Modulated Electron Bolus (MEB)

Adaptiiv’s MEB solution allows single-beam electron treatments to deliver modulated electron radiation therapy (MERT) dose distributions that conform to an irregular distal PTV surface. Our regulatory cleared workflow, backed by patented algorithms, automates the design and fabrication of patient-specific and plan-specific modulated thickness electron bolus. Custom modulated thickness bolus, designed and fabricated with Adaptiiv’s MEB solution, has been shown to result in MERT dose distributions that provide superior sparing of healthy tissues and distal OARs compared to uniform thickness bolus electron plans (Figures 1A & 1B).

Figure 1A. Patient with mycosis fungoides of the forehead, eyelid and nose. Uniform thickness bolus provides coverage of the PTV, however, a high dose to underlying healthy tissue and OARs is evident.

Figure 1B. Adaptiiv’s Modulated Electron Bolus is customized, changing the surface shape to allow for tailoring of dose distribution.

“Without Adaptiiv’s MEB, it is often difficult to develop a plan that tailors the prescribed dose to the tumor volume, resulting in overexposure to underlying healthy tissue.”

Key Benefits

- Adaptiiv’s MEB automates modulated bolus thickness optimization and fabrication. The software takes a few minutes to determine optimal shape and 3D printing can be done in a matter of hours, producing a bolus with spatial accuracy on the order of 1mm. In one case, MEB design time was reduced from 30+ hours of manual tuning within the TPS to under 2 minutes with Adaptiiv’s MEB module.

- 3D printed bolus improves the following: integrity of the bolus (compared to wax), reproducibility of patient setup, and the accuracy of treatment delivery through a better, more consistent fit to the patient surface.

- Adaptiiv’s patented hotspot correction algorithm allows users to determine the appropriate balance of dose homogeneity versus conformity. No other commercial solution provides this capability.

- Adaptiiv provides the only regulatory cleared solution allowing users to customize a bolus, seamlessly export the modified bolus structure back into their TPS, and use their clinically commissioned TPS to calculate dose.

- Adaptiiv’s solution replaces the need to use multiple versions of open source software when transforming a structure within the TPS into a 3D printed accessory. Using multiple versions of open source software requires excessive design time, treatment plans can’t be easily verified in the TPS, and they do not have regulatory clearance.

- MEB plans created in Adaptiiv’s software demonstrate superior sparing of healthy tissues and distal OARs while significantly reducing hotspots compared to photon IMRT delivery, i.e. VMAT (Figures 2A, 2B, and 2C).

Adaptiiv has FDA 510(k) clearance to market a 3D printing software solution intended for use in radiation oncology.
## Clinical Benefits

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<tr>
<th><strong>Patient Consult</strong></th>
<th><strong>Radiation Oncologist</strong></th>
<th><strong>Medical Physicist</strong></th>
<th><strong>Radiation Therapist / Dosimetrist</strong></th>
<th><strong>Administrator</strong></th>
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<td></td>
<td>- Improve treatment quality through OAR sparing.</td>
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<td>Increase efficiency and confidence. Manual bolus fabrication is replaced by a simplified, objective, and automated 3D printed bolus workflow.</td>
<td>- Provide an improved standard of care.</td>
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<td>- Improve reproducibility and accuracy during treatment.</td>
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<td>- Use of innovative, regulatory cleared technology.</td>
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<th><strong>CT Simulation</strong></th>
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<td>Improve patient comfort through simplified setup during CT simulation and treatment.</td>
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<td>Increase efficiency and confidence. Manual bolus fabrication is replaced by a simplified, objective, and automated 3D printed bolus workflow.</td>
<td>- 3D printed bolus meets requirements for existing billing codes - can be billed as a patient-specific complex device.</td>
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<td>- Eliminate the need to fabricate bolus in the CT suite, thereby increasing throughput.</td>
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<th><strong>Image Contouring / Bolus Design</strong></th>
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<td>Use standard TPS contouring/structure generation tools to generate a uniform bolus covering the desired treatment area on the CT scan. This will be input into Adaptiiv's MEB module for customization.</td>
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<td>- Use standard TPS process to generate a simple electron plan using the uniform bolus structure.</td>
<td>- Seamlessly integrate final bolus structures into existing TPS workflow following a regulatory cleared process.</td>
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<td>- Seamlessly export plan, structure set, and CT into Adaptiiv's software and automatically optimize bolus thickness in just a few minutes.</td>
<td>- A faster, cheaper commissioning and QA process.</td>
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<td>- Further customize the bolus using post-processing tools (patient ID label, cropping, smoothing, etc.).</td>
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<td>- Known bolus shape during treatment planning accurately reflects bolus shape during treatment delivery. This may not be true of conventional methods, such as wax and Superfab.</td>
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<td>Final MEB structure is exported back to the TPS for dose calculation.</td>
<td>Use standard TPS process to generate a simple electron plan using the uniform bolus structure.</td>
<td>- Final MEB structure will translate into a 3D printed patient-specific bolus with spatial accuracy on the order of 1mm.</td>
<td>- Seamlessly integrate final bolus structures into existing TPS workflow following a regulatory cleared process.</td>
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<td>Simple pre-Tx bolus QA (CT scan of accessory).</td>
<td>Verification of placement on patient need not impact patient workflow (CBCT).</td>
<td>Little overhead required for patient-specific accessory QA, without any impact on patient workflow.</td>
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<th><strong>Patient Setup at Tx Unit</strong></th>
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<td>Setup is simplified and objective versus manual bolus, provides increased confidence in accurate plan delivery, and can result in less consult calls to the unit.</td>
<td>Increase RT confidence as a result of simplified setup. This can result in less consult calls to the unit.</td>
<td>- Decrease setup time for complex cases by as much as 30%.</td>
<td>- Decrease need for extended treatment delivery time slots.</td>
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<td>- Increased efficiency and confidence. Setup is simplified and objective vs. manual bolus fabrication.</td>
<td>- Increase setup efficiency and reproducibility.</td>
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<td>- Increase treatment efficiency, throughput, and capacity.</td>
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<td>CBCT assessment of conformity demonstrates reduced frequency and volume of air gaps and improved reproducibility.</td>
<td>Improved confidence in the accuracy of dose delivery both superficially (due to improved bolus fit, reduced air gaps, setup reproducibility) and at depth due to improved bolus integrity and spatial accuracy achieved during 3D printing fabrication (vs. manual wax bolus).</td>
<td>Improved patient and staff experience:</td>
<td>- Reduce risk of compromised delivery due to use of unverified accessories during treatment.</td>
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<td>- Eliminate wax and wet gauze.</td>
<td>- Reduce risk of inaccurate bolus fabrication through use of regulatory cleared processes.</td>
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<td>- Reduce need for tape.</td>
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<td>- Increased confidence as a result of simple workflow.</td>
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