DR Doppler™

CASE STUDY - DOPPLER SYSTEM

A high level look at how INTEGRIS Group helped create the world's first dynamic ultrasound trainer.

Presented by:

INTEGRIS ENGINEERING

A high level look at how we helped create the world's first dynamic ultrasound trainer.

Executive Summary:

The development of a product is not an easy feat. The development of a product that has no equal is even harder, which is exactly what we set out to do when were approached with helping to develop DR Doppler. Our client, SIMnext, had received enough interest and completed initial research to show that this concept would be widely accepted in the ultrasound community. The product would have the ability to empower a multitude of clinicians to stay up to date on non-frequent diagnoses.

When reviewing someone else's working prototype, there are a lot of unknowns: Why did they do this? Why is it wired that way? How does this work? One thing was clear - we had to get this concept ready for its public launch as well as make it ready for manufacturing, both things a proof of concept is not intended to do.

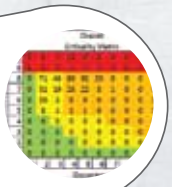
In this particular case, INTEGRIS was to work closely with the SIMnext engineering team to bring their first affordable, portable, simulation device to market. Both parties benefited immensely from this coherent relationship, and each added innovation along the way. Our project management team, acted as the glue that held this all togther, keeping the development moving forward and on track for an industry launch.

Overall, we experienced about 10 design changes, multiple design freezes, several failures, added creativity/innovation and one great release to the public! Follow along as we take you through what it took to take a proof of concept to market.

STAGES OF DEVELOPMENT

BEGINNING

Completed FMEA



Proof of concept received

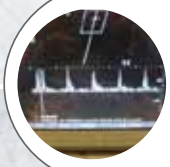
1st Proto Built “Prodigy”

2nd Proto Built “Hamm”

3rd & 4th Proto Built “SilverStone”

Prototype Development

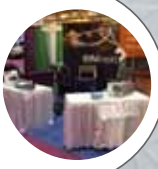
Identified need for proprietary fluid



Further defined application

Built 8 “SilverStone” units for pre-field follow

SilverStone unit successfully demonstrated at several conferences



Performance Development

Designed custom enclosure

Designed custom circuit board

Developed Blood Mimicking Fluid

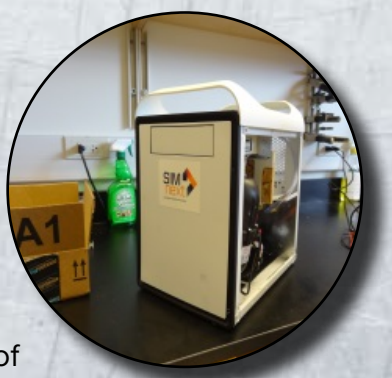
First anatomy - CCT Trainer

Final design testing and validation

LAUNCH

Performance Optimization

STAGES OF DEVELOPMENT



Prototype Development (Learn Quickly)

The first step was to complete a FMEA (Failure Mode and Effects Analysis) on the Waveform Emulator. The Waveform Emulator is the heart of the system and is “the box” that holds the electronics, fluid, and valves to generate the necessary waveforms. After completing the FMEA, we received the proof of concept emulator and began to plan out the development path to a commercial product.

Concurrent with the planning process, several initial prototypes of new emulators were built. INTEGRIS 3-D printed a variety of prototypes to help visually guide the design process, allowing the teams to rapidly develop new iterations.

These prototypes allowed us to begin testing and experimenting with a variety of configurations, valves, and electronics; as well as begin to identify and set baselines for performance. As we worked through prototype 1, prototype 2 was created to meet the SIMnext mission of portable, affordable simulation devices. Prototype 3 became the basis for the emulator we have today.

Every iteration of design and prototype further paved the path for the next development, allowing us to hone in on performance targets and usability, as well as think about mass production.

At this point, we had a real, repeatable prototype that we could share with the industry. SIMnext started to test the market and gather feedback at IMSH 2015 in New Orleans, Louisiana. This event established that DR Doppler would fill a gap within the simulation market, and its ability to utilize any ultrasound with stunning realism was received with excitement.

Performance Development & Optimization

Waveform Development

Subject matter experts were a huge help in determining waveforms to be generated by the system. Various waveforms were identified, with a request to generate both healthy and pathological waveforms. Many times, students do not have the opportunity to observe pathological waveforms during their classroom or clinical training. Having these waveforms available through DR Doppler allows for clinicians to become familiar and able to quickly recognize and react when one is observed in the clinical setting. Dozens of waveforms are continuing to be developed, including healthy and pathological, and high and low flow, both which simulate blood flow within the human body.

Created Blood Mimicking Fluid

In order to create a realistic system, we needed to have a system specific fluid that would meet performance requirements and would work within DR Doppler. The team researched the specific properties of blood, and by referencing several industry standards, were able to mimic those properties in DR Doppler. We further refined the fluid and completed acoustic testing to ensure the properties were an exact match to human blood, in order to ensure that DR Doppler would produce clinically accurate and consistent waveforms.

Core Competency Trainer Evolution/Creation

A silicone “test block” was developed for testing the system and developing waveforms. First it was used internally and then taken to conferences. It was found that there was value in developing something similar that would teach the fundamentals of ultrasound. A CCT (Core Competency Trainer) prototype was developed and shared with subject matter experts to validate the value, and define the teaching objectives. Several prototypes and iterations were made and tested, keeping realism and manufacturability in mind.

Software Development & Mobile Application

As part of the 21st century learning environment, a key feature of DR Doppler is a flexible and mobile platform to teach the fundamentals and diagnostic processes. In this digital environment, we utilize a custom DR Doppler application loaded on a tablet that is connected to the Waveform Emulator via Bluetooth technology. From the tablet, a student has the ability to learn about various pathologies and techniques through cases studies, self-guided practice and exams. The app tells the emulator to generate the appropriate waveform for the topic being learned by the student. On the back end of the application, we are able to gather analytical data to provide a platform for improvement, and even update the firmware and app remotely for new features.

Educational Curricula

As the CCT emerged to be the first anatomy offered with the system, we needed to determine the curricular content to be included. The CCT is great for learning ultrasound basics: the doppler effect, basic physics, and how to interact with an ultrasound machine. We spent a lot of time with a clinical subject matter expert, a radiologist with 30+ years of experience, to develop curricular content to go with the CCT. The ability to teach, test and reinforce the fundamentals of ultrasound, will have a positive impact on all learning objectives to come. As the anatomical phantom anatomies are added, the curricula will teach technique and processes specific to that area of the body.

Circuit Board Evolution

The circuit board was developed in three specific phases. Gen 1 was received from SIMnext with the original proof of concept system. This consisted of an off the shelf microcontroller connected to hand built breadboard style hardware for controlling the pump and valves. This approach was more than acceptable for the purpose, but it did lack the robustness and repeatability needed for multiple systems. For Gen 2, we kept the microcontroller board but replaced the breadboard with a custom circuit board. This approach allowed us to learn system requirements and sensitivities quickly and reliably. For Gen 3, we replaced the controller with purpose built hardware that allowed us better control, performance and scalability.

Instructional Design

The instructional design was led by an **INTEGRIS** engineer with years of experience as a professor who has written a textbook, created courses in computer science, physics, and electrical engineering, and designed many instructional materials. As this product is an educational tool, the design of the instructional curriculum's layout and content was critical. The app provides a wealth of educational content including background reference material, guided walkthroughs of various techniques, and assessments. This was complicated by the fact that several different groups with a variety of learning styles and at varying levels of experience may use the system. Interactive 3D models, animations, images, and interactive demonstrations allow the content to reach students in many modalities. The greatest benefit of the system is that it is scalable, and new content can be added through the purchase of additional phantom anatomies.

The instructional material has undergone many iterations of development, internal review, external review, and improvement. External focus groups of diverse experts were used to evaluate app look, feel, and usability. External ultrasound education experts provided valuable feedback on the technical content.

UL Safety Certification Process & Obtaining CE Mark

In order for SIMnext to sell DR Doppler, UL Safety Certification was required, as well as other various pieces of compliance. Since DR Doppler is not a medical device, it is not required to have FDA approval. It is designed as a teaching apparatus and will be

used exclusively for simulation purposes. UL Safety Certification included a variety of testing, including heat, power, and drop tests, to ensure safety in a variety of situations. Additionally, testing was completed in order to ensure EMC (electromagnetic compability) requirements were met. This was a requirement for obtaining the CE mark, which allows for selling DR Doppler throughout Europe.

Launch Event

DR Doppler was launched to the public on January 12, 2016 at Matter Chicago to rave reviews. INTEGRIS was on hand to give product demonstrations and provide technical support if needed. (It wasn't!) SIMnext is planning on selling DR Doppler beginning 2nd Quarter of 2016, with deliveries transpiring thereafter.

Future Plans

DR Doppler was designed as a scalable platform, which allows for a variety of phantom anatomies to be connected and disconnected based on the teaching objective. This interchangeable design allows DR Doppler to provide robust, realistic training with the release of each subsequent anatomy model. The ability to use many ultrasounds, means that DR Doppler can be used for years to come and truly is portable and affordable. The team is currently working on a variety of dynamic phantom anatomies to accompany DR Doppler, releasing them over the next several quarters.

Conclusion

Well there you have it, a high level look at all the components that go into developing a product with no equal! Over the coming months, clinicians will begin to use DR Doppler in their training. This training will allow them to gain experience with pathologies that they may only encounter once in their career, but they'll be able to recognize them due to their experience on the DR Doppler System.

We will be publishing more in depth case studies regarding some of the steps and the rigorous process it takes to put them all together. If you have an idea or a need, please get in contact with us to see how we can throw your project a curve ball.

About INTEGRIS

Founded in 2011, INTEGRIS Group is a product development group, organized around the core principles of engineering. INTEGRIS utilizes various engineering disciplines to ensure that the products created are game changers, and that their clients realize their visions.

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