



Cylite

EMBARKS ON CRUCIAL SCALE-UP

Cylite HP-OCT base units prior to the assembly stage.

The transition into production and sales is proving a pivotal moment for Australian OCT manufacturer Cylite, as the company outgrows its start-up status to bring its technology to the world.

Melbourne medical device company Cylite is at an important juncture, according to newly appointed CEO Ms Kylee Hall, transforming from an R&D-heavy business into a firm focused on how it will locally produce and deliver its unique Hyperparallel (HP-OCT) system for real world clinical use.

Hall's promotion from vice-president of sales and marketing to CEO in April is perhaps indicative of the current stage in Cylite's evolution, which began in 2013 followed by many years fine-tuning the hardware, micro-optics and software that make it unique.

"There is a heavy focus now on how we scale our business from production to sales, to support this pivotal point," Hall says, noting that former CEO and founder Dr Steve Frisken will remain involved with the engineering and optics team daily while also maintaining Cylite Board director duties.

"My main priority as CEO in the next 12 months is managing the change as we scale up our business to meet the planned demand. It is a transition time from designing a novel piece of technology to turning it

into a highly scalable product." Taking Cylite from start-up to a fully-fledged company is a monumental task on numerous fronts.

For example, the company's production capacity is set to triple at a new facility in Melbourne. There, it will need to transport and up-scale its rigorous production process and then obtain all new accreditation under standard ISO:13485, demonstrating it can consistently produce the incredibly complex HP-OCT as designed.

Next there's recruitment to consider. Because this is precision engineering, Cylite requires additional high-powered candidates for technician roles, often with PhDs and Masters qualifications in their respective fields. And then there's software development and the need for a salesforce to get the device into clinics to begin generating revenue.

While Cylite can control much of this, it's also at the mercy of a lagging international supply chain. Managing this is a full-time job for many staff.

Hall believes her experience will put the company in good stead during this transformational period. A combination of her prior roles at Zeiss and Device Technologies exposed her to skills that will be essential to successfully launch the HP-OCT locally and globally shortly after.

"I've built and managed sales teams and launched many products over my time in the optometry, ophthalmology, and wider medical space," she says.

"Years of first-hand experience from the distributor side of the business model has taught me what is needed from a manufacturer if your product is to be successful within a distributor's portfolio. I also gained intense education during my Global EMBA on all aspects of start-ups. My study notes from this post-grad study have been accessed regularly over these past two-plus years."

Few would probably realise that Cylite's headquarters are based in a nondescript building, tucked away in the back corner of a business park in Notting Hill, suburban Melbourne.

The company outgrew this site a while ago but still runs the bulk of its business from there. However, it has taken possession of another building around the corner, still within the Monash Technology precinct. It plans

to move all operations to the new site once the refurb is complete. An important part of this will be the clean room that will more than triple its production capability. This is where Cylite assembles the OCT and performs the crucial optical alignment process

"We have already moved some of our engineering team over to the new site, whilst downstairs is currently undergoing the fit-out of the new production facility with the aim for ISO:13485 accreditation before the end of this year," Hall says.

"Each area of the business is growing, most notably would be our production and engineering team – we have more than 70 full time staff. We have also expanded our clinical and customer facing team as we start more large clinical trials and look to build a local sales force later this year. We will also look to replace the leadership role I transitioned from in the next few months."

NEXT-GEN TECH 'THE INDUSTRY HAS BEEN LOOKING FOR'

While it's unusual for an Australian firm to design and develop an OCT in this country, what truly makes Cylite unique is its ability to obtain true volumetric, or 3D, images of anterior segment structures in a series of snapshot captures.

Users can then take a B-scan slice of the eye in any direction, X, Y or Z (enface) axis while obtaining precise measurements of the various ocular surfaces. Industry-leading rates of more than 300,000 A-scans per second allow it to capture a full biometry scan in seconds for motion artefact-free scans.

Hall says many eyecare professionals immediately assume the HP-OCT is another retinal OCT coming to market.

"It is actually quite the opposite; we are an anterior OCT that can measure axial length and also image the retina," she explains.

"The idea for this technology was borne out of the problem: 'Why when OCT technology is micron level accurate, is no one using this technology for critical measurements at the front of the eye? Why is technology that is greatly impacted by tear film still the standard of care when measuring the eye for custom contact lenses, or assessing the eye prior to cataract or refractive surgery?'"

Locally, Hall says Cylite has a great following among practitioners, many wanting to support an Australian-made product.

"Eyecare professionals working in the myopia management space and those who are fitting scleral lenses are areas where we feel the HP-OCT will make a positive impact to their daily workflow," she says.

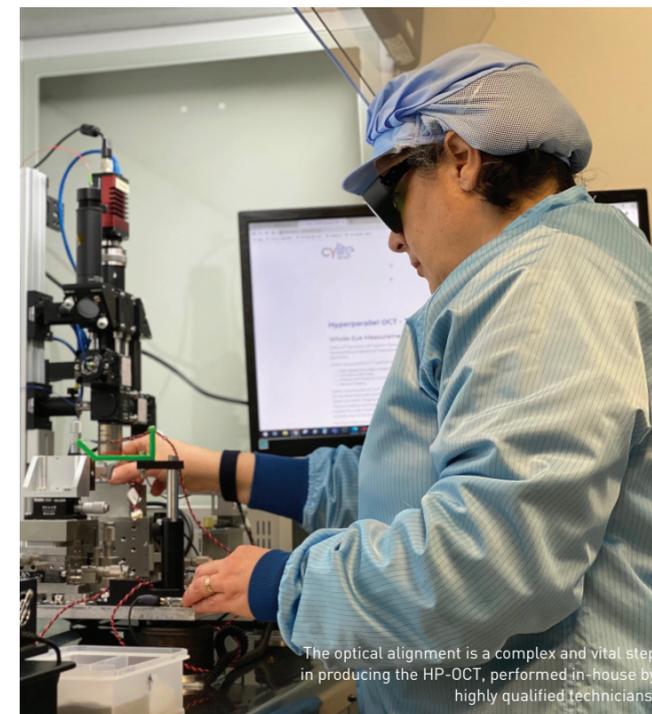
"We have many devices already in use at some impressive global research institutions. The feedback these sites are sharing, now they are back from COVID lockdowns, is inspirational. In the next one to two years, we will start to see some fundamental research be published on what Hyperparallel technology is now enabling. I believe this technology really is that next generation OCT imaging the industry has been looking for."

In terms of other areas where Cylite may further develop the HP-OCT, Hall adds: "You'll need to watch this space, we have some very exciting developments from our R&D team that will continue to improve the functionality of Focus, our user interface software. The team are also working on some next level hardware that I can't say too much about right now."

'THIS IS GROUND-UP DEVELOPMENT'

When visiting Cylite's current headquarters in Melbourne, it's phenomenal to see what's required to produce the HP-OCT from scratch. And the fact this occurs in a modest, two storey tilt slab building makes it even more remarkable.

The person overseeing activities in this building is Mr Simon Davis, appointed vice-president of operations in November 2020. Between 2012-2019 he worked with Cylite directors Dr Steven Frisken and Dr Simon Poole at Finisar manufacturing opto-mechanical fibre optic switches, and



The optical alignment is a complex and vital step in producing the HP-OCT, performed in-house by highly qualified technicians.

previously set up two manufacturing sites in China for a company he founded.

As Cylite matured, requiring more emphasis on manufacturing, he was appointed to build more operational rigor, creating water-tight production processes, better stock and inventory control and hiring of operations staff (25 of those since February 2021).

"What's so unique about the founders is that they have incredible theoretical knowledge that underpins the HP-OCT, but can then translate that into practical application, which they've accumulated from previous businesses," Davis explains.

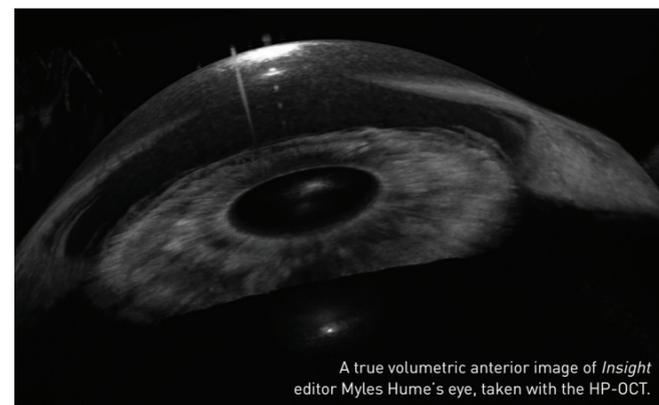
Davis is keen to stress everything about Cylite is from the ground up – and the significance of that. People often only consider the end product, but the company has devised its own equipment to manufacture the HP-OCT. All parts and components that go into the system are designed and assembled in-house. The company has also formulated its own intricate production processes, systems and manuals; it can't simply source critical processes like the optical alignment.

Cylite sources its components from suppliers in Australia and abroad, which often requires working with selected factories due to the bespoke nature of many parts.

The HP-OCT contains more than 500 unique part numbers, and over 1,300 components. When each part arrives at the factory, quality control inspectors check them against the purchase order before they are measured and tested against the original mechanical, electrical and optical drawings.

Approved parts are then grouped together in kits to be sub-assembled, removing the need for people to seek parts in a store-room, while ensuring traceability.

"Hundreds of components need to go together in a certain series of events and we need to ensure we maintain quality and traceability. There are serial numbers and every part that goes into the final device can be traced all the way back through to the purchase order and the supplier who provided it," Davis says.



A true volumetric anterior image of *Insight* editor Myles Hume's eye, taken with the HP-OCT.

The HP-OCT's design means it must be assembled in a clean room. That means every component goes through an intense cleaning process, including ultrasonic cleaning for some parts, to remove potential contamination or oils. Surface treatment and curing processes are also performed, before the sub assembled parts enter the clean room.

"While many industries work at the millimetre level, we are working at the micron level. A piece of paper is 100 microns, or 0.1mm, so we are going down to a magnitude thinner than a piece of paper," Davis explains. "Contamination for us is a spot of dust in the path of the optics, it is not like some people might think."

The clean room performs the most important function in the production process. To enter the room, one must wear shoe covers, a hair net, gown and protective glasses. The room's sophisticated ventilation system circulates the air 24 times an hour, and each of the workstations have laminar flow hoods to ensure no dust settles.

Why this is so important relates to the HP-OCT's free space optical system, comprising a complex network of lenses, mirrors and other micro optics that precisely manipulate light in various ways. While other OCTs use a fibre optic system, Cylite's free space optics design allows it to project a grid of 1,008 beamlets on the eye for its simultaneous A-scans to be captured within one millisecond per frame.

To achieve all of this, engineers need to perform the optical alignment process that involves high precision manufacturing processes and validation. Once complete, calibration is performed assessing various targets, and installing the fixation (crosshairs) target the patient looks at.

"We have numerous main optics stations in this clean room and there are a couple of extra calibration stations – and then we have several sub assembly feeders. This is what we refer to as one production line, but in

the new building the immediate capacity will be tripled, with more room for expansion in the next phase," Davis explains.

"The process of scaling up our production is both in additional equipment and operators, but also through machine learning and automation of processes that shortens the alignment time. These combined will allow us to meet our delivery target.

"The term 'continuous improvement' is very important in a manufacturing team and it's something we talk about regularly. It's cross functional in that you have core engineering designers working with process owners, technicians and automation staff working to identify opportunities, then people who can validate whether it is going to yield the benefit and enable us to grow." ■



The clean room at Cylite's new, under-construction facility in Melbourne will allow it to more than triple its current production capacity.