

## Vendor Provided Data, Tools and Test Procedures: What Is Safe Practice?

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UC San Diego Health

RETHINKING MEDICAL PHYSICS



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## Disclosures

- Founding partner
  - TreatSafely Foundation
    - [www.treatsafelyfoundation.org](http://www.treatsafelyfoundation.org)
  - Image Owl, LLC
    - [www.imageowl.com](http://www.imageowl.com)

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## Clinical Use of Linac Systems

- Equipment Specifications
- Acceptance Testing
- Commissioning (and clinical implementation)
- Periodic Quality Assurance (on-going)

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## How risky are closed systems?



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## Early Evidence

### Credentiaing results from IMRT irradiations of an anthropomorphic head and neck phantom

Andrea Molinaro, Nadia Hernandez, Terry Nguyen, Geoffrey Abbott, and David Followill  
 Department of Radiation Physics, The University of Texas MD Anderson Cancer Center, Houston, Texas 77030  
 Medical Physics, Vol. 40, No. 2, February 2013

### Conclusions

Some Linac-TPS combinations had higher passing percentages than others.

Causes for failures include incorrect data entered into the TPS, inexact beam modeling...

TABLE II. Pass rate versus IMRT technique, treatment planning system, linear accelerator manufacturer, and linac-TPS combination.

	Criterion failed			
	Pass rate (%)	Atrophic	Deer	DPA, Deer and DPA
<b>IMRT technique</b>				
Distant MLC	88	206	26	5
IMAT	86	103	11	3
Segmental	76	434	109	15
Wild assessment	61	7	4	0
Tomotherapy	93	99	6	1
<b>Treatment planning system</b>				
Eclipse	88	387	30	8
Pinnacle	75	425	84	13
Tomotherapy	92	99	6	1
XIO	76	137	19	4
Other	78	31	17	3
<b>Linear accelerator manufacturer</b>				
Elekta	67	130	37	4
Siemens	70	135	32	3
Tomotherapy	83	99	6	1
Varian	85	775	81	13
<b>Linac-TPS combination</b>				
Eclipse/Pinnacle	66	90	28	3
Eclipse/Edge	67	76	21	0
Tomotherapy/Eclipse	93	99	6	1
Varian/Eclipse	90	177	22	7
Varian/Pinnacle	81	327	36	5
Varian-XIO	77	74	10	1

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## Example: Halcyon closed system

Designed to offer a fast path from acquisition to clinical deployment: pre-commissioned, imaging based.



Images from: Lloyd et al. TG-51 reference dosimetry for the Halcyon: A clinical Experience. JACMP, 2018.

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## Early research on the Halcyon closed system

### Application of TG-100 risk analysis methods to the acceptance testing and commissioning process of a Halcyon linear accelerator

P. Troy Teo and Min-Sig Hwang  
 Division of Medical Physics, Department of Radiation Oncology, University of Pittsburgh School of Medicine and UPMC Hillman Cancer Center, Pittsburgh, PA, USA

William (Gary) Shields  
 D3 Oncology Solutions/CTSE, 580 South Allen Avenue, Pittsburgh, PA, USA

Pavel Kosterin, Si Young Jang, Dwight E. Heron, Ronald J. Latonde, and M. Saiful Haq<sup>†</sup>  
 Division of Medical Physics, Department of Radiation Oncology, University of Pittsburgh School of Medicine and UPMC Hillman Cancer Center, Pittsburgh, PA, USA

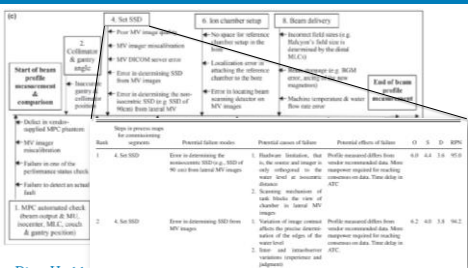
(Received 2 October 2018; revised 25 November 2018; accepted for publication 17 December 2018; published 4 February 2019)

Med. Phys. 46 (3), March 2019

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## Early research on the Halcyon closed system



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## Commissioning Top Failure Modes

- Error in setup due to multiple options provided for reference dosimetry by the manufacturer
- Error in determining non-isocentric SSD (e.g., for SSD = 90 cm) from lateral MV images
- Incorrect field sizes
- Failure to detect an actual fault (with MPC)



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## Additional research on the Halcyon

### Clinical Safety Assessment of the Halcyon System

Todd Pawlicki, Todd Atwood, Kristen McConnell, Grace Kim

UC San Diego, Department of Radiation Medicine & Applied Sciences, La Jolla, CA 92093 USA

### Systems Theoretic Process Analysis (STPA)

60<sup>th</sup> Annual Meeting of the American Association of Physicists in Medicine, Nashville, TN, July 29 – August 2, 2018  
Under review in *Medical Physics*

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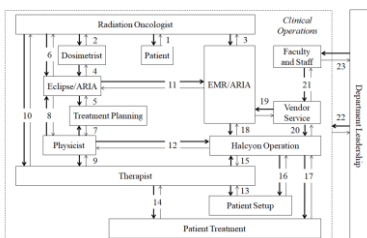
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## Description of Halcyon Usage



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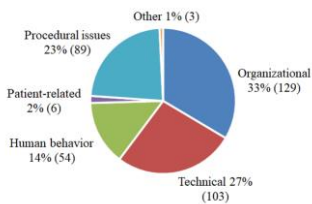
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## Key Results



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## Main Conclusions

- Majority of safety concerns are related to non-technical issues
  - Accept closed system, vendor's responsibility
- Streamline, reduce, or eliminate some traditional commissioning and routine QA
  - Focus on organizational management, procedures, and human behavior
- Some checks are still warranted

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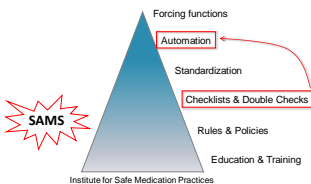
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## Automation and Machine Learning

- Automation
  - Knowledge-Based Planning
- Machine Learning
  - Reduce unnecessary QA
  - Trigger preventive maintenance
  - Model and predict machine performance issues
    - Machine performance logs + QA measurements



Kalet et al. *Med Phys.* 2019 Feb 15.

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## Da Vinci Robotic Surgery

- \$2 million device (cost)
- 10,000 individual parts
- 1.4 million lines of code



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## Pubmed Search for "Quality Assurance"

### Da Vinci

- FDA Cleared in 2000
  - 19 years on the market
- **3 publications on QA**
  - Surgical training program
  - Robot program implementation
  - Optical brain imagers (n/a)

### TrueBeam

- FDA Cleared in 2010
  - 9 years on the market
- **48 publications on QA**
  - All on machine performance or new ways to check the Linac

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## Summary

- Some evidence that closed Linac-TPS systems are less risky than open systems
- Automation and ML may help ensure quality and safety of closed Linac-TPS system
- May be better for physicists to focus on clinical operations and direct patient care rather than 'opening' closed systems

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