

# Biophan and MRI Safety Testing

*Biophan Technologies is committed to the improvement of MRI compatibility of all medical devices, as well as the improvement of MRI safety testing to validate the safety of these devices.*

Biophan believes that virtually all medical devices can be made safe for use with MRI. To demonstrate the safety of new devices, safety testing must be performed to accurately reveal problems and potential safety concerns. Testing should encompass all clinically relevant testing conditions, and should be conducted to reveal what is actually experienced by the patient. Recent Biophan data has demonstrated some of the limitations of conventional testing.

## Testing variables

One of the key factors affecting the temperature generated by a device is the location of the patient and device within the MRI tube. As seen in Figure 1, moving the pacemaker lead as little as 3 to 4.3 inches within the MRI system results in an increase in lead temperature of over 10 degrees Celsius, enough to cause significant tissue damage to a patient. The location of the patient within the MRI tube can therefore have a significant effect on generated heat and devices must be tested at all clinically relevant positions to truly demonstrate MRI safety.

Another key parameter that has a significant effect on MRI safety testing results is the type

of temperature probe selected. Figure 2 shows some recent data that Biophan has collected with two different temperature probe designs, both of which are acceptable according to the ASTM standard\*. Probe type #1 has the sensor at the very tip of the probe, whereas with probe type #2, the actual sensor is offset by about 0.5 mm from the tip. As the data indicate, the type of probe selected can result in temperature differences of 8 or more degrees Celsius, under identical, physiologically-correct test conditions. Incorrect probe selection can result in incorrectly missing the maximum generated temperature increase, causing a device to appear to meet safety specifications, when it actually does not.

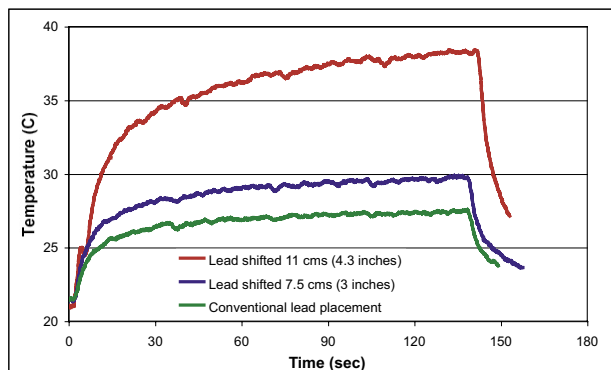


Figure 1 – Effect of position in tube on heating

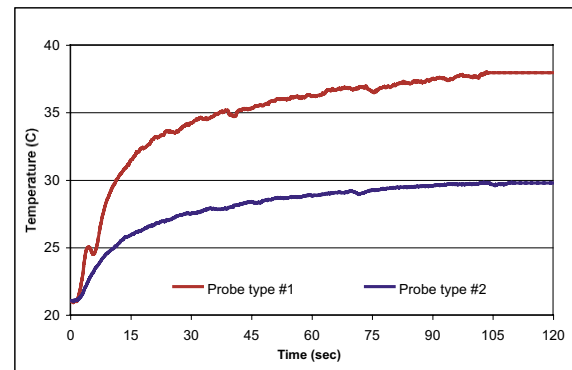


Figure 2 – Effect of temperature probe design

## Placement of temperature probe

Finally, the location of placement of the temperature probe on the device can also be a significant source of temperature measurement variability. Figure 3 shows the results of mathematical modeling of the temperature profile around the tip of an actively fixated pacemaker lead.

This temperature profile shows clearly that the location of placement of the temperature probe near the distal tip of the device can result in temperature differences of up to 10 degrees Celsius. Biophan has confirmed that sub-millimeter movements in temperature probe location can result in a significant effect on the measured temperature increase.

Biophan is committed to working with medical device manufacturers to ensure that the testing that is performed is adequate to validate the

MRI safety of devices, taking into account the worst case, clinically relevant conditions, to ensure that devices are truly safe for the patients that receive them.



Figure 3 – Temperature profile from mathematical modeling of active fixation pacemaker lead in an MRI field.

## Intellectual Property

Biophan’s internally developed technologies and patents, in combination with exclusive license to a Johns Hopkins patent on lead safety provides comprehensive intellectual property coverage for Biophan’s MRI safety solutions. Biophan’s patent estate, including assigned and licensed patents, stands at 36 issued patents and more than 75 applications in various stages of prosecution worldwide. ■

\*ASTM F 2182-02 “Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging”.