INFORMATION YOU CAN COUNT ON

Manufacturer ablation zone reference values explained
Providing you usable information

We believe sharing clinically relevant ablation information will lead to better care for patients. That’s why we strive to provide you with the most clinically relevant ablation zone reference values.

Industry uses ex vivo tissue models

There is no common standard across manufacturers for tissue model temperatures to produce the ablation zone reference data. Further, as the tissue model temperature increases, ablation zones get larger.\(^1\)

**Emprint™ Ablation System Performance Across Varied Tissue Model Temperatures (100 W, 10 Min in Bovine Liver Model)**\(^{1,2}\)

<table>
<thead>
<tr>
<th>Temperature</th>
<th>n</th>
<th>W (cm)</th>
<th>H (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 C</td>
<td>6</td>
<td>4.2</td>
<td>4.2</td>
</tr>
<tr>
<td>25 C</td>
<td>6</td>
<td>4.7</td>
<td>4.5</td>
</tr>
<tr>
<td>35 C</td>
<td>6</td>
<td>5.0</td>
<td>4.8</td>
</tr>
</tbody>
</table>

Model temperature has a significant effect on the size of ablation zone created (P < 0.05 for all tests\(^1\)).

**Disclaimer:** Animal data is not necessarily indicative of human clinical outcomes.
NORMALIZING PERFORMANCE ACROSS SYSTEMS

Since there is no standard model, manufacturers may choose to use any temperature bovine liver model to create ablation zone reference charts. This makes comparing performance across systems difficult. We generated new data to make it clearer.

**25 C**
- **EMPRINT™ ABLATION SYSTEM¹**
  - Single Probe
    - 100 W, 10 min
    - 4.5 - 4.7
  - Double Probe
    - 65 W, 10 min
    - 4.7 - 3.0
  - Triple Probe
    - 65 W, 10 min
    - 5.0 - 5.1 - 6.6 - 4.7

**35 C**
- **EMPRINT™ ABLATION SYSTEM¹**
  - Single Probe
    - 100 W, 10 min
    - 4.8 - 5.0
  - Double Probe
    - 65 W, 10 min
    - 5.5 - 4.5
  - Triple Probe
    - 65 W, 10 min
    - 5.0 - 6.6 - 4.7

**CERTUS 140™ ABLATION PROBES³,⁴**
- Single Probe
  - 65 W, 10 min
  - 4.7 - 4.5

**ACCU2I PMTA APPLICATORS⁵,⁶**
- Single Probe
  - 140 W, 6 min
  - 4.5 - 5.5

**CURRENT MWA MANUFACTURER MODEL TEMPERATURES**

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>17 C</th>
<th>25 C</th>
<th>35 C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic</td>
<td></td>
<td></td>
<td>□</td>
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<tr>
<td>J&amp;J</td>
<td></td>
<td></td>
<td>□</td>
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<tr>
<td>Angiodynamics</td>
<td></td>
<td></td>
<td>□</td>
</tr>
<tr>
<td>HS Medical⁴</td>
<td></td>
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<td>□</td>
</tr>
</tbody>
</table>

Manufacturer reference values using 25 C liver shows overprediction of ablation zones in comparison to clinical outcomes.⁴

**DISCLAIMER:** Animal data is not necessarily indicative of human clinical outcomes.

*Dimension not provided by manufacturer
DEFINING CLINICALLY RELEVANT MODELS

We know being predictable matters. That’s why we provide ablation reference values from clinically relevant models.

EMPRINT™ ABLATION SYSTEM PROUDLY PROVIDES BOTH IN VIVO AND EX VIVO DATA IN OUR INSTRUCTIONS FOR USE.²,³,⁵

IN VIVO
• Live porcine liver tissue
• Preclinical model simulates in situ organ perfusion

EX VIVO
• Bovine tissue, chilled to 17 C
• Chilled tissue calibrates ablation performance to live models⁷,⁸

THE DIFFERENCE IS PROVEN

Using a clinical relevant model means you see the results you expect.³

Comparison of Ablation Zone Diameters: Prediction versus clinical observation at 100 W⁹

References

1. Based on internal test report #RE00100439, Emprint™ variable temperature ex vivo ablation performance evaluation. Statistics for differences in ablation diameter at varying temperatures: 17 C vs. 25 C, P = 0.006; 17 C vs. 35 C, P = 0.001; 25 C vs 35 C, P = 0.03. May 2017.
5. MLC 506 US Rev E. AngioDynamics, Inc.

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