



### **Eradicate hypothermia: Wearable warming revolutionising the healthcare industry**

#### **Announcer:**

This is a podcast by Lumina, the perfect space to innovate, collaborate, and grow in health, science and tech.

#### **Host - Rebecca Griffin:**

Nick Ralph, welcome to HealthTech Talks. It's a real pleasure to have you here today.

#### **Guest - Nick Ralph:**

Oh, thanks very much. Thanks for having me.

#### **Host - Rebecca Griffin:**

You're the founder and director of Thermal Armour, which is what we're going to talk about today, but you also have a clinical background and background as a researcher, and you're currently a professor in the School of Health with the University of the Sunshine Coast. Thank you so much for joining us. Can you talk us through your career and about your clinical background?

#### **Guest - Nick Ralph:**

Yeah, sure. I started my career as a nurse and then began to work a lot more closely in surgery and developed an interest into perioperative optimization. My interests were really around a frustration that I had of a lot of patients who would be booked for surgery, and you'd see them four, six weeks beforehand, and they'd turn up on the table, and in some perverse sort of way, they actually had become functionally worse. And I thought there's got to be a way of optimizing patients for surgery so that we can prepare them a little better for it and help them recover afterwards.

So a lot of my clinical roles have been around managing projects and initiatives that coalesce around that. And then subsequently moved into research, where I have focused on a little bit of educational research, but also clinical research. I see the two as joining together and complementing each other quite well.

#### **Host - Rebecca Griffin:**

And then you're the director of Thermal Armour, which is what we're talking about today. Your product aims to eradicate surgical hypothermia. What is surgical hypothermia, Nick?



### Guest - Nick Ralph:

Surgical hypothermia is just hypothermia that happens in surgery, and it's typically defined as a temperature of below 36 degrees. There is a current frustrating push in the industry to see how low we can go. We've seen a number of major clinical trials that have come out and recommended that 35.5 or even 35 is potentially safe. We've seen that in the release of the ProtecT trial last year, where they've advocated that that 35.5 was perhaps safe. But really what we know is that there's major flaws in that recent study, and what we need to see is staying as far away from the edge as possible.

Hypothermia is a really interesting measure of clinical importance because we know that it's a vital sign. And yet right up until the nineties, we had almost no research done in normothermia, which is the homeostatic state of temperature, and no research in hypo- or even hyperthermia.

I actually remember when I was training, we learnt more about very rare cases of hyperthermia, which were induced by anesthetics than we did about hypothermia. Hypothermia is actually, to my knowledge, probably the most common serious surgical adverse event in the world. And I developed my passion in it around 2014, where we kicked off some studies at St. Vincent's Health Australia. And after implementing a thermal care bundle, which looked at actively warming patients and monitoring their temperature, one of the first things we recognized was that there was no temperature monitoring devices in hospitals around surgery. We just couldn't find thermometers. So we had to go and buy a whole bunch. When we started measuring things, it was a little bit of the detection paradox in that when you start paying attention to things that you didn't realize were there, we started to observe a rate of hypothermia that was quite concerning.

So after we did everything, implemented the active warming, the risk management, parts of that bundle that were meant to actually reduce the rates of hypothermia, because it was a fairly simple before and after study, we actually saw an increase in the rate of hypothermia just by watching it more closely. So we observed 42% of patients were hypothermic in that.

And that's over 10 years ago. Unfortunately, rates are just not getting any better. And that compelled my journey towards figuring out why this was happening. A lot of my colleagues have gone towards the implementation side of things, where they've looked at implementing more guidelines, going more intensive with the current technology. I totally agree with that. I'm part of an NHMRC-funded study on that. But I think that we should also look at the technology. The technology is a little concerning in my view, and we could do more to try and offset this problem.

Just on that note, I often ask people when I lecture on it, who likes undergoing surgery? And I've undergone surgery not that long ago. I know that it's a really unpleasant experience. And for me, as somebody who finds it pretty overwhelming to go into surgery and you see lots of people with funny masks and funny clothes and funny hats on, and it's a very cold and clinical place. And oftentimes you go into surgery after what can be a life-changing diagnosis, and all of a sudden you wake up freezing cold. And I often ask people, have you ever actually experienced hypothermia? Have you felt what it's like to have a core temperature of below 36 degrees? There's a reason why we coalesce around the



temperature of 37 degrees. It's because it's a vital sign. It's fundamental for our life. It's really good for sustaining metabolic processes. To wake up post-surgery shivering, every muscle tensed in your body, is a very unpleasant experience that I can vouch for.

**Host - Rebecca Griffin:**

As can I, Nick. So how is it treated then? Is it the aluminium blankets?

**Guest - Nick Ralph:**

No, they don't work at all. Typically, there's two modalities that are used. So we use forced-air warming or we use conductive warming. There are some water-based warmers of varying efficacy, and certainly they're very seldom used. Forced-air warming is perhaps the most common therapy. There's many studies that have proven it's safe and effective, but there are also some concerns that are emerging in the industry. So we know from studies that patients lose about 140 watts of heat, and the current devices are really only getting about half that much back into the patient. So what's now happening is we're slowing down surgery because we're having to warm patients for at least 30 minutes beforehand. And what we found in a recent study that we've just done is some of those devices take up to 50 minutes to heat up. So any of the pre-warming that's happening is just not effective at all.

**Host - Rebecca Griffin:**

So Thermal Armour, how did you get the idea?

**Guest - Nick Ralph:**

I'm not a polymer scientist, but I do read an awful lot. I became frustrated after I had a procedure that I kept pretty close my chest, but I woke up hypothermic and was just wondering how on earth could this happen in my place of privilege where I was a professor, I was doing research in the hospital, and they let me get cold. And that was the last thing that I said to them before going under, "Don't let me get cold." I woke up, I had a horrific infection. I was off work for eight weeks. There's a known associate between infection and hypothermia, because our first line of defense is an immune response that's predicated on being warm. We don't have that if we're hypothermic. So it was unpleasant to say the least.

And I began to, in my convalescence, think maybe there's a better way of doing things. There are some conductive warmers on the market, but I'd looked at a particular polymer in the literature for probably the preceding five years and thought, I wonder if I can actually make this. Good old ChatGPT had just come online then, and I figured out a way to make it in the underneath of my house. I've got an old Queenslander, and I think the time came when I realized that when I shorted out the power circuit that it was time to go and consult the engineers.



The first thing that they asked me was, "What sort of engineer are you?" That compelled me to take it to a design firm, and they've now helped me formulate it into a product that we know works really well and has a beautiful, what we call heat transfer coefficient, which was really about getting the most uniform temperature onto a patient, which is actually surprisingly very difficult to do.

**Host - Rebecca Griffin:**

Can you explain the product, how it works and how it improves patient outcomes?

**Guest - Nick Ralph:**

Yeah. Basically we have a conductive heat layer, which is based off a polymer. That polymer, through our patented design processes, which I can't talk about too much, heats up to a very, very rapid level. So we've got the fastest heating product on the market. It heats up in under two minutes. We can actually get it to heat up in about 30 seconds, but it's a compromise between battery life and whether you're on wall power or not. What we did notice was that when we were working on this polymer and heating it up, that it was very uniform, very fast to heat, and very well insulated. So my view was if we use some fairly revolutionary approaches to not only conveying a very uniform, drug-like precision dosing of heat onto a patient, but also via a device that was well insulated, that we could really get the temperature up to the level that we wanted quickly and then keep it there with not too much power. And that actually sparked interest from external sources that we never thought, like the military. So it was quite exciting.

**Host - Rebecca Griffin:**

Is it like a blanket that you put on the patient or something you put under the patient?

**Guest - Nick Ralph:**

Yeah, look, a couple of my mates actually have a bit of a joke and say, "Nick and his blankets." Some of it are blankets, some of them are wearable suits. We've had some trialing of the wearable suits in the military because there's military applications to warming patients, or warming soldiers rather, in very adverse conditions. So we actually went overseas and did some military trials in Scandinavia in the snow and nearly froze to death because they were wearing Thermal Armour and I wasn't.

**Host - Rebecca Griffin:**

You were not. So then tell me, the combat solution is an Australian-first innovation. Can you talk us through the design process and how you went into R&D?

**Guest - Nick Ralph:**

The combat solution was a very, shall I say, surprising turn of events. I won't mention him by name, but I had a wonderful gentleman who I've got so much time for that works in the Australian military, and he's



actually a specialist emergency physician. And I got a phone call late one afternoon, I believe it was on a weekend, and it was about six o'clock. Without giving too much away, he has an accent. So I made a very foolish assumption that he might not be Australian military, he might not be who he was saying he is. So I think I actually hung up the phone on him because I thought it was a joke, but that was a bit fuzzy. But basically they were looking for a combat solution, and there's no battery powered warmers that exist on the market to actually deal with combat-based injuries.

Let's say something traumatic happens to a soldier in field and there's an associated blood loss. What happens with blood loss is that you begin to get quite cold. And our ability to clot rests on whether we're at a normal temperature or not. And you may have heard of what's known as the golden hour. So how survivable an injury is within that golden hour to try and get a patient to hospital. As I understand it, the changing nature of battle is such that air evacuations are no longer possible. We've seen all the horrible footage from Ukraine and so on.

What happens now is that, as I understand it, they're trying to look as irrelevant as possible in the battle space. And so that means that they don't want generator-powered solutions. I've been told that if you jump out of a Bushmaster, even if you've got a big red cross on it, then you could potentially, if you set up a generator, look like a command post, because command posts usually have generators and so on. But you're actually a fighting force, or a medical force rather, of medics and you're just trying to save a life. Unfortunately, what you look like on reconnaissance of drones and so on, you look relevant. You look like you're about to make a decision that could mean you fire back.

And so the concern being, and there's been a paper that's been released in the last couple of years that talks about lessons from Ukraine, the concern being is that if you've got a generator, you light up like a Christmas tree on the battlefield. And we know that the current solutions for warming consume a huge amount of power and are just not feasible to be delivered by anything other than a generator.

That's where our tech came in. And so we use a very small battery that's about the size of your fist that can heat up an entire body. And that's where the genius of the engineers that work with me and some of the crazy ideas that I've had have sort of created a little bit of alchemy and delivered this solution that's currently been successfully trialed in Scandinavia and is about to be trialed in the dead of winter in Norway and by US special forces in January. So I'm going over there and hoping that I don't have to jump out of any planes again.

### **Host - Rebecca Griffin:**

For our listeners who are in product development phase, can you share any key learnings from your experience designing the combat solution?

### **Guest - Nick Ralph:**

It's not so much just the combat solution. We've got a platform that effectively lends itself to both surgery and the combat solution. When I say combat solution, we should be clear that this device that





we've invented, it doesn't just apply itself to surgery, but it also works well in any first response situation, including military. So we envisage one of these units being in the back of every ambulance or fire brigade in the world, potentially police as well. Once someone's injured, it's really important to whip out something that can keep them warm. And those aluminium blankets, they're nice and cheap, but they just don't work at all.

**Host - Rebecca Griffin:**

And is that what's being used now?

**Guest - Nick Ralph:**

Currently, yeah. They don't work. All they do is insulate the cold that's already there. So if a patient is hypothermic, they have absolutely no active warming properties whatsoever. They don't warm anybody up, they just keep you at the temperature you're at.

**Host - Rebecca Griffin:**

So basically it's up to your body to then self...

**Guest - Nick Ralph:**

Exactly, which is if-

**Host - Rebecca Griffin:**

Do its normal processes.

**Guest - Nick Ralph:**

If you're critically injured or if you're in surgery, then your body doesn't have the capacity to warm itself because your metabolic rate has been greatly reduced to compensate for the variety of influences that are happening there. So back to your question around product development, I can only share from my experience. I was at a crossroads in a lot of ways in life, I guess, and was having to think about whether I take a big deep breath and click the pay button on the bank to really kick off this first tranche of product development. Obviously, it had a very crude prototype that I'd worked on. Nearly electrocuted myself developing that. There was a time where I realized that this was something I was going to take forward, that I needed to take a big deep breath and put my money where my mouth is. To that extent, I've spent a lot of money on developing this product and I've been incredibly lucky to find excellent people to help me throughout.

For instance, very first engineering firm I spoke to after talking to a couple of engineers before that, had a chat with an engineering firm, Boost Design from Sydney, and I toddled off early in the new year of

## HealthTech Talks Podcast Series



2023, I think it was, and took my polymer and my very terrible drawings and had a head full of hubris and excitement around, "Hey, I'm going to develop this device and it's going to cost maybe fifty or a hundred thousand dollars." We're about a million dollars into that spend now. But they have been unbelievably helpful and just the most excellent project managers.

And a lot of the short circuit is product development. You've got to know your stuff. There's a reason why we haven't spent 3 million, and that's because I'm very fortunate to have had that experience as a clinical researcher working in hypothermia where I've seen a lot of the problem, but I've just never seen the solution. And it wasn't until in my spare time I had this thought, let's just provide the solution. Let's figure out if I can do this. And to be really passionate around my own topic too was a key learning. Hypothermia is not just a business for me, it's a hobby. I find it fascinating. If that makes me a nerd, so be it. It's good to do what you love.

### **Announcer:**

You are listening to HealthTech Talks, a podcast series delivered by Lumina. To find out more about Lumina, visit the website, [luminagoldcoast.com.au](http://luminagoldcoast.com.au), and sign up today to receive your Lumina Opportunities Pack.

So, your product is able to reduce the incidence of hypothermia. Could this mean shorter hospital stays for patients? And then this would ultimately mean less cost for the health system. Can you talk us through that?

### **Guest - Nick Ralph:**

Back in 2020, I actually led one of the two economics papers on hypothermia. What we found was that hypothermia was coming at a cost of \$1.2 billion a year to the Australian economy, and that was largely off the back of the complications that we know are associated with it, such as infection, bleeding, and cardiac events. It's probably time to revisit those economics. But we also found that in a separate paper as your general sort of St. Everywhere's general hospital, 10,000 surgical patients a year, 500 beds, et cetera, that it was costing them around 700,000 a year, which I think probably in today's inflationary terms is about 10 times the figure. That's an inflation joke. But also looking at around \$8,000 a patient.

And people sort of, when we presented those results at conferences, they said, "Oh, really? \$8,000 a patient?"

I said, "Well, you think about it. If somebody has hypothermia and then they have a sternal chest infection that needs to be kept open. So you've got an open chest in ICU, you dress it for months on end until it heals up. Someone's not healing very well. Those wounds cost millions of dollars to care for. And you can't send someone home with an open chest, believe it or not."

Hypothermia can actually, by its avoidance, save an awful lot of money, and that's where we say think about spending a penny to save a pound. People might wince at the cost of hypothermia prevention



products, but as we've seen in recent clinical validation of our own product, there's some products out there that are just, they're actively... I would say cautiously, this is probably a crude way of saying it, but actively cooling a patient. And what I mean by that is they're not actually reaching a temperature above 37 degrees. And people think that just because you go and spend anywhere from 8 to \$25,000 on some of these devices per unit that they're going to get something that works. And what we see in the global standards, so IEC 606001, that you only have to hit a maximum, it doesn't actually mean that you have to hit a minimum. So you could actually invent a device that hit 30 degrees and it would actually be compliant.

So we see the standards themselves are actually allowing poor competitors onto the market, and so we're going to work in that space to try and tighten up things and perhaps even shrink the market to the few good ones left.

**Host - Rebecca Griffin:**

Nick, Thermal Armour has also broken into the European market with a major distribution deal. How has the product been received in the international space?

**Guest - Nick Ralph:**

Yeah, look, we were really pleased to sign that deal. Without mentioning any names because there are a few legal things that I can't mention, they're a massive firm or they're backed by a massive firm that does over 2 billion in sales a year in Europe. So in a very short space of time, we're hoping to be across 14 European countries. And that's come off the back of a really positive military and surgical test in Scandinavia earlier this year. So I was actually diagnosed with Ross River fever earlier this year and decided two months post-diagnosis and only just being able to walk again with all the joint pain, I decided to load myself up to the eyeballs with anti-inflammatories and whatnot and jump on a-

**Host - Rebecca Griffin:**

Head to Europe.

**Guest - Nick Ralph:**

Jump on an Emirates flight and head over to Europe. It was a bit crazy in hindsight. It was so much fun to actually see this in field and working. We've just had so much interest from various militaries. It's kind of unprecedented. And there's something quite heartwarming, no pun intended, around the prospect of actually saving troops' lives or even being used in humanitarian crises. That's the other thing that we see as a big potential market that when bushfires, floods, earthquakes, et cetera happen, you need a stockpile of Thermal Armour sitting there ready to go. And ours has a long shelf life. It's batteries. It's unlike anything else on the market.





One of the things that people don't know is that the earthquakes in Turkey that happened in the last couple of years, many of the people that died, I think there was around 200 people died, many of those died actually froze to death because, they were trapped in buildings at sub-zero temperatures and people couldn't get them. So what we're thinking is that potentially you could keep our device because it's very small, you could attach it to a robot or something like that and try and reach people where humans can't and keep them alive, keep them warm under those pretty awful circumstances. So yeah, humanitarian crises is a big opportunity.

But look, the European market's really interesting. Our goal has always been to get to North America first and get FDA approval, but we're working furiously on getting what's known as CE marking, which is European regulatory approval for our devices. Some of the military stuff, there's military exemptions in place just because what they're asking for, "Can we jump out of the back of a plane and do a HAHO?" Which is what I now know is a high altitude, high open. And so they're floating on a parachute for hours on end until they land somewhere and presumably do some stealthy stuff and then know hightail it out of there. And obviously floating around at 40,000 feet for a fairly decent length of time means that you're going to get very cold because your temperatures are up to minus 70 degrees. So you need something lightweight to keep you warm during that space. So who would've thought that a humble little blanket would open up all these different opportunities?

But to answer your question, how has it been received? Really positive feedback. And we've got pages and pages of end user feedback from both the Australian military and European militaries and various hospitals as well, just saying, "Look, this is the solution that we need. This has been a really good product for us."

And one of the things that I just love doing is going off to conferences and you'll demo the product. And in particular for a lot of the special forces guys, they're pretty blunt. They'll come up and they'll touch the product and they'll go, "Oh, this actually works." There's a great commercial opportunity, but really to me it's the clinical opportunity that's more exciting because we can actually do some good in the world.

### **Host - Rebecca Griffin:**

So, you received Ignite Ideas funding by Advance Queensland. How did that funding propel your product?

### **Guest - Nick Ralph:**

Oh, look, they've been fantastic. What we've been able to achieve is predominantly at 10 conferences get our face in front of some key decision makers, largely in that first response military market. We've also been able to work on some pitch decks. I find pitching hypothermia, people go, "Well, there's plenty of products on the market." And people really struggle with that concept that there are devices on the market that are just not up to scratch. So we've been able to really focus on pitch decks. We're actually



at a point where we're starting to look at a subsequent raise so that we can go global and really expand into North America.

**Host - Rebecca Griffin:**

If there's people listening and they're also looking for grants, what advice would you have for them?

**Guest - Nick Ralph:**

Look, there's a lot of people I've found that will tell you that they can write your grant or so on, but really it's up to you to really put in the work, really write the grant. And think about the old problem statement, what your solution looks like and how you're going to make money from it. I kind of keep a fairly simplistic view on most of the government grants. That's the old political slogan, jobs and growth. And so really you want to show that your business can employ people and will grow.

**Host - Rebecca Griffin:**

You were a participant in the LuminaX HealthTech Accelerator Program here at the Gold Coast Health and Knowledge Precinct. How did the program help you?

**Guest - Nick Ralph:**

Oh, good grief. I love those guys. Dren, Janine, Ben, Ariana, a shout-out to all of them. They have developed something that is absolutely world-class. People think I'm just being nice. I mean, I am but it's the truth. It's the best HealthTech accelerator in the country. I've been in a couple of others. They are so passionate, they're so supportive. I actually learned stuff. And I met some people that I've become friends with. I've met business contacts that weren't looking just to try and take a clip, they were really looking to try and help elevate my business.

And the way that the curriculum, for want of a better term, of the accelerator is structured is that week upon week, you just felt as though you were spiraling upwards towards having a real business. And I find startup is a bit of a dirty word in the sense of you should be a startup for the shortest possible time, and then you got to be a business. But those guys have absolutely delivered. It's a world-class product.

**Host - Rebecca Griffin:**

Along with that, you had an office in Cohort Innovation Space here at Lumina, but you will be opening very soon at Northshore Brisbane, which is another project by Economic Development Queensland, the master developer of both Lumina and Northshore. Can you tell us about your move and what is it about Economic Development Queensland that has made you stay within their development precincts?



### **Guest - Nick Ralph:**

Yeah, so we'll be moving into our own little factory in Hamilton fairly shortly, which is about 220 square meters. So we'll really start pumping product out from that fairly shortly. To move into Hamilton Northshore is just fantastic because there's some world-class businesses that are just across the road, for instance Vaxxas. There's a lot of potentials that we could have to collaborate and learn from each other.

But there's probably a bigger part of me that feels as though Hamilton Northshore is a natural home for the business. I'm very much a believer in... I love going to cafes on the weekend and having a nice little breakfast, and sometimes they will have a farm-to-plate brand pitch. And I've often thought, wouldn't it be nice to have the farm-to-plate equivalent of manufacturing, advanced manufacturing in Queensland? And so this thing was invented a kilometer down the road underneath the house in Hamilton. A lot of the people that I've come into contact with that have helped in engineering and marketing and business and fundraising, my accountants, are all within a five kilometer radius. And so we've been able to prove that we can develop a world-class product in a very small footprint and show that it can be done.

### **Host - Rebecca Griffin:**

And last month you won the Gold Prize at the 2024 Good Design Australia Awards for product design, which is amazing. And this is a big deal because the awards are recognized by the World Design Organization as Australia's peak design promotion organization. So what does this mean for your product?

### **Guest - Nick Ralph:**

What it's done is opened doors. So for instance, we've been able to go and have a chat to various movers and shakers politically, I guess, to say, "Look, we've won the gold prize. This is an Aussie designed product. We're trying to take this to the world. We need some help to get it there." So we've seen some really courteous and enthusiastic responses from politicians, from design firms, from people who are just willing to help and be part of the ride without trying to get their clip. So that's been really important.

I think the other thing too is that good design, when you look at the fact that it is recognized by World Design Organization criteria, people begin to sit up and take notice, I think, in that this is a product that's actually had some thought put into it. We've really designed it to provide a comprehensive response to this very big problem of hypothermia. And that shows that platform that we're building out -- a platform for surgery, for first response, military, humanitarian crises, et cetera, we're looking at temperature monitoring, we look at AI-based monitoring in operating theaters and so on -- this whole system that we're developing is backed by people who know what they're doing. And so, I think it's probably elevated us to a level of conversation where people are really starting to take us seriously now. I think they already were because of some of the military feedback, but I think just getting that recognition has been really crucial.



**Host - Rebecca Griffin:**

What's next for Thermal Armour? Are we likely to be wearing your product during our next surgical procedure here on the Gold Coast?

**Guest - Nick Ralph:**

Absolutely. That's a key goal. We want to try and take a significant share of the Australian market, both in surgery and first response. Very clearly our strategy for the next little while is to obtain CE marking. We're just being overwhelmed with interest at the moment in regards to sampling, trials, products from Europe in particular. North America, we're just about to appoint a major position there. Somebody that comes to us with decades of experience at the very top of multi-billion dollar surgical organizations who wants to be part of our organization. We're really flattered. And has a tremendous background as a surgeon. We're going to go with FDA and TGA approval fairly shortly, so that should be on track next year as well.

And really what we're looking to do is raise, which is a lot smaller than people might think, it's only a couple of million, just to really scale our product. Because what we've done is the work in design for manufacturing to make sure that our product is made very simply but to a very high standard. And so, initially we'll have a phase one where we outsource a lot of componentry to Australian firms, and we'll gradually start to bring them in house as we get more comfortable with dealing with the hundreds and hundreds of pages to track and make sure that what we're doing is world-class and according to standard. Really excited to see what the next couple of years brings.

**Host - Rebecca Griffin:**

Yeah, so am I. And congratulations on what you've achieved so far. It's really phenomenal.

**Guest - Nick Ralph:**

Thank you.

**Host - Rebecca Griffin:**

Thanks for talking with us.

**Guest - Nick Ralph:**

Very welcome.

**Host - Rebecca Griffin:**

## HealthTech Talks Podcast Series



Thank you for listening. If you've liked this episode and other episodes of HealthTech Talks, we'd love it if you could write a review or give us a five-star rating so that others can find our podcast.