

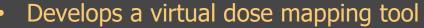
Monte Carlo Simulations as a Product Design Tool

Tobias Funk, PhD, and Daniel Badali, PhD



- Co-development company
- 100+ employees in Newark, CA and Boston
- Focus on life sciences and medical device development
- Internal R&D partially funded by government grants
- Spins out internal ideas as independent products

DOSE INSIGHT



- Seeks to deploy the tool with
 - Medical device developers
 - Sterilization vendors
- Visit us at: <u>www.doseinsight.com</u>



Requirements that a tool can be used for Product Design

Make decisions and changes informed by the tool

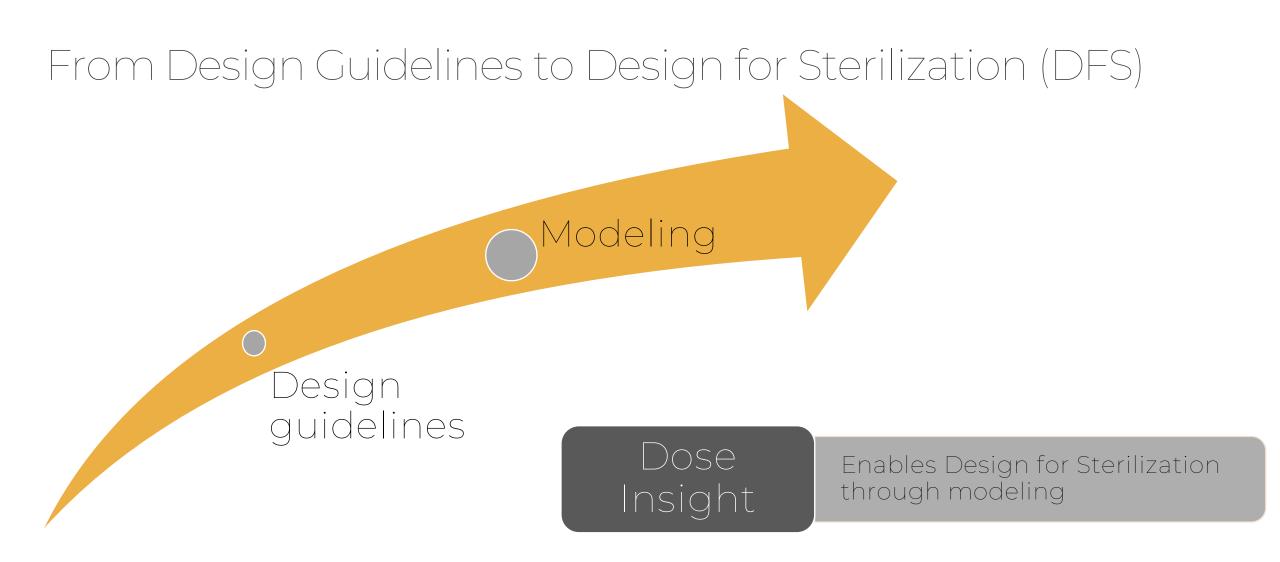
- Accuracy
- Ability to iterate on a design
 - Can be used without relying on a physical device
 - Delivers results fast (hours vs days)
- User-friendly and usable by an expert in product design
- Deliver results with small uncertainty



From Design Guidelines to Design for Sterilization (DFS)

Design	Design rules	EtO: avoid cavities where gas can get trapped, conformally coated circuit boards, etc.
guidelines	Material compatibility	AAMI TIR17 <i>Compatibility of materials subject to sterilization</i> , 2017
	Consulting with vendors	Leverage decades of experience

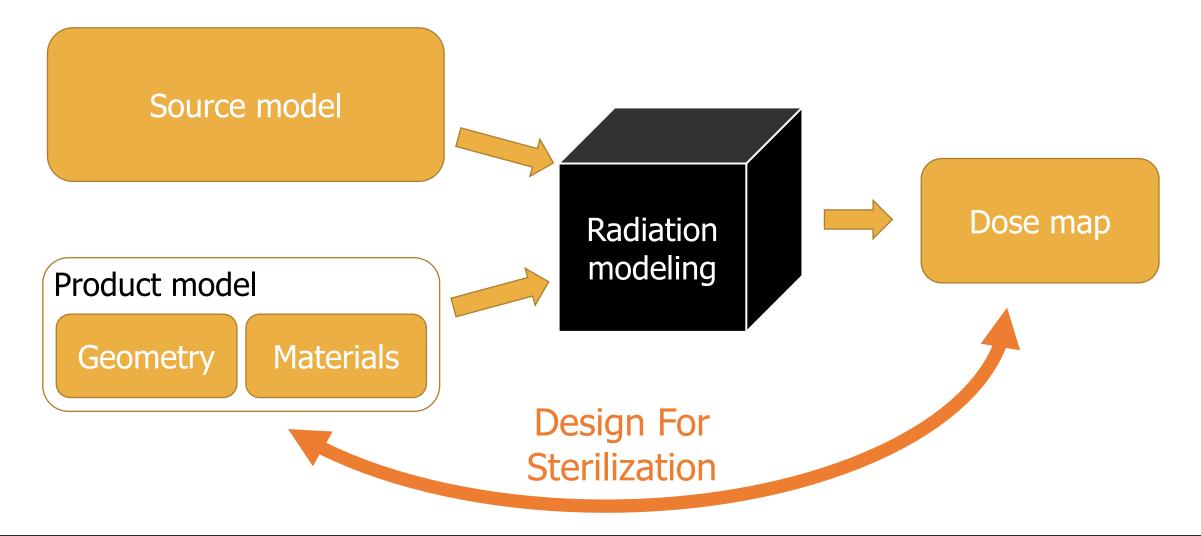




Many industries went from design guidelines to modeling. Examples: flow simulations for injection molding, data center design.



Predicting the dose map using modeling





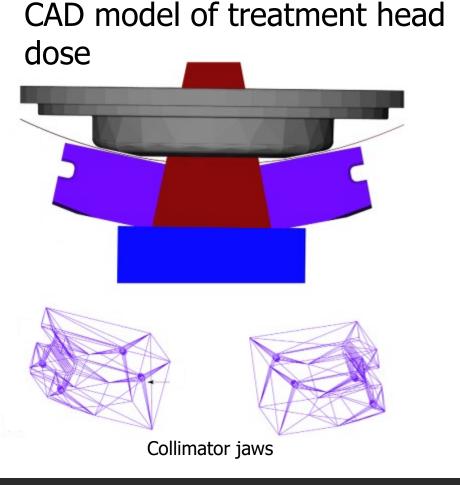
Are Monte Carlo simulations accurate?

Yes!

See for example: "Monte Carlo methods for device simulations in radiation therapy," by Park et al. in: Physics in Medicine and Biology, vol. 66, no. 18, pp. 1361-6560, 2021



Validation of Geant4 with a 6 MeV X-ray beam M. Constantin et al., Medical Physics, 38 (2011). Collaboration between Stanford and Varian

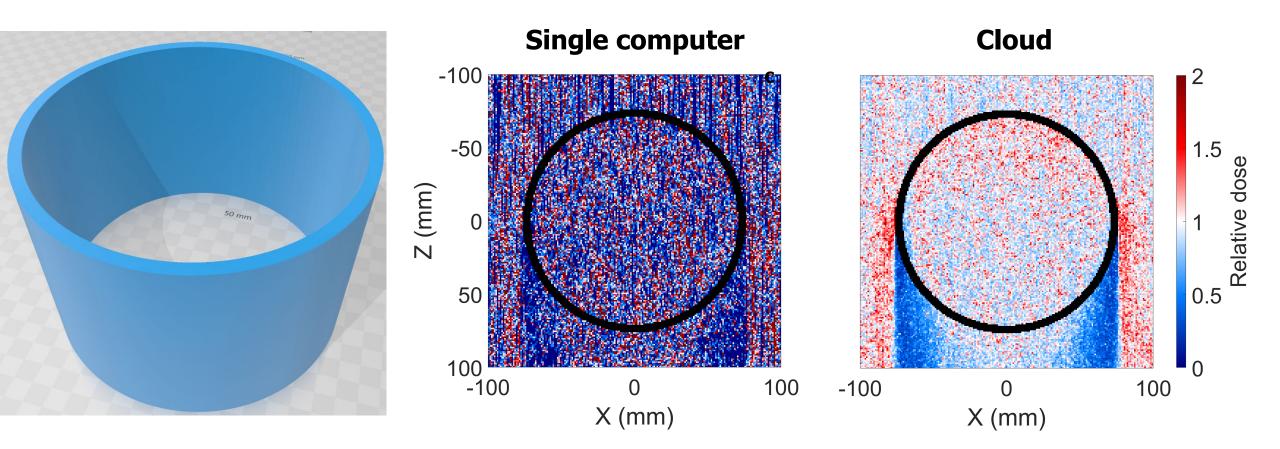


Experiment and Monte Carlo Dose (cGy/MU) 0.6 0.4 0.2 4×4 0 10x10 40x40 50 100 250 300 200 150 (a) Depth [mm] 0.06Dose Difference 0.04* 0.02 -0.02-0.04-0.06^L 50 300 100 200 250 150(b) Depth [mm] 98% of measurement values are within 2% of simulated dose





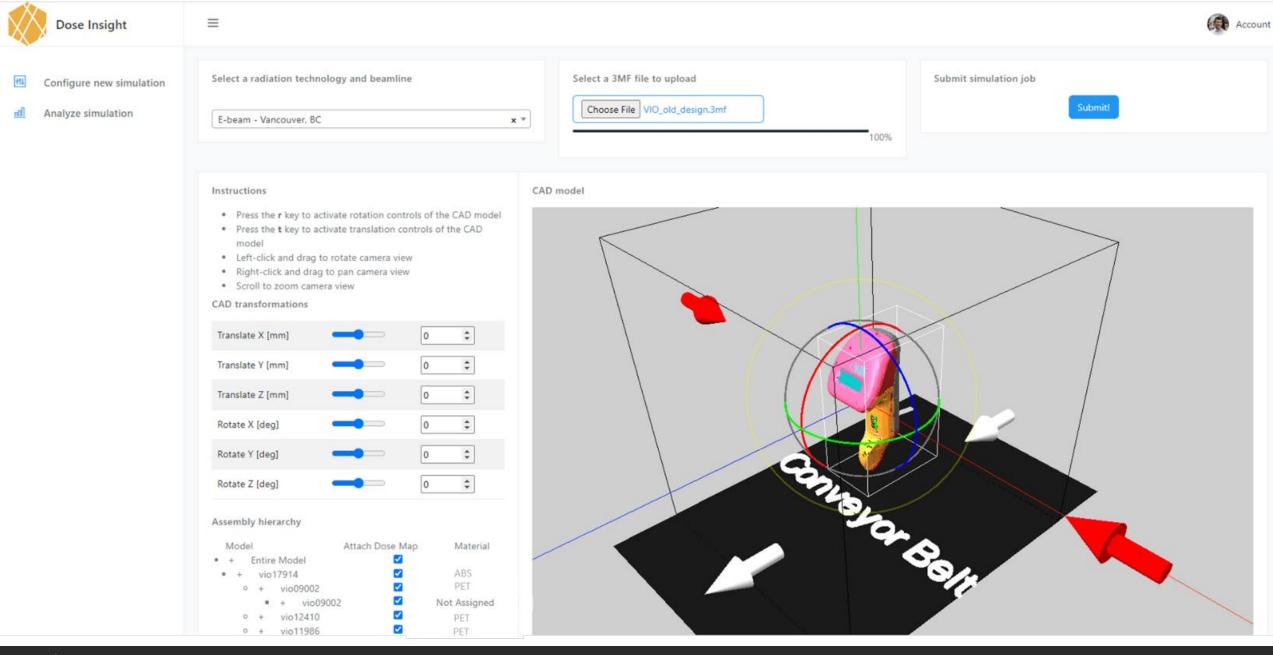
Are Monte Carlo simulations fast?





Are Monte Carlo Simulations user friendly?







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Controls

491 Configure new simulation

- Analyze simulation nNi
- 3D dose map Instructions Change the lower/upper dose thresholds to only display low/high dose regions Change the colorbar's lower/upper dose to change which color is assigned to which dose Change the reference dose to scale the dose map · Left-click and drag to rotate camera view [kGy] • Right-click and drag to pan camera view · Scroll to zoom camera view 31 Reference dose [kGy] 25 ‡ 30 Colorbar lower dose [kGy] 17 32 28 Colorbar upper dose [kGy] 32 17 27 Threshold lower dose [kGy] 17 \$ 26 Threshold upper dose [kGy] \$ 31 CAD display Solid ~ 25 23 22 21

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Mean Configure new simulation

Analyze simulation

Instructions 3D dose map • Change the lower/upper dose thresholds to only display low/high dose regions • Change the colorbar's lower/upper dose to change which color is assigned to which dose • Change the reference dose to scale the dose map • Left-click and drag to rotate camera view [kGy] • Right-click and drag to pan camera view Scroll to zoom camera view Controls 31 Reference dose [kGy] 25 \$ 30 Colorbar lower dose [kGy] 32 17 28 Colorbar upper dose [kGy] 17 32 27 Threshold lower dose [kGy] \$ 29 26 Threshold upper dose [kGy] 31 ÷ CAD display Solid ~ 25 23 22 21 19

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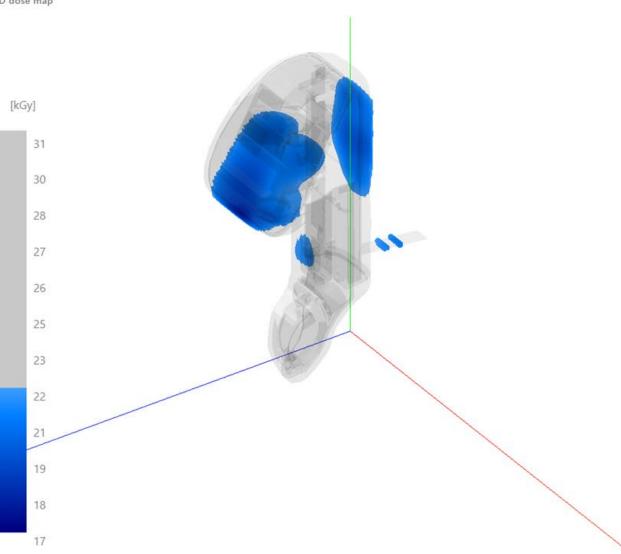
Analyze simulation nfil

3D dose map

- Change the lower/upper dose thresholds to only display low/high dose regions
- Change the colorbar's lower/upper dose to change which color is assigned to which dose
- Change the reference dose to scale the dose map
- · Left-click and drag to rotate camera view
- Right-click and drag to pan camera view · Scroll to zoom camera view
- Controls

Instructions





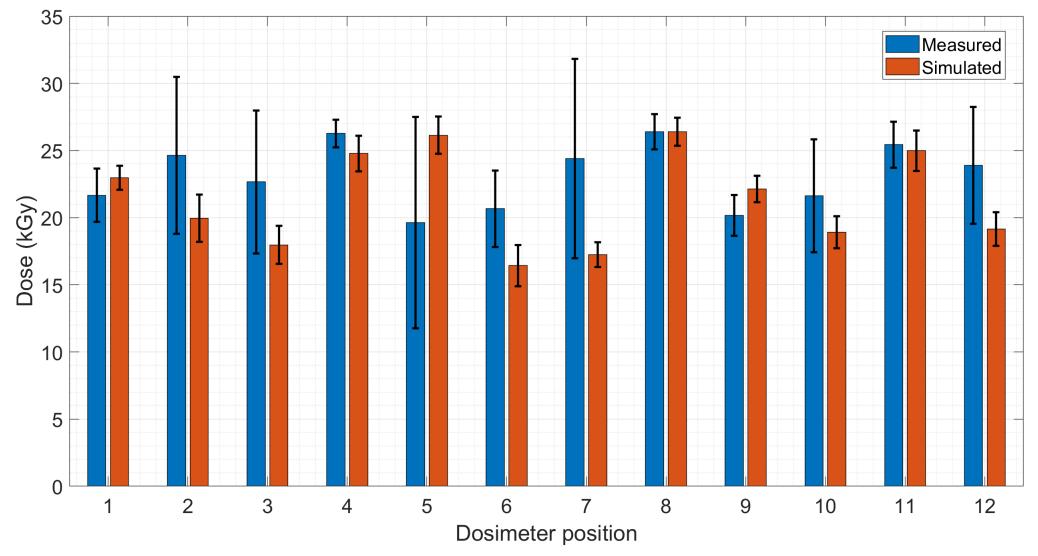


Comparison: Measurement vs. Modeling

Product Name:	Handheld Medical Device	Configuration: All Edited Date: N/A
1. Â 2. Â	Open Device View	 On top of device parallel to the beam. On the button of device parallel to the beam. On device handle parallel to the beam. On the bottom of sensor parallel to the beam. On the right side of device handle. On left side of device handle.
		Perpendicular –
	MILES CONTRACTOR	Visible – Other –
19 millin	4.	Hidden – Wrapped –



Comparison: Measurement vs. Modeling



Good agreement withing error bars, but measured data has large uncertainties



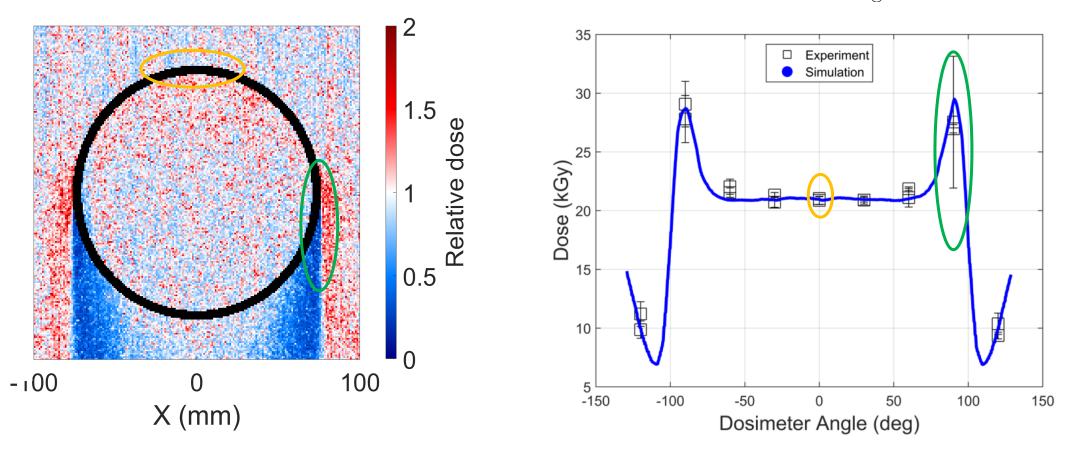
Comparison: Modeling vs. Measurements at a 10MeV e-beam sterilization facility



We explore measurement uncertainties on a much simpler system. Dosimeters were placed at the circumference of the cylinder



Comparison: Modeling vs. Measurements at a 10MeV e-beam sterilization facility



Areas with small gradients have small uncertainty, areas with large gradients have large uncertainties



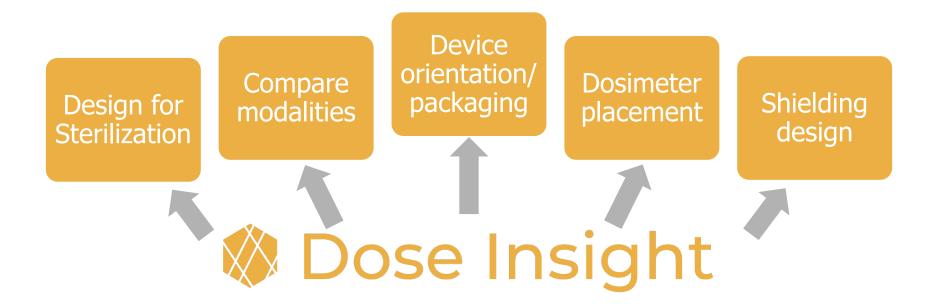
Requirements that a tool can be used for Product Design

Do Monte Carlo simulations meet these requirements?

- Accuracy 💊
- Ability to iterate on a design \checkmark
 - Can be used without relying on a physical device
 - Delivers results fast (hours vs days)
- User-friendly and usable by an expert in product design \checkmark
- Deliver results with small uncertainty \checkmark



Dose Insight's approach



- Dose Insight enables any engineer to produce virtual dose maps
- Collaborate with us to use modeling in your development process
- Get in touch today! <u>https://doseinsight.com</u> or <u>info@doseinsight.com</u>

