

Overview

- **Organization:** ReGear Life Sciences Inc. Founded in 2006, headquartered in Pittsburgh, Pennsylvania.
- **Challenge:** Validate that the SAR value complies with all applicable regulations for a new therapeutic deep heating garment for the shoulder.
- **Solution:** Use EM simulation to determine SAR; outsource this part of the project to Remcom.
- **Result:** Simulation results proved safe SAR levels and Remcom provided necessary documentation for release of ReGear's shoulder garment to market.
- **Product used:** Remcom Consulting

Customer

Maria Fattore-Gill
Vice President, Product Manager,
ReGear Life Sciences

ReGear manufactures and markets an FDA cleared, therapeutic deep heating solution that accelerates healing and reduces pain associated with injury and aging. Their flagship product, ReBound™, uses technology that was originally developed by the US Navy to warm deep sea divers.

In addition to rehabilitation, physical therapy, and sports medicine applications, ReBound promises to become a standard of care in the long term care market for the aging, especially as populations

continue to live longer and strive to maintain active, pain free lives. Safety is ReGear's number one concern, and complying with FDA and other safety regulations is the most important requirement in being able to release their products to the market.



ReGear's ReBound shoulder garment

The Challenge

ReBound uses a control unit that heats various types and sizes of anatomically specific garments. ReBound's light weight, portability, ability to treat large and small surface areas, circumferential heating, and safety are the features



that set ReGear apart from traditional diathermy systems that utilize a drum applicator to provide therapy.

When ReGear decided to create a new shoulder garment, they faced tougher safety considerations than they had with their other garments. Because the shoulder is much closer to the head and core of the body than the limbs and lower back, careful design and testing were needed to meet the FDA's and FCC's Specific Rate of Absorption (SAR) requirements.

Maria Fattore-Gill, vice president and product manager for ReGear, along with Bob Unetich, owner of GigaHertz, LLC, led the prototype design process. To begin designing the shoulder garment, the team had to measure the electromagnetic waves, or radiation, delivered to and around the head during typical use. Without an internal expert to perform this type of testing, they searched for an external resource to complete the work. Obviously they needed to find someone with electromagnetic expertise who also had the right tools to quickly and easily perform these tests and provide the documentation needed to prove the product's safety.

How Remcom Helped

In looking at other organizations whose devices require similar approvals, such as cell phone manufacturers, ReGear discovered electromagnetic simulation software could provide the needed measurements. Maria compared several software vendors, including Remcom. "Remcom's Consulting offering was our clear choice," said Maria. "Some of the other vendors we talked to wouldn't even entertain the

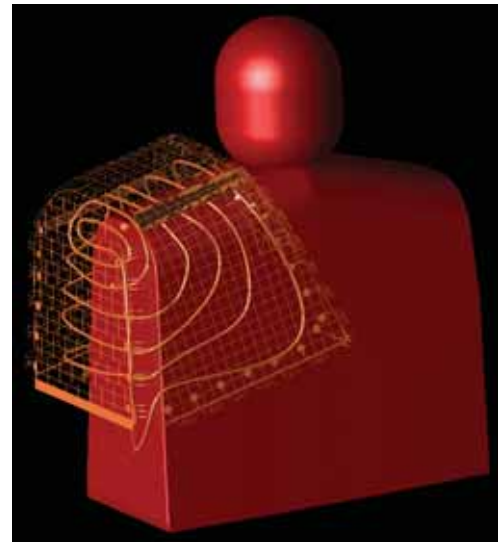


Figure 1: CAD representation of shoulder garment mounted on human body phantom in XF7.

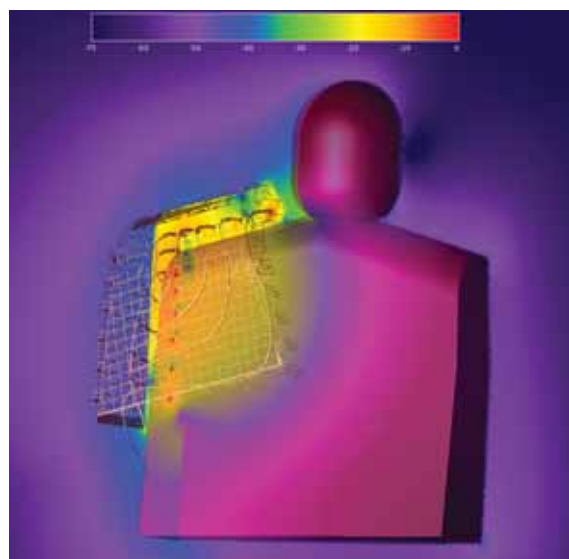


Figure 2: XF7 simulation showing undesirable field leakage near head.

idea of consulting, providing us only one option, which was to purchase expensive software. Remcom Consulting was a much better solution for us, saving us from having to hire an EM engineer onto our staff as well as the time investment that would have been required to train them."

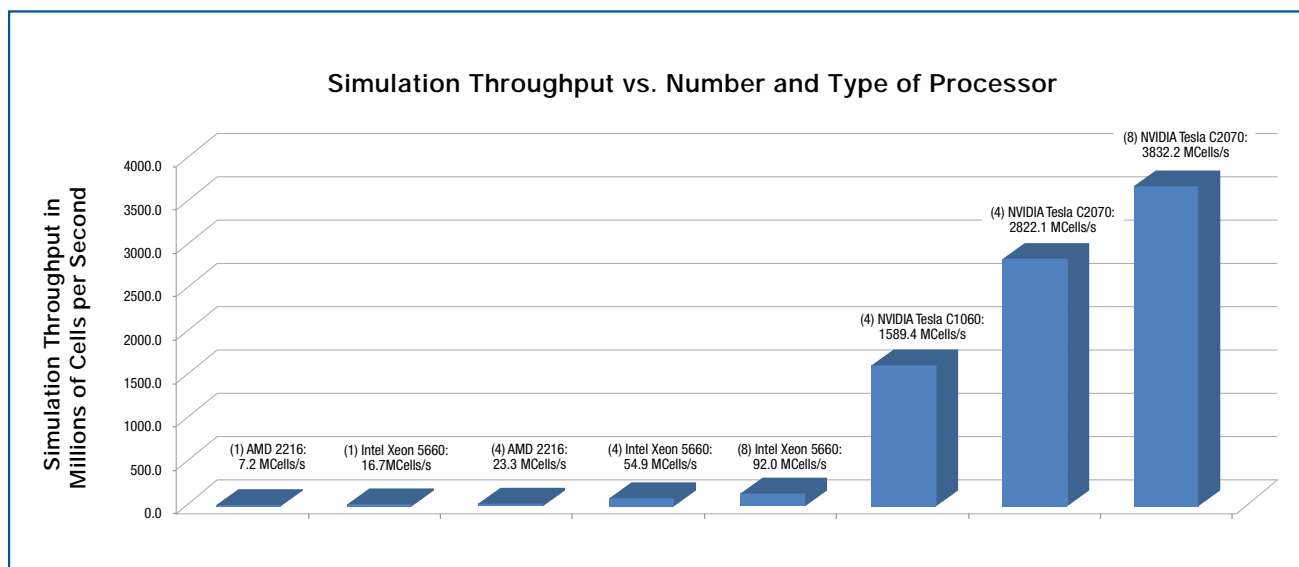
Remcom engineer Jim Stack worked closely with ReGear to test and provide feedback on two iterations of the shoulder garment. He began by importing the CAD model of the device that Maria provided into XF7. The imported model was mounted on the shoulder of a human body phantom (Figure 1).

The initial simulations indicated that there was undesirable field leakage at the top of the shoulder

near the head (Figure 2). Jim recommended additional shielding in this region and provided images to demonstrate the area of concern. ReGear decided on a shielding strategy and provided images and physical dimensions to Jim which he incorporated back into the CAD representation using the powerful modeling capabilities of XF7's CAD tools.

The second iteration showed that the field leakage was reduced to nearly zero. The electromagnetic radiation of the device was now confined to the target warming area, and the simulated SAR data indicated absorption significantly lower than the 1.6 W/kg threshold required by the FDA and FCC. Jim created a report documenting the simulation process and final results for Maria to present in her documentation to release the shoulder garment to market.

Remcom's XStream® for XFtd was critical in completing this project quickly. The combination of low frequency excitation and detailed physical structure generally led to long simulation times. Jim was able to divide the problem across multiple NVIDIA Tesla GPUs to achieve throughput speeds which were orders of magnitude faster than a traditional CPU. This type of speed advantage allows multiple simulations to be completed in a single day on a GPU as compared to the possibility of weeks on a CPU.



Note: Simulation speeds at the time of the printing of this paper are continually improving. Please visit Remcom's website at www.remcom.com/regear for the most recent measurements.

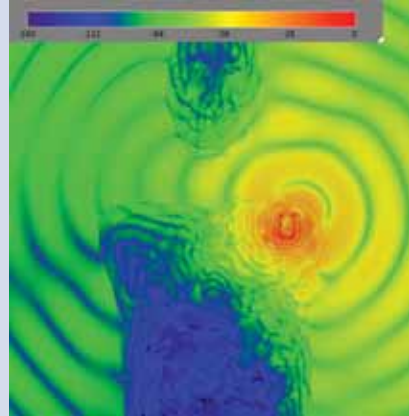
Results

Maria's team received the information from Remcom showing the SAR values complied with all appropriate regulations for the shoulder garment and released the product to the market in February, 2010. "Outsourcing the tasks that required EM expertise and specialized software tools allowed us to focus on marketing and selling the product," she said. "Remcom Consulting was not only more cost effective but saved us valuable time as well. We could not have released the new product without Remcom's expert recommendations and documentation."

Consulting Project Examples

Remcom offers consulting across all electromagnetic applications, from bio-medical to antenna analysis. Please visit www.remcom.com/consulting-examples to read examples of past consulting projects, including:

- On-Platform Antenna Analysis and Optimal Placement
- SAR Analysis of Implantable Medical Device
- Proof of Concept Experimental Design Analysis
- EM Analysis of a Therapeutic Device



Remcom has been leading the EM market with innovative simulation and wireless propagation tools for 15 years. In addition to our flagship product, XFtd, we offer a suite of innovative software and services, accessible and responsive support provided by a staff of experts, and comprehensive training. Our family of products includes:



XFtd[®]: 3D EM simulation software package that provides engineers with powerful and innovative tools for modeling and EM software simulation.



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Rotman Lens Designer[™]: A tool for the design, synthesis, and analysis of Rotman Lenses.

Please contact Remcom to learn more about Remcom Consulting:
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