NARRATOR: Welcome to Intersections: The RIT Podcast. Heart failure costs the U.S. $34 billion a year, with most of those costs due to repeated hospitalization. Today, David Borkholder, RIT’s Bausch and Lomb Professor of Microsystems Engineering talks with Nicholas Conn, a postdoctoral fellow and founder of Heart Health Intelligence, about new invention that could help patients easily monitor their health in the privacy of their own bathrooms.

DAVID: Like most of my research, it started with a phone call. We’d had a successful DARPA program to create wearable technology for soldiers to help address traumatic brain injury from blasts. That program manager had moved to Google to participate in a new group that was supposed to be DARPA-like there to pursue crazy ideas that might have a big impact. So, he called and he wanted to do something in the in-home cardiovascular monitoring space and asked if we had ideas. That’s when I called Nick in, and we started brainstorming.

NICHOLAS: So, I came down to Dave’s office, and he told me about the opportunity. It was super exciting. And we started thinking about what the biggest challenges are with in-home monitoring. Adherence and people’s ability to utilize technology in their home was always the forefront of the problems with monitoring. So, we thought about, could we integrate the technology that we already have expertise in into a steering wheel or a computer mouse? And none of those are something that we used every day. And I don’t remember how we came to the bathroom, but you suggested waste analysis, which I didn’t want to do for my Ph.D.

DAVID: Actually, the waste analysis came after we had the idea, where we said, “Maybe we could do this, too.” That was part of brainstorming for patents. I think we got on the bathroom because it was the one place where you could ensure skin contact and people were going to use it every day. And then you think about when people do measurements. So, usually people are using the bathroom first thing in the morning, they’re at rest, it’s before food and caffeine. And so you could begin to imagine having a regular cadence of data collected in the home without the patient having to do anything out of the ordinary. So then, Nick, what did we have to do to see this was even possible?

NICHOLAS: So, then I ran upstairs, I strapped some electrodes on my butt and I wanted to find out if we could measure an ECG. And with some basic proof of concepts, I showed that we could actually measure this. I went to Lowe’s or Home Depot and bought a wooden seat, which I cut out slots from to put some custom circuit boards in and test if we could measure some of the other things that are currently in the seat. I ran some testing in the lab – without curtains yet, we hadn’t built up our clinical testing area. So, I’m in the corner in a hospital gown, back open to the corner, trying to measure all these things and making sure it works. And then once the data looked pretty good, and we were able to do a basic proof of concept, we included that in the grant proposal that we then submitted to Google.
DAVID: Right. And we started with the electrocardiogram, but that platform allowed you to do some other measurements that were really important as well. So we could do a ballistocardiogram, which has a very long history. But with modern signal processing capabilities, we’re really able to extract robust signatures out of those waveforms. And then a photoplethysmogram. The combinations of those three measures allowed us to really open the aperture for the different measures that we could get out of this one platform.

NICHOLAS: So the ballistocardiogram is a measure of the mechanical forces of the heart. As the heart contracts, it builds up pressure, the aortic valve opens and blood is forcefully ejected up into the aorta. That upward momentum pushes the body down ever so slightly. So, we’re able to pick up those and measure things like stroke volume and cardiac output. However, we didn’t know how to do that at first, and it took us a long time of explorations.

DAVID: Absolutely. When Nick and I started brainstorming how we would do this, it became clear that we really needed some clinical expertise. And I had done some collaborations with Karl Schwarz at the University of Rochester Medical Center. He runs their echocardiography unit. We got together and brainstormed the different things that we might do with this technology and integrated a lot of those ideas into the proposal.

NICHOLAS: And Karl loved the concept. He, from the beginning, thought it had a lot of potential for heart failure, and worked with us in his knowledge of physiology, especially those with cardiovascular disease and the types of signals and measurements that we could capture. And he was working with us in the lab brainstorming what the ballistocardiogram even meant from a physiology standpoint. And that helped us make pretty rapid progress in understanding the waveform and going about estimating clinically relevant parameters.

DAVID: We did a series of studies over a number of years. We started with normative subjects here at RIT where we were developing some of the base algorithms, refining the technology. We had other collaborators in the College of Art and Design, in Industrial Design, that were helping us with how do integrate all of these components into the seat and make functional elements out of components that are usually static like standoffs. How do you integrate measurement and mechanical forces into those and design hinges that don’t carry any load when the seat is down? But we did a series of human subject studies, and as the technology was refined, we started adding in subjects at the University of Rochester. So there we’re able to recruit heart failure subjects and test the same things we were doing with our normatives, test those subjects when they were coming in for routine exams. And then we gathered a large number of subjects when they were coming in for a standard echocardiogram. So we got a broad range of disease states, ages, etc. And I think that really gave us confidence in the core technology and what was possible with the technology.

NICHOLAS: It was a long path from developing the hardware, running the studies. And then we had data in had for a while before we really cracked the code for stroke volume
and blood pressure. We always knew that the seat had a lot of potential for excitement. Anyone we ever talked to loved the concept. It was out of the ordinary and something that captured people’s imaginations. But also kind of was a thinker. You had to think through why this was worthwhile and then you realized this is great. Dave, you and I had talked about potentially publishing early or not publishing certain things. When was the right time to put out our work? And I think that it was unexpected when I published my most recent journal publication where we did finally have robust numbers and robust studies, that allowed us to ride the wave of attention. Do you want to talk about why we didn’t publish sooner?

DAVID: With technologies like this a lot of the advancements are algorithm based and, Nick, you’ve done a fabulous job in terms of creating really novel and robust algorithms because you are doing these measurements outside of the clinic. So there is no adult supervision at all as you gather this data. You have motion artifacts, etc. So you need to be able to take that dirty data stream and make it a clean data stream. [laughter] No pun intended. As he graduated, this was a time to be thinking about could we translate this technology so that it could have a profound impact on the way that we treat cardiovascular disease.

NICHOLAS: And I always wanted to be an entrepreneur and start a business. This was the perfect platform to do that. We had a lot of scientific background and work that went into making this really unique technology robust. So I began, after I finished up the work, the algorithm development over the first year or so after my Ph.D. I then focused effectively on publishing, writing grants and business development to figure out how to commercialize this.

DAVID: So, Nick, as you look at the commercialization path for this, there could be a consumer path, there could be a path where this is managed through the healthcare system. Can you talk a little bit about what that looks like and how you think that commercialization will proceed?

NICHOLAS: I’ve had a lot of interest from people wanting to buy the seat directly from Heart Health Intelligence. I’ve gotten calls from people all over the world, actually, already – people wanting to buy the seat now. And while that’s a very interesting use case, and we think there’s a potential for a consumer product, our passion is to bring regulated medical devices to market – clinical-grade devices that can have an impact on people’s lives and provide meaning and actionable information. Part of the challenge with this data set and the type of data we’re capturing is: What is the average consumer going to do with the data? It’s going to be an important element for us to research that over the years. And we’ve got some grants we’ve submitted where we’re looking at how to present data to people in a meaningful, actionable way. But we see, really, the healthcare market and going through as a regulated medical device as our first entry into the market. And that’s really focused on heart failure, which is a specific type of cardiovascular disease because there is a pressing need there to reduce hospitalization rates. These patients are in and out of the hospital. Almost half of patients end up back in the hospital within 90 days of discharge, three months. Because of that we want to be
able to help people live a better quality of life in their own homes and prolong the comfort that they have, while not necessarily being in the hospital.

DAVID: What do you think the impact could be on cost of healthcare?

NICHOLAS: Heart failure costs the U.S. $34 billion per year with 80 percent of those costs due to hospitalization. So, if we can reduce hospitalizations by a rate that an implantable device, CardioMEMS, achieved, we could potentially save the U.S. over $10 billion per year.

DAVID: That’s pretty significant.

NICHOLAS: Yeah. That’s part of the motivation for going after this market rather than the consumer market.

DAVID: And the types of monitoring that you could do would be similar to what many hospitals are trying to do with in-home monitoring today.

NICHOLAS: Right. So, a lot of heart failure clinics across the country are sending their patients home with connected blood pressure cuffs, bathroom scales and even handheld ECG monitors such as AliveCor. While there is some promise with these devices, there is one overarching problem that is consistent with everyone we’ve spoken with, and that’s adherence. Patients just won’t use these as often as they should. Despite having every single heart failure patient being told by their doctor to measure their body weight every day, only 14 percent do. Those numbers are low, and we seek to change that with a device that everybody uses no matter what.

DAVID: Everything we do in my lab is very applications driven, so we’re trying to solve problems.

NICHOLAS: Which is what brought me to your lab. I didn’t want to do a research project that was just on the books, that had no practical relevance, that would take five years, minimum, to be seen in a product. Although…[laughter] six years later I’m still working on it.

DAVID: So, when we have a challenge, we like to brainstorm in a really open way. We’re very comfortable together, so we’re able to brainstorm and toss out crazy ideas. Then you build on those crazy ideas. In my lab we tend to work with people across many disciplines – a lot of non-traditional collaborations. I think that helps you view things through a very different lens. I know that when I was doing the original DARPA program, I worked really closely with Kim Sherman in industrial design. It opened my eyes to what they do and how they think and how that brings a different dimension to how you tackle problems. I think that this was the same way.

NICHOLAS: And one thing: while you’re very tough on us with publications and scientific rigor, you are always open to any suggestion as far as how to solve a problem.
Nothing’s too whacky if it makes sense and we articulate it clearly. Thinking things through is important, but also thinking about where could we put in technology that no one else would think of. There’s a need there, it’s unsolved, there’s a way to do it, and we’ll just figure it out.

DAVID: And you have to take risks.

NICHOLAS: Right.

DAVID: Almost every time I start a project I don’t know that we’ll be able to do what we say we want to do. You just have some degree of confidence that you’ve got the right skill sets and you’ll find the path that gives you a workable solution.

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