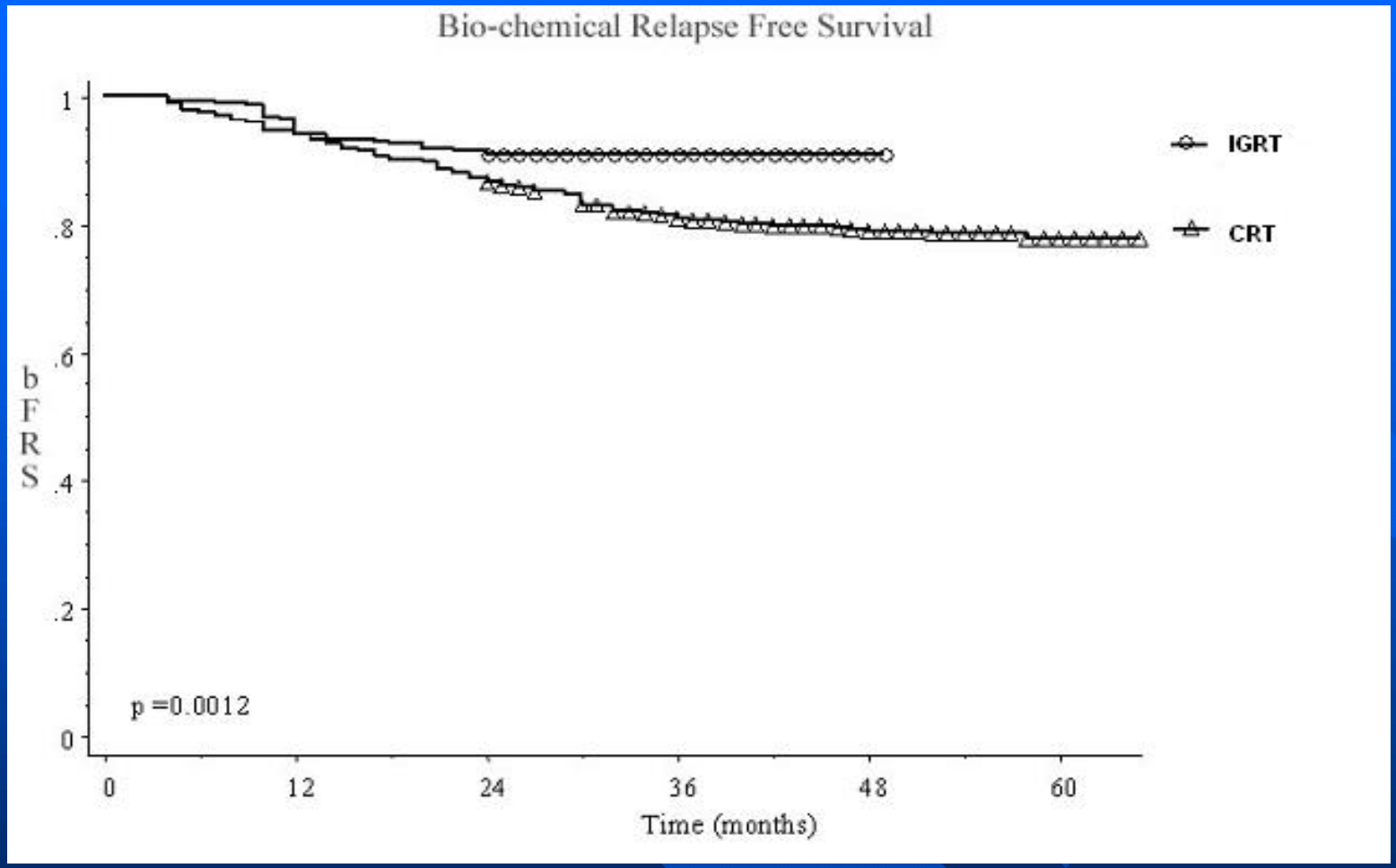
- **PTV**:

  -Clarity or CBCT = CTV + 5 mm post, 8 mm lat/ant/sup/inf

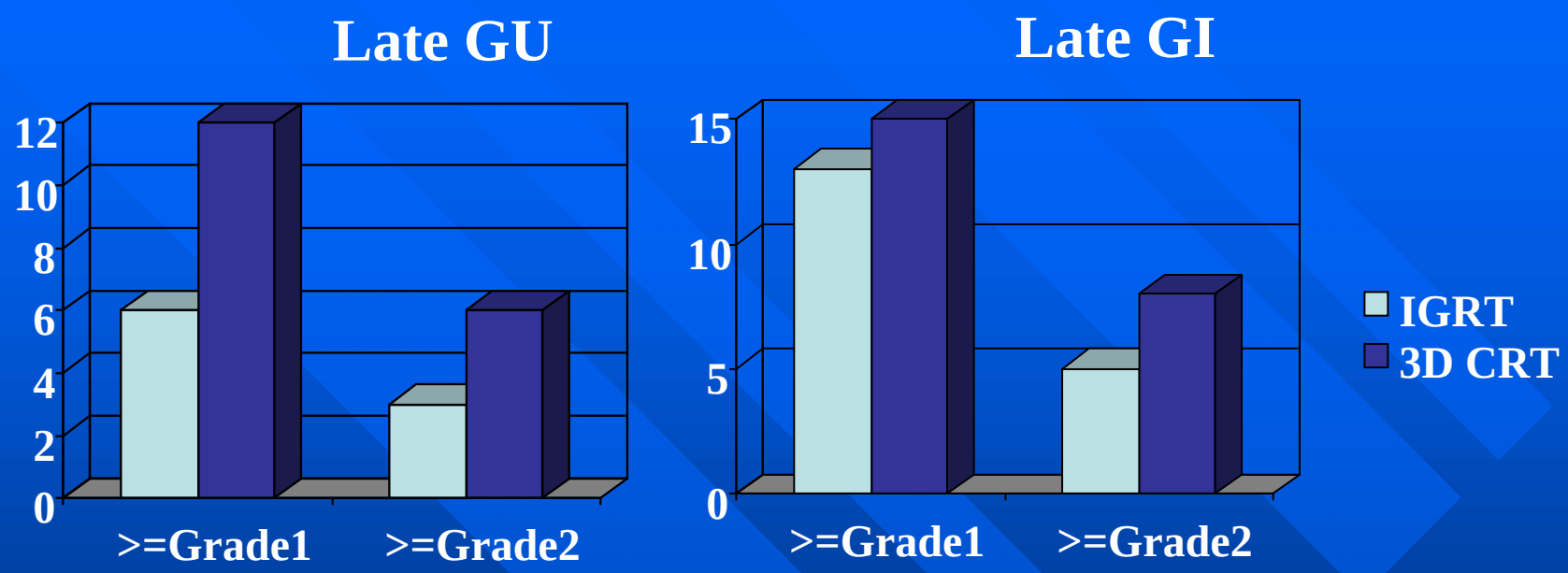
  -Calypso = CTV + 4 mm post, 6 mm lat/ant/sup/inf

- **Sim**:

  Supine, empty rectum, full bladder, no specific immobilization, urethrogram, no intra-rectal devices



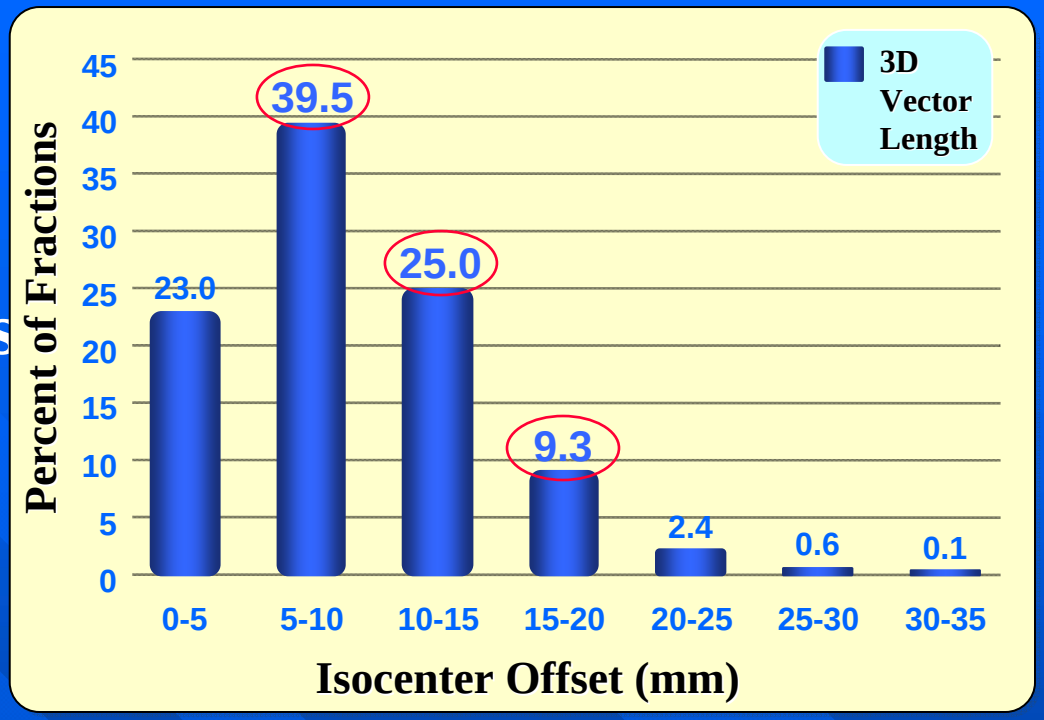
- **1,765 EBRT treatments @ CCF from 1996-2003**
- **All fractionations included (2Gy, 1.8Gy, 2.5Gy)**



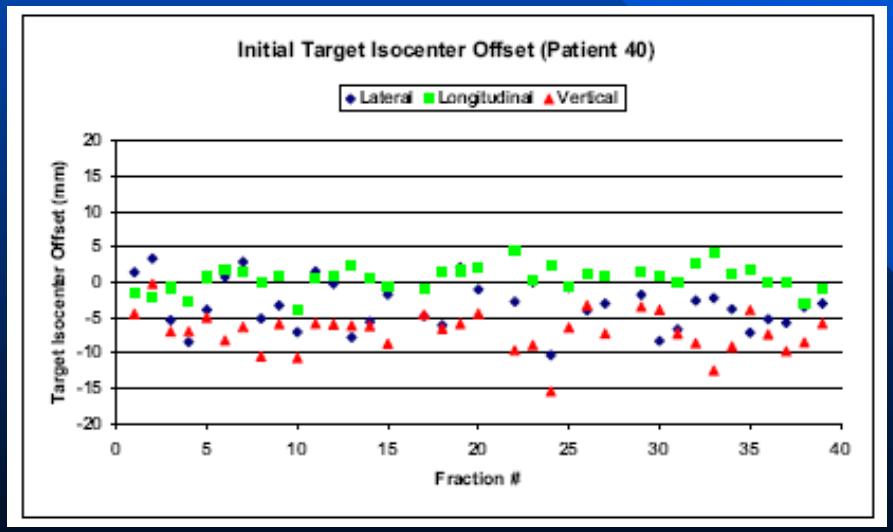
- 1,765 EBRT treatments @ CCF from 1996-2003.
- All fractionations included (2Gy, 1.8Gy, 2.5Gy)

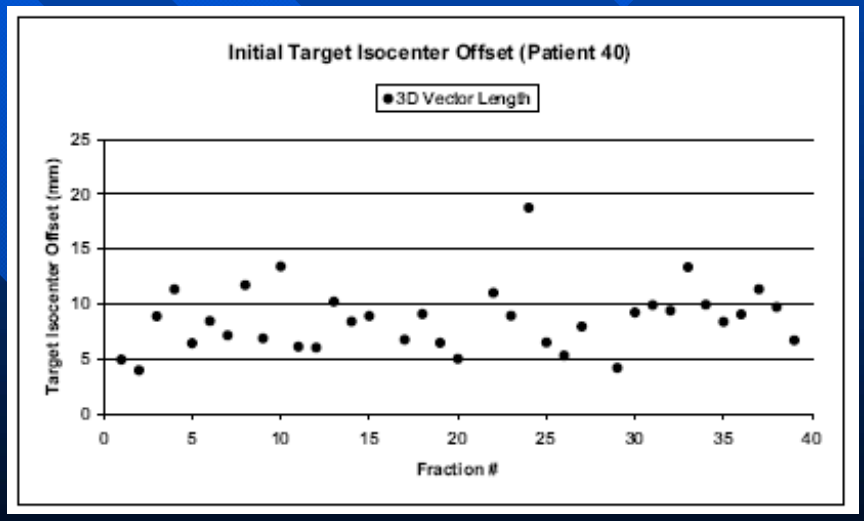
IGRT/Calypso: Patient Setup

- Initial offset corrections often systematic
- Relatively stable with significant outliers



*Alignment relative to laser/skin mark setup (1524 fractions) showed initial offset shift >5 mm in vector length in >75% of fractions



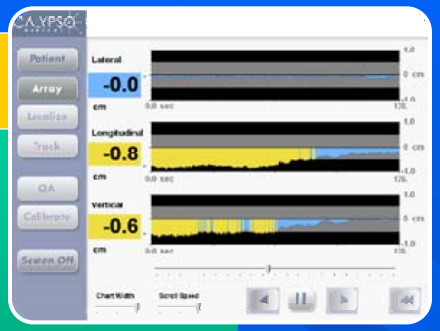


Kupelian et al., IJROBP 2007;67(4):1088-1098

Clinical Results – Patient Tracking

Clinically relevant prostate motion observed

- In **97%** of patients motion exceeded pre-set thresholds
- Motion was unpredictable and variable day-to-day and patient-to-patient



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		#	%	#	%
All (N=35)	1157	473	40.88	179	15.47

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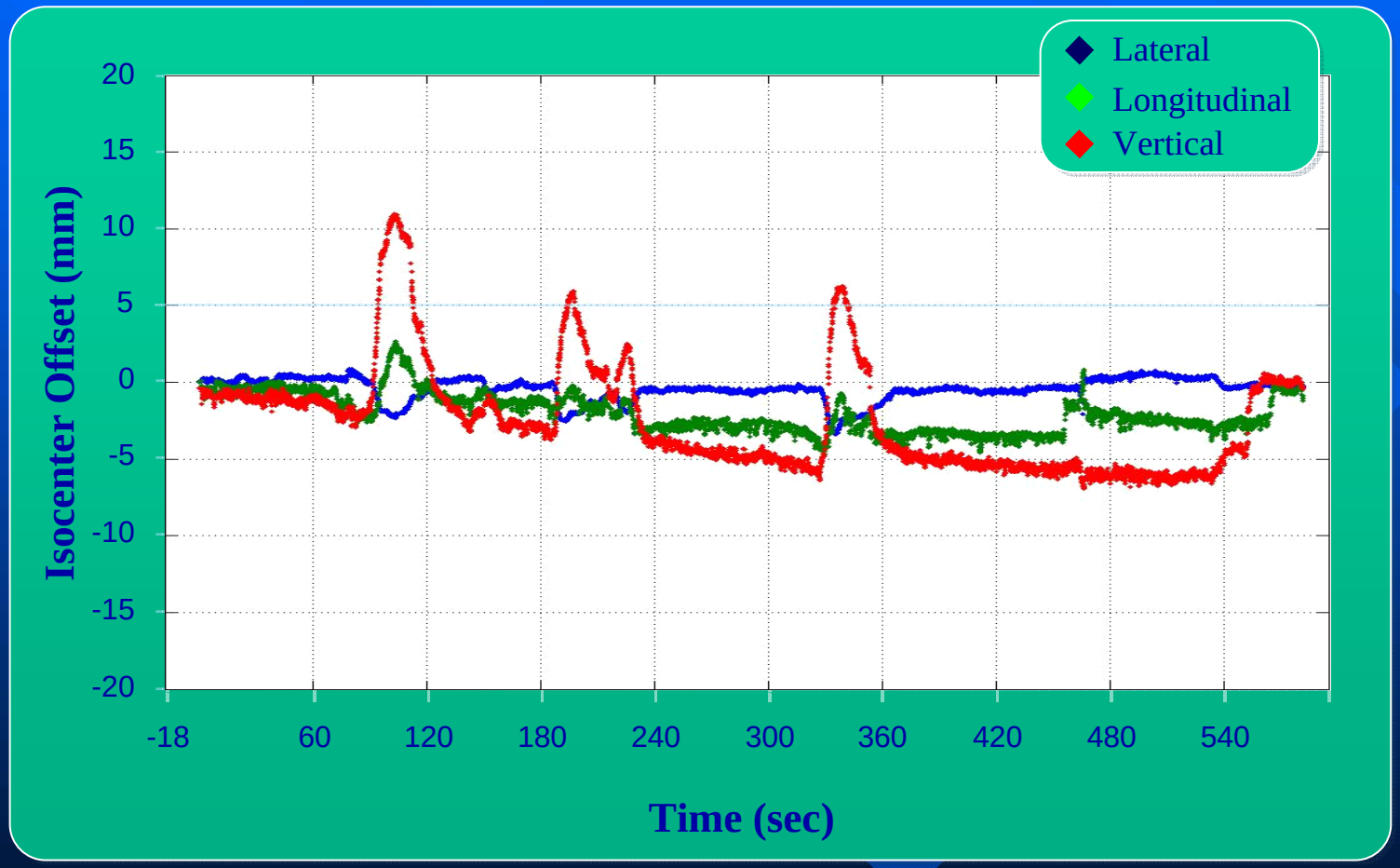
3D Variable Motion

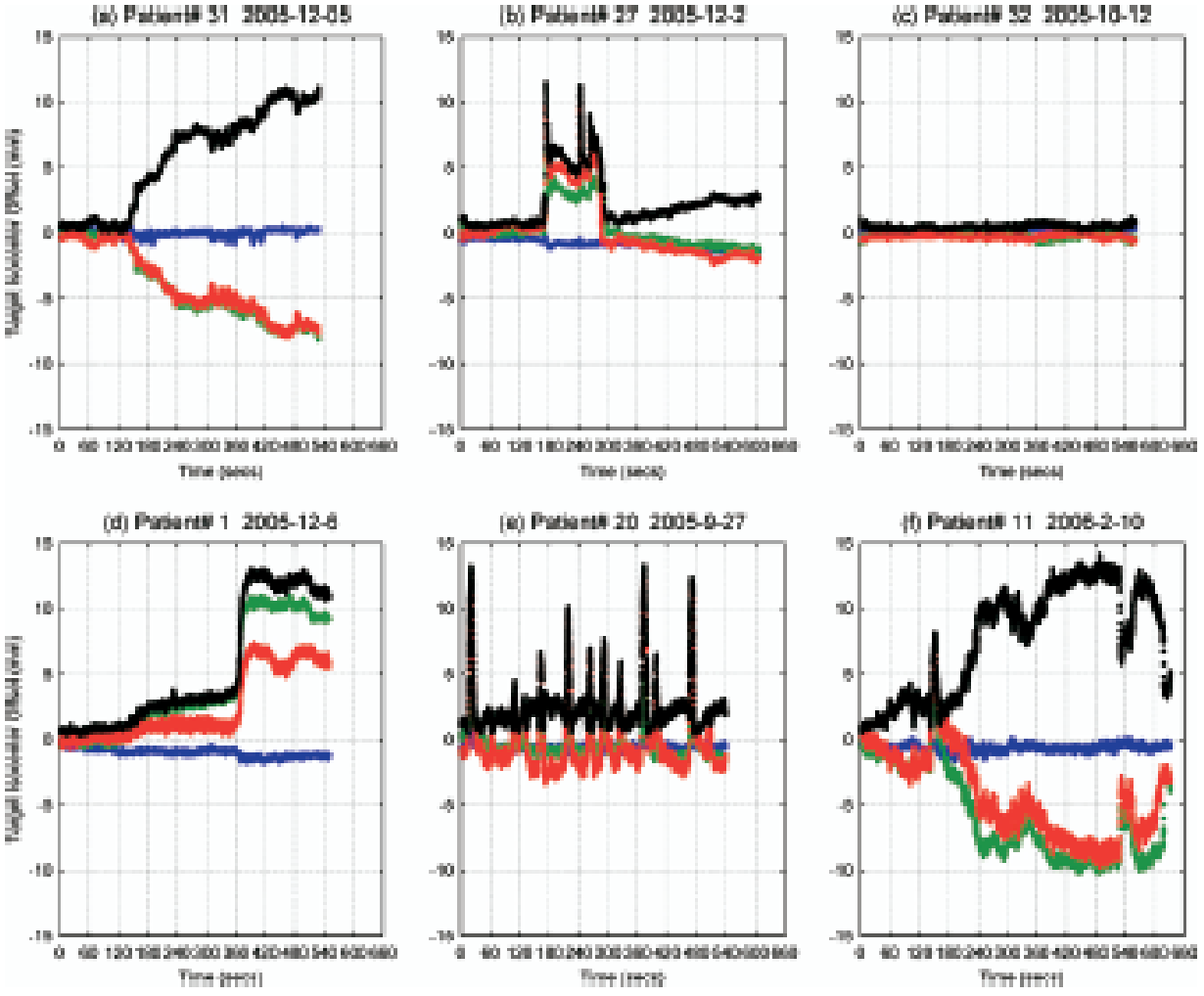


Clinical Results – Patient Tracking

Transient Excursion

Continuous Drift

Stable



Persistent Excursion

Erratic Behavior

High-Frequency Excursion

Kupelian et al., IJROBP 2007;67(4):1088-1098

How Much Interruption?

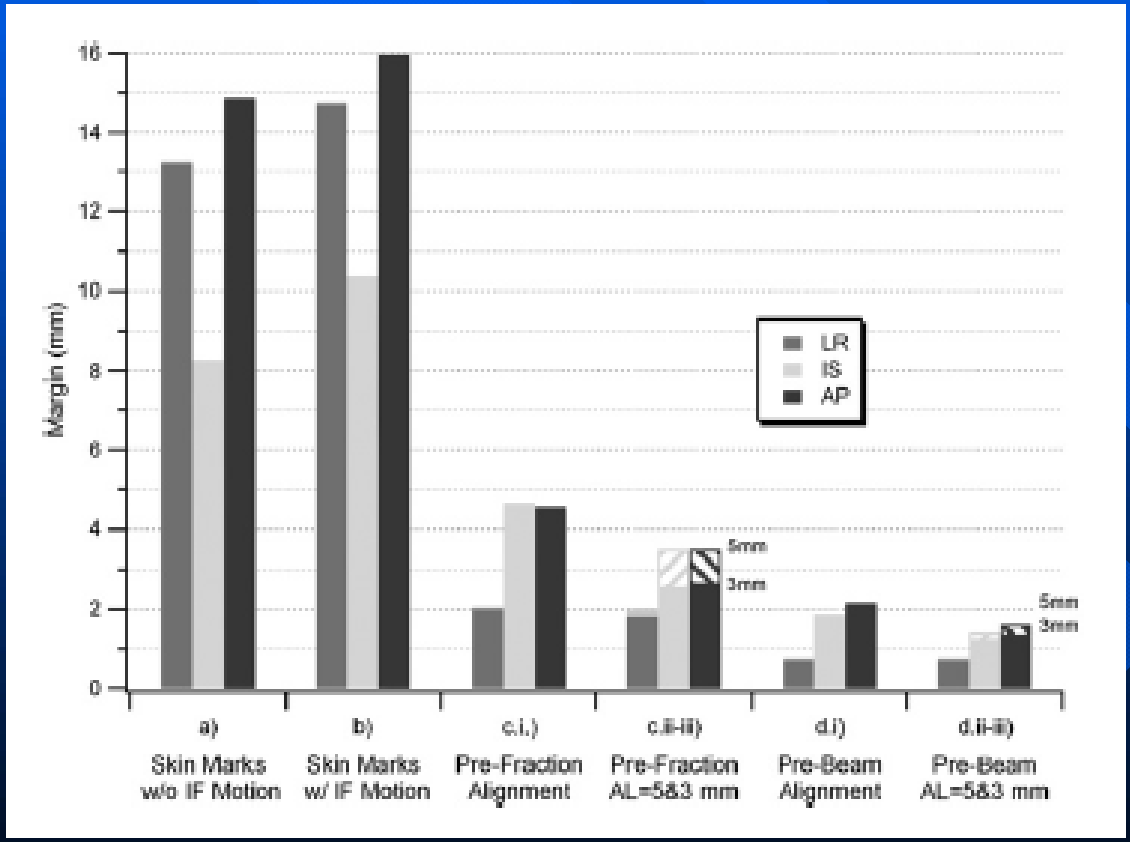
- Review of actions taken at 5 centers on multi-institutional study (35 patients)
  - Four used 5mm action threshold (998 fx)
  - One used 3mm action threshold (159 fx)

- Interventions in 36.2% of cases exceeding threshold, avg delay 35-120 seconds (interruption – realignment).

Enke et al., IJROBP 2006 66(3):S363

How Much Margin Do We Need?

- **Patients on Calypso intra-institutional protocol reviewed**



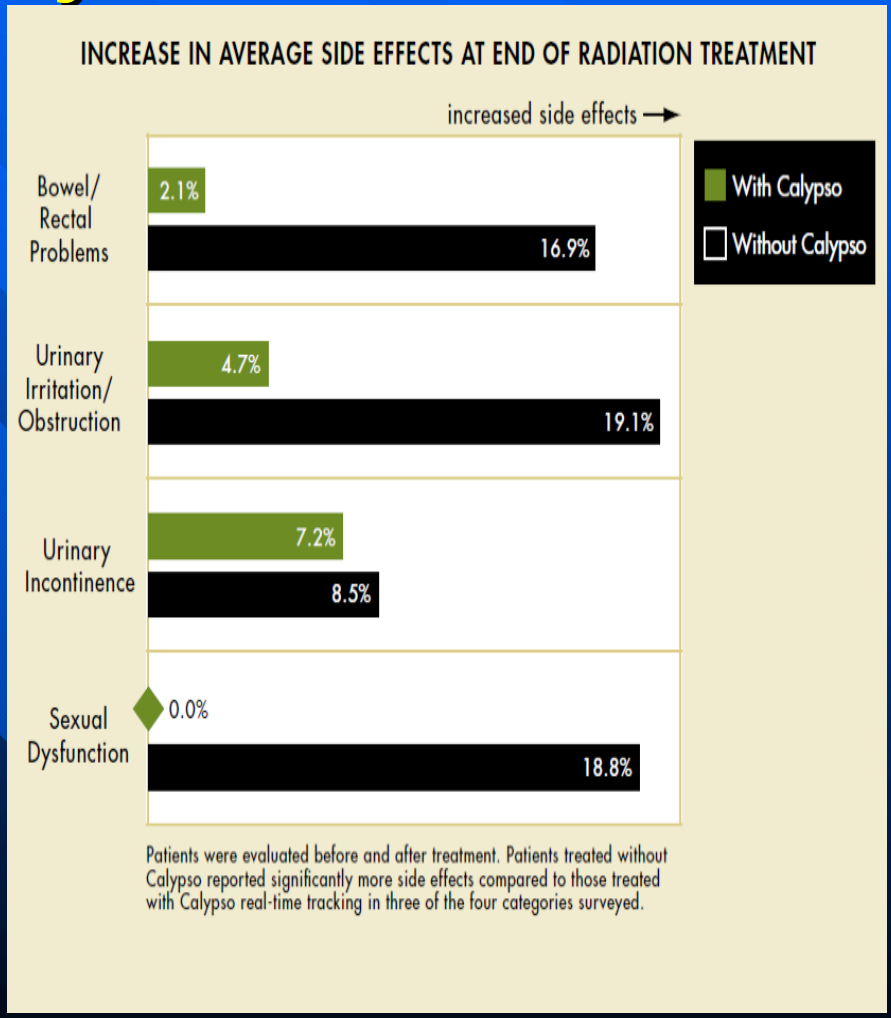
Litzenberg et al., IJROBP 2007

69(3):S363-S364

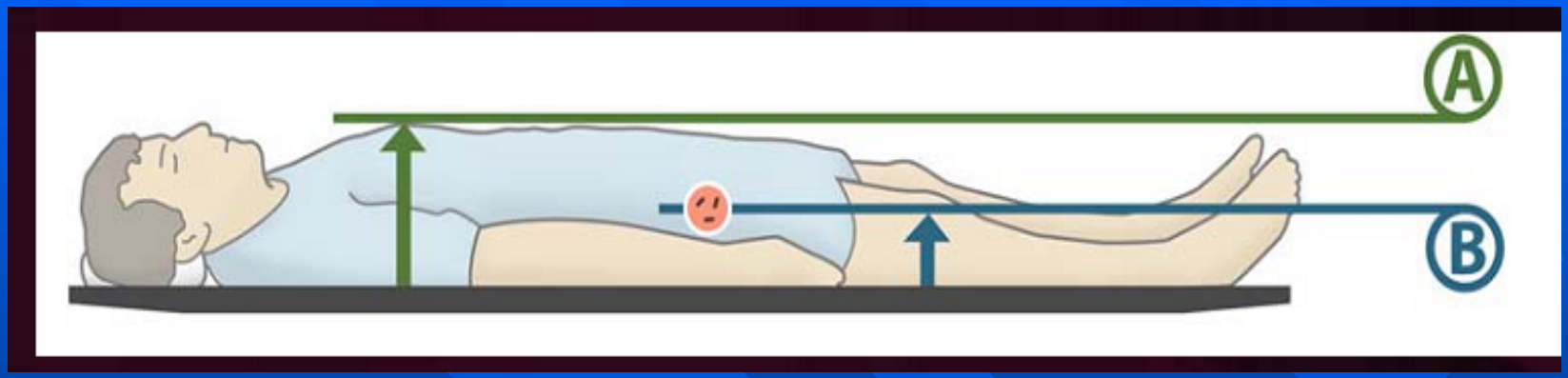
Margins forecasted by method of Van-Herck

Assessing the Impact of Margins (AIM) Outcomes Study Publication

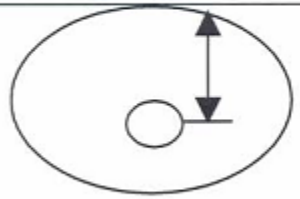
- **Published in *Urology* in May 2010**
- **Assessed effect of reduced treatment margins and real-time tracking on patient-reported quality of life (QOL), using previously published comparator cohort (Sanda et al, NEJM, 2008)**
- **Conclusion: AIM patients had significantly reduced acute GI, GU and some sexual symptoms compared to comparator cohort**



Treatment Planning



Patient Selection

	Prostate position from anterior surface	Designation
 Supine patient	< 17cm	Localize and track
	17-23 cm	Localize only
	>23 cm	Not a candidate for the Calypso System

Treatment Planning

Calypso® 4D Localization System
Localization Designation Worksheet
After Implantation

CALYPSO MEDICAL
On Target, On With Living™

DETERMINING A PATIENT'S LOCALIZATION DESIGNATION AFTER IMPLANTATION

1. Use the treatment planning system's distance-measuring tool to measure the patient's maximum anterior skin surface to table surface distance (A). Record this distance in centimeters on the worksheet below.
2. After selecting the isocenter position, measure the distance between the isocenter and the table surface (B). Record that distance in centimeters on the worksheet below.
3. Measure the distance from the most posterior transponder to the table surface (C). Record that distance in centimeters on the worksheet below.

LOCALIZATION DESIGNATION DETERMINATION WORKSHEET

Patients Name: Mc Qa Novalis Med Rec #:11335577

Anterior Skin Distance to table surface distance (A): " " cm

Isocenter or Prostate center to table surface distance (B): " " cm

Posterior transponder to table surface distance (C): " " cm
(Value < 6 cm system accuracy- see User's Manual for complete details)

Skin surface to prostate center or isocenter distance ((A minus B): " " cm

Skin surface to posterior transponder distance (A minus C): " " cm

LOCALIZATION DESIGNATION DETERMINATION

	Localization Designation		
	Localize and Track	Localize Only	Not a Candidate
Skin surface to prostate center or isocenter distance (A minus B)	< 17 cm (max 19 cm from array)	< 23 cm (max 25 cm from array)	> 23 cm (> 25 cm from array)
Skin surface to posterior transponder distance (A minus C)	< 19 cm (max 21 cm from array)	< 25 cm (max 27 cm from array)	> 25 cm (> 27 cm from array)

If the measurement is near the cutoff value between Localize and Track and Localize Only, you may need to determine the patient's localization designation during the first patient localization session.

CIRCLE THE PATIENT'S FINAL LOCALIZATION STATUS:

" " Localization and Track "" Localization Only "" Not a Candidate

Calypso® 4D Localization System
Treatment Planning Data Worksheet

CALYPSO MEDICAL
On Target, On With Living™

TREATMENT PLANNING (INPUT) CRF

Philips Pinnacle

INPUT UNITS

Centimeters

COORDINATES FROM TREATMENT PLANNING

Isocentric Coordinate: X: " " Y: " " Z: " "

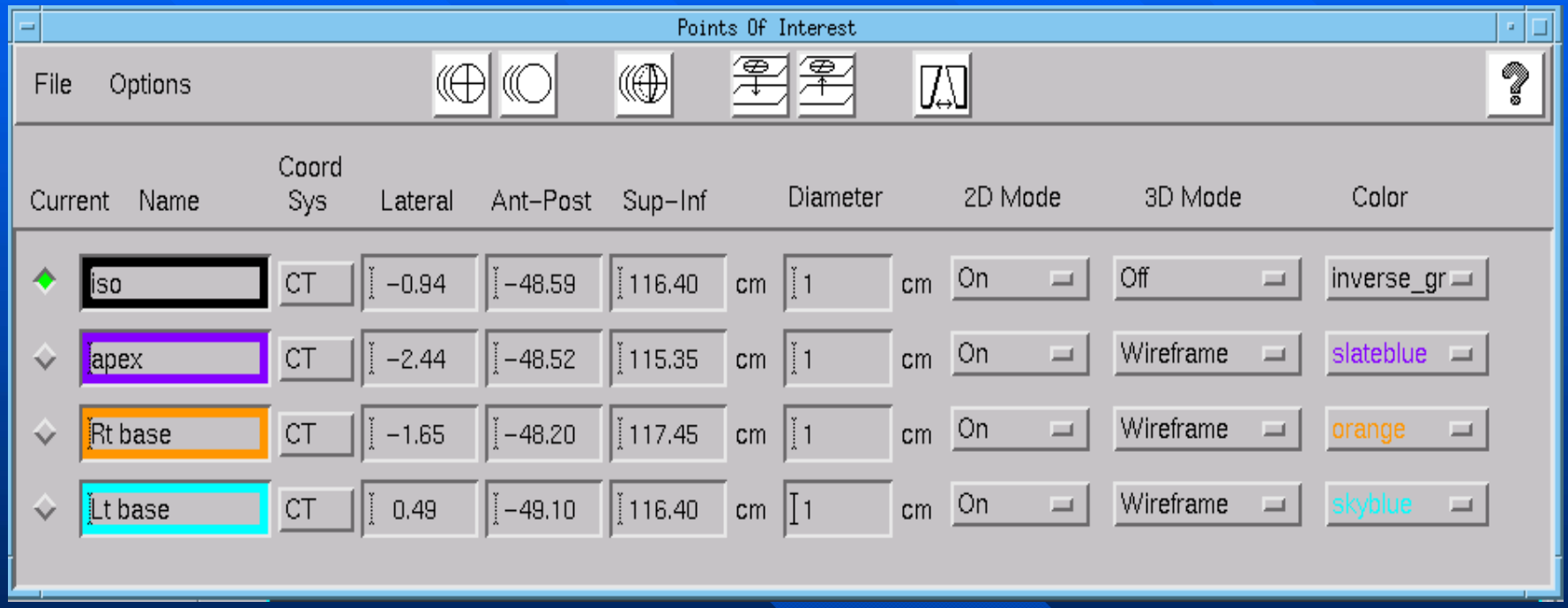
Apex transponder coordinates X: " " Y: " " Z: " "

Left base transponder coordinates: X: " " Y: " " Z: " "

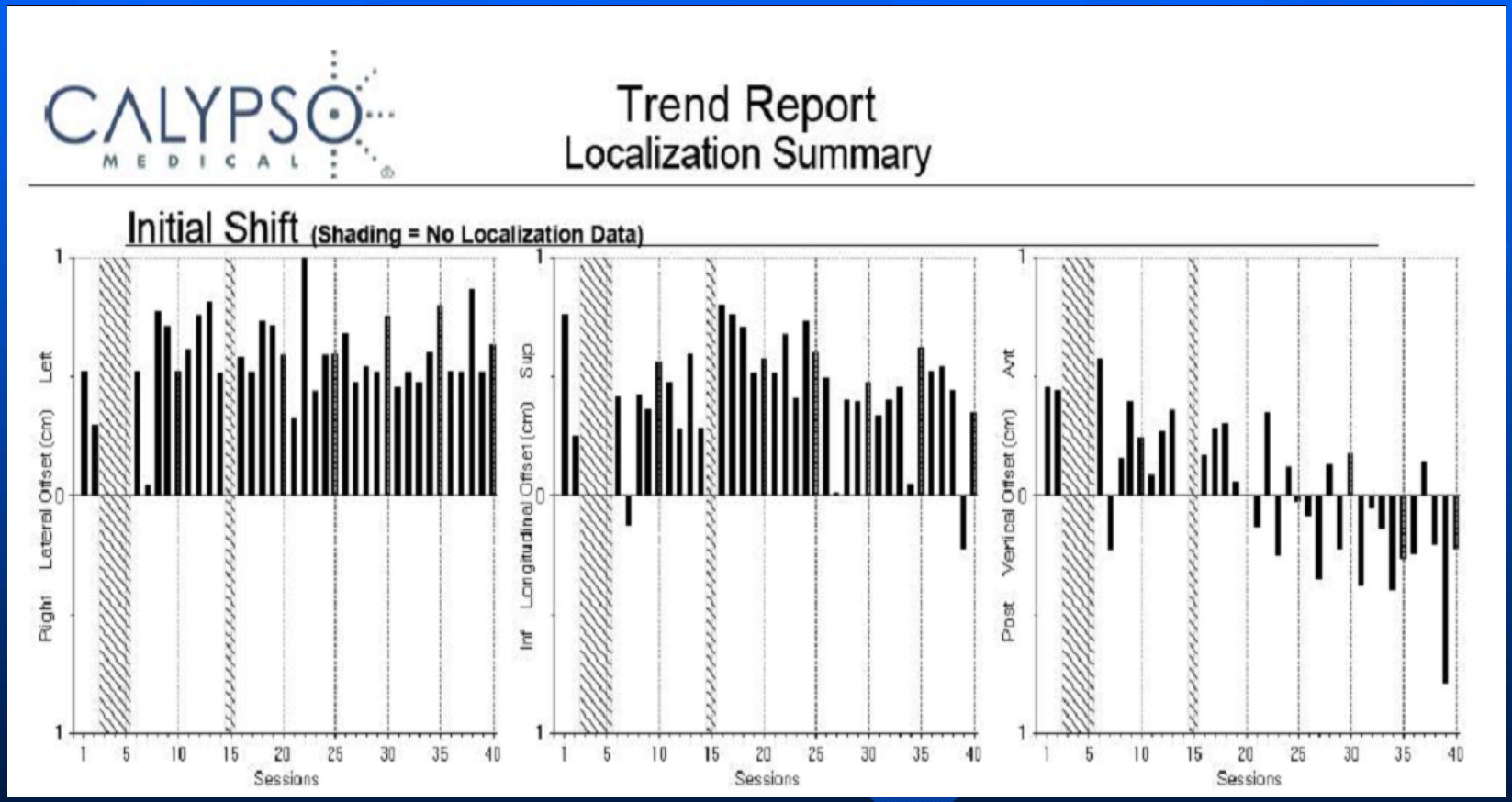
Right base transponder coordinates: X: " " Y: " " Z: " "

Document completed by:

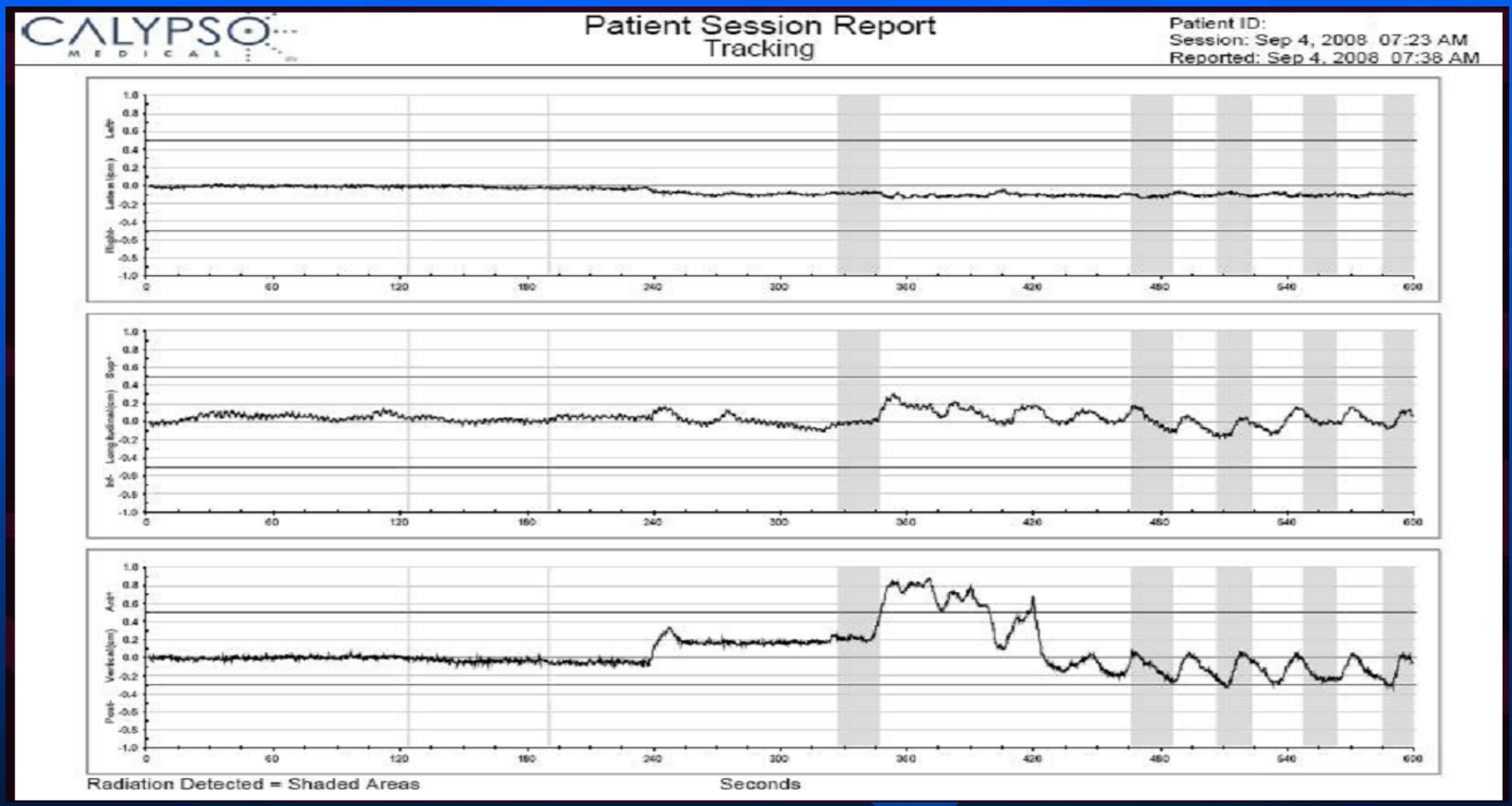
Treatment Planning



Generated Reports



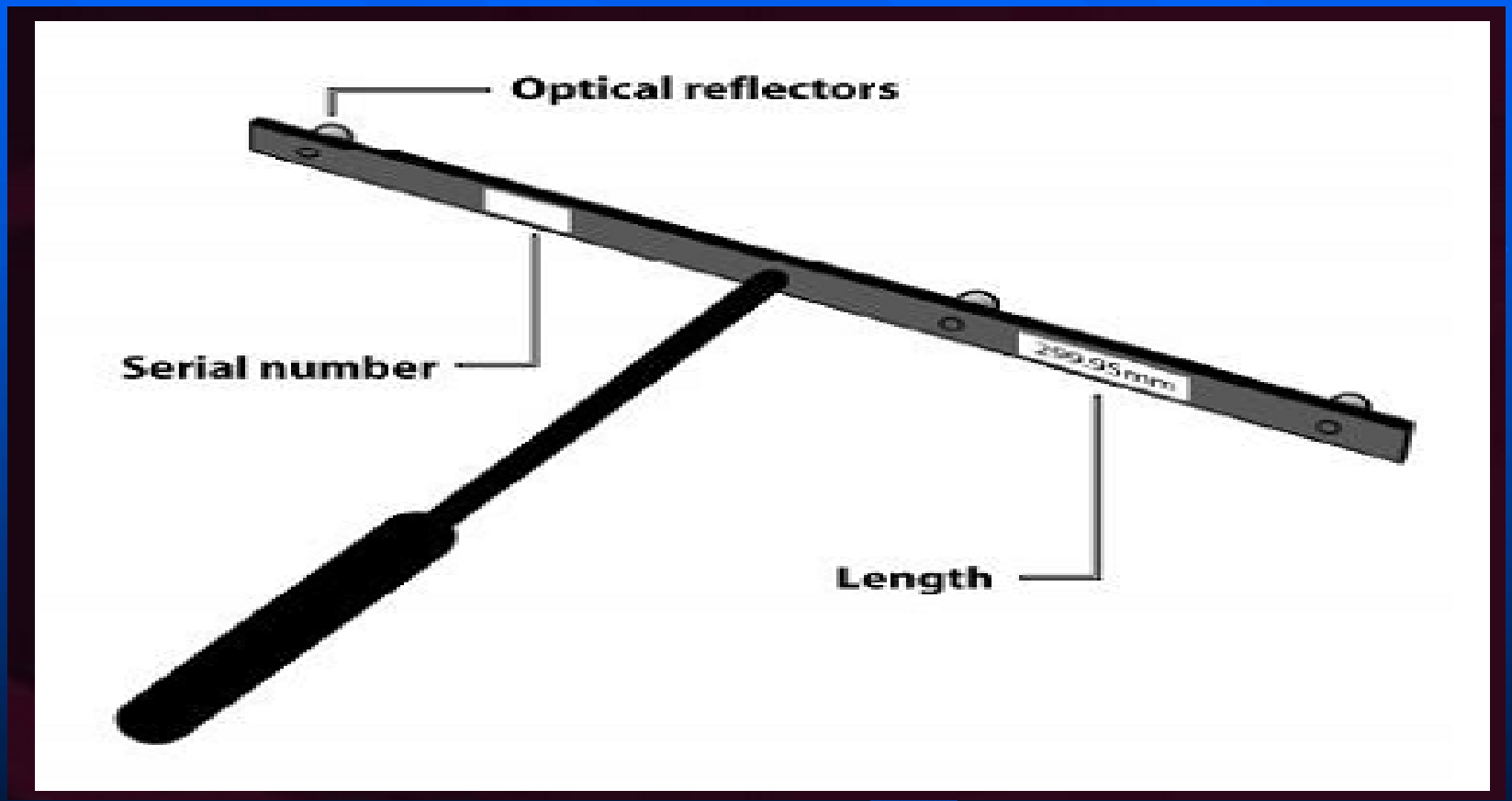
Generated Reports



QA

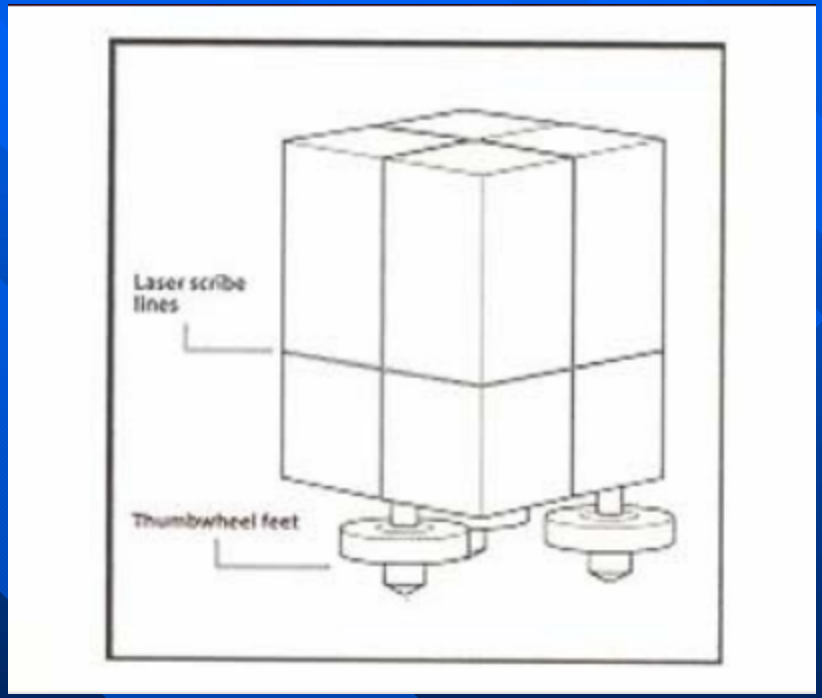
- Camera Calibration
  - Quarterly
  - L -Frame fixture
  - T-Frame fixture
- System Calibration
  - Daily and Monthly
  - Isocenter fixture

Camera Calibration

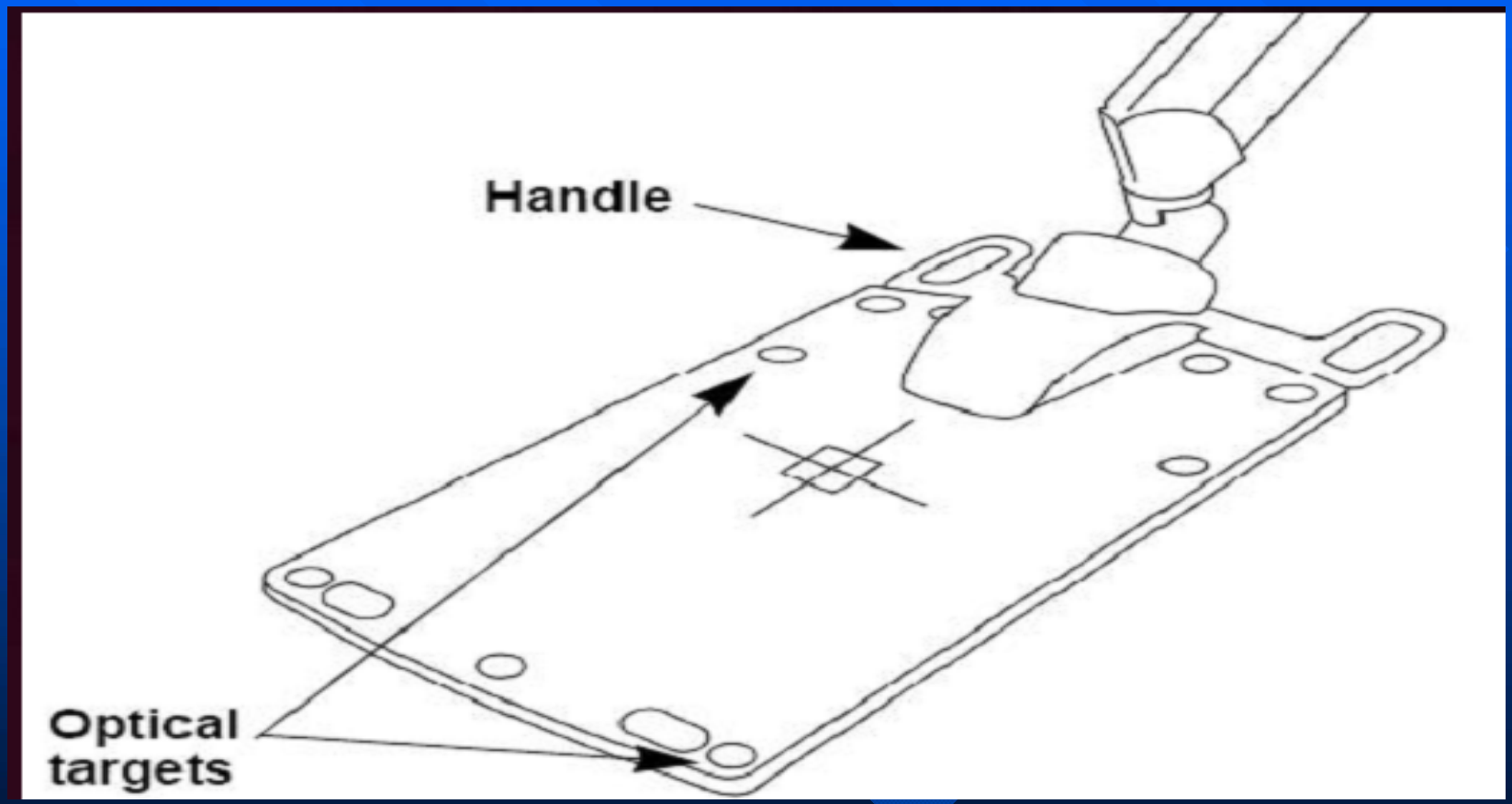


System Calibration

Calibrate Calypso coordinate reference frame to Machine isocenter (treatment room laser positions).



Panel



Calibration

Horizons

- Dynamic Dose Reconstruction
- Post-prostatectomy
- Hypo-fractionated prostate SBRT
- Lung Cancer
- Breast Cancer
- Pancreatic Cancer
- Spine SBRT

Prostate SBRT
RTOG 0938

- **36.25 Gy in 5 Fx**
- **2 Fx / week, 3 to 4 days apart**
- **5 or more IMRT non-coplanar beams or VMAT**
- **6 or 10 MV**
- **Fiducials, and possibly rectal balloon to immobilize the prostate**
- **GTV = CTV = Prostate**
- **PTV = CTV + 5 mm (3 mm Post)**
- **Prescription dose (PD) to at least 99% of prostate and 95% of PTV**
- **Max dose within PTV </= 7% above PD**
- **Urethra visualization required if max dose > 38.78 Gy**
- **If Tx time > 7 min, need tracking or repeat IGRT**

Prostate SBRT Dose-Escalation Study (Timmerman)

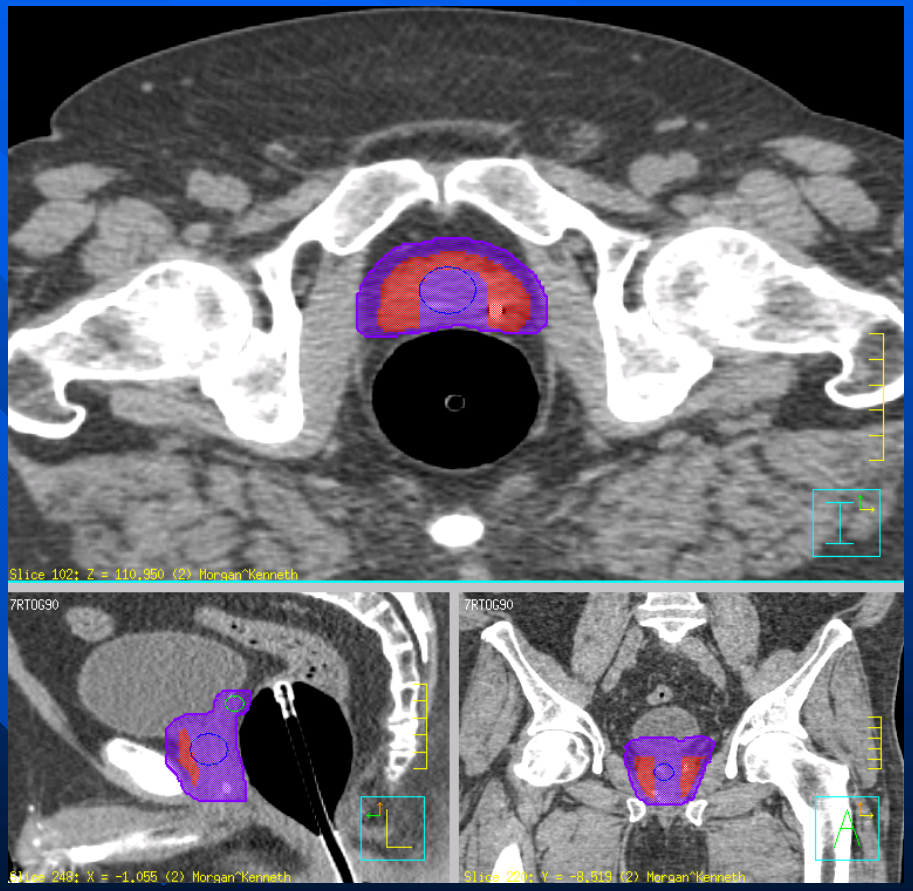
- **45, 47.5, and 50 Gy in 5 Fx**
- **Min 36 h between fractions**
- **6 to 15 MV Tomotherapy or Trilogy**
- **IMRT with Tissue Heterogeneity on**
- **Markers (gold seeds or Calypso) implanted 1 week before sim**
- **60-100 cc rectal balloon**
- **Urethra delineated with flexible catheter in sim**
- **CBCT before each fraction to confirm fiducials, ballon, and filling of bladder**
- **PTV = Prostate + 3 mm**
- **Prescription dose (PD) to at least 95% of PTV**
- **Urethra, Bladder wall and Ant Rectal Wall Max Dose </= 105% of PD**

Prostate SBRT CCF Experience

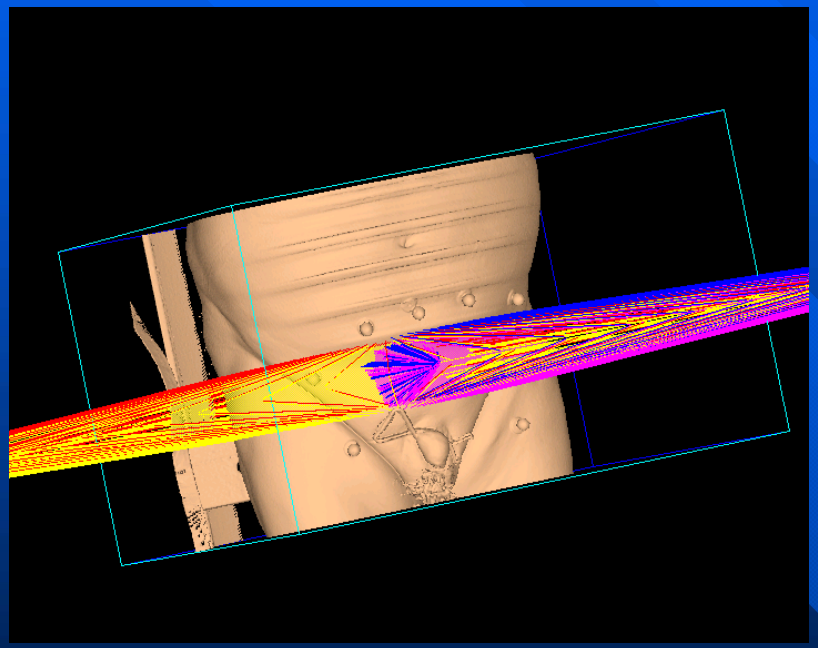
- **Combination of both protocols: Prostate and SV to 36.25 Gy and part of the Prostate to 50 Gy.**
- **Mimic highly conformal brachytherapy dose distributions**
- **5 Fx every other day**
- **6 or 10 MV Novalis TX**
- **IMRT VMAT or HybridArc with Tissue Heterogeneity on**
- **Markers (Calypso) implanted 1 week before sim**
- **100 cc rectal balloon**
- **Urethra delineated with flexible catheter and contrast in sim**
- **PTV = Prostate + 5 mm (3 mm post limited by rectum)**
- **PTV SV = SV + 4 mm (3 mm post limited by rectum)**
- **High dose area: PTV-50 = Prostate – Bladder – Rectum – Expanded Urethra**
- **Expanded Urethra: 7 mm lat and ant, 2 cm post**
- **CBCT before each fraction to confirm fiducials, ballon, and filling of bladder**
- **Tracking using Calypso**

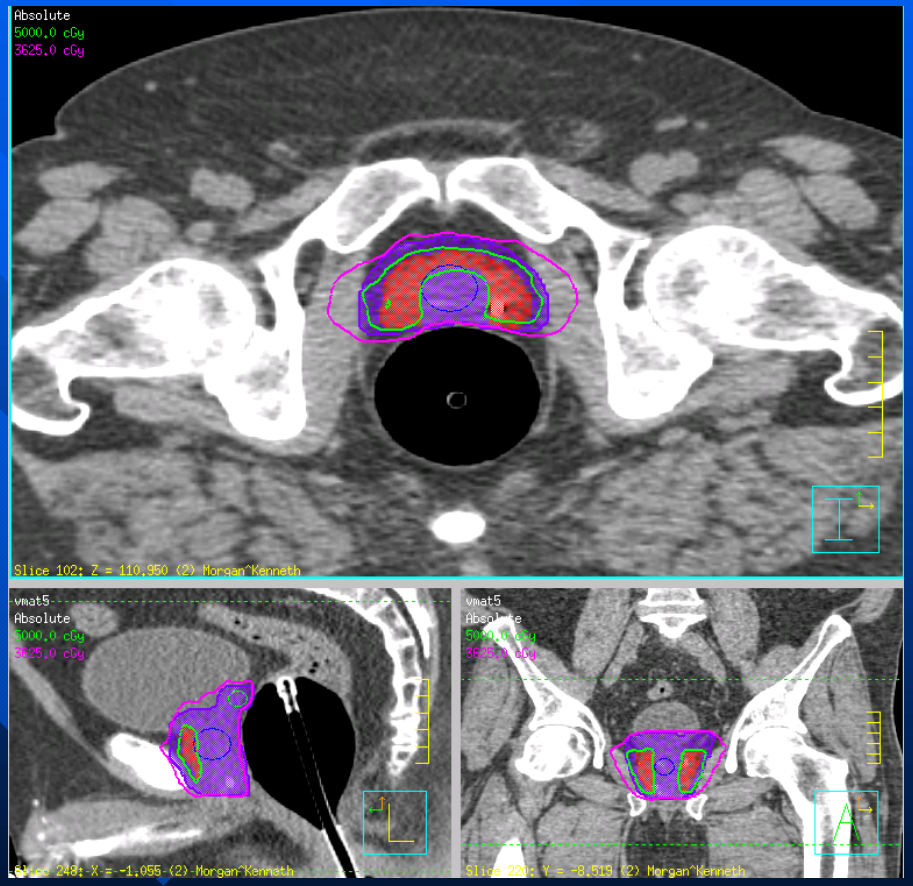
Prostate

- Prostate implanted with calypso transponders
- Balloon inserted during the sim
- High risk area delineated
- 36.5 Gy in 5 fx QED
- 50 Gy HRA
- Use VMAT or Hybrid arcs



Prostate




Absolute
5000.0 cGy
3625.0 cGy
Slice 102: Z = 110.950 (2) Morgan^Kenneth
vmat5
Absolute
5000.0 cGy
3625.0 cGy
vmat5
Absolute
5000.0 cGy
3625.0 cGy

Spine SBRT (with instrumentation)

- Tested in acrylic phantom with up to 6 cm of medium density bone slabs (1.6g/cm^3) or up to 2 cm bone cement.

- Tracking accuracy <0.5 mm for 30 second tracking demos.

Djemil et al., IJROBP 2007 69(3):S2105

Lung and Spine (Clinical Phase I)

- Calypso transponders successfully implanted into 4 spine and 2 lung SBRT patients

- Position of transponders verified by kV X-ray prior to treatment
  - All 4 spine cases remained stable
  - One lung case stable, other pt evacuated transponder

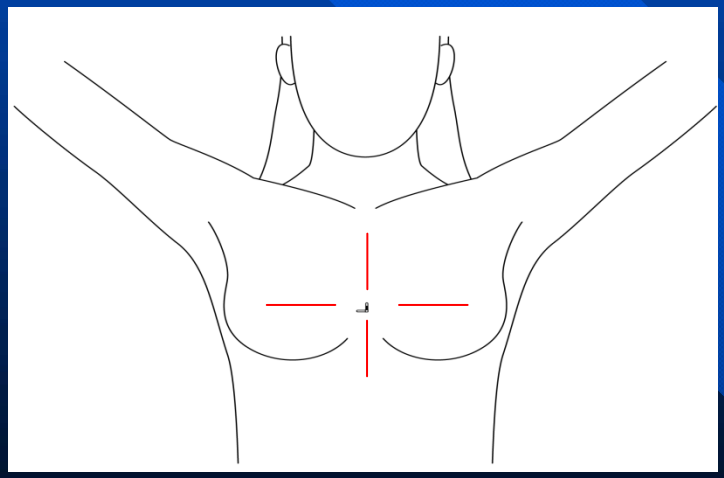
- All 6 patients tracked successfully. Spine transponders approached maximum distance for tracking (25 cm).

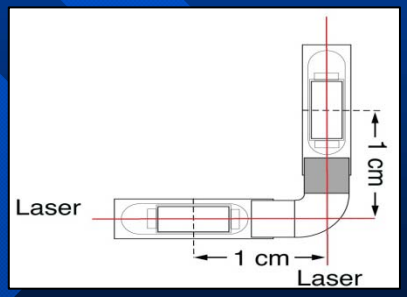
Willoughby et al., IJROBP 2008 72(1):S642-S643

Breast Cancer

Use Surface Transponder For Motion Monitoring During Treatment

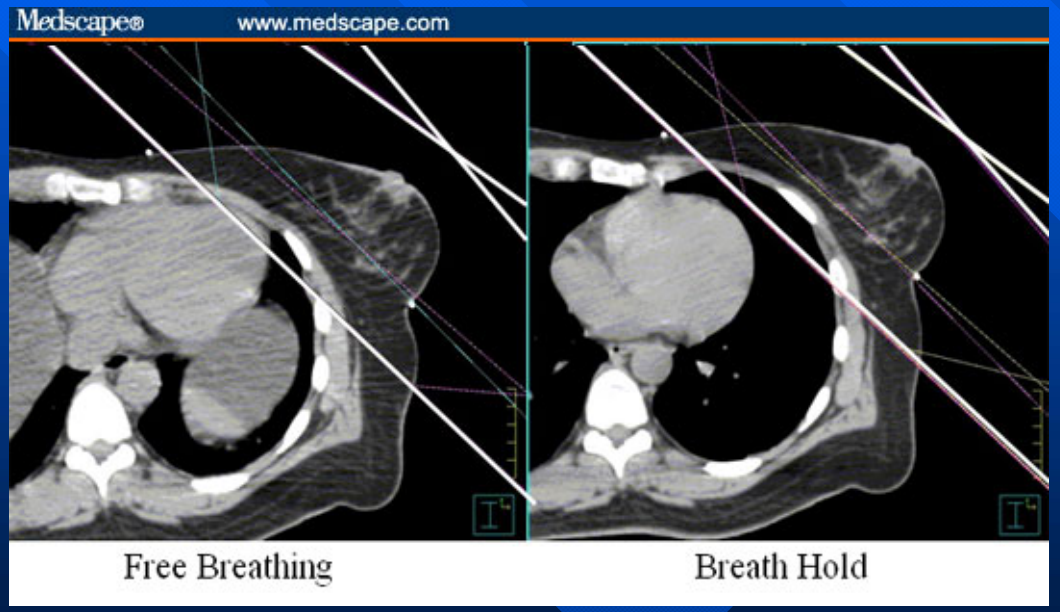
- **Single patient, multiple use**
- **Place on skin mark and align with lasers**
- **Use orientation indicator + setup notes to ensure correct device orientation**
- **Confirm patient set-up with alternate alignment method (lasers and tattoos, SSD measurements or imaging)**





Breast Cancer

Utilize Calypso Surface Transponder with left-sided breast patients to monitor breath hold position during radiation delivery and reduce cardiac exposure



Acknowledgements

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