



Dose Insight

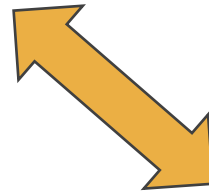
Dose uniformity ratio changes due to
device movement in radiation sterilization

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CIRMS Annual Meeting 2026, Rockville, 4/14/26



- We are helping our clients to develop medical devices and in-vitro technologies
- 100+ employees in Newark, CA and Boston
- Spins out internal ideas as independent companies



Dose Insight

Offers virtual dose mapping to:

- Medical device/packaging developers
- Sterilization vendors

www.doseinsight.com

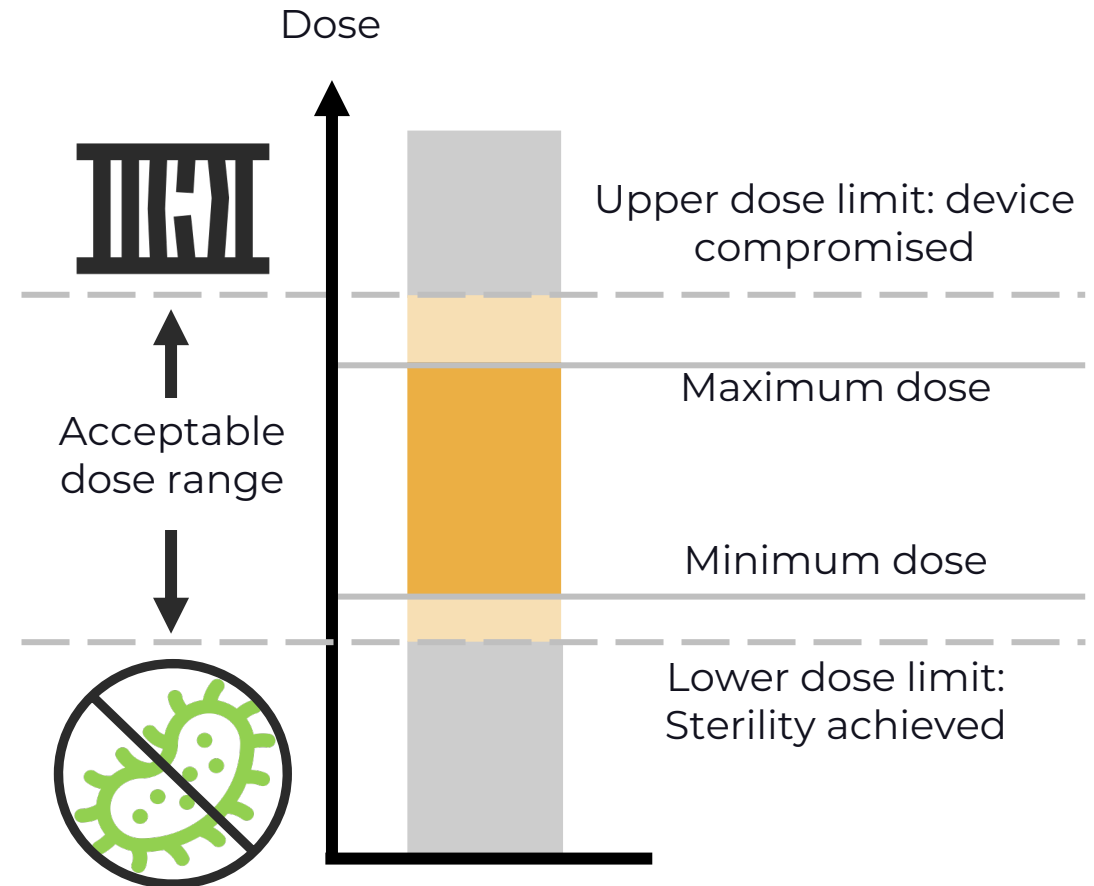


Acknowledgments

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(The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government)

Primer on radiation sterilization

- About 50% of all medical devices will be sterilized with radiation.
- The goal of radiation sterilization is to expose the product with at least the dose needed to achieve sterility.
- However, it is also important to not overexpose the device leading to material degradation
- We want to achieve a low Dose Uniformity Ratio (DUR)

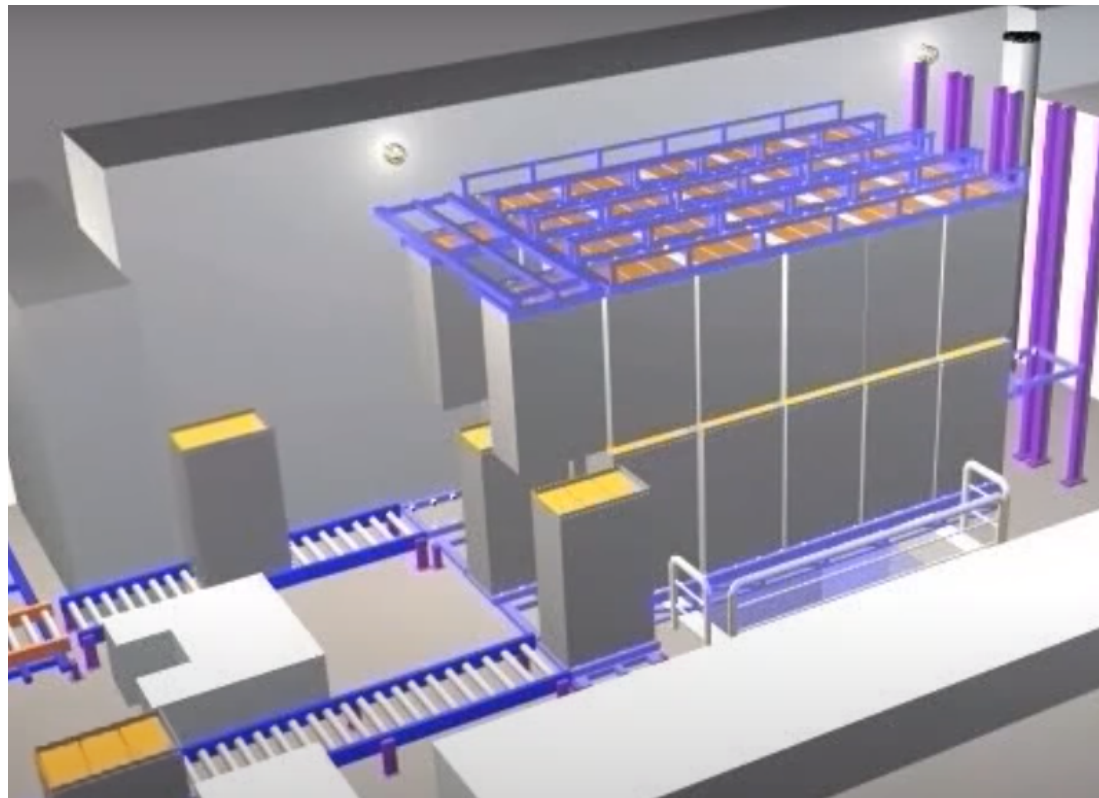


$$\text{DUR} = \text{Maximum dose} / \text{minimum dose}$$

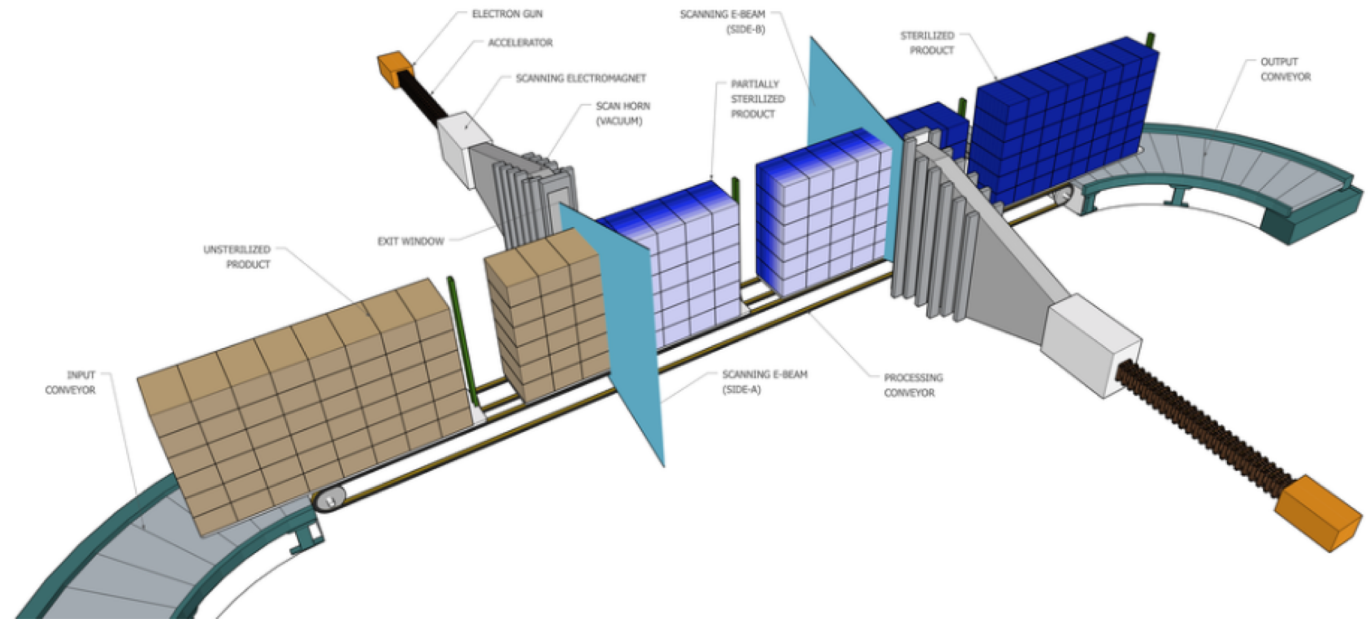


Radiation sterilization technologies

Gamma



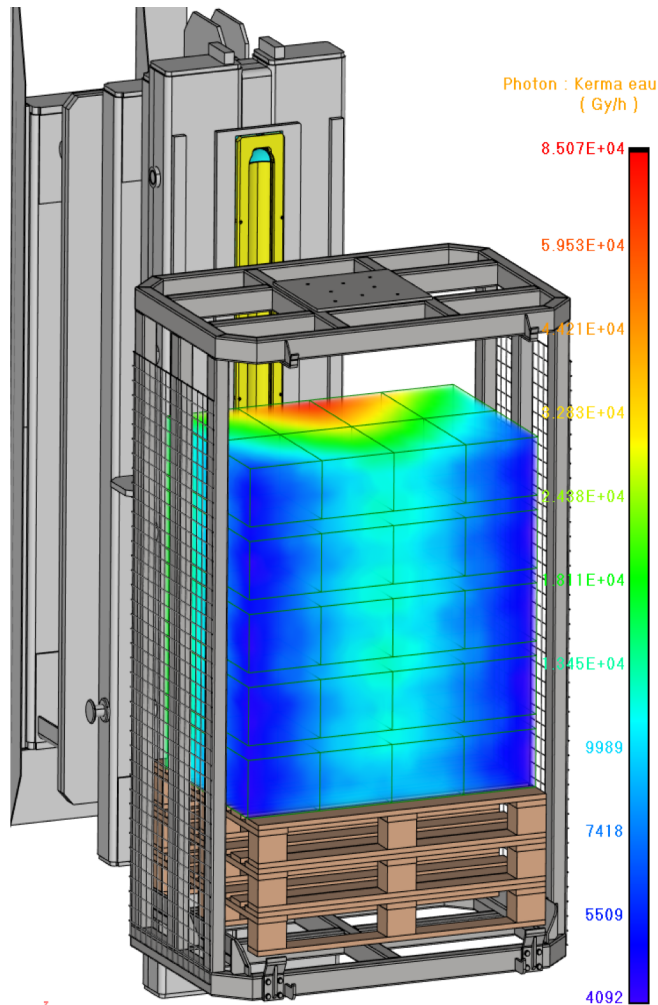
X-ray



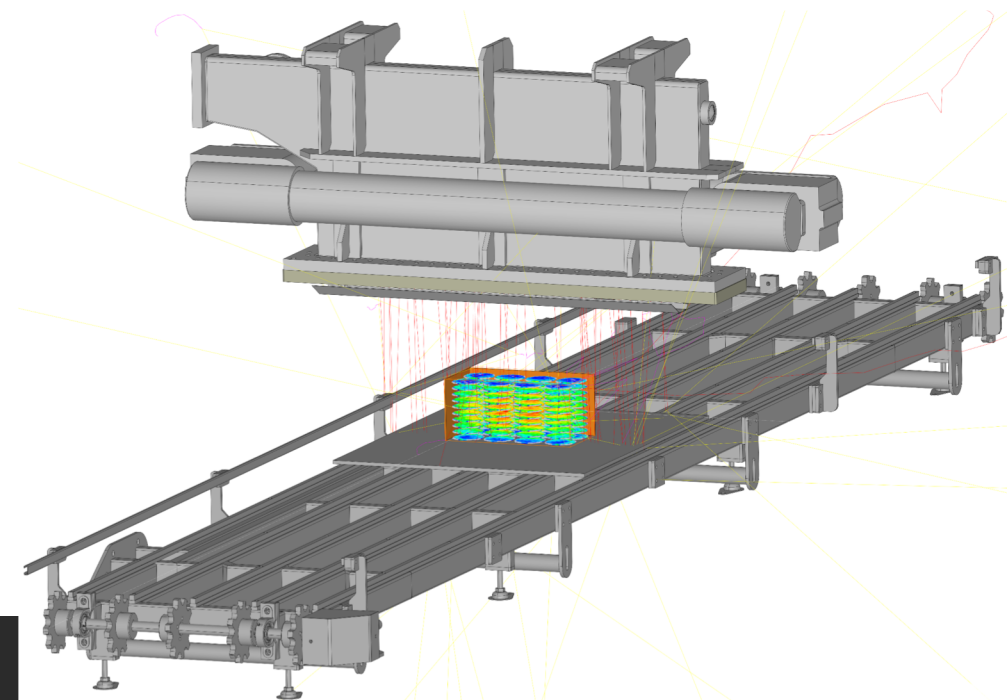
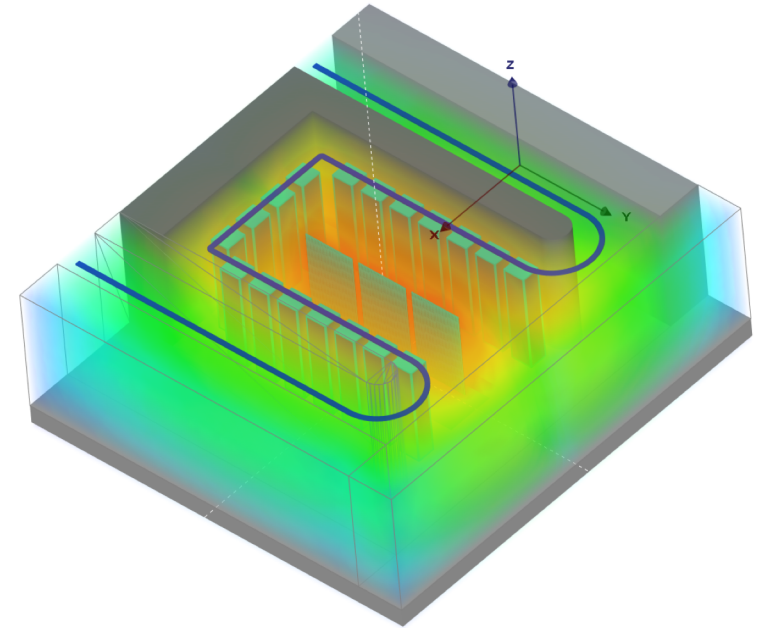
E-beam



Dose Insight has partnered with TRAD



SIMULATE
ALL DOSE
MAPPING
XRAY – EBEAM –
GAMMA



How does the randomness of packing influences DUR?



- Case Study:
 - Off the shelf package of 100 blood lancets
- Questions:
 - Is the DUR influenced by neighboring lancets?
 - If so, do different packaging configurations of the 100 lancets change the DUR?



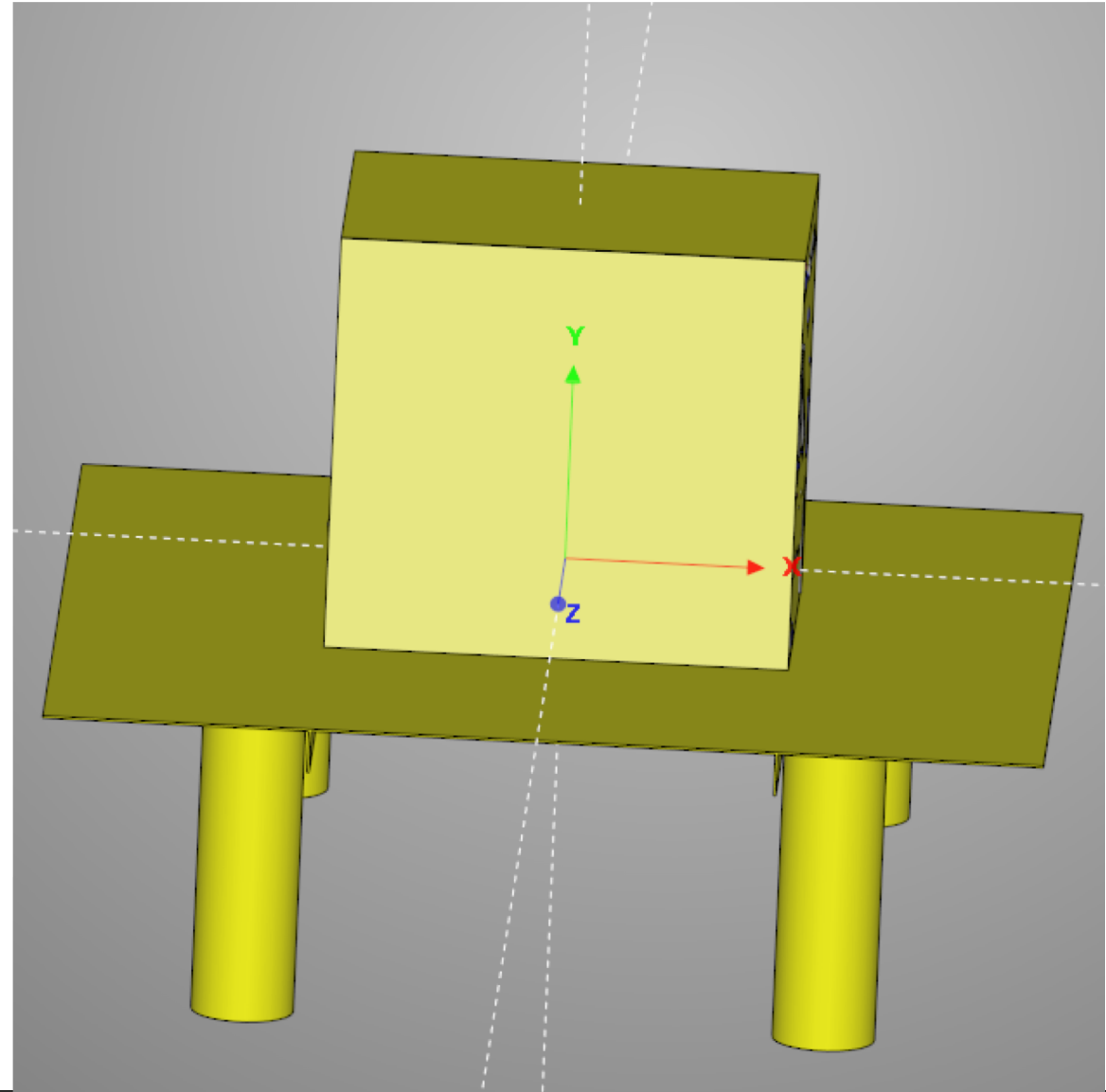
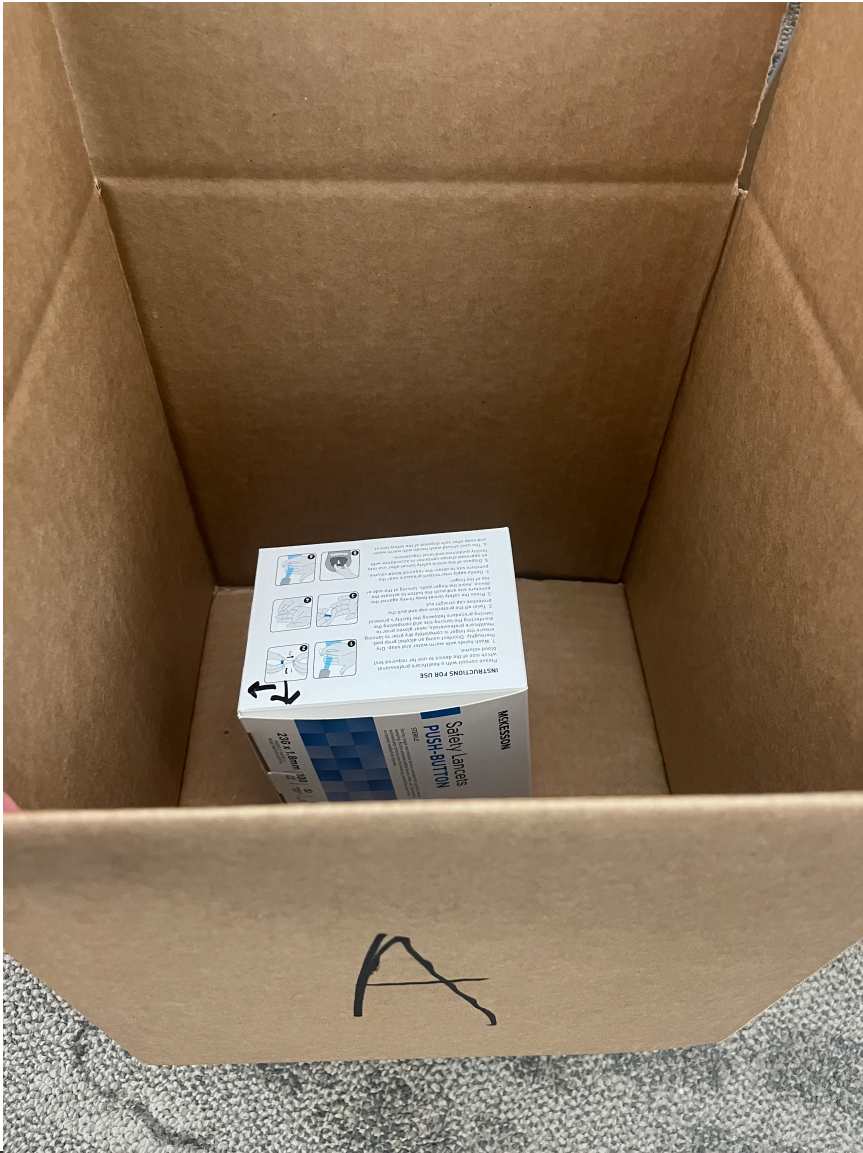
How do we measure a specific lancet w and w/o neighbors?



- Problem:
 - How do we just change the neighborhood of certain lancets?.
- Build a fixture:
 - We hold 3 lancets in place. This way the only thing that changes is the neighboring lancets



Isolate the lancets from scattered radiation



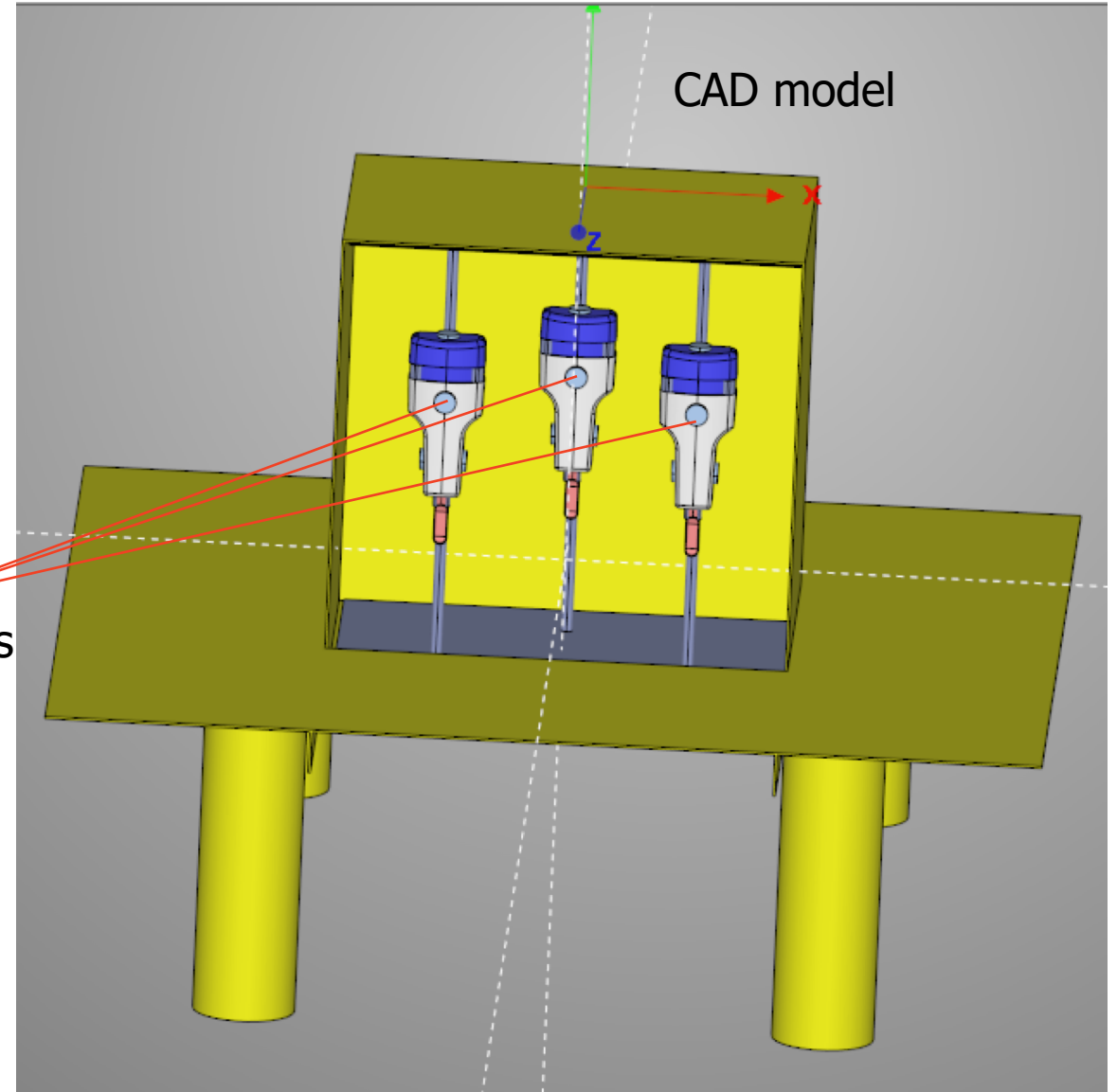
Isolate the lancets from scattered radiation



Measurement vs. Simulation



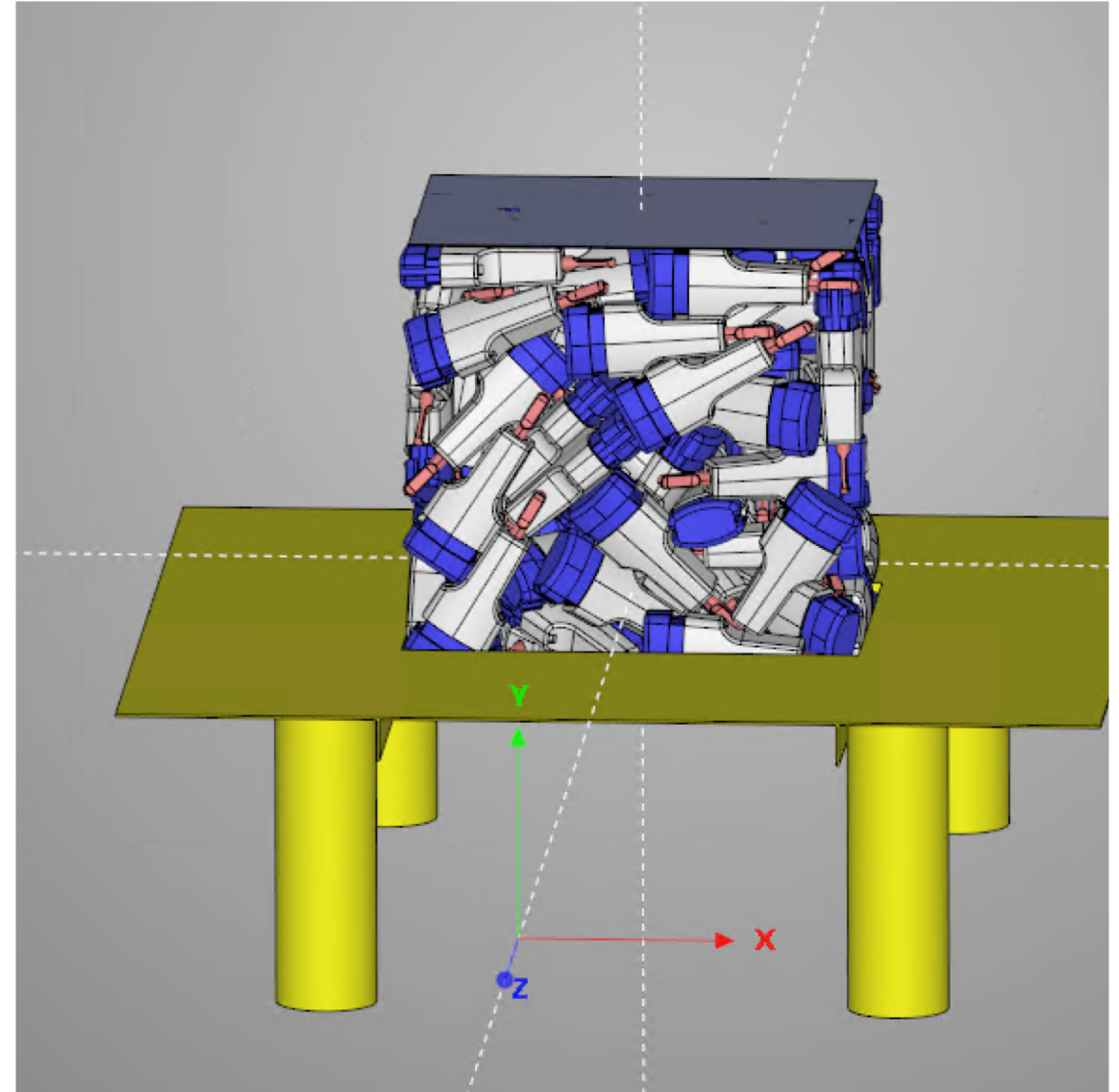
Dosimeters



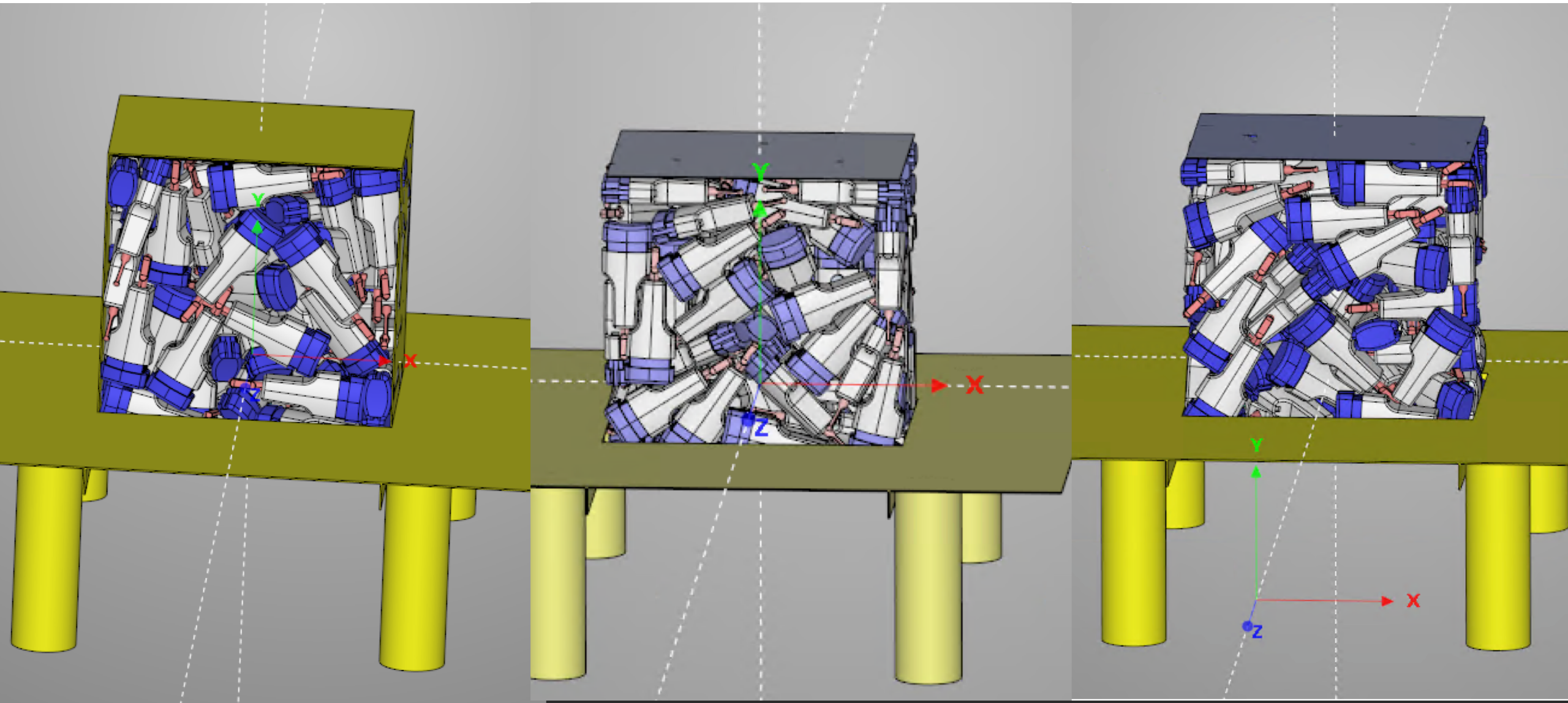
Create random packaging configurations with packaging algorithm



Actual vs simulated random placement in the box

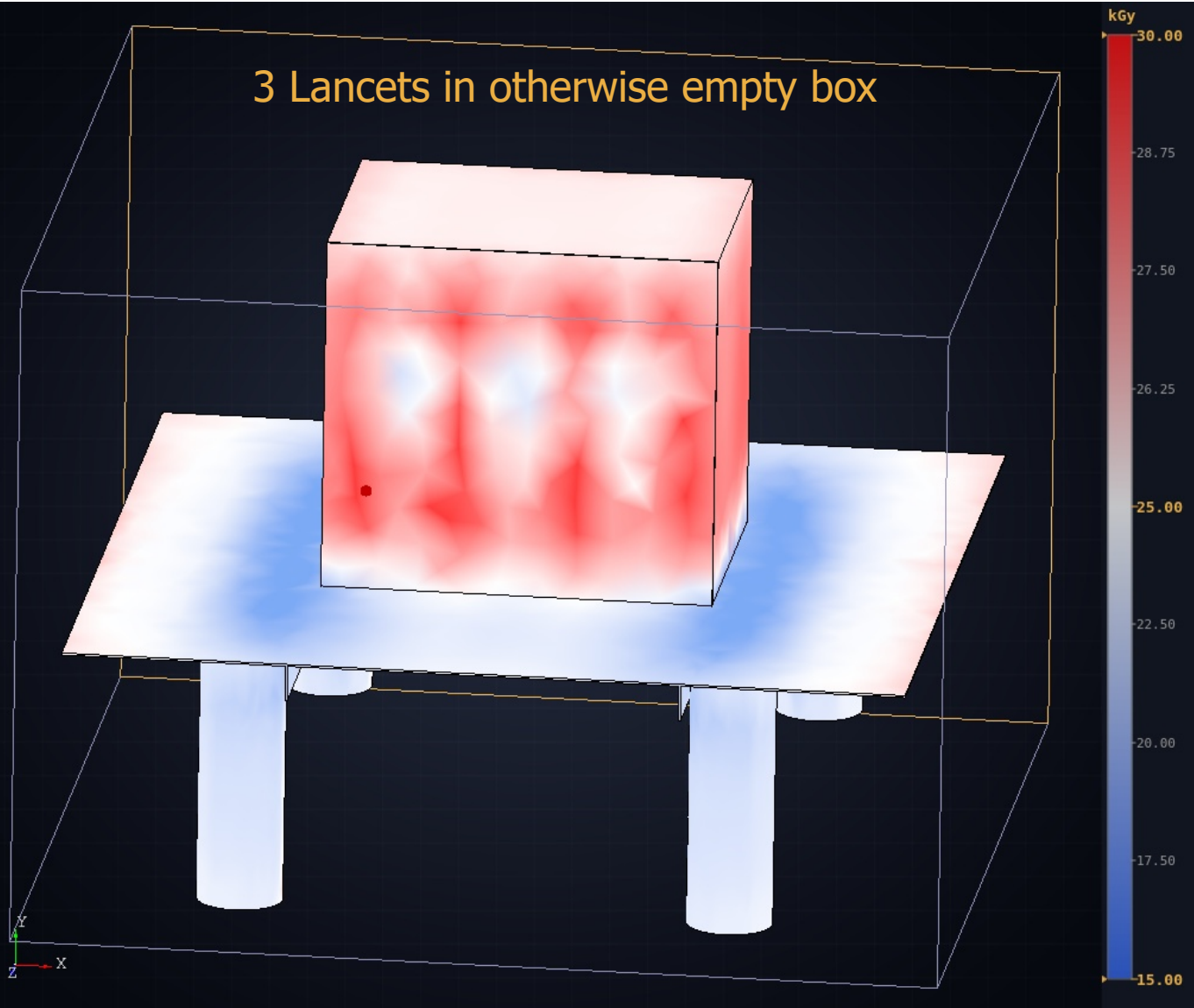


Families of random configurations can be produced



Virtual Dose Mapping: dose is visualized on surfaces

3 Lancets in otherwise empty box

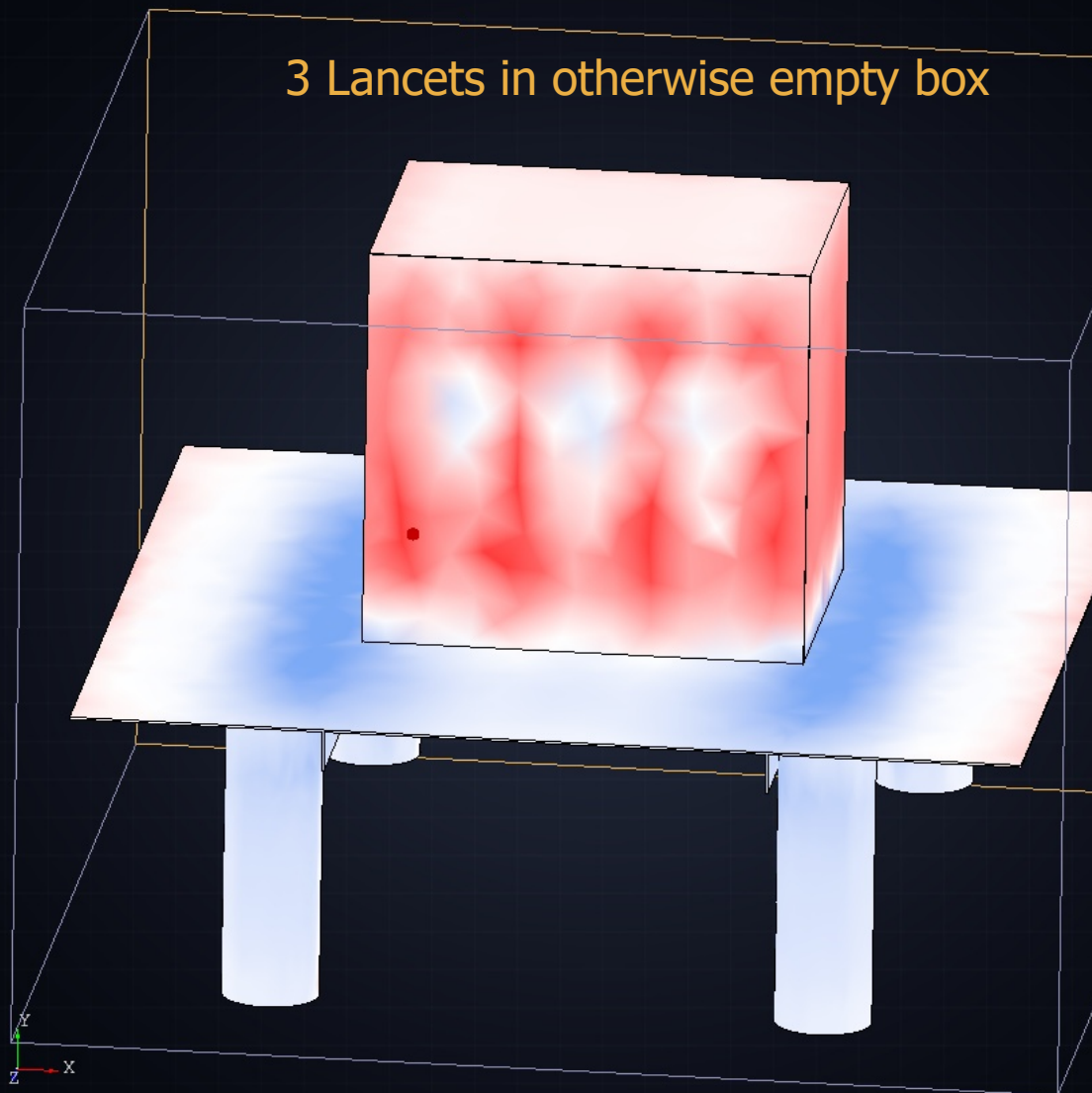


Dose is visualized on the packing box surface

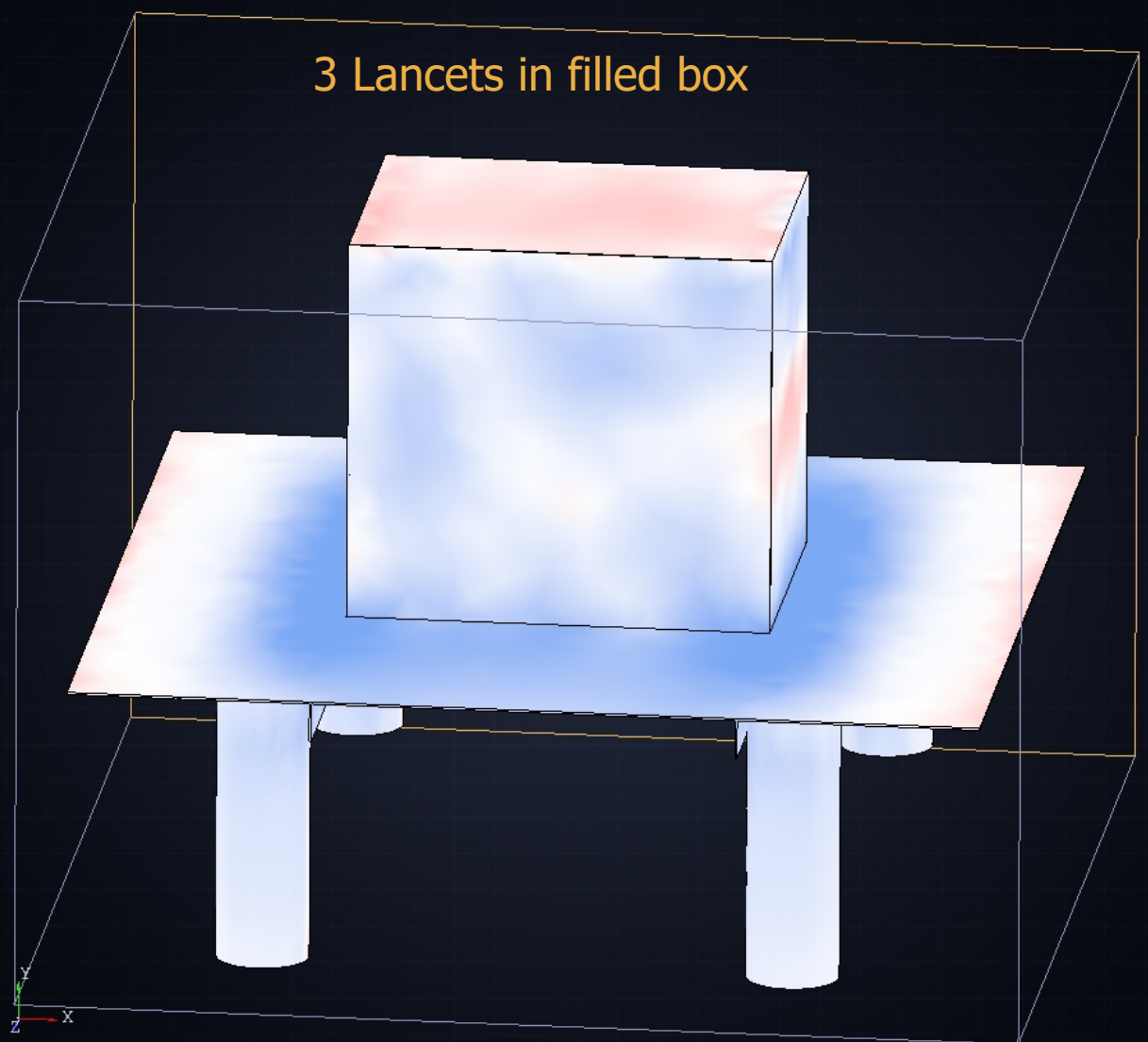


Virtual Dose Mapping: dose is visualized on surfaces

3 Lancets in otherwise empty box

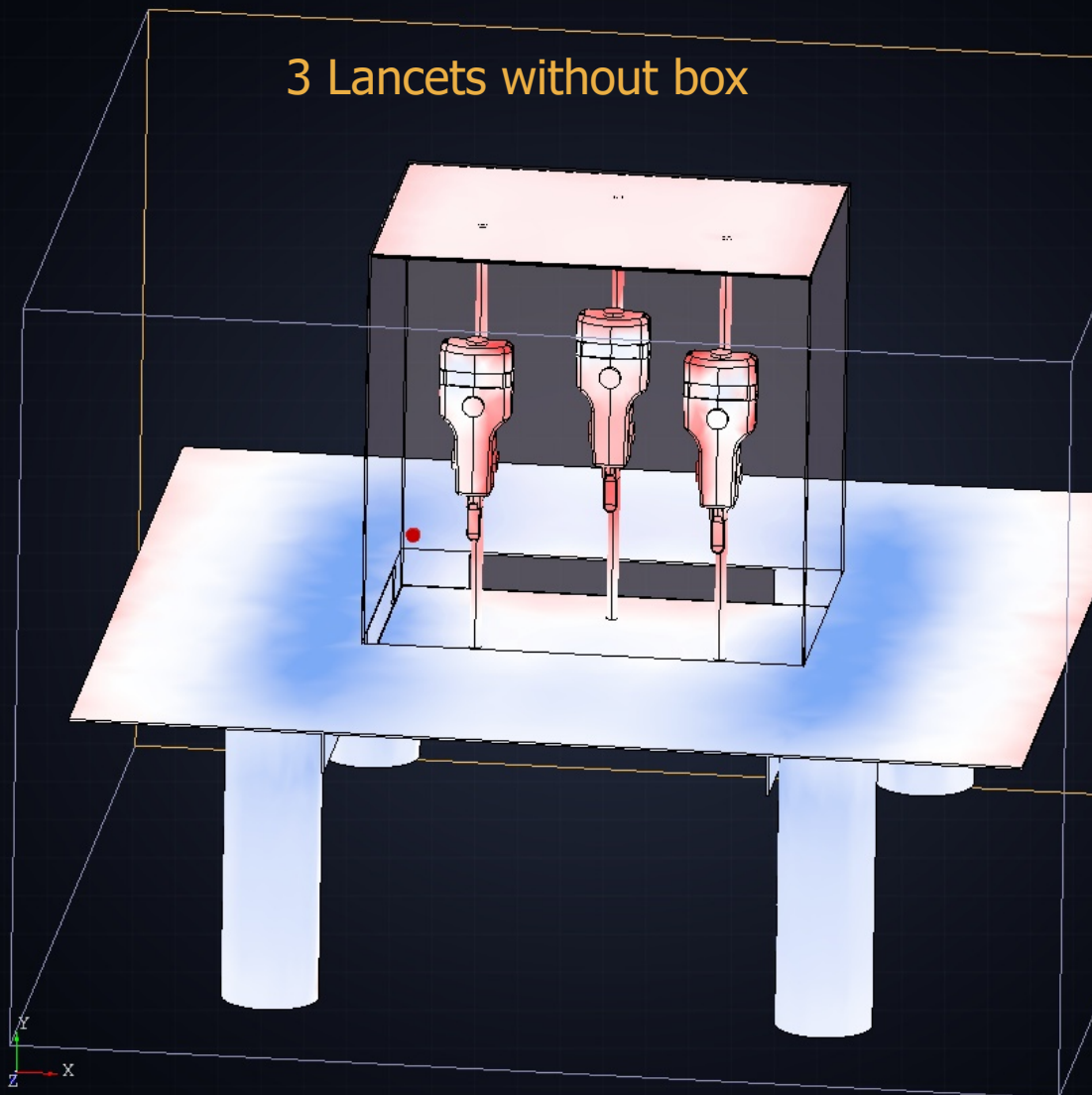


3 Lancets in filled box

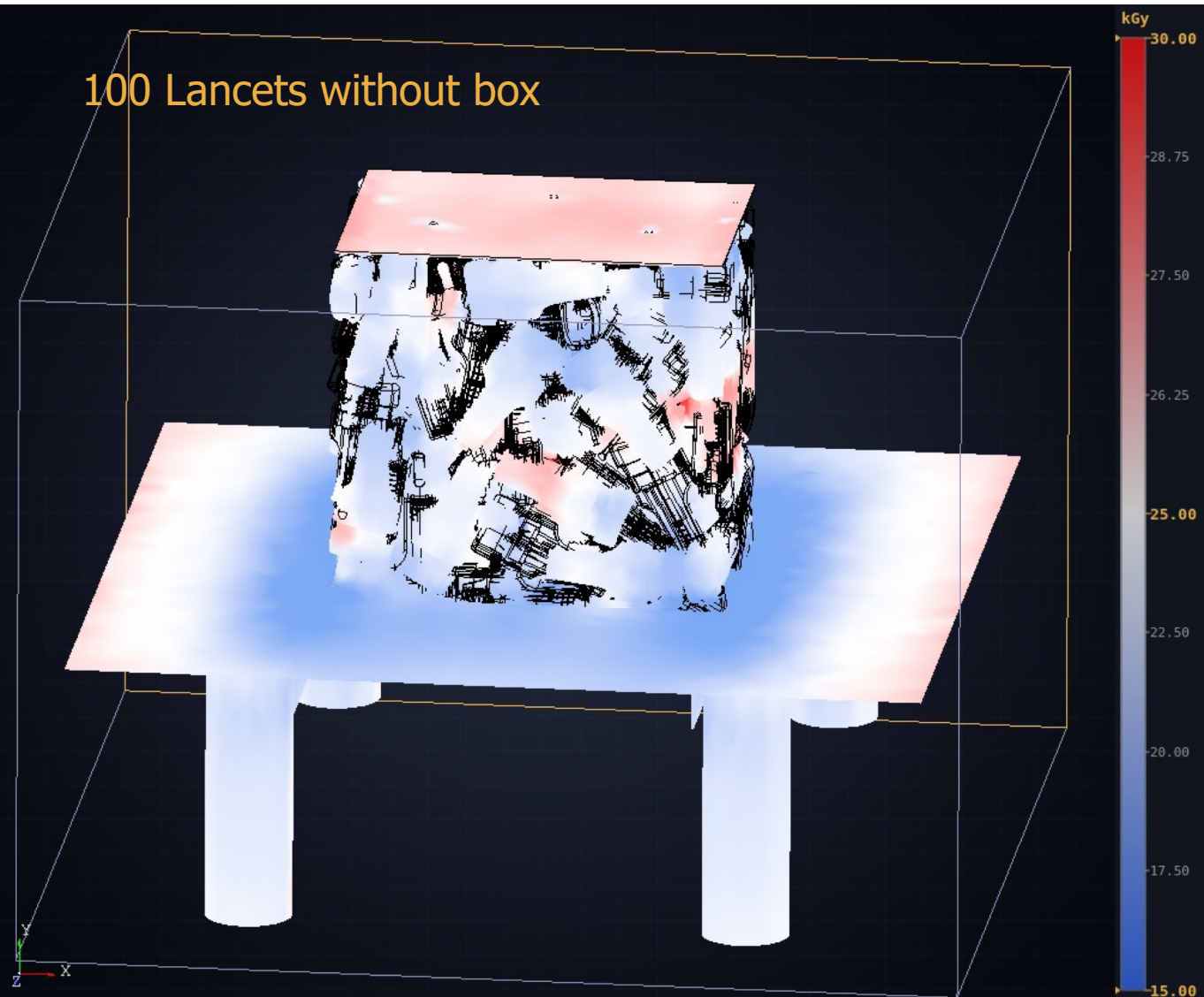


Peeling down the layers

3 Lancets without box

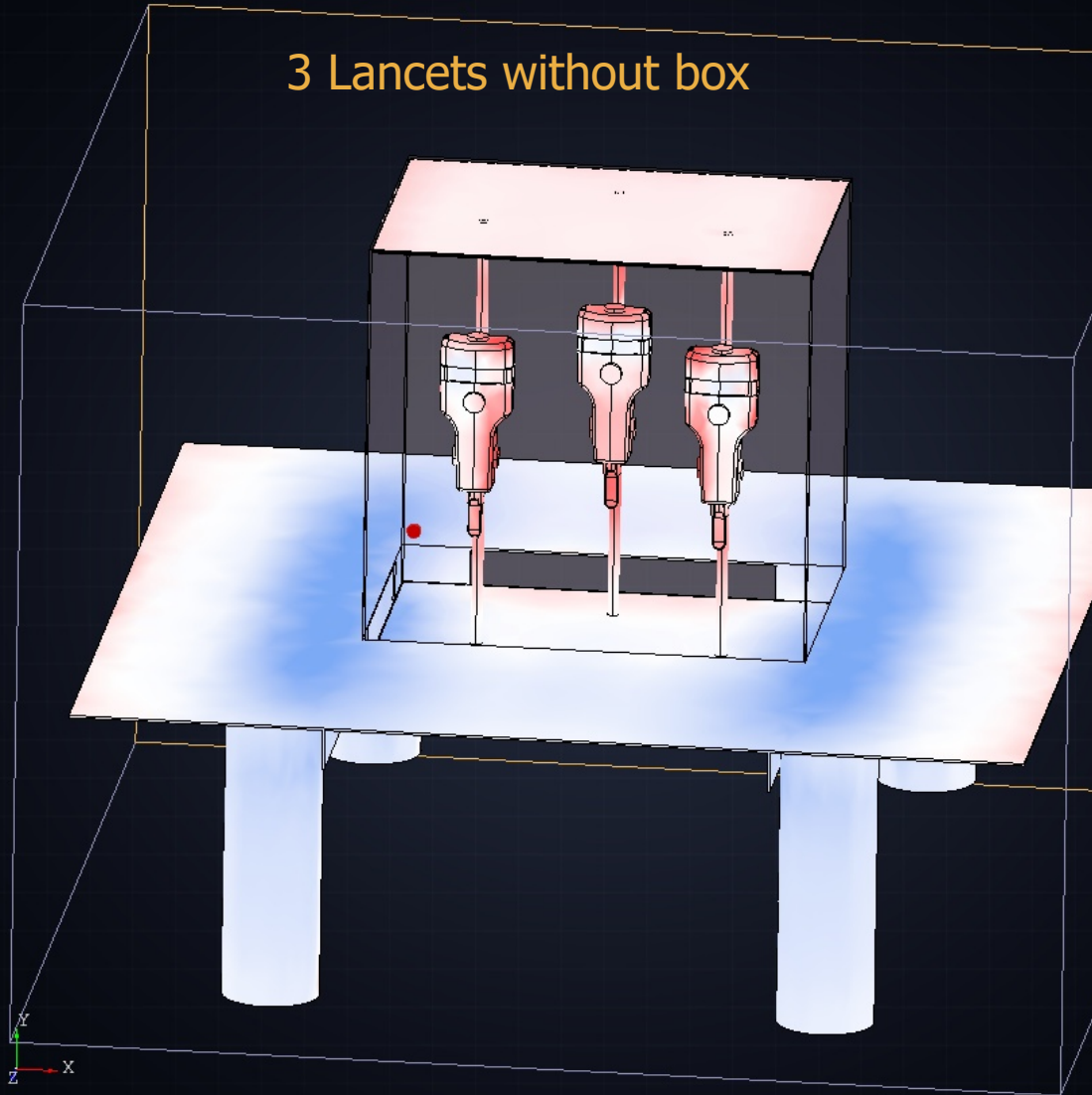


100 Lancets without box

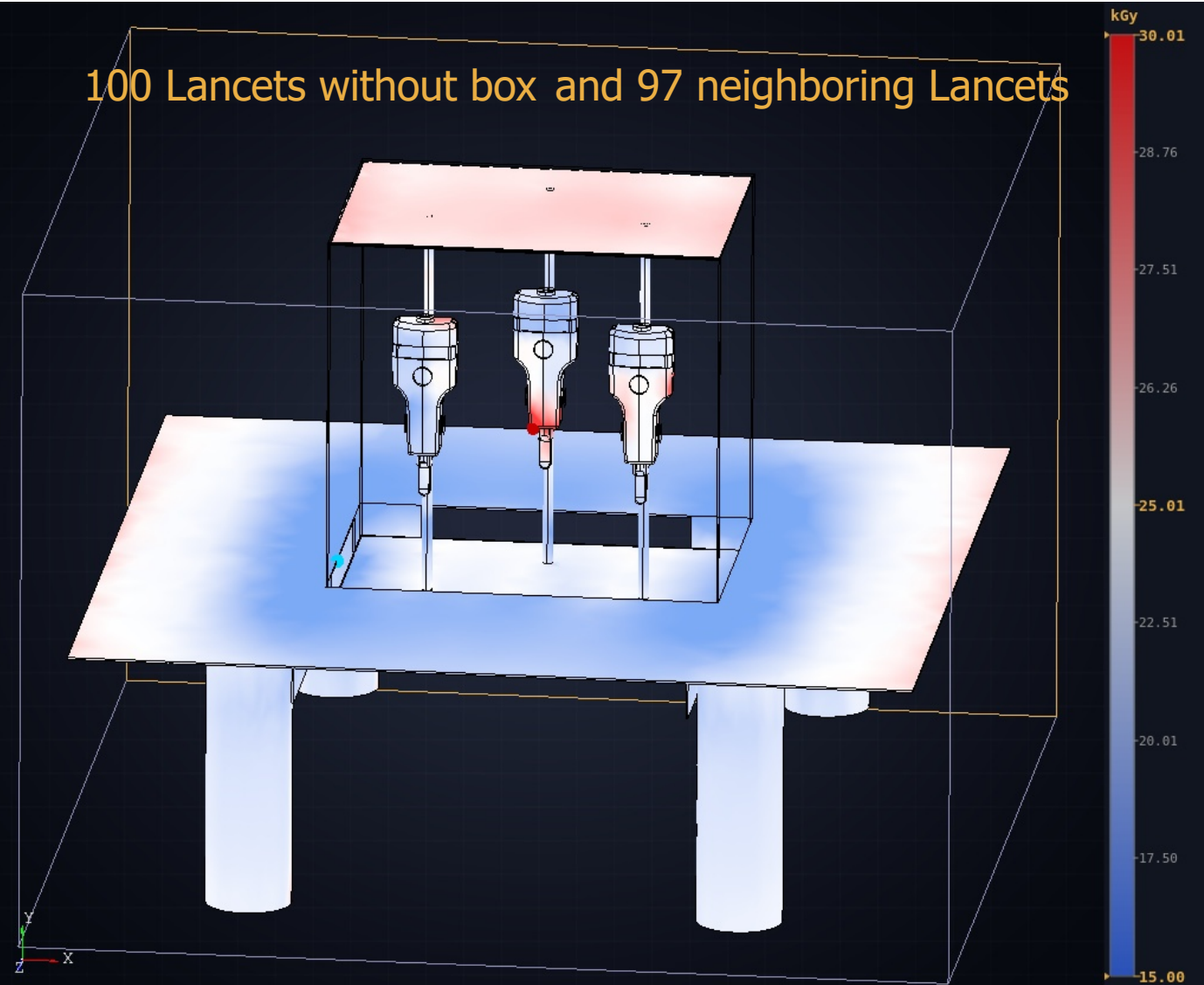


Peeling down the layers

3 Lancets without box

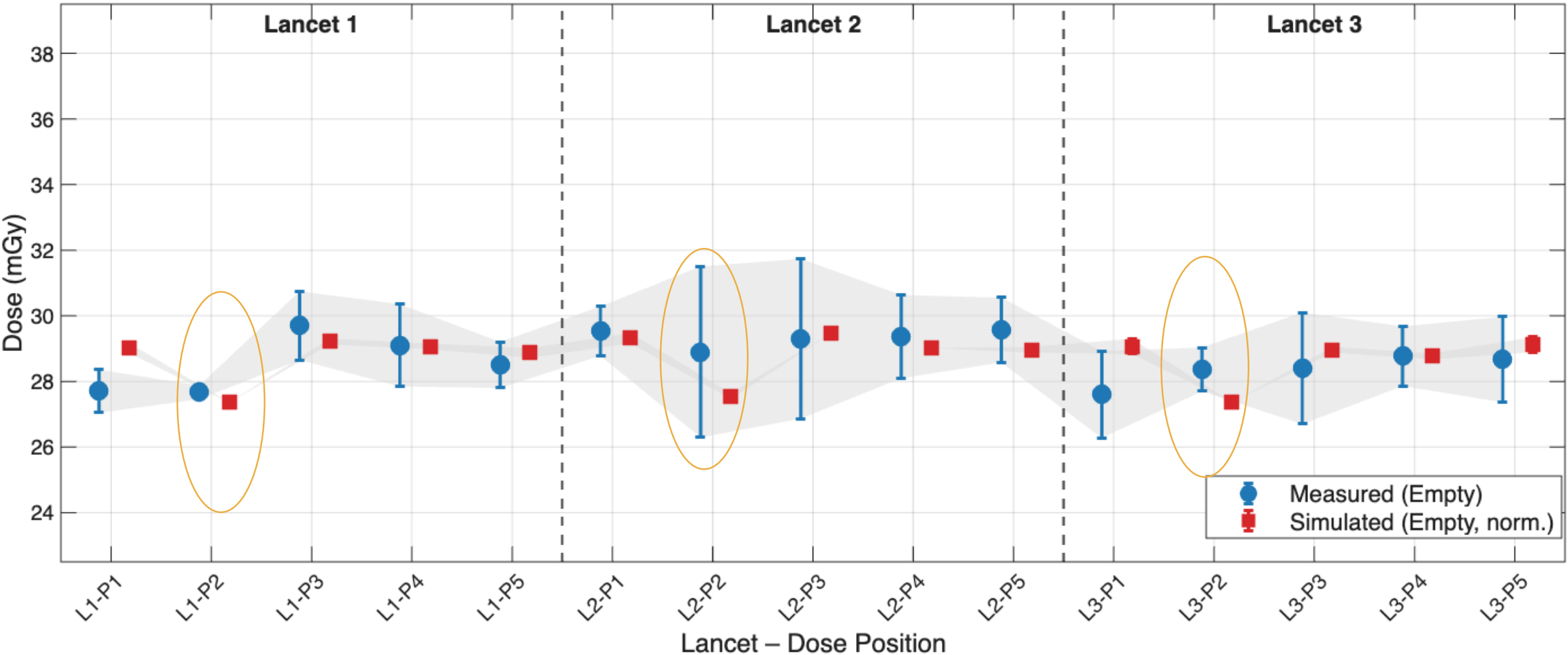


100 Lancets without box and 97 neighboring Lancets



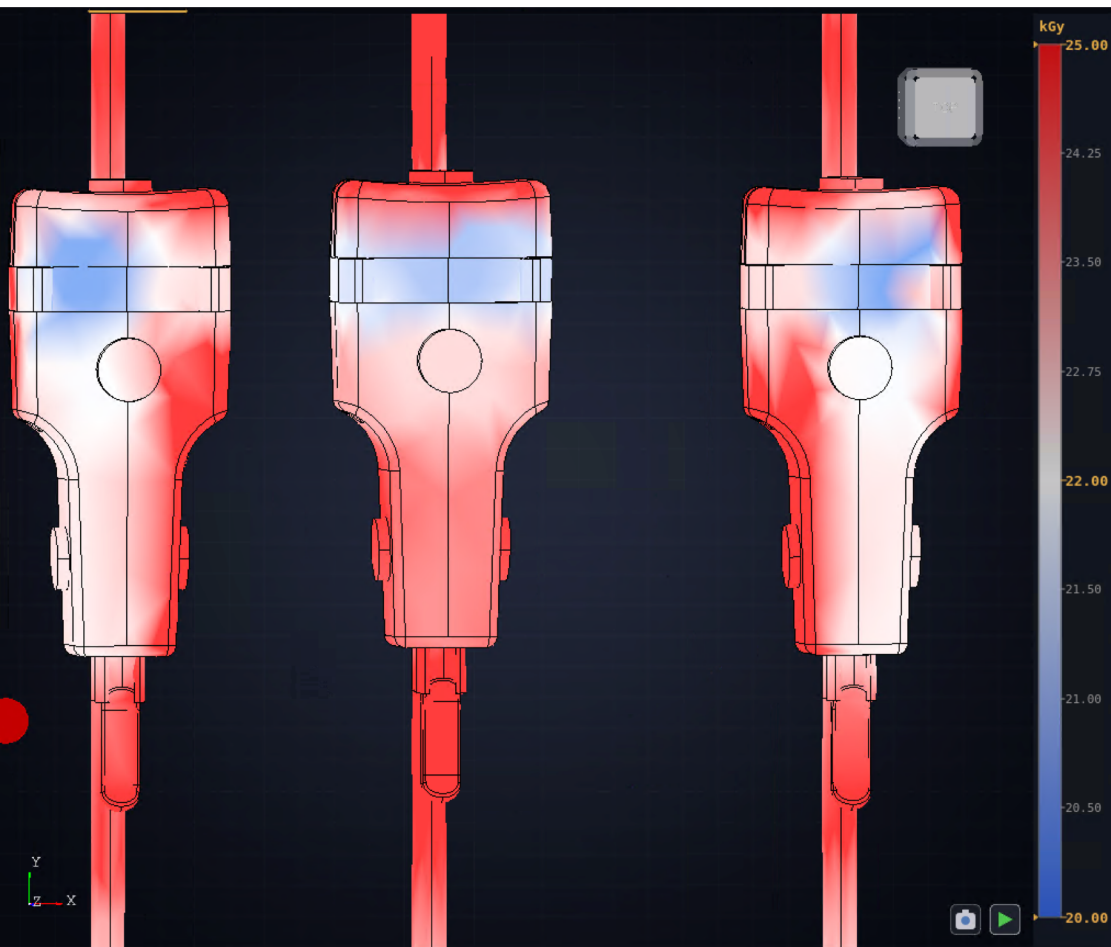
Measurement vs. Simulation: 3 Lancets in an empty box

Data are the average of 3 realizations

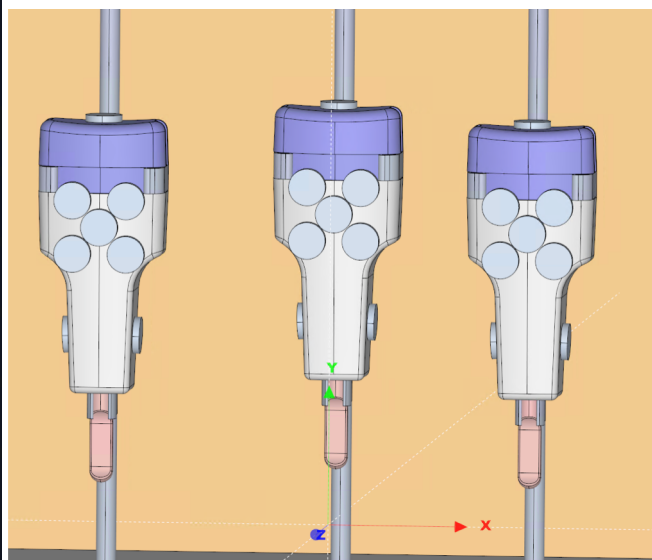


Why is the error bar for the measured data so large?

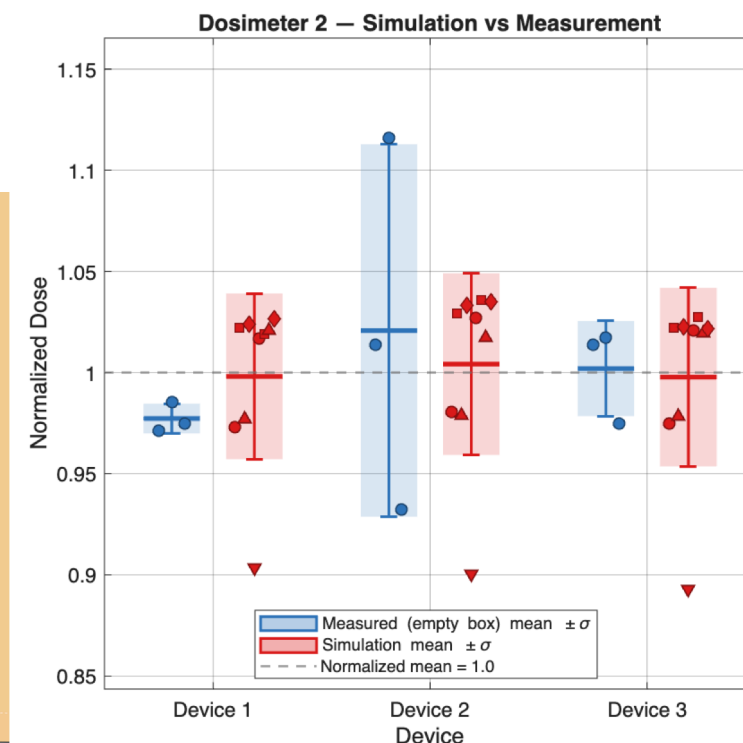
Surface dose shows large deviations by location



Sample dose with multiple dosimeters on surface

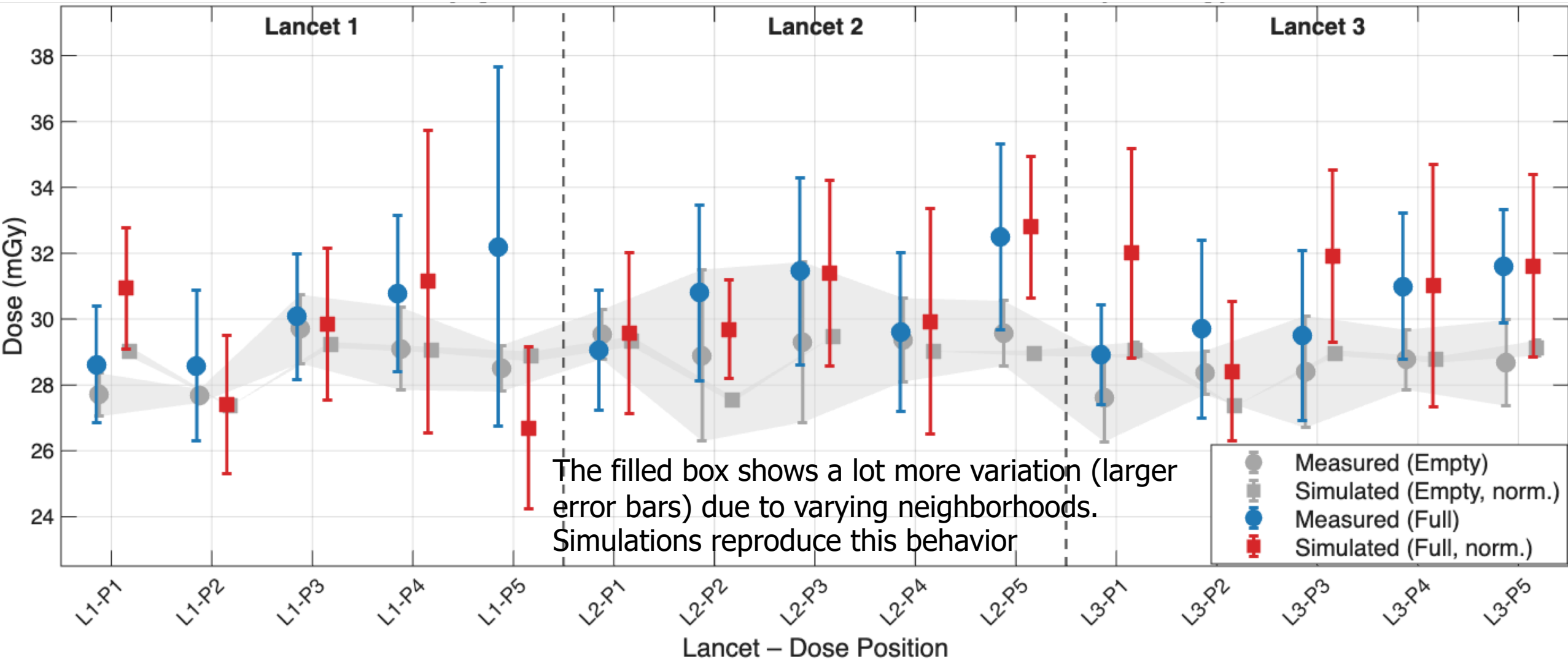


Simulation shows variation in dose depending on location.
Conclusion: measured variation caused by positioning error of the physical dosimeter



Measurement vs. Simulation: 3 Lancets in a filled box

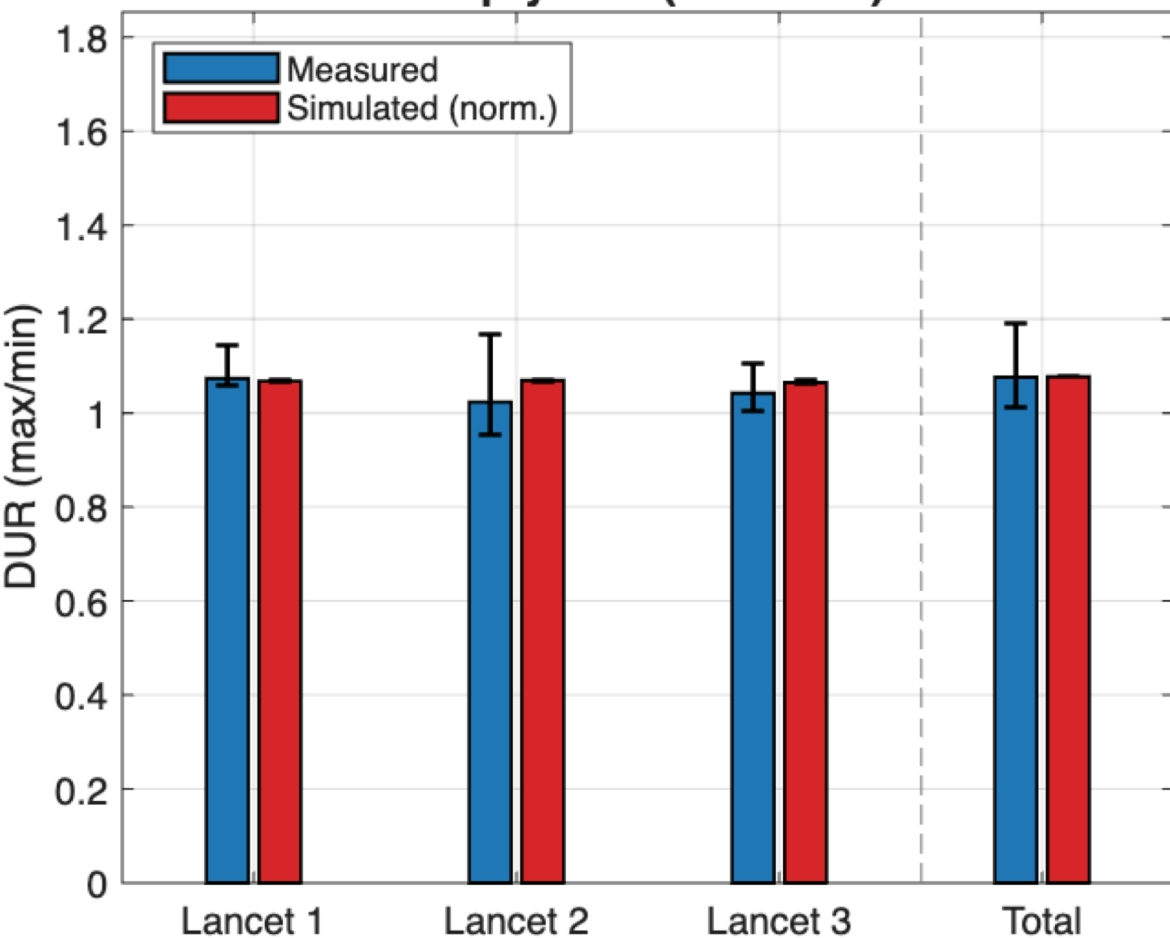
Data are the average of 5 realizations



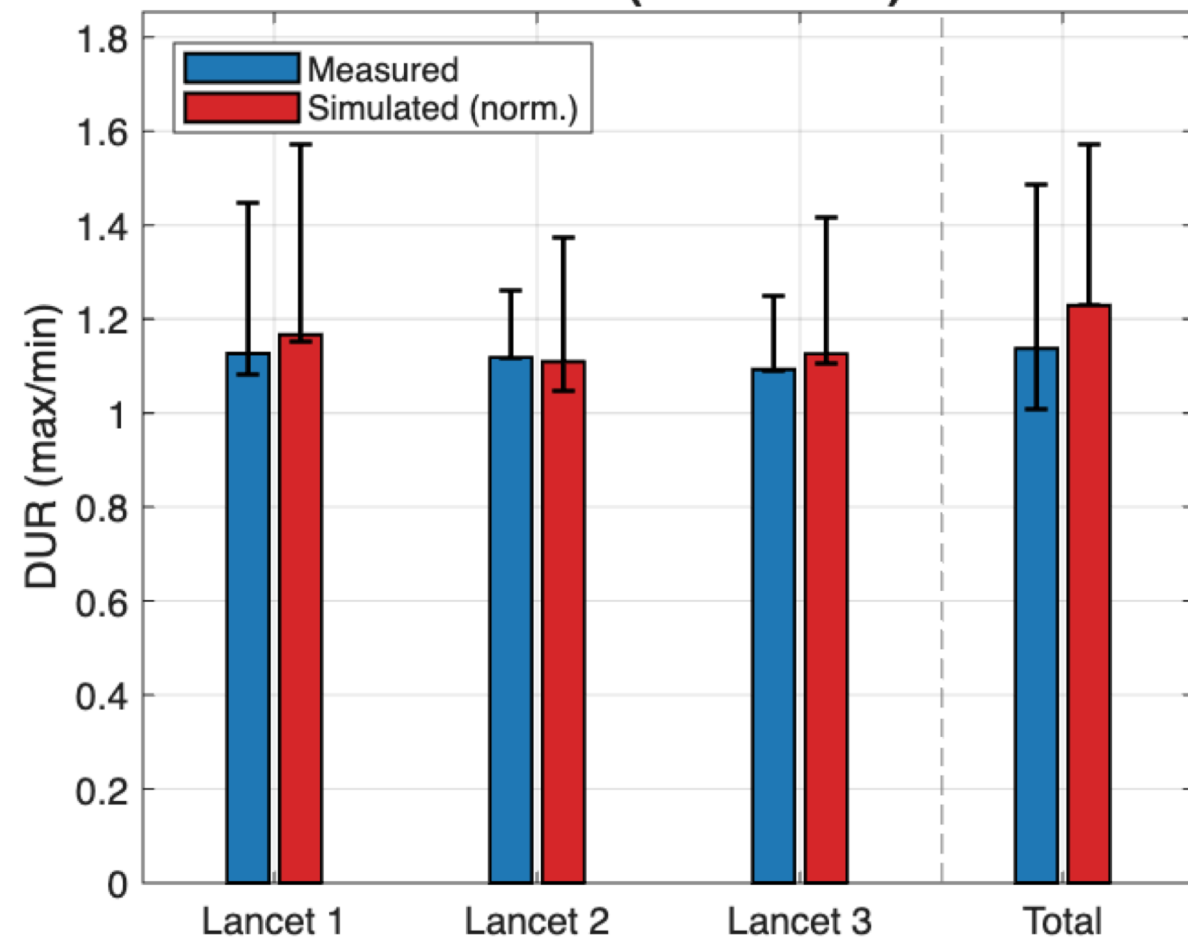
Comparison of Dose Uniformity Ratios

DUR by Lancet and Total — Mean with Best/Worst Case Range

Empty Box (3 lancets)



Full Box (100 lancets)



How can companies harness virtual dose mapping?

In-house

- Acquire dose mapping software RayXpert® from Dose Insight
- In-house expertise

Out-sourced

- Contract Dose Insight to perform virtual dose mapping with RayXpert®
- Dose Insight is a trusted advisor

Partnership

- Build up in-house expertise with RayXpert®
- Dose Insight helps to train resources
- Dose Insight guides projects



Conclusions

- Virtual Dose Mapping correctly reproduces measured data
- DUR increases in a fully packed box of lancets
- The DUR of a randomly packed box varies significantly depending on the actual packaging configuration
- Taking device motion into account is important to fully capture the full range of possible DURs



CIRMS 2026 — Need

Annual Meeting · April 13–15, 2026

Progress in **virtual dose mapping** is currently blocked because we lack **resources to do systematic experimental validation of virtual dose mapping**, which prevents **adoption on a broad scale and thereby simplifying sterilization validation**.



Dose Insight

Thank you!

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