by Enrico Denna*
Flex

Using Simulation and Modeling for medical Radio Frequency design

A study demonstrating the benefits of simulation over prototyping

The growth of technology and end-user expectations is ever more important in many application areas and medical devices are at the forefront of this innovation process. The requirements of an even more connected world have had a significant impact on electronic design and specifically on the area of radio frequency (RF) which by its very nature represents a major design challenge. Modeling and simulation are valid instruments to assist in achieving this goal because performance in electromagnetic design cannot be easily predicted in advance by relying solely on the experience of the designer.

The world is changing and becoming more and more "smart". Not more than ten years ago, the word "smartphone" was unknown, instead today it is normal to talk about smartphones, smartwatches, smart TVs and so on. Words like "connectivity", "apps" and "data connection" have become part of our everyday lives and vocabulary. Medical devices have obviously followed this trend and have adopted connectivity as their must-have to align with market demand.

Several medical devices are becoming even smarter and more connected, storing big data, using apps, and enabling functionality that is of real benefit to users.

The design of these new features presents several challenges, one of the most critical aspects being the creation of a stable and reliable connection within a user-centric usage model. Here we are talking about a wearable model where devices are powered by smaller, sometimes non-rechargeable or non-replaceable batteries; devices that are typically either handled or directly in touch with the human body, such as insulin pens or drug delivery patch plasters; devices that are used or stored in varying environmental conditions, not only at room temperature at home, but also in the mountains, inside a car, or kept in a refrigerator.

These new design requirements have spurred the development of simulation tools to help designers refine their projects while saving time and costs on development which, until now, has always been undertaken with a trial-and-error approach. HFSS by ANSYS is one of the most powerful tools available to assist designers with their projects.

Flex is a leader in the design of medical devices for major pharmaceutical companies and its Milan office, which is its largest design center, has grown over the years by integrating all aspects of design from concept definition to mass production. In the Milan office, the electrical team that I am proud to lead has also grown and effectively adapted to the changing market by following this trend. Aiming to surmount the

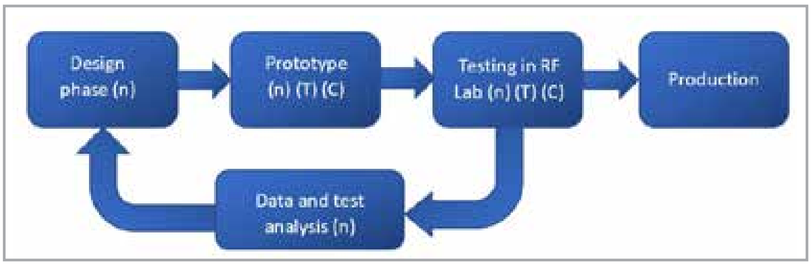

Fig. 1 – Standard Trial-and-Error Approach. Final cost of the process is calculated according to the (T)ime and (C)ost of prototyping multiplied by the number of prototyping iterations (n)

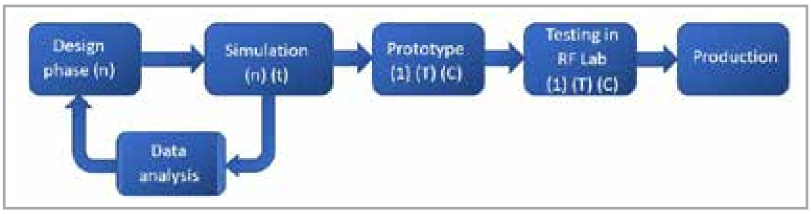

*Fig. 2 – Simulation Approach. Final cost of the process is calculated according to the (t)ime of simulation multiplied by the number of simulation iterations (n). It is clear that the cost of the first approach (n*T*C) is not comparable with that of the simulation approach (n*t + 1*T*C).*

trial-and-error approach, we improved RF knowledge with training, by accessing know-how from external experts, and with laboratory interaction, until finally introducing the simulation tool.

The benefits and advantages of the simulation approach

The comparison process flow (Fig. 1) immediately reveals that in a trial-and-error approach the number of design phase iterations (n) to fine-tune and adjust the design leads to the same number of prototypes and tests which must possibly be conducted in an external lab with the RF instrumentation and accreditation to issue a formal certification. The cost of this process (C) is calculated from the costs of the prototyping and external laboratory testing, while the time to mass production (T) is derived from the time it takes to construct the prototypes, book the external labs, conduct the tests and issue the test reports. All of these steps must be multiplied by the number of iterations (n).

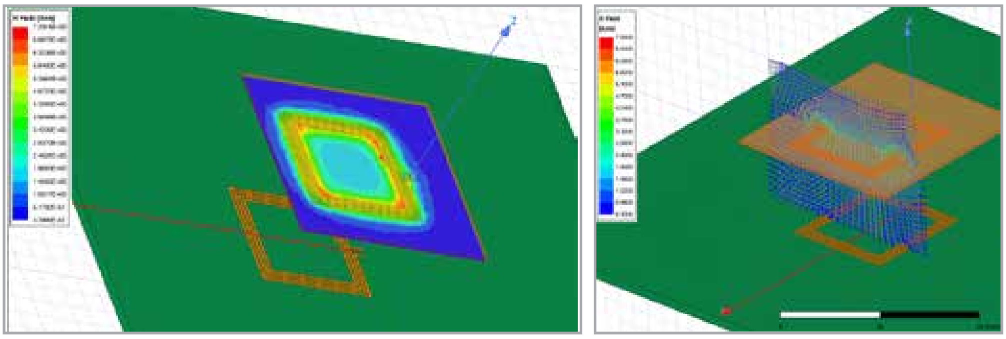

Fig. 3 (a)(b) – modeling and simulation of an RFID tag with its reader.

In the simulation approach (Fig. 2), the number of iterations only affects the number of simulations which may take a time (t) of some hours or days depending on the complexity – this time is obviously not comparable to the weeks necessary to realize and test a prototype. Furthermore, the only person involved in a simulation is the designer, while any prototyping test involves several players (layout engineer, purchasing office, test operator, local prototype producer and financial office).

Another disadvantage of prototyping is linked to the time needed to take delivery of the prototype during which the designer is unable to work on this project. It is clear that the prototyping process is inefficient and easily justifies the investment in a simulation tool which can be amortized in just a few years of design activity.

The improvement realized by introducing simulation is clearly evident examining some examples of design. In Flex products the connectivity designs primarily involve the Bluetooth-NFC/RFID interface typical of wearable devices, but Wi-Fi and 5G connectivity have also been analyzed. Fig. 3 (a)(b) shows the modeling of the coupling of an RFID tag and reader: the simulator enables the engineer to replicate the coils of both the tag and the reader and then to examine the magnetic field coupling between the two elements according to the spatial distance.

Typically, electrical designers begin by focusing on the PCBA and antenna design, applying their experience and radio frequency knowledge to implement the application notes and guidelines of the RF module and the integrated or chip antenna selected. This leads to a PCBA design that respects the ground planes and transmission lines and has controlled impedances, which then guides the layout engineer to design the microwave traces with the appropriate thickness and dimensions (see Fig. 4).

However, this approach may be inadequate: the mechanical parts of the device, particularly where there are multiple boards assembled together, and the metallic parts, like the battery body, motor engine or display holder, can significantly affect the electromagnetic field. All of these side effects are difficult to predict in the trial-and-error approach, resulting in an increase in the number of iterations (n). The simulator makes it possible to import complete mechanical and electrical files (such as STEP and BRD files, for instance), to obtain a complete model of the device in which it is possible to assign a material to any component using the simulator's internal library.

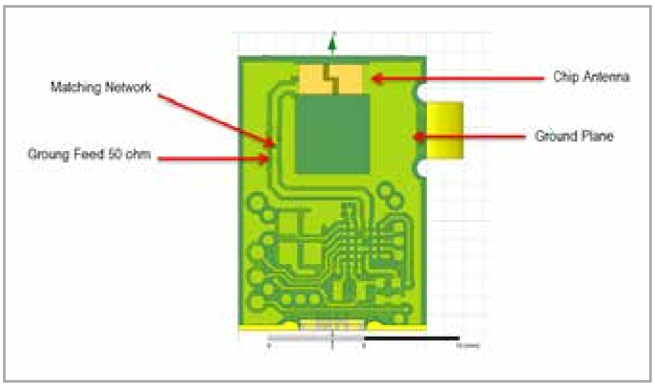

Fig. 4 – Example of PCBA with a chip antenna.

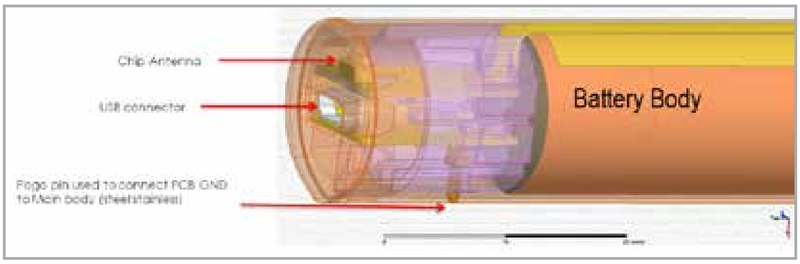

Fig. 5 – A 3D design of the final device including electronic PCBA and mechanical parts.

Fig. 5 shows part of a pen-shaped device into which the PCBA illustrated in Fig. 4 has been introduced and connected to a Micro-USB connector. The device housing is made of steel and there is a rechargeable battery on the back of the electronic location. The PCBA is connected to the housing via a pogo pin which grants a ground connection.

This setup and similar systems can dramatically affect both the RF transmission and the Bluetooth antenna. Once assembled, as seen in Fig. 5, this system has a completely different radiation pattern compared with the initial configuration visible in Fig. 4.

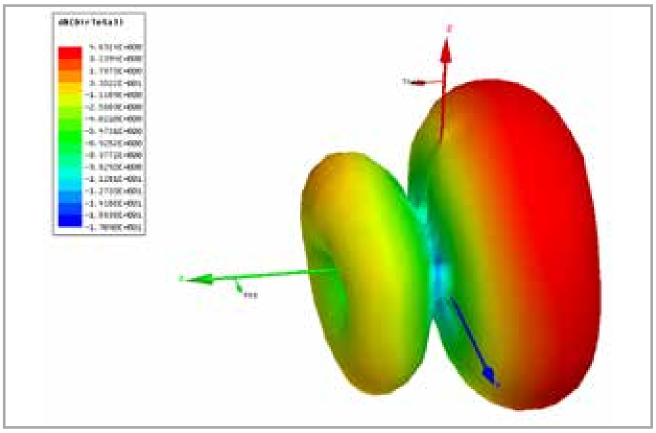

Fig 6 – 3D radiation lobe.

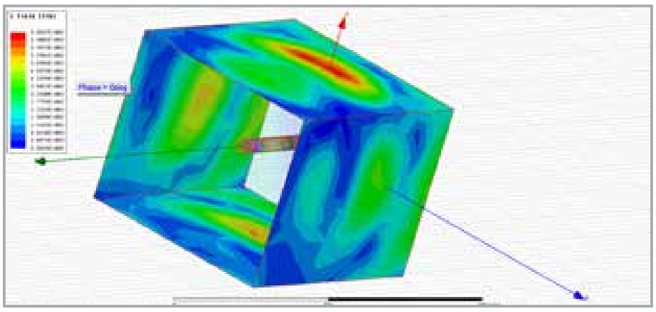

Fig. 7 – Animation of 3D phase radiation.

Fig. 6 illustrates the 3D radiation pattern generated by the simulator, which immediately informs the designer that the best direction for radiation is on the back, as opposed to on the body of the battery. This could be due to internal reflection caused by metallic parts or to the mechanical portions of the opening, both of which are compatible with this wavelength. This result is very unusual and therefore difficult to predict. The simulation result has therefore avoided a prototype round because, previously, the only way to have discovered this behavior would have been to test a prototype and then to rework the device to increase the performance in the forward direction; the simulation allows this behavior to be addressed in advance.

The simulator makes several pieces of data available both graphically and numerically: 3D radiation lobes, animations of 3D phase radiation (Fig. 7), and impedance and Smith charts suitable for S11 tuning and power transmission (Fig. 8).

Simulation makes another major contribution during the design of a PCB antenna. In the trial-and-error approach, often the application note or reference design are only indicative (and sometime ideal), which generally increases the number of iterations required because it is not always possible to rework the antenna – particularly for high radio frequencies where some tenths of a millimeter in the track dimensions can make a difference. Some challenging solutions could be accomplished using an antenna derived from the metallic parts already present in the mechanical device. This design would be easier to simulate several times before moving onto creating a prototype device once the engineer is closer to achieving the final solution.

In medical and wearable devices, the effect of the human body is not negligible: microwaves generated by Bluetooth or Wi-Fi-connections are absorbed by human tissue. Simulation plays another fundamental role here by providing a model of the human body complete with skin, bones, and internal organs into which it is possible to introduce the device to study its behavior and the effect on the radiation patterns.

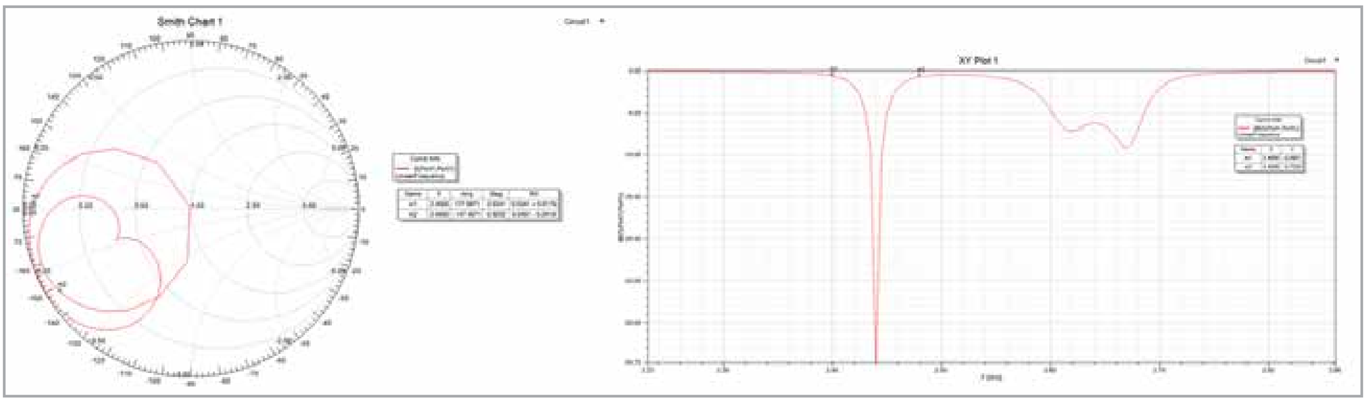

Fig. 8 – The simulator provides substantial engineering data. Here you can see the Smith Chart and the S11 parameter suitable for antenna tuning and Q factor definition.

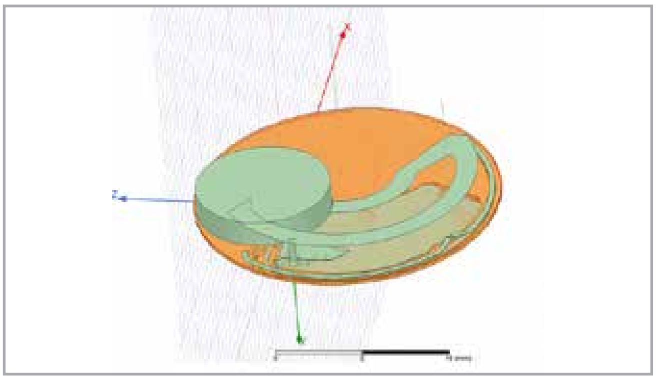

Fig. 9 – Metallic antenna derived from the battery clip.

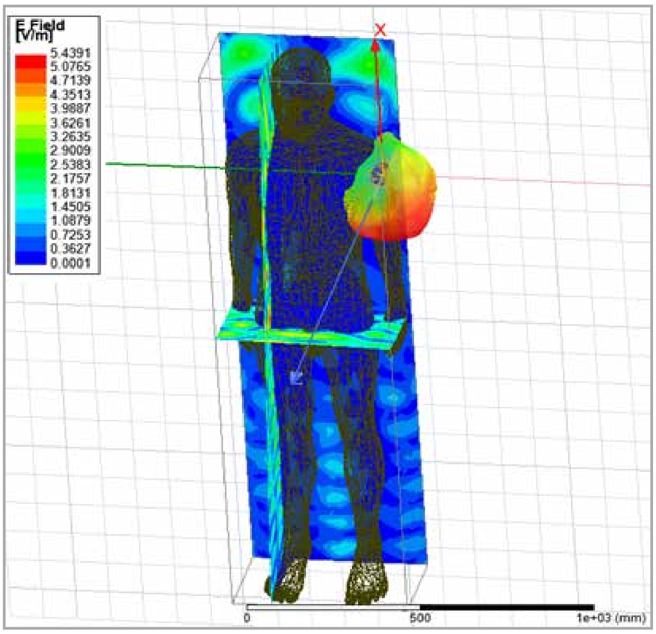

Fig. 10 – Human body model available in the simulation tool.

About Flex

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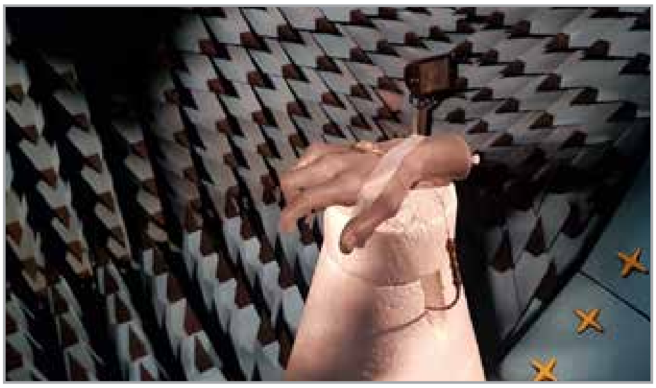

Fig. 11 – Measurement of a device in an anechoic chamber using a biological dummy

Fig. 10 shows the simulation of a Bluetooth device attached to the shoulder of a patient. The field strength is measured at the level of the trouser pocket where a smartphone may normally be present to receive the data. This simulation allows the designer to better understand the result and the reference direction of the radiation in the presence of a human body, making it possible to tune the design but also providing useful information for the usage model. It also provides an indication of other safety parameters, like the Specific Absorption Rate (SAR).

Fig. 12 – 3D radiation pattern measured in anechoic chamber

To optimize the confidence of the simulation result, the model can be validated during the first prototyping round. In this case, the results of tests done in an anechoic chamber using RF instrumentation and possible human dummy material (see Fig. 11 and Fig. 12) can be compared with the results obtained with the simulation allowing the simulation model to be fine-tuned by adjusting some of the parameters or corrective coefficients in its configuration. After this final step we have a powerful model that truly represents the functioning of the device inside its usage environment and that can easily be used to evaluate modifications, or as a reference for similar new devices.

The power of this tool can be supported by other sub tools, like Optimetrics which enables a parameter to be optimized or the optimal coefficient of the design to be found using automatic and iterative simulations. Other tools and add-ins can also be introduced to support thermal or impedance simulations.

The clear advantages of the simulation approach are pushing more and more companies to consider investing in these tools to improve the design process. There are several benefits: the cost and time to production, the improvement of the designers' know-how and competence because of the ability to experiment and thereby increase their knowledge and motivation in a field that is not always intuitive or easy to master, and last but not least, simulation provides a structure to the design process that will inevitably be recognized by customers who will appreciate a more professional approach.

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