Dose Insight

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# Dose Insight: A virtual dose mapping tool to assess dose delivered during terminal radiation sterilization

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Sterilization validation is a capstone of the medical device development process, and yet the critical steps to pass sterilization validation are only addressed at the end of the process. This is contrary to the fundamental design process rule of retiring risk early, but, unfortunately, no alternatives have been available since up to now a physical device has been required for sterilization validation. Dose Insight is here to change this paradigm by introducing a computational approach to calculate virtual dose maps from CAD models. This enables "Design for Sterilization" starting from the first CAD model of the device. We envision a dynamic process where form factor, component selection, and packaging are part of the entire trade space during development.

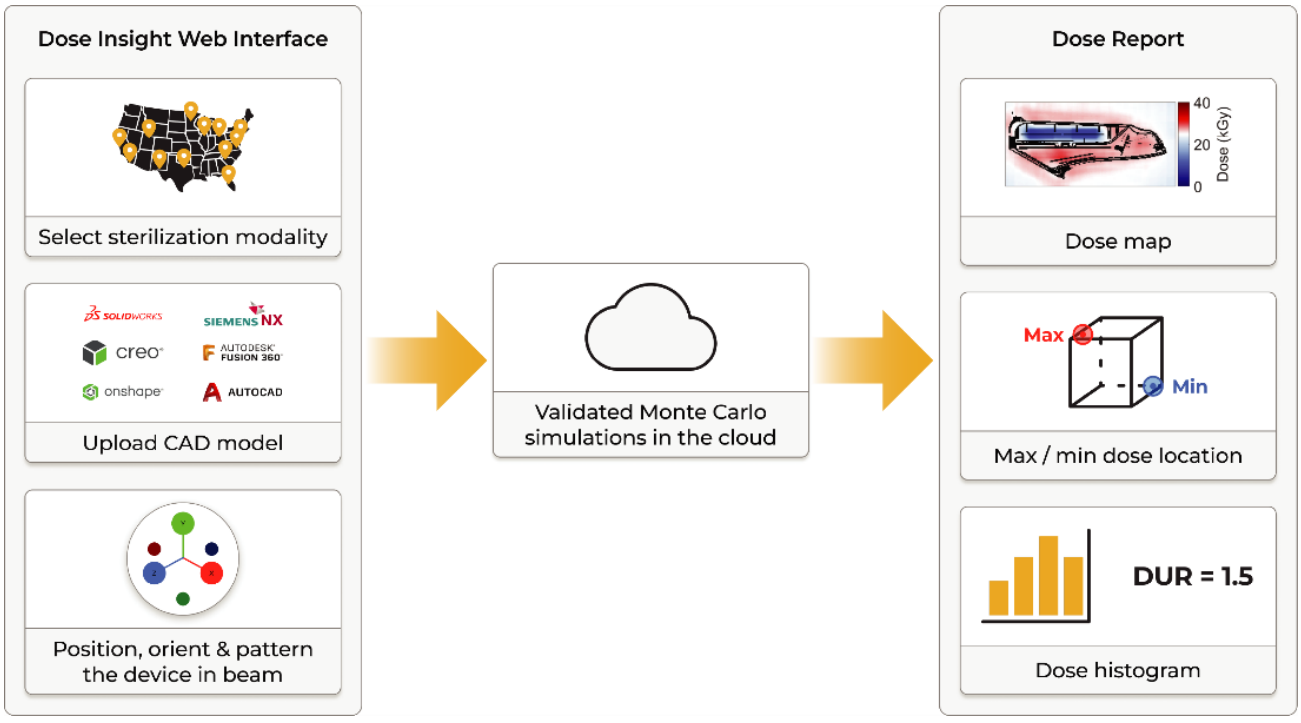
The Dose Insight's modeling tool is able to address a wide range of sterilization-related questions that today either cannot be answered or need expensive experimental explorations late in the design process. Simulated dose maps can help with:

1. Choosing an appropriate sterilization modality
    a. Which type of radiation should we use? Is e-beam, gamma, or X-ray best? Simulated dose maps can quickly compare different modalities
    b. While modeling is not available for EtO sterilization, simulated dose maps could enable manufacturers to evaluate radiation sterilization first, and only go to alternatives such as EtO if radiation is not a viable path.
2. Guiding the placement of dosimeters
    a. Placement of dosimeters can be optimized to achieve reliable readings by avoiding areas with large dose gradients. Simulated dose maps can be used to identify such areas, as well as areas with relatively uniform dose, which would be better suited for dosimeter placements.
3. Identifying the location and magnitude of the minimum and maximum dose
    a. During radiation sterilization validation dosimeter must be used to measure the maximum and minimum dose delivered to the device. ISO 11137-3 allows simulated dose maps to guide the positioning of dosimeters in the maximum and minimum dose areas during dose mapping studies.
4. Ensuring that difficult or impossible to access areas receive sufficient dose, e.g., dose to the inside of a needle.
    a. Dosimetric film is commonly used for dose mapping during sterilization validation, and typically comes in 1 cm x 1 cm squares. These dosimeters cannot be used to measure the dose in small features of the device, and so simulations are the only way to know the dose inside such features.
5. Designing packaging
    a. Movement of a device within its packaging can impact the dose distribution delivered during terminal sterilization. Simulations can be used to identify how much movement is acceptable, which can inform packaging design.
    b. Many devices are composed of multiple parts (e.g., tubing, syringes, etc.), that are all contained in the same packaging. The orientation of these parts relative to each other can impact the dose distribution, and so simulations can be used to identify the optimal configuration.
6. Sterilization process optimization
    a. One of the many questions posed during terminal sterilization is what arrangement of packaged devices within a shipping container should be used? Simulations can quickly identify the best arrangement in terms of dose distribution.

7. Guiding change of sterilization modalities, e.g. from EtO to e-beam or gamma to X-ray
    a. There is a concerted effort to move away from EtO sterilization. The ability to simulate a dose map to evaluate a radiation beamline without engaging a radiation sterilization vendor will dramatically reduce the time, resources, and money required to move to a radiation modality.
    b. Similarly, gamma sterilization is facing ongoing supply chain and security concerns. Evaluation of the implications of changing radiation modalities to either e-beam or X-ray can be readily done in simulations.
8. Assessing suitability of radiation sterilization for devices with integrated electronics or other radiation-sensitive components
    a. Simulated dose maps can be used to identify the dose delivered to radiation-sensitive components.
    b. If the dose to the radiation-sensitive component is high enough to impact the component's functionality, simulations can be used to quantify the effectiveness of potential shielding designs.

Dose Insight unlocks all the features listed above by simulating the dose received by a medical device during radiation sterilization using Monte Carlo simulations. Monte Carlo simulations of radiation transport are the "gold standard" in the scientific community for producing accurate and precise predictions of radiation processes. However, available tools require highly specialized expert users and are therefore not broadly used in medical device development community. Dose Insight brings the accuracy of Monte Carlo simulations to non-expert users by providing an easy-to-use interface designed specifically for medical device engineers.

Dose Insight's tool is designed to be used by engineers with familiarity of common CAD tools and operates completely in the cloud for fast processing. The engineer first uploads the CAD model of their medical device through a secure portal, and then selects the intended sterilization modality and, if known, the specific beamline that will be used at a given contract sterilizer. Then the engineer positions the CAD model in the beam, configures a few parameters such double vs single sided exposure, and starts a simulation run. Once complete, a dose report will be emailed to the engineer. The figure below illustrates this workflow.

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