

# ANNUAL REPORT

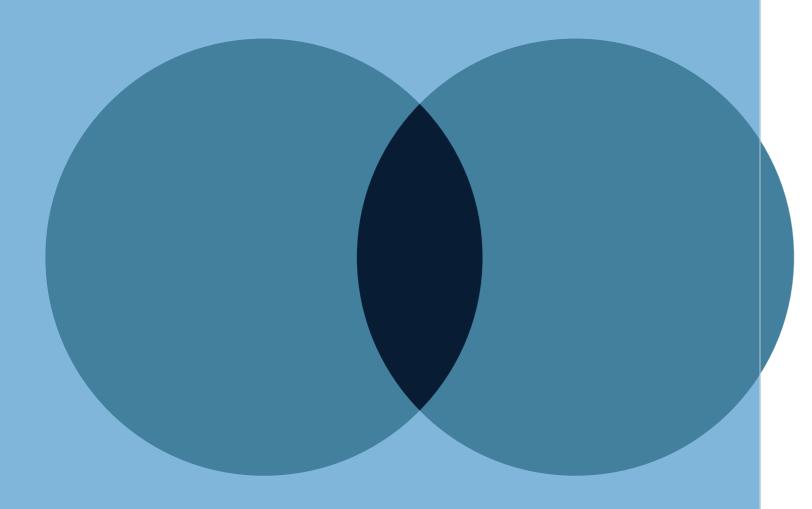
January - December 2023

Annual Report Paxman AB (publ)

Jan - Dec 2023

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Our past year

Summary of the Year

# SUMMARY OF THE YEAR

Paxman has another record year achieving a growth of 44% on its prior record year! Key investments are now providing a strong return.

All figures in parentheses in the following refer to figures for 2022

In 2023, Paxman set out a clear goal at the beginning of the year, a company that would deliver sustainable revenue growth, a positive and consistent EBITDA quarter on quarter, and most importantly a drive towards cash flow positivity by the end of 2023. The company has clearly delivered its vision with strong momentum for 2024.

Paxman achieved the company's strongest sales to date setting new records in terms of revenues and profits. Net revenues of 210 MSEK were achieved for the year, compared to 146 MSEK in 2022, a 44% growth. An EBITDA of 31 MSEK for the year was achieved compared to 16 MSEK in 2022. The company sold and installed 601 (528) systems globally.

The USA continued to be Paxman's major growth market with 126 (170) systems installed, with utilisation and average daily treatment revenue (ADTR) being a key growth driver over systems installed. ADTR reached its highest to date in Q3 2023 being 467 TSEK. The implementation of the company's insurance-based billing model gathered momentum and accounted for around 25% of the US income in the last two quarters, although lower than originally anticipated. Coverage data collected by the company is showing an estimated 80% of patients scalp cooling through the new reimbursement model are having positive

coverage determinations. The patients with no coverage or poor coverage are being supported by Paxman's Patient Assistance Program (PAP), ensuring greater access for all patients delivering the company's mission to ensure all patients have the opportunity to scalp cool, no matter their income. This model is a key driver for the growth in 2023 and will continue to provide greater impact through 2024.

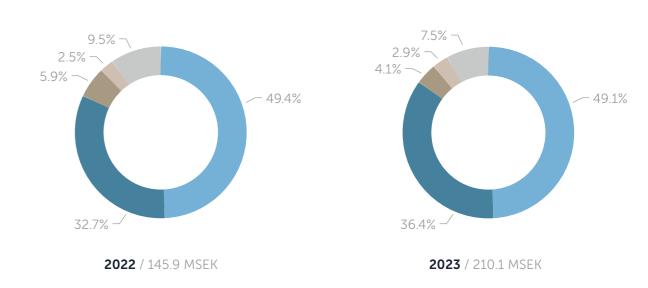
The UK and overseas markets delivered strong growth throughout 2023 with direct markets being a key focus for 2024, including Germany, where the Paxman Group has increased its investment from 20% to 49% in Paxman GmbH.

The development of the Paxman Limb Cryocompression System (PLCS) to prevent chemotherapy-induced peripheral neuropathy (CIPN) achieved continued progress in 2023 with clinical trials in Singapore continuing. In addition, a large, randomised phase 3 trial in the USA with the SWOG Cancer Research Network has recruited 120 patients from the intended cohort of 777 with over 22 locations opened. This has been a significant investment over the last 12 months.

"Paxman has clearly delivered its goal with strong momentum for 2024."

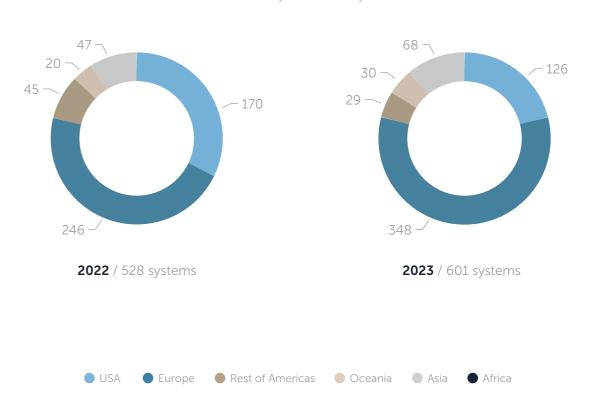
# Global Sales

MSEK



# Sold and Installed Systems

Number of systems for each year



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# Selected events in 2023

In January the company announced that it received EU Medical Device Regulation (MDR) certification from its Notified Body, the British Standards Institution (BSI).

Paxman is among the latest companies to achieve MDR approval, reaffirming its commitment to the market, its customers and, most importantly, the patients who will continue to benefit from the use of the Paxman Scalp Cooling System.

In January, the company incorporated Paxman Canada Inc., as a corporation in the province of Ontario. Following a successful pilot of the business through 2021 and 2022 the decision was taken to fully launch the company and incorporate. The company shall operate a hybrid business model offering pay for use services through Paxman personnel in large academic and high-volume cancer centres and the sale of capital equipment to smaller regional cancer centres.

Paxman have shipped its first clinical trial Paxman Limb Crycocompression Systems (PLCS) to the USA in the months of April and May for the initiation of the ICE COMPRESS: Randomized Trial of Limb Cryocompression versus Continuous Compression versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy. Sites among the first to participate include Columbia University Medical Center, University of Washington Medical Center and Caromont Regional Medical Center.

In August Paxman signed a further agreement with Concord Medical, China. Both parties have decided to cooperate in introducing the scalp cooling system before it officially obtains the medical device registration license issued by National Medical Products Association (NMPA), in order to facilitate market research, customer interest data collection, and product promotion in the early stages - a further step in developing the company's profile in Asia.

Also, in August Paxman signed an agreement with TACRO in China. TACRO provides medical device manufacturing companies with NMPA registration services and is headquartered in Wuhan,

with branches in Beijing, Suzhou, Shenzhen, and Shanghai. Now, the total employee number is 170+. They have more than 30 regulatory consultants assisting companies to access China's fast-growing market.

Later in August, Paxman signed its first insuranced-based billing agreement in the state of New York, which adds a further 12 locations to its newest business model. A large initial order for cooling caps was received equating to over 2.5 MSEK.

At the beginning of October Paxman announced that the Palmetto GBA Medicare Administrative Contractor (MAC) has issued a Local Coverage Determination (LCD) to provide coverage guidance for Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia. According to the final LCD guidance from Palmetto GBA, "the use of a scalp hypothermia device that has been approved by the United States (U.S.) Food and Drug Administration (FDA) for the prevention of chemotherapy-induced alopecia (CIA) shall be considered reasonable and necessary for patients with solid tumors." In addition, there were no changes between the Proposed LCD and the Final LCD. This is the first LCD that has been approved for scalp cooling and is a result of a request made to Palmetto GBA in February 2023 by Paxman. This important Palmetto LCD provides a pathway for reimbursement of Medicare scalp cooling claims for patients in the seven-state service area, effective November 12, 2023. Paxman currently serves 55 locations within the Palmetto GBA jurisdiction.

Paxman conducted its annual employee engagement survey in November 2023 with a 95% completion rate, making it one of the most engaged employers on the survey platform. Survey results were highly positive, with 98% of respondents proud to work for Paxman and 97% would recommend Paxman as a great place to work. The employee engagement survey helps Paxman to gauge the internal success of its company initiatives and culture overall.

126
Installed systems in the USA

601
Installed systems globally

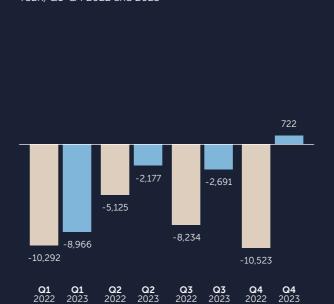
# Recurring Revenue

MSEK, Q1-Q4 2022 and 2023

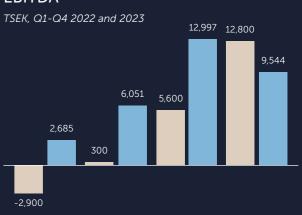


# Cash Flow

TSEK. Q1-Q4 2022 and 2023



# **EBITDA**





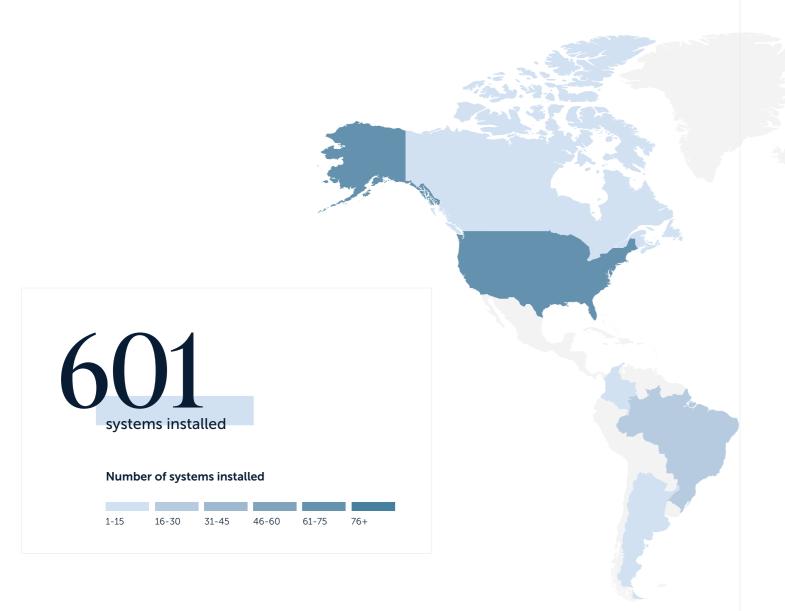
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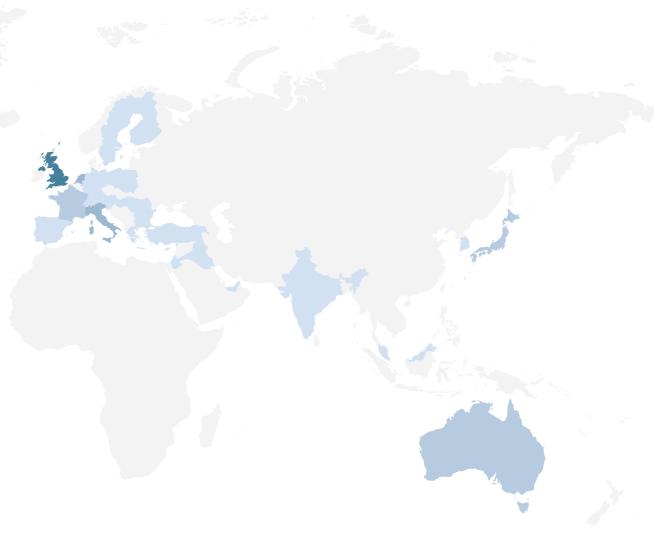
Our past year

Summary of the year



# Installed systems Jan - Dec 2023

The systems are installed on-site following a signed delivery and rental agreement (in the USA, Canada and Mexico) or after being sold to the customer (rest of the world).



	2022	2023		2022	2023
Argentina	3	2	Hong Kong	1	1
Armenia	1	1	Hungary	2	2
Australia	20	30	India	16	10
Austria	1	4	Iraq	-	2
Brazil	28	18	Ireland	2	6
Bulgaria	-	1	Israel	-	10
Canada	12	5	Italy	25	40
Colombia	-	1	Japan	15	25
Cyprus	-	1	Jordan	-	1
Finland	-	1	Malaysia	-	1
France	17	29	Netherlands	38	42
Germany	5	3	Poland	7	5
Greece	2	2	Portugal	-	2

Romania	1	3
Singapore	4	4
Slovenia	1	1
South Korea	-	5
Spain	-	5
Sweden	-	3
Switzerland	11	9
Turkey	2	2
UAE	1	7
United Kingdom	124	188
Uruguay	2	3
USA	170	126

2022 2023

Total systems installed: 601 (528)



# **Our Vision**

Paxman has made scalp cooling available to hundreds of thousands of cancer patients in many parts of the world. However, the company has a much more ambitious long-term goal, both when it comes to global outreach and the effect of scalp cooling.

Paxman's long-term vision is to ensure that any eligible cancer patient has access to scalp cooling no matter their geographical location, ethnicity, financial situation, gender, or treatment regimen. The condensed slogan "Changing the Face of Cancer" encapsulates our determination that chemotherapy-induced hair loss does not have to be inevitable, with Paxman's System as the natural scalp cooling treatment choice.

The practical application of this aim divides into several clear areas of action within the business.

At the regulatory level, Paxman's determined work in recent years has contributed to gradually improved opportunities to realise this long-term vision. In 2019, scalp cooling was included as a recommendation for the prevention of chemotherapy-induced hair loss in breast cancer patients in the leading clinical guidelines published by the National Comprehensive Cancer Network® (NCCN®), and inclusions for additional cancer types were added in 2020. Similar inclusions to a varying extent were made in guidelines published by European Society for Medical Oncology (ESMO) in Europe as well as Cancer Australia and Association Francophone Des Soins Oncologiques De Support (AFSOS) in France, Germany and Japan.

In 2021, the American Medical Association (AMA) in the USA issued two CPT codes for scalp cooling, making billing for scalp cooling a possibility. In 2022, customers in the USA started to implement Paxman's insurance-based billing model that facilitates reimbursement using these CPT codes. 2023 saw further adoption of this model with 35% of all sites transitioning by the end of 2023. Read more on reimbursement in the USA on pages

Geographically, Paxman extended its outreach in 2019 by establishing the company in Japan, the world's second largest market for cancer

care with over 1 million new cancer cases per year. In 2020 the company established itself in South Korea, with the initiation of a large clinical study in Q4 2020, and market clearance granted in November 2022. The study in South Korea will support the company's continued expansion in Asia, including a greater presence in India and a future expected establishment in China where a letter of intent was signed with a Chinese marketing and distribution partner in April, 2022 followed by finalisation of a distribution agreement in 2024.

2023 has seen the expansion of Paxman's direct markets with Canada incorporating, the launch of Spain as a direct market and we saw the best sales to date within the UK, our most established market. During 2023 the company worked with Paxman GmbH to finalise an agreement further invest with a view to expand the market in 2024. Read more on Paxman's internal markets on pages 36.

Patients remain Paxman's priority, as we continuously work to improve the efficacy of scalp cooling. The company founded the Paxman Research & Innovation Centre, the world's first scalp cooling-focused research and development centre, together with the University of Huddersfield in 2019, and the first-of-its-kind global Scalp Cooling Summit was held in May 2022 with almost 50 leading researchers and clinicians and over 1,400 participants. More information on Paxman's R&D efforts, which also includes the development of a product to prevent chemotherapy-induced peripheral neuropathy (CIPN), can be found on pages 30-42. Paxman have also redeveloped with patient facing resources including a new iteration of coldcap. com, a patient facing website, and a suite of patient education literature, more information can be found on pages 57.

We're moving excitedly through 2024 with the Paxman vision firmly in focus.



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Our past year

Comments from our CEC



# A COMMENT FROM OUR CEO

66

The people in our organisation make Paxman what it is today, driving growth and activity whilst offering the best patient care.

Dear Shareholders, this time last year we were celebrating our best year to date. However, there was growing pressure due to the macroenvironment to shift our focus to delivering a strong return on prior year investments following the directed issues, to deliver a positive EBITDA and a drive towards cash flow positivity.

This was to be no small feat; to stabilise costs and reduce spending in areas, limit capital investment, and drive growth at the same time. I am delighted to report the Paxman team did it. We have had another record year. We delivered a 44% net revenue growth, an EBITDA of 14.2% and delivered a cash flow positive quarter by the end of the year, even with strong capital investments into the USA and R & D. Operating cash inflows were strong. This sets us up for an exciting year ahead with momentum already being seen in Q1 2024.

Throughout 2023, we have had to contend with multiple macroeconomic pressures including global political instability, continued supply chain issues, high and lingering levels of inflation, increased interest rates and general economic uncertainly and slowdown. Paxman have continued to perform despite this which puts us in a good position as we see a return to at least some certainty. We continue to hold in our thoughts those affected by the difficulties we are seeing globally.

As we move into 2024, our focus continues to be delivering strong sustainable growth, improved consistent EBITDA margins and cash flow positivity throughout the year, building on our reserves whilst still investing in both the USA, China and direct markets.

Reflecting on our achievements, primarily our sales growth, I am proud of our successes in the USA, which continues to be our core focus. As I have previously mentioned, the pace of transition to our new model may not be where I want it. albeit momentum is growing and results are promising with regards to coverage and payment, key indicators of success of the transition for our US customers, ultimately driving utilisation and patient access. At the end of 2023, direct provider income generated from the new model accounted for approximately 25% of our income. Early in 2024, we have seen an increase to 40%, only a slight delay in my hopes. An example of the success of this model is our key customer in the state of New York. Since transitioning, they have seen an notable increase in patients accessing scalp cooling. It is important to note this customer was already enrolling our largest volume of patients in the USA.

The announcement that the Palmetto **GBA Medicare Administrative** Contractor (MAC) issued a Local Coverage Determination (LCD) in the year to provide coverage guidance for Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia was an impressive achievement. According to the final LCD guidance from Palmetto GBA, "the use of a scalp hypothermia device that has been approved by the United States (U.S.) Food and Drug Administration (FDA) for the prevention of chemotherapy-induced alopecia (CIA) shall be considered reasonable and necessary for patients with solid tumors." This important Palmetto LCD provides a pathway for reimbursement of Medicare scalp cooling claims in this region 2024 will see a drive for Paxman to work with more MACs across the USA. Increased attention during 2024 will also include the American Medical Association reviewing the current CPT III coding with a drive to move towards a CPT I code.

Our UK business continues to provide strong revenues streams, where the NHS and private sector are now actively replacing older equipment to offer the latest in scalp cooling. Paxman can now be found in nearly 100% of the UK market, a clear signal of what can be done

elsewhere in the world. Our international department continue to perform showing further growth in many markets around the world, with key regions including The Netherlands, Japan, Italy, France, Australia and Brazil. Notwithstanding a delayed start to entering China. significant headway was made with our partner Concord Medical and 2024 will see the development of this relationship and progress with our NMPA registration for access to the mainland China market and beyond - an exciting opportunity. Further focus will be given to our direct markets through 2024 including Canada, France, Spain, Scandinavia, India and Germany, where we have recently taken over a greater share in the business. The company continues to build on its global brand being present at key international oncology conferences, strengthening its relationships with the world's best key opinion leaders. I am proud of the relationships we have developed globally with some of the biggest names and thought leaders in oncology and healthcare.

The company still made strong investments in CIPN in 2023 (13.4 MSEK) as well as US capital installations (8.7 MSEK) which have equated to over 22 MSEK through 2023. US capital will still be deployed, however, there will be significant reductions in spend on capital for the CIPN clinical trials resulting in stronger cash inflows for the business throughout the year.

Clinical trials looking at chemotherapy induced peripheral neuropathy in the USA and Singapore continue to progress well. We continue to be excited about the opportunity to support this clinically unmet need. With regards to our multicentre phase I clinical study, currently expanded to phase II in Singapore, to evaluate the safety and efficacy of the Paxman Limb Cryocompression System (PLCS) device in preventing CIPN in 80 patients receiving any taxane-based chemotherapy, we plan to have an early analysis of 50 patients which is hoped to be published at the Multinational Association of Supportive Care in Cancer (MASCC) conference in June 2024. Our large, three-armed, phase III randomized efficacy study supported by the National Cancer Institute in USA, which plans to recruit 777 cancer patients across a minimum of 25 sites, is now gathering some pace. The study aims to compare the proportion of participants who develop clinically meaningful CIPN at 12 weeks, in participants treated with Taxane-based chemotherapy randomized to cryocompression therapy, versus continuous compression therapy versus low cyclic compression therapy administered via the PLCS devices. The PLCS devices have been deployed in 22 clinical study sites and the study has currently accrued 120 patients randomized into the three study arms. Read more on the trials on page 42.

The people in our organisation make Paxman what it is today driving growth and activity whilst offering the best patient care. Therefore, it is critical we continue to put a strong focus on ensuring Paxman is a great place to work and we shall continue to make this a priority. In 2023 Paxman joined the West Yorkshire Combined Authority Fair Work Charter. It is designed to promote and recognise the positive impact of fair work on businesses and their people. Another step towards fostering a vibrant, positive company culture.

I would like to take this opportunity to thank all our stakeholders, our patients, their families, our people and the incredible work they all do to make Paxman a success, and of course our shareholders for their continued support and belief in what we do. 2024 is set to be another record year!

Huddersfield, April 2024, **Richard Paxman OBE, CEO** 

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About us

About the Compan

# ABOUT THE COMPANY

Paxman AB (publ): an international group with its parent company in Sweden

Founded in the UK in 1996, Paxman is the global market leader in scalp cooling to prevent chemotherapy-induced hair loss with nearly 6,000 systems installed globally. The company has a strong connection to Sweden as the CIMON group, an investment company with approx. 200 MSEK in annual turnover, became a large shareholder in 1999.

Paxman is investing substantially in research and development and a target-focused global expansion. The company has conducted multiple successful clinical studies with leading clinics and cancer centres all over the world, including the world's first randomised multicentre study with a scalp cooling system in the US in 2017 (read the study <a href="https://example.com/here">here</a> the basis of market approvals in Europe, the United States, Japan and Australia as well as additional markets in South America and Asia.

Paxman was listed on Nasdaq First North Growth Market in 2017.

Market leading and personal scalp cooling

Paxman develops and offers the Paxman Scalp Cooling System, a market-leading mechanised form of scalp cooling used to minimise hair loss in connection with chemotherapy treatment.

Today, the system is used at a large number of cancer centres and hospitals in Europe, North-, Central- and South America, Asia and Oceania, and more installs are added continuously. The company is also developing and trialling a medical cryocompression device to prevent chemotherapy-induced peripheral neuropathy (CIPN) which causes permanent nerve damage in hands and feet, with initiated clinical studies in Singapore in 2021 and a large clinical study in the USA, initiated in 2023.

The company was founded as a family business by Glenn Paxman following his wife Sue Paxman's hair loss in connection with chemotherapy treatment. Seeing the trauma that Sue experienced as a result of her hair loss, Glenn realised that there were shortcomings in the existing methods for scalp cooling that needed to be improved, so he developed a liquid-based cooling system with the support of his brother.

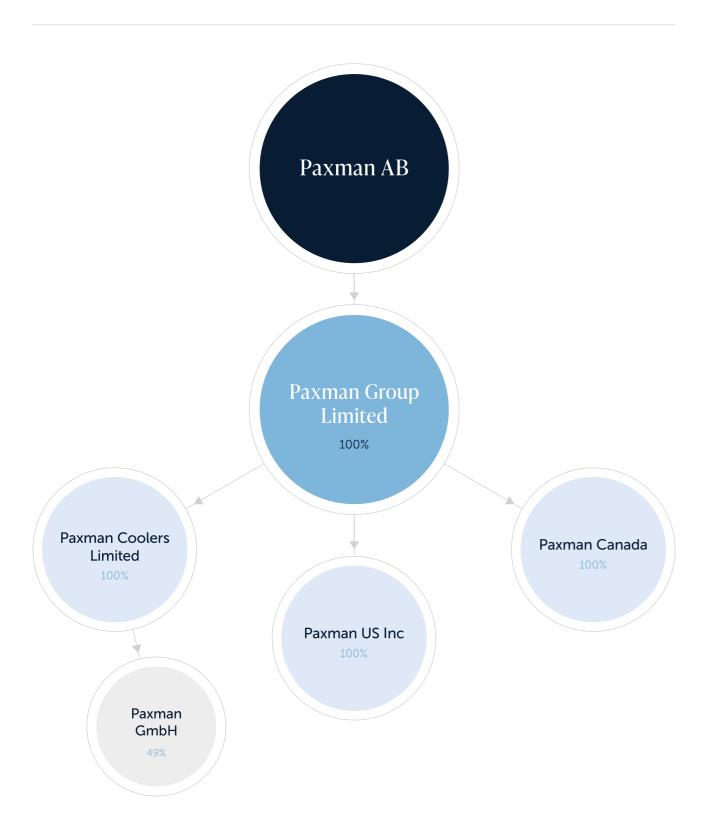
Today, Glenn and Sue's son Richard Paxman is the CEO of Paxman, and their daughter Claire Paxman holds the position Brand Ambassador & Director of Global Training. Their personal understanding of how important it is for cancer patients to keep their hair, and thereby a degree of control over their daily lives, is reflected in all of Paxman's business operations. The company's vision is to make the technology available for all cancer patients worldwide who would like to use it.

Paxman has a close collaboration with HairToStay, a US organisation that contributes financially to patients who cannot afford to pay for scalp cooling themselves. In honour of Sue Paxman, the parties have started a separate fund in her name specifically aimed at mothers with very low income.

The company's vision is to make scalp cooling technology available to all eligible cancer patients worldwide.

About us About the company

# Group Structure 2024



# Senior Leadership



Richard Paxman



Claire Paxman Brand Ambassador & Director of Global Training



Emma Thornhill Finance Director



Karin Buck VP of US Operations



Patrick Burke Head of Research & Development



Alexandra Sheldrake Susy Brown Head of Quality & Operations Head of Brand & Marketing





Stuart Rowling Head of UK Sales & Training



Anna Parker Head of International Sales



Liza Hirst EA to CEO / Head of HR

# **Paxman History**

(1996 - 2023)

# O 1999

Systems are installed in Norway as the first country outside of Great Britain

CIMON Venture Trust AB based in Karlshamn Sweden, invests in Paxman

O 2003

The first clinical study Paxman's system

**Q** 2014

O 2012 Paxman reaches 1,000 installed systems

Paxman initiates the world's first randomized multicentre study in the USA

**Q** 2016

Paxman's randomised multicentre study in the shows good results

O 2020

Patent applications submitted for Paxman's CIPN product in development.

The American Medical Association (AMA) decides to create CPT codes for mechanical scalp cooling.

European Society for Medical Oncology (ESMO) in Europe includes scalp cooling as a category IIB recommendation to prevent chemotherapy-induced alopecia in its clinical practical guidelines.

O 2022

First customers start to use the new insurancebased business model in the USA

Paxman's hosts the global Scalp Cooling Summit conference

Letter of interest signed with potential distributor in China Market clearance granted in South Korea

# 1996

Paxman is founded, the first scalp cooling system is launched after many years of research and development

The company's first system is installed at Huddersfield Royal **O** Infirmary

# 2000

The company meets the regulatory guidelines in Great Britain in compliance with ISO 9001:2008

International launch with installations in Ireland, Netherlands, Australia, Sweden, Switzerland and Egypt

Paxman reaches 500 installed systems

2006

# 2013

Q

Richard Paxman is appointed as Paxman's

# 2015

The company initiates clinical studies with five leading cancer centres in Japan

Paxman reaches 2,000 installed systems

# 2017

The company obtains Food and Drug Administration (FDA) clearance in the USA Paxman AB (publ) is listed at Nasdaq First

O 2018

License agreement for

Mexico is signed with

global pharmaceutical

installed systems in the

12 months of receiving

company Teva

Pharmaceutical

Milestone of 250

FDA clearance

extended FDA

Paxman receives

clearance in the USA

covering solid tumours.

A large number of systems are installed in the USA, including prominent cancer centres such as Texas Oncology and Memorial Sloan

Paxman obtains market approval in Taiwan and Argentina.

# 2019

Development of a cooling and compression system to prevent chemotherapy-induced peripheral neuropathy (CIPN) is initiated with the National University Hospital in Singapore

Paxman Scalp Cooling Research Centre is founded in collaboration with the University of Huddersfield

National Comprehensive Cancer Network® (NCCN®) in the USA includes scalp cooling as a recommended treatment to prevent hair loss in its guidelines for breast cancer patients

Paxman obtains market approval for its scalp cooling system in

Milestone of 500 installed systems in the O USA achieved

# 2021

The AMA in the USA issues CPT codes for mechanical scalp cooling.

The CMS in the USA decides that Medicare claims for scalp cooling reimbursement shall be subject to a National Average Payment of 1,850.50 USD, effective January 1, 2022.

Clinical studies with Paxman Crycompression System are initiated.

### 2023

Paxman achieves record sales, its best year to date.

Paxman receives EU MDR approval

Paxman Canada Inc. is incorporated in the province of Ontario

Paxman signs further agreements with Concord Medical and TACRO in China

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Scalp cooling and the system

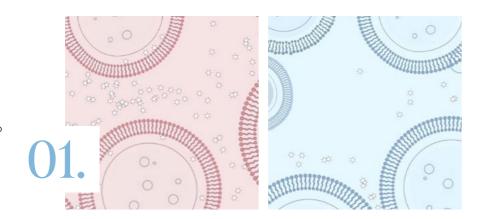
# How scalp cooling prevents hair loss

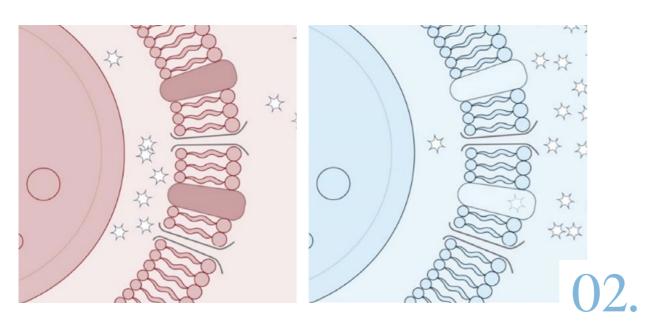
# Vasoconstriction

Cooling induces vasoconstriction.

Reduces cutaneous drug perfusion to 20-40%.

Therefore, less drug enters into the hair follicle cells.





# Reducing chemotherapy transport into hair follicle cell

Reduces active transport/diffusion of drug into cells.

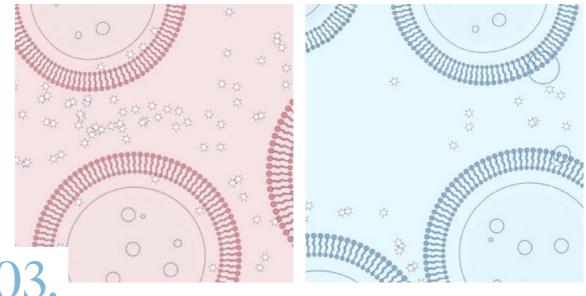
Lowers hair follicle cellular activity.

Reduces kinetic energy  $\vartheta$  membrane fluidity.

# A fundamentally simple, yet still very efficient method

Scalp cooling is a simple, yet highly effective method to prevent hair loss in connection with chemotherapy treatment of solid tumours. Globally, the number of potential users amounts to at least 4 million annually.

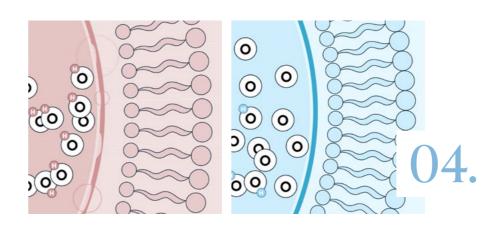
Scalp cooling in connection with chemotherapy works as follows:



# Reducing rate of hair follicle cell division

Cell division is an energy dependent process.

A slower rate of division makes cells less susceptible.



# Reduced metabolic activity

Thereby reducing chemotherapy cytotoxicity in hair follicle cells, as range of processes decelerate.

I could be as normal as possible. I didn't have to explain myself to anyone, and that meant I had control of the cancer. Which was powerful for me and meant I could be positive.

# The Paxman Scalp Cooling System

Paxman's scalp cooling system (PSCS) and the technology behind the product have been developed over decades. This allows PSCS, the latest version of the system, to deliver strong clinical results for different types of chemotherapy treatments and patient groups. At the same time, the system is easy to use for medical staff and offers an unmatched user experience for patients.

PSCS is available in versions for one or two simultaneous users. The version for two users provides the opportunity to treat up to twice as many patients per day without taking up too much additional valuable space.

To ensure optimal results as well as excellent comfort and hygiene, PSCS has the option to be used with single patient use cooling caps available in different sizes and versions. This opportunity is offered in several markets, and it is especially utilised in the United States and Japan. The single patient use cooling caps allow each patient to find a size with an optimal fit and prepare for the treatment in advance. Additionally, Paxman is able to continuously refine its range of cooling caps to fit different head shapes, and the company launched cooling caps produced specifically for the company's Asian markets in 2019. Paxman is also developing a new version of the cooling

cap, striving for an improved fit, lower cost and increased sustainability, as well as one or several products with antioxidants to be topically applied to the scalp with the aim of increasing the scalp cooling effciency. More information on the company's R&D projects can be found on pages

In addition to offering Paxman's most efficient scalp cooling to date, PSCS has both single patient use and reusable options for its vast global customer base, offering flexibility for commercialisation. This flexibility allows the company to customise its business model to establish its offering in many different markets with varying healthcare and cost reimbursement systems, and thus to reach out to an increasing number of patients.



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Articles

Spotlight on the quality team



→ Ensuring safety, efficacy and compliance

# Spotlight on the Quality Team

The Quality Team play a pivotal role at Paxman, ensuring the safety, efficacy, and compliance of the Paxman Scalp Cooling System (PSCS). Through their meticulous oversight and commitment to excellence, they have upheld our reputation as a trusted provider in the medical device sector and leader in the scalp cooling industry.

# Alexandra Sheldrake

### Head of Quality & Operations

Alexandra oversees both Quality and Operations at Paxman and has been an integral part of the company for over 15 years. In this time, she has worked within the Quality, Regulatory and Technical fields gathering experience and exceptional knowledge of the medical device sector.

As Head of Operations, Alexandra develops strategy aligning with long and short-term business goals ensuring accurate and informative communication between teams, the wider business and the CEO. Alexandra also crucially ensures production capacity is optimised, supporting and facilitating Paxman's growth.

In her capacity as Head of Quality, Alexandra is the Management Representative and is responsible for regulatory compliance, ensuring all products manufactured by Paxman are safe, effective, and compliant. During her time at Paxman, Alexandra has been instrumental in securing global regulatory approvals including, the FDA in the USA, PMDA in Japan, MDR in Europe, the harmonised standard MDSAP, amongst others including Malaysia, Mexico, Singapore and Taiwan.

# Dr Simon Taylor

### Technical Manager

Simon is responsible for the technical files for all Paxman Products and ensuring all products are compliant to local/international legislation and standards. Amongst these key responsibilities, he manages the Quality Control team to maintain the highest product quality in addition to the Paxman risk management system. Simon was pivotal in the recent MDR transition, ensuring Paxman regulatory files remain state of the art.

Simon Taylor holds a 1st class Master's degree in Medical Engineering from the University of Leeds, followed by a PhD in Medical Devices. He brings extensive experience in product development, compliance, quality, and risk management within the medical device industry to the company.

Beyond medical devices, Simon has worked in a diverse range of engineering fields such as HVAC, Automotive, Robotics, and Oil and Gas. As a Chartered Engineer, Simon brings a wealth of experience in the regulatory session and technical expertise as a Technical Manager.

# **David Roberts**

### Senior Technical Improvement Engineer

David's journey with Paxman began in 2017 as a Quality Engineer where he gained a thorough understanding of medical device standards like ISO13485, IEC60601, and IEC62304, and was involved in ensuring the PSCS system passed all medical device safety testing for worldwide release in 2018. After promotion to Technical Manager, he was heavily involved in gaining MDR certification together with the rest of the Quality team. The change of job role to Senior Technical Improvement Engineer gives him the opportunity to focus on what he enjoys the most which is technical problem solving, where David contributes to enhancing released devices, providing electrical expertise, and ensuring Health and Safety compliance for Paxman's manufacturing site.

His achievements include replacing key components within the Paxman Scalp cooler to improve reliability and ensuring continued production due to parts obsolescence, and ensuring Paxman's medical device software is bug free and compliant with IEC62304.

With over 30 years of experience in quality engineering, David honed his skills across various domains. His journey began with 18 years at a Japanese company, where he focused on inspecting and testing consumer products—from R&D development to mass production. He subsequently delved into supplier quality while working with a manufacturer of laser scanners.

# Dr. Aishwarya Bandla

### Clinical Innovation Manager

Dr. Aishwarya Bandla has led the development of a wearable limb cryocompression devices to prevent chemotherapy-induced peripheral neuropathy. She holds a Ph.D. in Biomedical Engineering from the N.1 Institute for Health, National University of Singapore (NUS), specialising in wearable technology for cancer care.

Dr. Bandla is an Insitute of Electrical and Electronics Engineers (IEEE) senior member, serving as Chairperson of the IEEE Engineering in Medicine and Biology Singapore chapter. She is also an Adjunct Senior Research Fellow and Head of Translational Core at NUS. A recipient of multiple awards, including Outstanding Mentor by the Singapore Medical Association Charity Fund, Dr. Bandla was named among Singapore's 100 Women in Tech in 2020 for her influential contributions to the tech industry.

# Francesca Slater

# **Quality Manager**

Francesca has been a member of the Quality department for 4 years and has been involved in Quality, Technical and Regulatory projects throughout her time in the team. She has a 1st class master's degree in chemistry from the University of Huddersfield and has spent her full career in the medical device and IVD sector.

Francesca initially joined the team to assist with non-conforming product fallout from production which developed into being a key member of the team that implemented the EU MDR at Paxman including significant contributions to the Technical Documentation.

From there, Francesca has taken over management of the global complaints process, presenting vigilance data and post market surveillance reports to aid continuous improvement, leading the Paxman Internal Auditing Program, implementing the company's quality

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Spotlight on the quality team

standards and education on the importance of quality throughout the business. In addition to the Quality Management responsibilities, Francesca provides regulatory support for distributor renewals and new product registrations.

# Jordan Bamforth

### **Quality and Complaints Coordinator**

After having first started as a Production Operative, Jordan's current role is to ensure accurate and compliant records of all complaints received from the Paxman global network are continually maintained. Jordan ensures correct procedures are followed and where necessary provides colleagues with analysis for vigilance data and trends new and current issues.

Jordan has a diverse experience within the manufacturing sector, having previously been a Carding Machine Setter, Quality Controller, and a Maintenance Team leader in the textile industry. Jordan also holds a wide and versatile range of academic experience, having studied Business with Financial Services at the University of Huddersfield, as well as more practical skills acquired from motor vehicle mechanics studies, building, landscaping, and quarry work.

# Louis Registe

# **Junior Quality Engineer**

Louis Registe is the Junior Quality Engineer in Paxman's Technical team, investigating component faults and deviations in manufacturing. Analysing faults before they reach the customer maintains the quality of Paxman products and highlights opportunities for improvement which lead to updated design specifications, new work instructions and preventive measures with suppliers.

Louis brings to the team an MEng in Biomechanics, training through the British Standards Institution (BSI) and four years of medical industry experience. Combining roles in software management, product testing, regulatory documentation and graphic design, Louis has fostered a strong appreciation

for healthcare compliance and usability. Louis has designed, processed and produced specifications and procedures, in addition to developing new ways of working for cross-functional, international teams. Louis is consistently dedicated to viable solutions for excellent product, service, and process.

# Nick Doherty

# Lead Quality Controller

Nick has had a commendable journey at Paxman, showcasing a strong work ethic and a dedication to quality. His progression from a warehouse operative to a Lead Quality Controller is a testament to his commitment to learning and continuous improvement. His role in ensuring products meet global safety standards is crucial. Before Paxman, his experience in an engineering firm provided him with a solid foundation in shot blasting and warehouse operations, which contribute to his skill set in his current position.

# Kyle Matthews

# **Quality Controller**

Kyle's trajectory within Paxman has been swift and impressive, moving from a Production Operative to a Quality Controller in just over a year. His previous experience in retail, where he honed his customer service skills, has played a role in his positive and proactive approach to quality control. Kyle's enthusiasm and forward-looking attitude is a valuable asset to the Quality Control team as he continues to pursue his passion for quality assurance and control.

# Maria Escreet

### **Project Support Officer**

Maria joined Paxman in 2006 as Operations Co-ordinator. As the company started to flourish, Maria became Key Account Manager, working on tenders, contracts and with NHS sites throughout the UK to secure funding with the charity Walk the Walk to acquire Paxman systems. With her knowledge of a second language, German, Maria

became more involved in international growth and moved from Operations to Marketing. As the Events and Marketing Manager, she organised attendance at events worldwide for the International and UK enabling the development of networks with health care professionals and groups.

Gaining a diverse knowledge of different areas at Paxman, Maria now works as Project Support, primarily within the Quality and Operations Department, but also assists with occasional projects for the International Team.

With personal experience of family and friends using the scalp cooling system during cancer treatment, Maria is committed to raising awareness of the importance of side effect management and ensuring that patients have access to this vital therapy.

"Effective compliance with regulation within a medical device setting requires hard work and diligence, which is only possible thanks to the impressive team we have at Paxman"

























# Reimbursement in the US

Though demand for scalp cooling in the US continues to grow, Paxman are deeply aware of the current disparity in access to such a vitally important treatment. With self-pay being the only option until relatively recently, many patients have been unable to take on the additional financial burden. Things are changing - reimbursement for scalp cooling is now a reality.

Expansion within the US market has been the main focus for Paxman since achieving Food and Drug Administration (FDA) clearance for the Paxman Scalp Cooling System in 2017. While the last 5 years have seen significant growth, with Paxman scalp cooling offered at 9 out of the 10 top cancer centres in the US, the lack of insurance coverage for the treatment has limited equitable access to a vital side effect management treatment. Even as a self-pay treatment, scalp cooling had become a signifier of high-quality cancer care. However, the financial barrier that a lack of insurance reimbursement has created means that scalp cooling is not a realistic option for many patients, who struggle with the substantial financial burden that goes handin-hand with a cancer diagnosis. As a result, Paxman have only been able to scratch the surface of market expansion in the US and ensuring that scalp cooling is an option for any eligible cancer patient, no matter their geography, ethnicity, financial situation, gender, or

Paxman's years of hard work actively exploring and expanding several approaches to ensure that insurance reimbursement for scalp cooling becomes a reality are coming to fruition. As 2023 concluded, many tangible successes were achieved, not only from a coding and coverage perspective but with the insurance-based billing model that is allowing cancer centres to bill patient insurers directly.

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# The reimbursement landscape timeline

The journey towards reimbursement is a long and complex one that has taken many years of work to travel. There are a number of hurdles that stand in the way of insurers taking a treatment seriously, ranging from established utilisation to recognition by notable organisations.

The first milestone along the way was the Paxman Scalp Cooling System achieving FDA clearance for breast cancer in 2017, with an expansion of this clearance to all solid tumour cancers in 2019. Food and Drug Adminstration (FDA) clearance opened the doors to trade in the US and established the Paxman System, alongside its international reputation, as a trustworthy and high-quality choice within the scalp cooling field.

In 2019, another significant hurdle was overcome when the National Comprehensive Cancer Network® (NCCN®) updated their Clinical Practice Guidelines to include scalp cooling as a category 2A recommended treatment to reduce or prevent chemotherapyinduced alopecia for invasive breast cancer patients. The Guidelines are a highly respected benchmark within the oncology sector and marked scalp cooling as an important and necessary form of side effect management. NCCN® further updated their Clinical Practice Guidelines in 2020 to recommend scalp cooling for those with ovarian cancer. The support of such an esteemed organisation for scalp cooling helped to further emphasise the importance of the treatment and align it with the highest quality cancer care. Along with growing patient demand, scalp cooling was being adopted with increasing frequency across the United States.

2021 was a busy year, with notable achievements falling into place over the year. In July 2021, the American Medical Association (AMA) issued two CPTIII codes to be used for scalp cooling treatment. 0662T was issued for the initial measurement and calibration of the cap, to be charged once, and 0663T, to be used for each scalp cooling treatment.

The assignment of these codes was a fundamental step in ensuring cancer centres were able to bill insurers for scalp cooling treatment on behalf of their patients.

"Establishing the new model requires a multidisciplinary approach with input from clinical staff, prescribers and administrators"

While the codes are temporary, they stay in place for a number of years to establish whether a permanent code is justified. There is an annual review of the code and associated payment rates, which could result in payment rates going up or down.

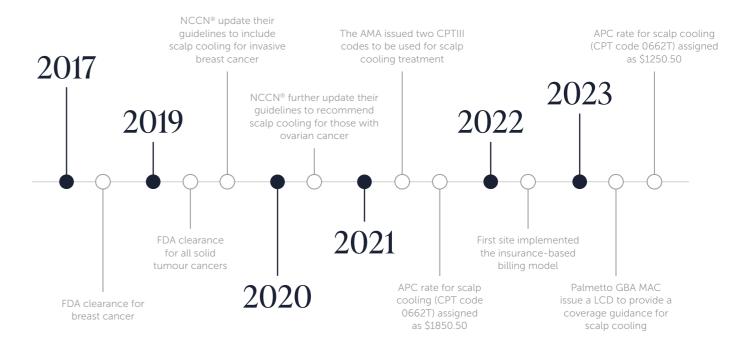
Under Medicare, hospitals are paid based on the assignment of CPT billing codes to Ambulatory Payment Classifications (APCs). Medicare sets the payment rates for each of these APCs. In July 2021, CMS made the initial proposal to assign CPT code 0662T to APC 5732 (Level 2 Minor Procedures) with a proposed national payment rate of just \$33.84, and for 2022 the proposed payment rate was just \$34.72. Paxman and others commented for physicians and health systems to implement scalp cooling. Based on comments to the proposed ruling and information presented at a panel meeting in August 2021, Centers for Medicare & Medicaid Services (CMS) reassigned CPT Code 0662T to New Technology APC 1520 in a new Hospital Outpatient Prospective Payment System (HOPPS) ruling. This APC had a much higher proposed payment rate of \$1,850.50, taking into account the substantial hospital resource costs associated with the calibration and fitting of the scalp cooling cap. While the payment rate does not impact commercial plans, they often look to Medicare and CMS's actions as informative or guiding in their own

payment policies and determinations. This achievement set the scene for insurance reimbursement to become a reality, with the codes announced in November of 2021, coming into effect in January 2022.

2022 saw the real work of crafting the Paxman Insurance-based billing model and beginning the work of rolling this out to existing self-pay model sites across the US. While the adoption was not as swift as initially hoped for, this slower pace allowed for Paxman to iron out any potential issues with the process, ensuring successful, if demanding transition, for the sites that engaged with the new model. Establishing the new model requires a multidiscipline approach with input from clinical staff, prescribers. and administrators to ensure a deeply embedded and structured approach, factoring in the billing requirements; a more complex process than previously seen with self-pay which could be adopted with buy-in from clinical teams

for each of these APCs. In July 2021, CMS made the initial proposal to assign CPT code 0662T to APC 5732 (Level 2 Minor Procedures) with a proposed national payment rate of just \$33.84, and for 2022 the proposed payment rate was just \$34.72. Paxman and others commented on this proposed rate as it was insufficient for physicians and health systems to implement scalp cooling. Based on comments to the proposed ruling and continuing.

February 2023 saw Palmetto GBA Medicare Administrative Contractor (MAC) issue a Local Coverage Determination (LCD) to provide coverage guidance for scalp cooling - the first of its kind. The final LCD guidance from Palmetto GBA stated "the use of a scalp hypothermia device that has been approved by the United States (U.S.) Food and Drug Administration (FDA) for the prevention of chemotherapy-induced alopecia (CIA) shall be considered reasonable and necessary for patients with solid tumors."



This important determination created a pathway for reimbursement of Medicare scalp cooling claims for patients in the seven-state service area, coming in to effect in November of the same year. Paxman Scalp Cooling Systems are available in 55 locations within the Palmetto GBA jurisdiction.

A MAC is a private healthcare insurer that has been awarded a geographic jurisdiction to process claims for Medicare beneficiaries. The Palmetto GBA services two jurisdictions in the US Medicare system covering seven states in the southern US: Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia.

CMS assigns MACs the task of developing LCDs to describe reasonable and necessary services within the Medicare program. CMS also assigns MACs the task of developing coverage articles that give direction on how to bill or code for a service or to provide education on a specific topic. In the Billing and Coding Guide: Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia, Palmetto GBA reaffirms guidance from CMS, "CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 2, 110.6 Scalp Hypothermia During Chemotherapy to Prevent Hair Loss is

not a barrier to coverage or to pricing/ payment of the Category III Temporary CPT® codes for professional/facility services related to scalp cooling (CPT® Codes 0662T and 0663T)."

This achievement helped to solidify localised coverage taking a further large step towards reimbursement, as well as creating a strategy to be utilised with other MACS around the US.

In November 2023, CMS announced that the HOPPS Final Rule for 2024 was decreasing the APC rate assigned to scalp cooling (CPT Code 0662T) from \$1,850.50 (APC 1520 – Temporary New Technology Code) to \$1,250.50 (APC 1514 – New Technology-Level 14). This decision was made on data available for 2022, before the CPT code for scalp cooling became effective, equating to 11 paid claims for 0662T. As this is below the threshold of 100 claims for a service within a year, CMS designated the code as a low volume service assigning the lower rate.

The reassignment only impacts hospital outpatient payment for services under Medicare - not Medicaid or physician payment. At a local level, MACs can set their own rate based on a calculation for pricing, likely at a higher rate, which will take precedence. The reassignment

also has no impact on commercial plans although they may look to Medicare and CMS's actions as informative or guiding in their payment policies and determinations, but to date, Paxman have seen no negative impact, with commercial insurers reimbursing scalp cooling at a significantly higher rate.

As we look to the future, with more sites adopting to the insurance-based billing model, there will be increasing quantities of data that will reflect positively on scalp cooling claims and Paxman anticipate this will push up the average claim amount. We believe it is likely CPT Code 0662T will be assigned a higher APC rate.

The goal set for 2023 was to transition 40% of existing sites offering scalp cooling as a self-pay treatment to the insurance-based billing model. As we move towards 2024, over 30 unique sites or healthcare systems (many with multiple locations) have adopted the model representing around 35% of the total US sites offering Paxman scalp cooling. The sites represent a mixture of both academic and community institutions, with some of sites acknowledged to be among the best cancer treatment facilities in the world. The projections for 2024 look even more promisina.

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# The Paxman insurance-based billing model

The Paxman insurance-based billing model allows the cancer centre to bill the patient's insurer, via CPT codes. While it is relatively simple, the multidisciplinary team needed to execute successful implementation of the model which requires time and fully engaged stakeholders from clinical staff (RNs and MDs), administration, compliance, regulatory affairs, billing, patient financial services, supply chain director, and legal.

Workflows are simplified for patients and clinicians with Cap Kits purchased by sites and given to patients at their appointment, rather than being managed and distributed by McKesson as is done in the self-pay model. Patients receive their Cap Kit as soon as they decide on scalp cooling, allowing more time to prepare for treatment, which is fundamental to success and a positive patient experience.

Sites that have been offering scalp cooling as a self-pay treatment require around 6 to 9 months to transition to the new model, reflecting the complexities that often occur when deploying projects involving so many stakeholders.

### The model process is as follows -

- Providers and health systems contract with Paxman to install systems for its facilities (if not already installed)
- Paxman sells Cap Kits in all sizes through McKesson Plasma Biologics, McKesson Specialty Distribution or OnMark/Unity, McKesson's Group Purchasing Organization.
- McKesson sells the cooling Cap Kits to providers and health systems, who maintain an inventory of each size of the Kits
- McKesson distributes orders to providers and health systems. When a provider prescribes the Cap to the patient, the patient is enrolled in the Paxman Hub Scalp Cooling Program
- Either the Paxman Hub or the provider will carry out a benefits investigation to determine if the patient's insurance will cover scalp cooling
- The patient is measured, the Cap is calibrated, and then the patient
  is given the Cap Kit which they will bring to each treatment. At this
  point the provider will bill the payer using code 0662T. In connection
  with all treatments, the provider bills 0663T, which is for the cooling
  treatment itself
- Under the insurance-based billing model only, the Paxman Patient Assistance Program (PAP) provides free goods to allow access to treatment for those who are under or uninsured

# The Paxman Patient Assistance Program

To ensure the most equitable access possible, Paxman have developed a generous Patient Assistance Program (PAP) to support the insurance-based billing model. If patients qualify for the PAP, they will receive a Cap Kit free of charge from their provider, and the Paxman Hub will send a replacement Cap Kit to the provider. The provider will not charge the patient for the Cap Kit or any scalp cooling treatments.

This Program is a best-in-class offering and emphasises Paxman's commitment to ensuring equitable access for all patients who want to scalp cool.

# Under the insurance-based billing model contract, the Paxman PAP assists patients who –

- · Are uninsured or underinsured for scalp cooling
- Reside in the US and have a physical US address
- Have an on-label diagnosis
- Have a valid prescription for scalp cooling from a licensed prescriber
- Have a household income of 6x US Federal Poverty Level or below



"I was able to 'live' my life whilst undergoing treatment; I felt 'normal' and retaining my hair enabled me to remain confident and positive"

- Kare

# **Commitment to transition**

The acknowledgement of the value of scalp cooling from guideline organisations such as NCCN® and the integration of scalp cooling into legislation represents the importance of the treatment and the impact it can have on a patient's experience of cancer treatment. Countless clinical studies reflect the trauma of chemotherapy hair loss and the option to limit and manage that process can be invaluable to patients.

Paxman's commitment to the insurance-based business model stems from the recognition that no patient should have to face hair loss if they don't want to, and the intention to convert all existing sites to the new model by the end of 2024 will ensure that chemotherapy-induced alopecia does not have to inevitable for any patient in the United States.

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# Reported payment rates

Reported payment rates have outstripped all expectation, with continuous evidence that insurers are not only paying for scalp cooling treatment but are paying well. This is fundamentally important information to share with Health Systems who are considering transitioning, as it gives evidence of the revenue that is achievable for their cancer centre. While government payers are paying slightly less, the standard is still good, with commercial payers frequently exceeding this.

# Government plans

СРТ	Exchange	Medicaid	Medicare	Medicare Supplemental Plan	TriCare	VA
0662T	Up to \$2115.44 - \$3507.21	Up to \$1629.22 - \$2158.20	Up to \$928.87 - \$980.79	Up to \$928.87 - \$1870.44	Up to \$3597	Up to \$2210.24 - \$3034.82
0663T	N/A	Up to \$70.84 - \$72.45	N/A	Up to \$35.08 - \$62.79	Up to \$120.75	Up to \$70.84

# Commercial plans

СРТ	Aetna	BCBS	Cigna	Humana	UHC/Optum
0662T	Up to \$3453 - \$3597	Up to \$1870.44 - \$3453.12	Up to \$1342.88 - \$2158.20	Up to \$3549.04 - \$3692.92	Up to \$3357.20 - \$3501.08
0663T	Up to \$115.92 - \$120.75	Up to \$112.70 - \$115.92	Up to \$112.70 - \$120.75	Up to \$119.14 - \$123.97	Up to \$112.70 - \$117.53

"I didn't realize how lucky I was until almost after the fact that I had 100% coverage. But it shouldn't come down to finances. It should be available to all that have the opportunity to experience it."

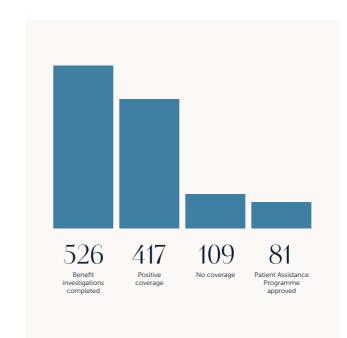
**Brooke**, whose scalp cooling treatment was covered by insurance

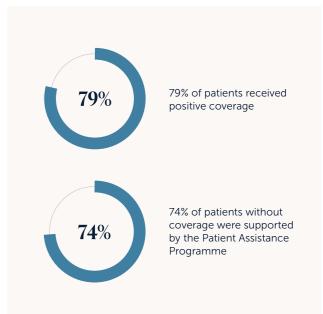
# **Improved utilisation**

Since significant numbers of cancer centres are now deploying the insurance-based billing model, it is possible to see the increase in utilisation that occurs when removing financial burden from the scalp cooling decision-making process for patients.

There has been increased utilisation of scalp cooling systems across the board at sites who are able to bill insurers directly, with some sites seeing astounding increases of more than a 300% rise in patients using Paxman systems. This gives just a small indication of the potential expansion possible within in the US market and the demand for the treatment when cost is no longer a concern.

Paxman will monitor increases in utilisation in 2024.





Only providers using the full hub June 22 to January 24.

# Results for providers using the Paxman Hub services

Coverage data from the Paxman Hub compliments the positive payments being made by payers. While the above figures only show results from provider using the full Hub services (some of the larger sites carry out their own benefit investigations), the outcomes far exceed all expectations when the model was initiated. Those who are experts in the field have rarely seen such positive coverage from a model that is in its infancy.

In conclusion, while the road has been long and at times challenging, Paxman are proud of the progress they have been able to achieve in a relatively short time in the US. While there is still a long way to go, a momentum has been established that will ensure that in conjunction with further hard work, 2024 will be an even more successful year. We are determined that more patients than ever before will be able to access scalp cooling, an essential side effect management tool that is growing in importance in the oncology space.

# Lexicon project

one, and it is fundamental that Paxman are able to effectively and concisely communicate the details of the insurance-based billing model to all stakeholders. Several members of the marketing and US teams have spent time with consultants, Innovation Partners, on a lexicon workshop, exploring language and messaging to ensure accuracy and consistency in communication. This work has not only been helpful in seeing how far Paxman have come within the reimbursement landscape, but a valuable way of distilling ideas to create confidence for all the teams supporting the growth of the insurance-based billing model.

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# DIRECT MARKET ACTIVITY

### The prevalence of cancer is growing globally.

On average, one in two people will get cancer in their lifetime. There were approximately 19,976,499 new cancer diagnoses in 2022¹, around 90% of which were solid tumour cancers². As awareness of the efficacy of scalp cooling and other chemotherapy side-effect management grows in both patient and clinician populations, so does the demand for the treatment.

Paxman saw its most successful year to date in 2023, due in part to its endeavours in its internal markets, the UK, France, Spain, Scandinavia, India and now Germany, where Paxman sells directly to the customer, rather than a distributor.

<sup>1</sup>Ferlay J, Ervik M, Lam F, Laversanne M, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2024). Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available from: https://gco.iarc.who.int/today, accessed [10 April 2024].

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This year, scalp cooling was added to the French cancer care guidelines as a recommended treatment, which is fantastic news for patient access to this important means of managing the devastating side effect of chemotherapy-induced alopecia.

We continue to work hard in France to educate the public and clinicians about the science and benefits of the treatment, so they understand the importance of scalp cooling as a way of improving quality of life and giving patients increased control during chemotherapy treatment.

# Charlotte Fraser

Regional Manager – French Speaking Markets

# France

Active since 2006, there are 56 hospitals utilising 136 Paxman systems. 2023 has been a year of substantial growth, building on the back of a series of significant achievements:

- Paxman is directly mentioned in the supportive oncology care guidelines for France.
- Paxman is the preferred supplier for mechanised scalp cooling in the country and for the Helpévia Group, a private sector purchasing platform.
- Paxman is currently partnering with the first ever clinical scalp cooling study in France, funded by the Ministry of Health.

# SME of the Year 2023

In 2023, Paxman was awarded SME (Small and medium-sized enterprise) of the year at the Franco-British Trade and Investment Awards in Paris, presented to the company by His Majesty's Ambassador to France, Dame Menna Rawlings.

Paxman was originally shortlisted alongside 8 companies after a rigorous application process undertaken by 31 UK and French companies, from all regions of the two countries.

Paxman are thrilled to have won this prestigious award, particularly against such strong competition.

### **ICELAND MASCC Trial 2024**

A new ICELAND MASCC trial will begin in 2024 across France, where manual gel cold cap (MGCC) forms of scalp cooling treatment are commonly used. Working in conjunction with authors from 7 different sites, the trial will compare efficacy between the MGCC (Multinational Association of Supportive Care in Cancer) and Paxman's mechanised scalp cooling technique (MSCT).

The study aims to demonstrate a significantly higher rate of chemotherapy-induced alopecia prevention in patients in the MSCT arm of the trial. This research should also provide new knowledge on the benefits of scalp cooling during chemotherapy in preventing chemotherapy-induced alopecia, with guidance on the choice between the two techniques. Paxman anticipates positive outcomes from the trial which will fuel continued growth and greater patient engagement.

### **MASCC and AFSOS**

Paxman looks forward to the affiliation between two major conferences that will be hosted in France in 2024. MASCC and AFSOS work hard to improve training, practice, and research in supportive cancer care and to promote knowledge and implementation of supportive care measures. After the success for MASCC in Japan in 2023 for Paxman, we look forward to the show raising the profile of side effect management and supportive cancer care in France.

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# Spain

Spain, a part of the Paxman distributor network since 2014, transitioned to a direct market model in 2023. Currently 24 hospitals are utilising 26 Paxman systems since 2014. Between 2013 and the establishment of the direct market model, 12 devices were offered to hospitals. The direct market model has resulted significant expansion with 14 additional Paxman systems being placed in the Spanish market since April 2023 alone.

In January & February 2024, Paxman installed devices in 2 new hospitals with an additional 2 hospitals already involved in the implementation process.

### Medical group relationships

Spain's leading oncology medical groups such as Quironsalud, GenesisCare, Vithas, and Sanitas, have chosen Paxman scalp cooling technology, establishing the company as pioneers in the field throughout the country. The relationships established with these groups will pave the way for further expansion in the market.

### **System placements**

2024 is set to be another promising year for the Spanish market, with an expected growth rate of 40% in terms of number of Paxman systems to be installed in the country. Paxman has additionally loaned devices to 2 sites in Barcelona for an upcoming clinical trial into scalp cooling.

# **Spanish exhibitions**

Begoña Parrado, Paxman's Regional Representative for the Spanish market, presented at IX Foro Extremeño Multidisciplinar De Cáncer De Mama Tumores Ginecológicos in April 2024 about how to manage and diminish chemotherapy-induced alopecia and also attended the Jornada de Humanizacion de Cancer de Mama in March.

These events posed fantastic opportunities for Paxman to build new relationships and partnerships with key stakeholders in the Spanish market, which we are looking forward to developing and strengthening through 2024 and beyond.

"Representing Paxman in Spain, I take pride in our scalp cooling technology being the preferred choice among top oncology medical groups. Its successful use in the country's most prestigious hospitals showcases its efficacy in preventing chemotherapy-induced alopecia and significantly enhancing the quality of life for cancer patients."

Begoña Parrado





This business model allows on going revenue, but also enables hospitals to offer the treatment free of charge.

# India

India is a market with huge potential that has been active for Paxman since 2013 under the care of distributor Access Devices. In 2021, Paxman placed Garima Vyas as the Regional Manager for India, an additional resource and influence on the ground providing training and implementation guidance to hospitals using the Paxman system. There are now 45 hospitals using 47 systems in India.

# Medical group relationships

As of 2023, the Paxman Scalp Cooling System is offered at major hospitals chains such as MAX, Fortis, Manipal, Apollo, ASTER, HCG, Rajiv Gandhi Cancer Institute, Hinduja, Mumbai Oncocare Centre and Narayan Health. These relationships not only show the hard work that has been put in place in India but will also pave the way for further expansion within the market

# New business models

Paxman launched its first Indian Pay For Use (PFU) model in 2023 in collaboration with Dr. Reddy's Laboratories. Dr Reddy's Laboratories purchases treatment cards, which activate the Paxman Scalp Cooling System, directly from Paxman in India, which are then donated to hospitals enabling them to offer scalp cooling treatment to patients. This business model allows ongoing revenue, but also enables hospitals to offer the treatment free of charge. This model is now in place at Thangam Hospital in Namakal City, Ashirvathnam Hospital in Madurai City and Rajagiri Hospital, Kochi City.

# **Indian Cancer Congress**

Paxman hosted a symposium 'Scalp Cooling – an Indian Perspective' at the Indian Cancer Congress in 2023. Drs Udip Maheshwari (Mumbai Oncology Centre) and Vamsi Krishna (AIG) presented their experiences of scalp cooling and the difference it can make to a patient's experience of treatment.

## Indian research

A prospective study from HCG Ahmedabad assessing the efficacy and safety of scalp cooling in the prevention of chemotherapy-induced alopecia in cancer patients was presented at SABCS in San Antonio, Texas in 2023.

In addition, a clinical study titled: "The Efficacy of Paxman Scalp Cooling System in Preventing Hair Loss in Breast Cancer Patients Receiving Chemotherapy in Western India – Multi-centre Retrospective Cohort Study" was conducted by Dr Ashish Joshi from the Mumbai Oncology Center. The study paper was published in the Indian Journal of Dermatology in 2024



# Germany

Germany has always been a strong market with enormous potential for Paxman, where we worked in partnership with Novidion to build the market. Paxman has been active since 2011 and currently has over 60 systems installed in over 50 hospitals across the country.

Paxman began 2024 by increasing its investment in Paxman GmbH from 20% to 49% and as a result Paxman will be working with its partner Novidion to relaunch in the German market. Taking greater ownership and investing in Paxman GmbH in every sense. Germany will be considered as one of Paxman's direct markets. With increased resource and support from the UK company's team

alongside hard work on the ground from the German team, traction is expected to improve throughout 2024. Raphael Fugger will be joining Paxman as a permanent member of the team from Novidion.

This approach has already seen a strong start to the year in Germany, with increased system orders and a stable rental business.

"We are excited to renew Paxman's energies in the German market and look forward to ensuring more patients are able to scalp cool."

Raphael Fugger

# Scandinavia

One of Paxman's longer standing markets, Scandinavia has been active for 25 years, with 25 hospitals using 39 Paxman systems.

2023 saw Paxman technology implemented at Radiumhospitalet, Oslo's University Hospital. It is a new branch of hospital currently being built in Norway's integrated into cancer

> Paxman is continuously working to find solutions with which to implement more scalp cooling devices in hospitals across the Nordic countries and the company looks forward to making more progress

in 2024. With more of a premium placed on quality of life in cancer care across Scandinavia, we are hoping to see scalp cooling better integrated into cancer pathways. Paxman will continue to work hard to move away from challenging and deep-rooted historical myths and aim to offer scalp cooling in a curative capacity.

clinical staff trained by Paxman throughout 2023

systems installed across

the UK in 2023



# **United Kingdom**

As Paxman's home market, the UK stands as a huge success story and an example of what can be achieved elsewhere in the world.

The UK market has been active since 1997, with a current count of 326 hospitals using over 1,000 Paxman systems. This is equivalent to 99% of all private and public hospitals utilising Paxman systems.

# Best year to date

1616 clinical staff were trained by Paxman in 2023 alone, and 192 systems were installed in the UK in the same time frame - a record number of sales and the best year to date.

This strong market performance within what could be considered a saturated market was driven by upgrades from older generation Paxman systems to the PSCS as these older systems became obsolete. This continual upgrading of systems which have proven their worth, providing scalp cooling as a standard of care within the National Health Service (NHS), has resulted in a strong sales pipeline that will deliver in the medium to long

# Paxman Clinical Pioneer Programme

2023 saw an expansion of the Paxman Clinical Pioneer Programme (CPP). After a pause and digitisation of the CPP over the pandemic, the CPP resumed in-person, delivering in depth training on scalp cooling to clinical teams creating in-house scalp cooling experts and champions delivers higher utilisation and improved treatment and outcomes, which ensures clinical team buy in and higher utilisation of Paxman equipment. Plans are in place to further expand the Programme in 2024.

Paxman are also looking forward to attending several events in 2024 such as the United Kingdom Oncology Nursing Society (UKONS) conference, with which Paxman has strong ties, in addition to the Professional Oncology Care conference and the IRE/NI summit.

The immense strength of the UK market is something that Paxman is not only proud of, but we believe that is provides a blueprint of what can be possible in many markets globally. The world looks to the NHS for guidance and direction in healthcare and Paxman Scalp Cooling Systems are an embedded part of oncology care in the UK. We look forward to a time when scalp cooling is a similar standard of care for all cancer patients around the world.

pathways."

"With more premium

placed on quality of

life in cancer care

across Scandinavia,

we are hoping to see

scalp cooling better

→ Care through sustainable innovation

# Research and development

Research and development has become an increasingly important focus for Paxman. A recognition of the potential provided by innovation, not only for our existing product, but also the huge opportunities that pushing the boundaries of cryotherapy brings, have led Paxman to prioritise an ambitious programme of research and development. The capabilities and improvements being unlocked by this ongoing work ensure that Paxman moves forward from a position of strength. We recognise that investment in innovation now paves the way for significant future growth.

2023 proved to be a successful year, with work coming to fruition, advancements in new technology and increased efforts to factor in sustainability.

"Trials have shown the potential that cryotherapy may have as an effective preventative treatment."



# Preventing chemotherapyinduced peripheral neuropathy

Huge progress was made in 2023 with the Paxman Limb Cryocompression System (PLCS), a portable cryocompression product developed to prevent chemotherapy-induced peripheral neuropathy (CIPN). This less high-profile side-effect is a potentially debilitating outcome of taxane chemotherapy treatment impacting the hands and feet, ranging from a tingling sensation to excruciating pain. Several pharmacological agents have been developed to prevent and treat CIPN, yet none have proven effective in largescale clinical trials. Trials have shown the potential that cryotherapy may have as an effective preventative treatment, creating the need for a clinically tested medical device that can deliver consistent, reliable cooling to replace the currently available unregulated manual cooling in the form of frozen gloves, or mechanised cooling that isn't supported by a large-scale trial.

PLCS prototype systems were placed in Singapore for use in a pilot clinical trial to establish the efficacy of cryocompression that commenced phase one, testing in healthy individuals, in November 2021. The trial has progressed to stage two, recruiting 47 cancer patients enrolled with positive initial findings. 2023 saw the initiation of a phase III trial in the US, a three-arm, multi-centre, randomised efficacy study using the PLCS, aiming to recruit 777 patients across 25 sites. To date PLCS devices have been placed at 22 clinical study sites with 120 patient recruited and randomised into the three study arms. Paxman have placed 6 PLCS devices at each site, delivering onsite commissioning and training, technology adoption support and related resources.

Read more on CIPN and the PLCS on page 48.

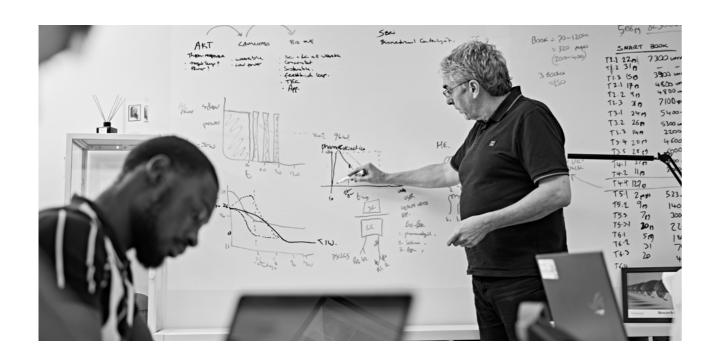
# Miniaturisation of cooling technology

Progression of the PLCS has allowed Paxman to create smaller and more compact cooling technology. The option to reduce the size of apparatus and therefore the amount of valuable space occupied in hospitals and cancer centres could have significant impact - making cooling more accessible and allowing for technology that can serve more patients without taking up additional room. Paxman continue to explore this area of vast potential.

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Articles

Research and Development



# New cooling cap technology

As demand for scalp cooling has risen across the globe, so has the demand for Paxman scalp cooling caps and covers. Continuous development of the cooling cap has been central to Paxman's approaches since the business began. Continuous feedback from clinical and patient users of the caps has ensured that improving efficacy and usability has been prioritised. The current cap and cover. launched in 2017, factored in the need for a robust but lightweight cap, with an improved fit that would suit as many of the head shapes found across the world as possible. The cap also needed to be suitable for both single-use and regular use markets.

While the current cap and cover have seen a notable improvement in fit, which has improved scalp cooling outcomes for patients, as well as easier utilisation, there are a number of areas that Paxman are keen to improve on. Utilising the medicaldesign expertise within the University of Huddersfield's award-winning product design team, Paxman have launched a project to explore ways to improve the cooling cap and cover, to factor in sustainability and the best possible fit for all head shapes and sizes. The team will focus heavily on innovation, advanced design and development and technical material research to push boundaries and develop new solutions.

Work by the team will ensure that scalp cooling treatment efficacy will be maximised through single-patient caps, promoting optimised cap fit and increasing treatment success. The cap will also factor in the need for enhanced infection-control essential for those with chemotherapy-induced immune suppression.

Crucially, this project will also address the environmental impact associated with increased demand of this single-patient medical devices. The current cap is manufactured from silicone, the cover is produced from neoprene, neither of which are biodegradable. The focus on eco-design promotes a circular economy approach, extending the lifecycle of products and minimising the cap's end-of-life impact.

We look forward to the completion of this project and the impact it will make not only on patient experience, but limiting the impact on the environment of increasing access to scalp cooling.

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The focus on ecodesign promotes a circular economy approach.

# Topical agent to improve scalp cooling efficacy

While scalp cooling efficacy has made significant improvements over the last decade, scalp cooling is not a perfect process, and even the patients with the highest levels of hair retention at the end of treatment will experience some level of shedding as a normal part of the treatment.

Paxman have been working with Dr Nik Georgopoulos at the Paxman Research & Innovation Centre to develop topical formulations which will aim to minimise or prevent chemotherapy-induced alopecia in conjunction with scalp cooling, improving patient experience and confidence in scalp cooling. The formulations use lipid nanoparticles with the ability to deliver antioxidants (AOs) to the hair follicle region in the skin, used as a precursor to scalp cooling.

During its final stage, the project focussed on completing the development of the production of nano-particulates for the formulation of a panel of three reactive oxygen species (ROS) inhibitors (AO1, AO2 and AO3) using a range of formulations to encapsulate these ROS inhibitors/AOs for optimized skin delivery. These are AOs for which the biology team at the Paxman Research & Innovation Centre have extensive laboratory (in vitro) data proving their ability to prevent hair follicle cell cytotoxicity when used in conjunction with cooling against a variety of chemotherapy drugs.

# Main results of the experimental work

Two AOs (AO1 and AO2) were successfully incorporated into nanostructured lipid carriers (NLCs), which are robust and stable formulations (stable over a 6-month period at 4°C). The NLPs exhibit the correct size and surface properties, such as electrical charge, to successfully reach the hair follicle.

Our experiments confirmed efficient skin permeation and AO targeting, with the NLCs successfully delivering the required amount of AO to the follicular area within less than 6 hrs of application. AO1 remained highly stable upon delivery to

follicles and was present more than 24 hrs post-application, and even following formulation of AO1-loaded NLCs using different concentrations of AO, particle characteristics remained optimal. This formulation method was suitable for encapsulation of AO2 and its delivery to the skin hair follicle area, and these observations are confirmed to be fully in line with the findings for AO1.

Notably, in addition to the NLP-based approach, excipients commonly used in hair serum products were tested, and such preparations for AO1 were tested in vitro. Although the serum-type product exhibited lower efficacy in skin permeation compared to the nanoparticle platform, in the team's studies, serum formulations were more efficient in targeting the follicle area compared to AO solution only as shown in controls.

Finally, as we took into consideration the chemical properties of each individual AO, bespoke formulations were designed, particularly for AO3, to efficiently deliver all AOs. As AO3 has different properties to the other AOs, being more hydrophilic, a different approach was required for formulation. This was shown to be successful, and the AO was stable. However for more efficient formulation and delivery to skin, the AO would be amenable to other type of liposomal products and polymeric nanoparticles.

# Implications of the results for future development

The successful formulation of a panel of AOs paves the way for a new era of scalp cooling-based patient care. The highly efficient delivery of the AOs, whether by nano-formulation or a serum-based product, combined with our knowledge that these AOs, in conjunction with cooling, can suppress or prevent toxicity to hair follicles under conditions when cooling may not adequately protect, can 'transform' the efficacy of scalp cooling. The ability to deliver AOs of different properties and efficacy to cryoprotect against different drugs, provides application flexibility and raises the prospect of chemotherapy drug-specific approaches.

The experimental evidence for rapid (less than 6 hours) delivery of the AOs to the hair follicle area has practical implications for clinical use of the topical products, and combined with the stability of the AO in the skin (more than 24 hrs) provides strong supportive evidence that clinical delivery to patients can not only be achieved in time for chemotherapy infusion but also, post infusion, the AOs remain in the hair follicles and will continue to protect.

Therefore, the formulations may not only dramatically enhance the efficacy of scalp cooling in protecting from hair loss, but also significantly accelerate recovery post chemotherapy treatment.

Paxman now looks to move forward with the advancements made by Nik and his team at the Paxman Research & Innovation Centre and in due course will look to find an appropriate commercial partner to make this research a reality.

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Patrick Burke, Jonathan Binder, Dr Ertu Unver, Dipo Olaosun, Gayathri Kopattil, Ethan Morgan, Jane Clayton and Riley Irving

# Spotlight on the Research & Development Team

Meet Paxman's Research & Development team, dedicated to improving and innovating our products to ensure the best possible outcomes for patients.

Paxman works alongside The University of Huddersfield in our research to better understand the cellular mechanisms by which cooling reduces the cytotoxic effects of chemotherapy on rapidly dividing hair follicle cells.

The Paxman Research & Innovation Centre in conjunction with the University of Huddersfield has fuelled some of our most far reaching and exciting research to date. Paxman has also worked alongside various other academic institutions and with some of the best minds within the fields of biological research, product development and clinical research to ensure we are pushing boundaries to develop the highest quality work and most innovative solutions.

# Patrick Burke

### Head of Research & Development

Patrick, currently Head of R&D at Paxman, has previously held roles in Quality, Production, and Operations within the company. His journey began in 2007 as a Technical Manager, leveraging over 30 years of engineering experience and hons degree in Maths.

Patrick initially worked on the Orbis systems which included development and regulatory pathway approvals. Patrick was responsible for securing funding through Kirklees innovation vouchers and winning a £400K Smart award in 2012, leading to a long and successful collaboration with the University of Huddersfield.

His achievements include securing Outstanding-rated Knowledge Transfer Partnerships (KTP) for biological research in 2012 and design in 2015. Patrick's contributions extend to obtaining US and Japanese approvals in 2017 and 2018, respectively, solidifying Paxman's global

# Jonathan Binder (BA MA)

### Lead Project Designer

Jonathan serves as the Lead Product Designer at Paxman and is a Medical Researcher/Medical Product Designer at the Paxman Research & Innovation Centre, the world's first Scalp cooling and research innovation centre. With over 8+ years of industrial experience and 6+ years in academia, Jonathan is currently pursuing a part-time PhD on 'Mass Customization in Cranial Anthropology for Medical Product Development.'

His master's thesis, co-funded by Paxman and Innovate UK, explored 'Additive Manufacturing in New Medical Product Development for Chemotherapy-Induced Alopecia,' earned Jonathan a Distinction and an 'outstanding' rating for the Knowledge Transfer Partnership (KTP) from the governing body.

Jonathan has contributed to 15+ academic outputs and holds patents. highlighting his expertise in New Medical Product Development, Design for Manufacture, Design for Additive Manufacturing, and more, with a focus on CAD using Solidworks complex surfacing.

### **KTP** Associate

Gayathri, a medical product designer, who has completed a Knowledge Transfer Partnership (KTP) working on a project aiming to develop a preventive solution for Chemotherapy Induced Peripheral Neuropathy (CIPN), funded by Innovate UK. Leveraging academic knowledge and clinical insights, Gayathri is dedicated to designing innovative technology. Alongside her role in the project, Gayathri pursues an MA by Research in Art and Design, specialising in medical product development. With 4 years of industry experience, including work at Paxman's Research & Innovation centre, she brings valuable expertise to the project.

# Ethan Morgan

### **Development Engineer**

Ethan, a Development Engineer at Paxman, has over 5 years of industry experience, which began in production of the Paxman Scalp Cooling System (PSCS) and transitioned to the role of Service Engineer, refining his hands-on approach.

Innovate UK and EU-funded projects. His current research interests span mass customisation, medical product development, AR/VR applications for industrial design, anthropometric & ergonomics analysis, and 3D simulation.

# Dipo Olaosun (BSc)

### **Product Design Researcher**

Dipo Olaosun is a multidisciplinary Industrial Designer with a passion for technology, innovation, and creativity. With prior experience as a web developer, he strives to amalgamate technology within design to elevate user experiences which is highlighted within his work.

Currently a Product Designer at Paxman, he focuses on the well-being of patient battling chemotherapy-induced alopecia while developing new products. Concurrently, Dipo pursues a part-time Master's in Product Design Engineering, researching testing methods for medical wearables. He also shares his expertise as a part-time lecturer, guiding students in digital and visual communication at the University of Huddersfield.

# Gayathri Kopattil (BSc)

# Rilev Irvina **Product Design Placement**

Riley Irving is a Product Design (BSc) student currently working as part of the research and development department at Paxman. His main areas of interest include, designing medical products that make a positive impact on people's lives and investigating modern design technologies such as artificial intelligence and virtual reality to see how viable they are as industrial design techniques. He also enjoys using software such as Blender and Keyshot to create digitally rendered visuals and animations to represent products.

Notably, he led the sustainable redesign

production of over 200 cryocompression

systems for a major international clinical

trial. Currently pursuing a level 3 NVQ

Diploma in Mechanical Manufacturing

Engineering, Ethan's diverse background

spans mechanical engineering disciplines,

including motor vehicle mechanics and

interests encompass engineering, design

for manufacture, additive manufacturing,

Passionate about hands-on work, Ethan

brings invaluable expertise to Paxman's

Jane, a Design Research Consultant for

Paxman's SMART project, specialises in

design. With a first-class Biology degree

through an R&D internship, evolving into

Joining Paxman's Research & Innovation

medical cooling and patient-centred

from The University of Leeds, Jane's

journey with Paxman began in 2010

European research funding expertise.

impactful studies and secured funding for projects such as eco-design and

innovative manufacturing for enhanced

2024). She is also involved in developing

Centre in 2019, Jane coordinated

patient access to scalp cooling

(InnovateUK SMART, £500k, 2022-

medical cooling solutions to prevent

chemotherapy-induced peripheral

neuropathy (KTP, 2022-2024).

and technical testing and validation.

Jane Clayton

**Design Research Consultant** 

camper van construction. His research

of the PSCS cap and spearheaded the

# Dr Ertu Unver (PhD)

### Principal Enterprise Fellow

Dr. Ertu Unver, a Principal Enterprise Fellow at the University of Huddersfield since 2014., serves as the principal investigator for the Paxman Research & Innovation Centre. With extensive commercial industry experience both in the UK and abroad, he previously worked as an Industrial Designer & CAD/CAM manager, contributing significantly to the design of various consumer products. Dr. Unver holds a BSc in Mechanical Engineering (1986) and completed his MSc in Industrial Design & Computer Programming in 1989. Following the completion of his PhD, he became an Assistant Professor at the University of Cukurova, Turkey, in 1994.

A key figure in Paxman's growth, Dr. Unver is credited with the patented design of the PSCS scalp cooling cap, introducing rapid cooling in sheet silicone thermoforming for the first time. His innovative contributions have been pivotal for Paxman's success. Dr. Unver has an impressive record of over 120 research articles, numerous keynote speeches, and active involvement in

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Articles

CIPN



# What is chemotherapyinduced peripheral neuropathy?

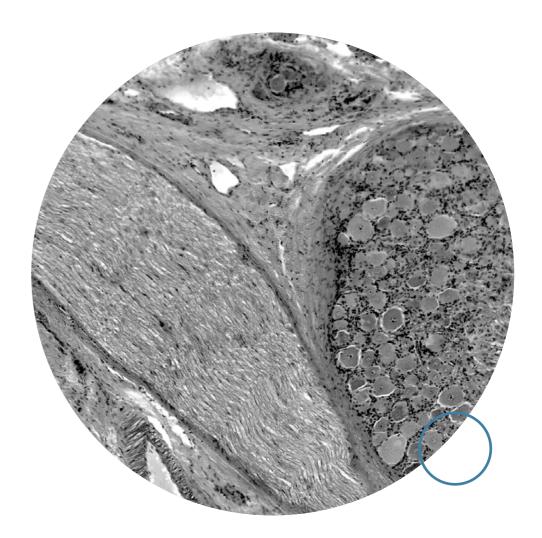
Chemotherapy-induced peripheral neuropathy (CIPN) is damage caused to the peripheral nervous system that carries messages between the brain, the spinal cord and the rest of the body, as a result of chemotherapy treatment. Sensory side effects are caused when nerves in the most distal parts of the limbs are damaged – the hands and feet.

Symptoms manifest themselves as deficits in sensory, motor, and/or autonomic functions of varying intensity and they can significantly reduce a patient's functional quality of life. Patients may experience numbness, tingling, altered touch sensation, gait and balance disturbances, burning pain, thermal allodynia or hyperalgesia, impaired vibration sense, extreme temperature sensitivity, paresthesia, and/ or dysesthesia. Although less common, motor symptoms can also occur including cramping, distal weakness, difficulty handling small objects, and impaired movements In severe cases, motor symptoms can lead to complete immobilisation and severe disability. A patient experiencing CIPN symptoms may have difficulty performing daily functions such as walking, dressing themselves, writing, typing, and other activities related to the hands and feet.

The prevalence of these symptoms is usually highest in the first month after the completion of chemotherapy at 68.1%, but as many as 30% of patients still report CIPN symptoms six months after the completion of chemotherapy and beyond. CIPN is predicted to effect 1.4 million cancer patients annually worldwide. It also contributes to significantly increasing economic burden in terms of healthcare costs estimated to be US\$ 17,000 more in cancer patients with CIPN than those without.

There are currently no known treatments to prevent or reverse CIPN. Several pharmacological agents have been developed yet none have proven effective in large-scale clinical trials. To date the most effective treatment for peripheral neuropathy is to prevent further damage to the nerves by lowering the chemotherapy drug dose, or even stop the treatment altogether. Reduction or cessation of treatment is something that both clinicians and patient alike are keep to avoid

Cryotherapy and compression have shown significant potential in preventing CIPN, with preventative cryotherapy gaining prevalence. Studies have shown that cryotherapy could be a valuable tool in preventing CIPN, but there is an urgent need to develop a medical device that can deliver consistent cooling. The only choice for patients presently is limited to unstable and unregulated manual cooling in the form of frozen gloves or mechanised cooling that is not supported by a large scale randomised study.



# **Research Partnership**

Recognising the need for a medical device solution within CIPN prevention bracket, and the ability to extend decades of cryotherapy expertise for side-effect management, Paxman have developed a compact cryocompression system that will deliver consistent and measurable cooling and well as compression that can help to improve tolerability. The Paxman Limb Cryocompression System has been a result of partnership and years of development work.

In early 2019, Paxman signed a research collaboration agreement with the National University Hospital in Singapore (NUH), for the development of PLCS. The research team in Singapore is led by Dr. Raghav Sundar, who has examined the possibility of using cooling and compression to prevent CIPN for some time. The development of the device

has been conducted by Paxman in collaboration with researchers from the Paxman Scalp Cooling Research Centre at the University of Huddersfield.

In 2020, Paxman further developed its relationships with key clinical opinion leaders, including the renowned Prof. Charles Loprinzi from the Mayo Clinic, Rochester, USA, who was elected as a new member of Paxman's advisory board and has been involved in designing the PLCS trial project clinical programme. Prof. Loprinzi is one of the world's most recognised experts in the CIPN field and the first author of the American Society of Clinical Oncology (ASCO) 2020 CIPN guidelines.

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Cryotherapy and compression have shown significant potential in preventing chemotherapy-induced peripheral neuropathy

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CIPN

# **Trial Design**

In 2021, a research grant of 1.57 million SGD was received from National Research Foundation (NRF) in Singapore, and a clinical trial was initiated with National University Hospital, Singapore, in collaboration with The N.1 Institute for Health, National University of Singapore, to evaluate the PLCS with healthy volunteers and cancer patients. The first phase of the trial was completed in 2022, and the second phase was initiated later the same year, to evaluate the safety and efficacy of the PLCS device in preventing CIPN in 80 patients receiving any taxanebased chemotherapy. By the end of 2023 47 patients have been enrolled. 37 (78.7%) patients have completed all planned treatment. 17 patients (36.1%) received concurrent scalp-cooling therapy; all managed to complete both treatments. The study is expected to complete in during 2024.

SWOG S2205 ICE COMPRESS, a phase III, three-arm, multi-centre, randomised efficacy study supported by the National Cancer Institute in USA and together with cooperative research group (SWOG), funded by the National Cancer Institute, initiated in 2023. The trial plans to recruit 777 cancer patients across a minimum of 25 sites, with with over 22 locations already opened.

The study will compare the proportion of participants who develop clinically meaningful CIPN at 12 weeks, in participants treated with taxane-based chemotherapy randomized into three arms: cryocompression therapy, continuous compression therapy and low cyclic compression therapy administered via the PLCS devices. Low cyclical pressure serves as a control. It is important to not have a non-treatment arm, given that the primary endpoint is a patient reported outcome, and not having a treatment could bias participant's responses.

To date, the PLCS devices have been deployed in 22 study sites and the study has currently accrued 120 patients. The study is being supported by Paxman providing 6 PLCS devices to each site, delivering onsite commissioning and training, technology adoption support and related resources. The study will accrue patients over 2.5 years and each patient will receive follow-ups for 52 weeks following treatment commencement.

"It has been amazing to offer the ICE-COMPRESS @SWOG, S2205 study to our patients @ValleyHealthNJ!"

**Eleonora Teplinsky** on X (formerly Twitter)

22 Study sites with PLCS

120

Patients accured onto the study

# **Early Trial Findings**

Initial findings from phase I of the clinical trial in Singapore are positive and promising.

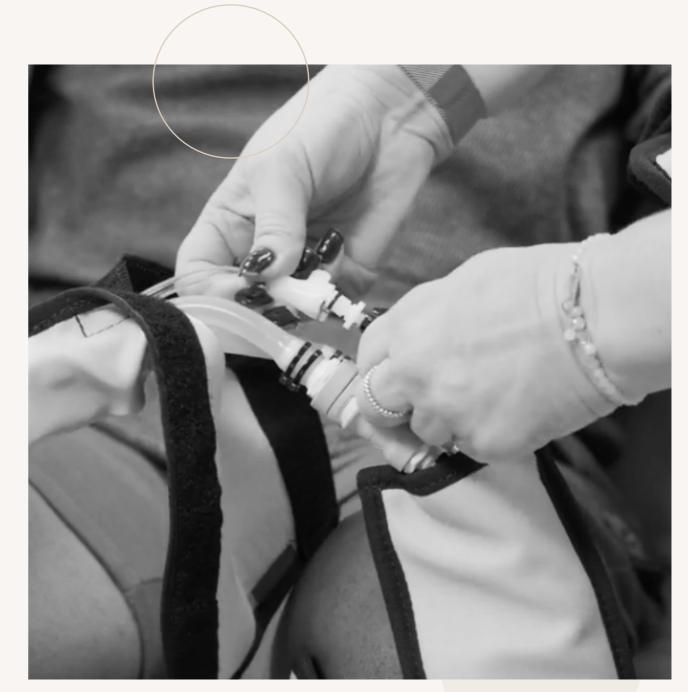
Concomitant scalp and limb cryotherapy during chemotherapy is safe and feasible

No core hypothermia was observed following 3-hour scalp and limb cryotherapy  $\,$ 

Limb cryocompression at 11°C and low dynamic compression is safe and tolerable

Limb cryocompression preserved CIPN-20 Quality of Life scores at 3 months post taxane chemotherapy

These results show how important extensive data from phase three of the trial will be to further confirm these findings as well as providing extensive data from such a sizeable cohort to enable rigorous data analysis.



# Product Useability and Regulatory Pathways

A trial of such a significant size has provided an opportunity to collect information beyond that which reflects on patient experience. Research teams have also taken the opportunity to gather highly valuable quantitative and qualitative device usability data from stakeholders (patients, nurses, device administrators). The enhanced product development that comes from this

feedback will ensure that the product is not only effective but simple to use and will increase the likelihood of buy in from clinical teams and ensure that implementation of the device, once commercialised, is smooth and has longevity. Alongside this work, a clear regulatory strategy has been created with the correct timing of deployment in consideration.

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Clinical studies

# Clinical studies and collaborations

Paxman's scalp cooling is continuously evaluated with different types of chemotherapy treatments and patient groups in order to gain further knowledge and improve the treatment effect. Paxman are pleased to have not only the most published peer reviewed data using its scalp cooling systems, but the most open and active studies, advancing our knowledge with a view to improve efficacy and access globally.

# Scalp Cooling in Metastatic Breast Cancer (MBC)

Location: Dana-Farber Cancer Institute

This study is a prospective, controlled, pivotal clinical investigation to assess the efficacy of the Paxman Scalp Cooling System (PSCS) at preventing hair loss in people undergoing treatment for metastatic breast cancer with either Sacituzumab govitecan (IMMU-132 or Trodelvy™), trastuzumab deruxtecan (DS-8201a or Enhertu®), or Eribulin (Halaven®). Participants will receive study treatment with scalp cooling with standard of care chemotherapy treatment and will be followed for 2-4 weeks after completion of treatment with

chemotherapy. It is expected that about 120 people will take part in this research study.

# Scalp Cooling for Chemotherapy-Induced Alopecia in Patients of Color

Location: Montefiore Medical Center

The purpose of this study is to evaluate hairstyling techniques aimed at increasing efficacy of scalp cooling in the prevention of chemotherapy-induced alopecia, determine scalp cooling effect on persistent chemotherapy-induced alopecia, and elucidate molecular

mechanisms and predictive biomarkers associated with scalp cooling success in patients with skin of color receiving chemotherapy for breast or non-small cell lung cancer.

This study is being conducted because prior studies have found scalp cooling to be highly effective in preventing hair loss resulting from chemotherapy. However, minority representation was largely limited in completed trials. A recent study found that scalp cooling devices are less efficacious in patients of color, likely because patients of color have hair is predominantly types 3 (curly) and 4 (kinky), that tend to become bulkier when wet and can interfere with scalp cooling cap fitting. The investigators plan to test

two techniques aimed at improving scalp cooling efficacy in patients of color through hairstyling methods that minimise hair volume in order to increase cooling cap to scalp contact: 1) cornrows/braids/twists or 2) water/ conditioner emulsion on hair. Preliminary data shows that breast cancer patients with type 3 or 4 hair receiving taxane chemotherapy and scalp cooling using these techniques to prepare the hair for scalp cooling cap fitting all experienced hair preservation. Additionally, the investigators will also assess persistent chemotherapy-induced alopecia outcomes and incidence by following patients up to 6 months after completing treatment. Finally, specific gene expression changes in taxane-induced chemotherapy-induced alopecia in vitro have been described previously. The investigators will test the hypothesis that scalp cooling reverses such changes in chemotherapy-induced alopecia, assess for biomarkers predictive for scalp cooling success, and investigate persistent chemotherapy-induced alopecia molecular mechanisms using non-invasive transcriptome sequencing on plucked hair follicles. Estimated enrolment is 30 participants.

# Safety of Lower Scalp Cooling Temperature to Prevent Hair Loss From Chemotherapy in Breast Cancer Patients

Location: Memorial Sloan Kettering
Cancer Center

This study is conducted to determine if using the Paxman Scalp Cooling System at temperatures lower than the current standard is a safe and tolerable approach to prevent hair loss in breast cancer patients receiving chemotherapy.

This is a single-centre, prospective study to evaluate the safety and tolerability of lower temperature (-7.5°C and -10°C) of the Paxman Scalp Cooling System (PSCS) to prevent alopecia resulting from adjuvant anthracycline plus cyclophosphamide and paclitaxel (AC-T) regimens in patients with newly diagnosed stage I-III breast cancer.

The primary objective of this study is to assess the safety and tolerability of the PSCS at lower temperatures (-7.5°C, -10°C) in preventing chemotherapyinduced alopecia (CIA) in women with

newly diagnosed early stage breast cancer receiving adjuvant doxorubicin plus cyclophosphamide (AC) followed by paclitaxel (T) at the completion of AC and T, which will be determined by the ability of patients to complete scalp cooling without any dose-limiting toxicities (DLT) during the 16-20 week period. Estimated enrolment 34 patients.

# Cooling Cap Trial to Prevent Permanent Chemotherapy-induced Alopecia in Breast Cancer Patients

Location: Samsung Medical Center, Seou

Adjuvant chemotherapy decreases the risk of recurrence. However, it has distressing side effects, including alopecia. Chemotherapy-induced alopecia (CIA) is a common and distressing side effect of many chemotherapy drugs. In previous studies, more than half of the breast cancer patients experienced higher distress due to CIA during cancer treatment, and this distress was strongly associated with negative body image, overall health status, and psychosocial well-being. Recently scalp cooling has been known to be one of the effective options for hair loss prevention. However, there was little information regarding the effect on prevention of permanent CIA (PCIA). This study aims to examine the impact of scalp cooling on prevention of PCIA as well as CIA.

Female adults who are newly diagnosed with stage 1-3 breast cancer and aged less than 70 years will be screened for plan of undergoing Adriamycin or/ and Taxane regimen as neoadjuvant or adjuvant chemotherapy. Eligible patients will be randomly assigned to intervention or control groups (2:1 ratio). Patients in the intervention group will have applied scalp cooling during 4 or 6 cycles of their chemotherapy whereas participants in the control group will be observed.

The objective of the study is to examine whether Paxman scalp cooling system is effective in reducing PCIA in women with breast cancer undergoing neoadjuvant or adjuvant chemotherapy. In addition, impact of Paxman scalp cooling on prevention of CIA, alopecia-related distress, quality of life and patient reported alopecia related side effects will be also explored. Estimated enrolment is 170 patients.

# Alopecia Prevention Scalp Cooling in Chinese Breast Cancer Patients

Location: Chinese University of Hong Kong

The Orbis Paxman Hair Loss Prevention System was introduced to Hong Kong in 2017. Although this device has been widely used in the United States, Europe and Australia, acceptability, efficacy and safety data in Chinese patients have not yet been available. The objective of this prospective study is to collect clinical data in Chinese patients using the Orbis Paxman Hair Loss Prevention System to prevent chemotherapy-induced alopecia.

This project seeks to demonstrate that the Orbis Paxman Hair Loss Prevention System is safe and effective in reducing chemotherapy-induced alopecia in woman with breast cancer undergoing neoadjuvant or adjuvant chemotherapy. Estimated enrolment 100 patients.

# Study Of Cold Cap Therapy For Prevention of Hairloss in Pediatric Patients Receiving Chemotherapy For Non-Malignant Indications and Solid Tumours

Location: St. Jude Children's Research Hospital

This study is conducted to see if the Paxman scalp cooling device can prevent hair loss in pediatric patients receiving chemotherapy for non-cancerous conditions or solid tumours.

The primary objective of this study is to assess the safety and feasibility for the usage of the scalp cooling device, while exploratory objectives are to assess the incidence and intensity of chemotherapy induced hair loss when using scalp cooling. Estimated enrolment of 40 participants.

 $\sim$  53

# HairToStay's impact report reveals major milestones

In February 2024, HairToStay released its Annual Impact Report for 2023, sharing significant statistics and milestones in relation to scalp cooling in the United States. HairToStay is the only national non-profit organisation in the United States dedicated to helping low-income cancer patients afford scalp cooling.

In the US, while the process of insurance reimbursement for scalp cooling has begun, there is a way to go until all sites offering Paxman scalp cooling are able to bill insurers directly. Therefore, many patients find themselves in a position where they are unable to afford the out-of-pocket expense of scalp cooling treatment. This can often result in a patient deciding not to scalp cool, not through choice but through financial restriction.

HairToStay had an incredible year in 2023 facilitating access to scalp cooling and changing the experience of cancer treatment for many patients. Subsidies from HairToStay ranged from \$1,000 to \$1,500 and 99.9% of applicants reported that the subsidy was an important factor in deciding whether to scalp cool.

A large majority of recipients of a HairToStay subsidy reported a positive impact on their everyday interactions including their sense of well-being, privacy and control and desire to be social.

Paxman are incredibly grateful for the work HairToStay does to increase access to scalp cooling for as many patients as possible, particularly for those unable to afford the treatment, who would have otherwise gone without the opportunity to preserve and protect their hair. We're looking forward to seeing new milestones met by the organisation in 2024 as we work together to make scalp cooling accessible for all.

5,000+

subsidies awarded between 2016 & 2023

\$1.1m

committed to recipients of subsidies

1,200

subsidies awareded in

\$1.7m

raised from over 345

800

from 2022

19%

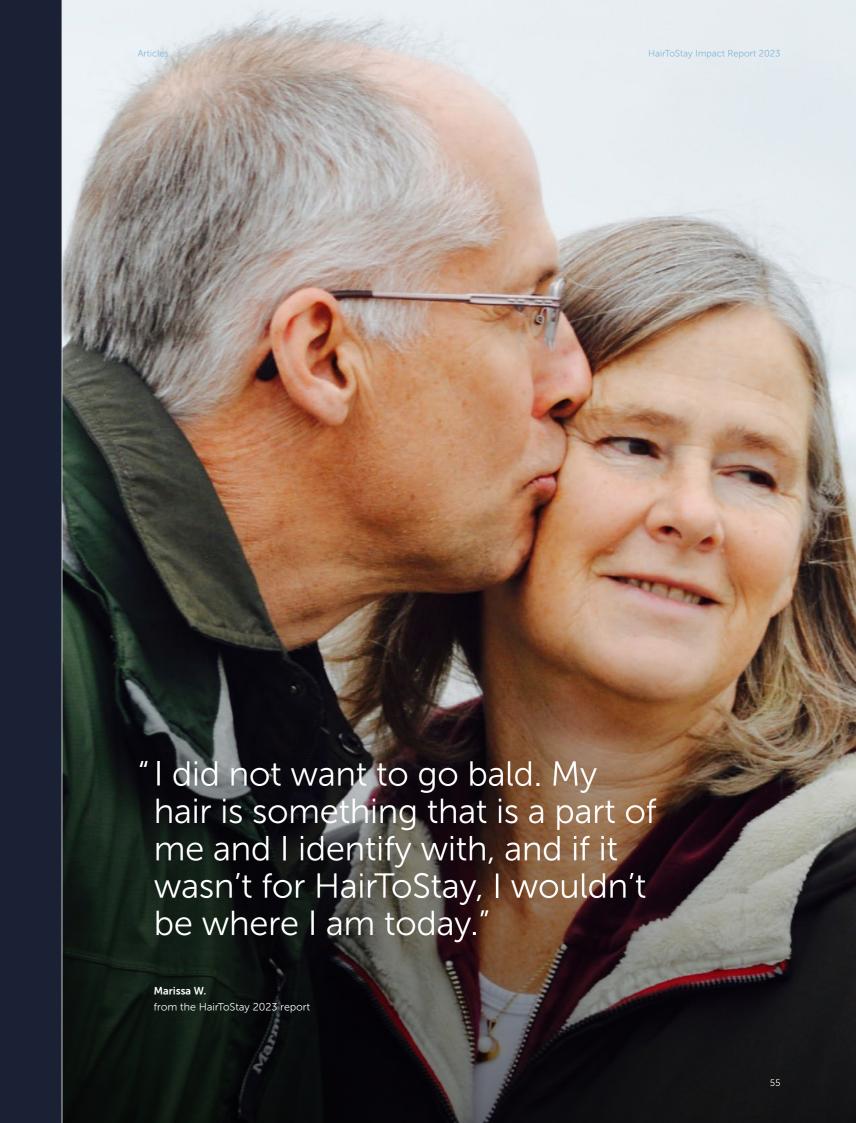
increase in applicants

mechanised scalp cooling sites in the US 23

recipients approved every week during 2023 on average

550

Paxman Scalp Cooling sites in the US



# Annual Report Paxman AB (publ) Jan - Dec 2023 PAXMAN Help me decide, should I scalp cool? An introduction to scalp cooling

# A focus on enhanced patient education

→ Revitalised literature and our patient-facing website

In 2023, Paxman focused its external communications efforts in elevating its messaging and educational resources for patients. The result was the launch of an updated Coldcap.com and supporting literature.

Coldcap.com was first launched in 2020 providing a patient-facing website with step-by-step information guiding patients through their cold capping experience. Although the website made a significantly positive impact on moderating patient expectation and ensuring understanding of the treatment beginning to end, leading to higher levels of scalp cooling continuation, the website was looking tired in comparison to the updated paxmanscalpcooling.com. There had also been so much change since the website originally launched in early 2020 in the world at large, but also in the way we were able to communicate with and support patients more comprehensively, that needed to be reflected in the dominant patient resource.

Recognising the importance of easily digestible information for cancer patients already grappling with overwhelming challenges, the educational improvement initiative centered around the Coldcap.

com website, with accompanying literature as an additional support. The platform needed to serve as a comprehensive resource for patients, enabling easy access to essential information regarding potential or upcoming scalp cooling treatment facilitating informed decision making and a simple guide through the preparation required to get the most from the treatment

The first port of call was to redesign the user interface and simplify navigation, more clearly identifying and accommodating for the various stages of a patient's journey with a more relatable and empathetic tone. The website equips chemotherapy patients with a substantial knowledge of scalp cooling tailored to each stage of their journey, encouraging informed decisions with the latest available information. It is also now available in over 40 languages.

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Articles

A focus on enhanced patient education

Articles







# Making a decision

This section focuses on introducing patients to the idea of scalp cooling and how it works, self-assessing their suitability, how to access scalp cooling, and helping patients make an informed decision about their treatment.

# Getting the most from scalp cooling

This segment is tailored to individuals who have chosen to undergo scalp cooling. It empowers them to better take ownership of their treatment and optimise their scalp cooling experience. It aims to also set realistic expectations with regards to hair retention outcomes.

# Supportive haircare

Dedicated to practical advice and guidance on scalp cooling, this section assists in identifying hair types and guides patients through haircare from the preliminary stages through to post-treatment. It includes frequently asked questions around hair care and provides a range of recommended hair care products that are safe for use while scalp cooling. Additionally, the haircare section offers a guide specifically for hairdressers, educating another support network for patients.

# New coldcap.com website key features

Paxman has incorporated a series of key features into the revamped Coldcap.com website to enhance the user experience. The 'How-to' video library demonstrates to patients how to prepare for their scalp cooling treatment in advance, including preparing their hair and putting their cap on properly – fundamental groundwork for a successful scalp cooling treatment.

The website also aims to develop realistic expectations for patients with the support of the Scalp Cooling Outcomes Calculator, allowing them to gain an indication of the hair retention they can expect, depending on their chemotherapy regimen, based on data from the Dutch Scalp Cooling Registry. In addition, the website offers a Paxman Scalp Cooling Systems Locator, to find their nearest Paxman system.

Paxman believes that the new coldcap. com will provide more effective guidance for patients and will add an additional layer of support for clinical teams, ensuring the best possible outcomes when it comes to scalp cooling.

All the information that can be found on coldcap.com is replicated and supported with new patient-facing literature, which is included in patient Cap Kits in the US and is available to all cancer centres free of charge.

Finally, the website has a translation function which facilitates access to information in more than 40 languages. This ensures the information provided on coldcap.com and the Paxman patient experience is as accessible to patients as possible, moving Paxman closer to its goal of making scalp cooling available to everyone who wants it.

# 2024 website and literature improvements

Continuing the trend of improvement to existing resources, 2024 sees the redesign of Paxman.se, a Paxman website aimed at investors and corporate affairs. The fresh new look has additional content aimed at attracting new investors and better encompassing what Paxman does, as well as easier access to financial reports.

As we move in to 2024, the marketing department will pivot from the 2023 focus of patient communication towards the clinical demographic.

Work has been underway for a number of months, with several new pieces of literature nearing completion that will focus on educating clinicians, increasing their knowledge of the benefits of scalp cooling beyond hair retention and ensuring that scalp cooling protocols are adhered to.

"We are delighted with how positive the patient feedback has been on the new coldcap.com and literature."

Susy Brown, Head of Marketing

238%

A 238% increase in website impressions

55%

A 55% increase in total

30%

Bounce rate dowr

# Website statistics since October 2023

The new coldcap.com website was launched in early October 2023. In the six months since launch, Paxman has noted considerable improvement in website analytics, including over 10,000 sessions on the scalp cooling outcomes calculator page, an average of 5mins 14s spent on 'Putting the cap on' How-to video and an increase in organic traffic engagement from 9.49% to 73.4%.



At Paxman, we are always happy to hear and receive inspiring scalp cooling stories from across the world. This French case study below is from the perspective of Armelle, diagnosed with ovarian cancer, who had lost hope after she lost her hair with her first regimen of chemotherapy, which also proved ineffective:

"Diagnosed with a stage II ovarian cancer in January 2021, I had major surgery (10 hours in the operating room) followed by a classic regimen of 6 sessions of taxol & carboplatin, and six sessions of taxol and gemcitabine, which both led to hair loss...

With my body resisting these regimens, I saw myself coming the end of my path... My hair grew back slowly and with a completely different texture. It was very curly, coarse, and dull but it was there..."

During her second regimen of Taxol and Avastin, she was offered scalp cooling on a clinical trial. Although the nurses informed her there was no guarantee of success, testimonials from other chemotherapy patients gave Armelle an idea of what to expect from scalp cooling and was very happy with the results.

"Every week from March to the end of October I received treatment with the Paxman cap. My hair stayed in place which gave me joy. When I returned home, I washed my hair and it didn't fall out.

Testimonials are very important for me. Knowing that during and after this illness, I no longer needed to wear a wig or a scarf, it gave me the feeling of being like everyone else.

# Thank you for this beautiful invention."

Currently, it is not known why certain people retain more hair than others. However, more and more frequently, Paxman are finding that the primary motivation to scalp cool has been to protect the follicles and ensure faster regrowth rather than focusing on hair retention.

There are a number of complex motivations when it comes to patients choosing scalp cooling, often beyond the first thoughts of retaining hair during treatment. Emma, from the UK, describes how scalp cooling helped her to protect her child from having to share her

diagnosis and helped her to move on:

"I feel so utterly grateful, I hated wearing a wig. I felt so self-conscious and was trying to hide my diagnosis. My daughter started school when I was midway through treatment and I didn't want anyone to make any comments to her. She was so young I tried to protect her from my diagnosis in every way possible and being able to discard the wig so soon after finishing treatment and everyone thinking I had just had my hair cut short was a huge relief."

Emma felt that the benefits of scalp cooling greatly outweighed the extra time spent in the chair.

"The time it adds to your treatment is a drop in the ocean. Cancer treatment takes so much from you which includes your physical appearance and the change is a constant reminder. My hair regrowth has been a huge part of my moving forward and feeling better and the cold cap has given me a piece of myself that cancer had stolen much sooner."

The structure of the UK Healthcare System means that scalp cooling is offered free at the point of access, however, in other markets, it is not always the case. In the United States, until recently, choosing scalp cooling as a part of treatment meant an out-of-pocket cost, which made scalp cooling inaccessible to many, despite financial assistance being available via some charities.

A development of particular importance has been the increased access to scalp cooling that has been facilitated in the United States through insurance reimbursement beginning to cover the costs of the treatment. This has meant that patients being treated at sites that have converted to the new Paxman business model are able to bill patient's insurers directly for scalp cooling treatment rather than paying out of pocket. This has led to a number of inspiring patient stories where, without reimbursement, scalp cooling would not be possible.

This patient story is from Nancy who was diagnosed with stage 4 oesophageal cancer and received scalp cooling during chemotherapy treatment in 2023. For Nancy, her scalp cooling treatment

was free at the point of access due to reimbursement.

"I was very focused on doing anything and everything to try and keep my hair."

When asked about her scalp cooling experience Nancy said:

"It was challenging and pretty accurate from talking to the sales rep Amber. She was a tremendous help.

I would definitely recommend [scalp cooling] and let [people] know that it is challenging but it is so worth it."

Diane from New Jersey also received scalp cooling during chemotherapy treatment in 2023. Her treatment was recommended by her oncologist and was free at point of access.

"I was cold at first but not too uncomfortable. It made a long day with the extra 90 minutes at the end but was worth it.

I was so happy not to lose my hair. I just didn't want to lose my hair if I can try to save it."

When asked whether Diane would recommend scalp cooling to others, her feedback was very positive:

"Yes definitely. When I was done with taxol and just doing herceptin I did talk to new patients starting out to show my results."

These experiences from the US highlight how important access to scalp cooling is, especially for those who may have found it difficult to pay out-of-pocket.

To read more case studies, visit coldcap.com.



Paxman is the superior global market leader.

# General Targets and Outlook

The company's long-term goal is that all patients undergoing chemotherapy shall have access to scalp cooling, no matter their financial situation, gender, age or ethnicity, and that the Paxman Scalp Cooling System will be the first choice for cancer patients all over the world.

Paxman is the superior global market leader with nearly 6,000 sold and/or installed systems in Europe, North-, Central- and South America, Asia and Oceania. In addition to the United States, Asia is becoming an increasingly important region for the company, with Japan as the single leading market.

The company has taken big strides in its distributor models both in Canada, with the incorporation of Paxman Canada, and Germany. Through greater ownership of its German distributor, the company plans to take advantage of significant opportunities within the German market.

Market approval (Shonin) in Japan for use in connection with treatment of solid tumours such as breast cancer was received in March 2019, and extensive marketing activities were then initiated together with the distributor CMI. With a recurring revenue model launched, Japan is set to be a strong growth market in the future. In addition to Japan, Paxman is already established in additional Asian markets such as India, Malaysia, Singapore and Pakistan, and the company is finalising a distribution agreement with Concord Medical for a launch into the very large Chinese market.

To further increase the global growth rate, Paxman's commercialisation strategy continues to focus on strengthening the company's sales organisation with direct presence as well as new and established distribution partners in key regional markets

including China, India, Europe and the Middle East, supported by enhanced marketing support based in the UK. Paxman will also continue to advance the company's reimbursement strategy in the USA. Customers started to implement the new buy-andbill model in 2022 to facilitate reimbursement using established CPT III codes with leading institutions now already using this model resulting in Paxman seeing strong coverage in 2023. Paxman will continue to invest in its R&D pipeline in both scalp cooling and cryotherapy to prevent chemotherapyinduced peripheral neuropathy (CIPN). Paxman Limb Cryocompression System (PLCS) devices have been deployed to over 20 clinical study sites for efficacy studies in Singapore and the United States which will continue into 2024.

Paxman will also continue the transition from selling equipment to clinics to generating income for each treatment in more countries in addition to the United States, where this is already fully implemented. A similar business model is used in Canada, as well as in Mexico in collaboration with the licensing partner, and a modified model is used in Japan where the company sells scalp cooling systems to the distributor and receives payment for each single-patient-use cooling cap sold. This model will also gradually be implemented in additional markets when the company is offering or upgrading existing equipment to its PSCS model.

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Paxman and its people



Paxman and its people

A successful year in terms of investment both in Paxman and its people, 2023 saw landmark results in engagement and investment in its people, charitable work, and government funding.

# **Engagement Survey**

Paxman is committed to fostering a vibrant, positive company culture and values the perspective of its teams. Consequently, the company regularly gains feedback from its people with an annual engagement survey, most recently taken in November 2023.

The surveys have been a useful tool in understanding the unique fabric of Paxman's organisational culture. Results have previously led to company initiatives, spearheaded by Kathy Morris, our Culture & Learning Development Manager, and aimed at at supporting employees, growing their knowledge, and allowing them to thrive. The 2023 survey delivered promising results across the board that have helped Paxman to gauge the success of these initiatives and the company culture overall.

### Survey results

The employee engagement survey was conducted across the Paxman group with a 95% completion rate, compared to a platform average of 72%, making Paxman one of the most engaged employers surveyed.

The Paxman engagement survey highlighted an area of improvement for the company in 2024. Whilst still receiving a high score, it was felt that inter-departmental communication could be improved. As a business that always strives to do better, Paxman has made committed to communication and refining this skill as its area of focus for 2024.

94% 94%

95%

Overall engagement score



92% agree that their manager encourages and supports their development

00000

9/10 agree that their manager communicates in an open and honest way

87%

feel valued by **Paxman** 

97%

understand the company values

97%

would recommend

Paxman as a great

place to work

88%

feel that senior leaders are taking the company in the right direction 95%

agree that **Paxman** cares about their wellbeing

95%

feel they belong at **Paxman** 

9/10 are satisfied with the flexibility they have in their work schedules

98%

understand how their work contribute: to the success of **Paxman** 



84%

are motivated to do their best work



Area of Focus for 2024

5/10

feel there is good ommunication between different teams and departments 98%

are proud to work for **Paxman**  85%

feel they are treated fairly, equally and with respect

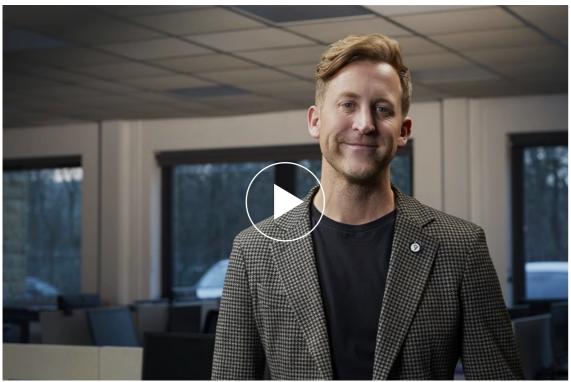
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Paxman and its people

# It's making Paxman a better place to work



we sty ork s-ca. gov. uk/a-may or al-combined-authority/may or al-pledges/fair-work-charter/paxman-scalp-cooling/linear-scale-cooling-coo

# **Investing in people**

Paxman is committed to learning and development within the organisation and is part of the West Yorkshire Combined Authority Fair Work Charter. It is designed to promote and recognise the positive impact of fair work on businesses and their people. Fair work can include good pay, fair and flexible working conditions, as well as greater wellbeing, diversity, and social mobility within the workplace. Its core pillars are centered around employee voice, fulfilment, opportunity, wellbeing and security.

Watch CEO Richard Paxman talk about the Fair Work Charter and the Paxman People Pathway (PPP) here.

Paxman believes strongly in investing in its people and continues to run its PPP to allow individuals to deliver their best work, supporting them to achieve their personal career goals within the business.

It is important that people at Paxman are valued and feel satisfaction in their roles and work. With the PPP, colleagues can see how their targets and professional development contribute to the wider business objectives.

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People are at the heart of our organisation and we've got to do the right thing by the people that work with us.

### Cultural initiatives

Paxman is now an international business with teams and distributors all over the world. As such, it's important that individuals are understanding of other cultures and customs in order to better do business and ensure success.

As a result of the Paxman engagement survey, the company has established regular cultural sessions which have proven to be very popular. These sessions are centred around a particular country or culture led by a Paxman employee originating from that region with India, France and Brazil being introduced so far. Other key country and community sessions are planned for 2024.

# Increased focus on individuals' wellbeing

Healthy colleagues make a healthy business. Paxman understands that employee wellbeing is a key investment into future prosperity. As a result of the annual survey, the business has expanded on its duty of care to encompass mental health support. Monthly mental health drop-in sessions have been available for some time, and this continues to help people feel supported in the crossover between work and wellbeing.

In addition, the company benefits from quarterly seminars and support from external speakers, each session delivering relatable wellbeing support. Themes this year will include developing healthy routines, managing anxiety and depression, sleep hygiene and healthy eating.

### Supporting the community

Paxman allows its people to take a paid volunteering day once a year to give back to the community in a capacity that the individual feels passionate about. In addition to individual volunteering, the business assists Holmfirth High School in preparing their pupils for the world of work. The people at Paxman have dedicated time to supporting pupils through mock interviews, helping pupils to gain important life skills and positively impacting future generations' careers. Paxman will also be hosting a number of students in work experience roles this

# Diversity & inclusion

At Paxman, we believe in the power of inclusivity and representation and wish to ensure that anyone who wishes to access to scalp cooling can. That belief extends to our internal activities, fostering an inclusive environment where diversity is embraced and celebrated.

Throughout 2023, Paxman was proud to deliver a number of seminars around diversity and inclusion in the workplace for the team. Initiatives such as these help refine our culture of respect and acceptance and allow the company to work more cohesively as an international team. It opens us up to new perspectives and improves decision-making capabilities. Moreover, diversity & inclusion initiatives make Paxman a more attractive place to work and do business with.

# More responsible manufacturing

In alignment with the company's environmental and social commitments, the Paxman design team are exploring new and innovative approaches to manufacturing, emphasising the use of sustainable and recyclable materials. This collaborative effort, spanning two years and conducted in partnership with the University of Huddersfield, is nearing a promising and positive outcome. Paxman anticipate that the results will not only advance the sustainability of production processes but also enhance the cap quality for the benefit of patients in the future.

Paxman works very closely with the UK's National Health Service (NHS) with 99% coverage in the country. The company is therefore working towards an environmental policy that aligns with the NHS Carbon Footprint targets. Their targets are as follows:

- For emissions under direct control the NHS will reach net zero by 2040, with an ambition to reach an 80% reduction by 2028 to 2032.
- For the emissions under their influence the NHS will reach net zero by 2045, with an ambition to reach an 80% reduction by 2036 to 2039.

Paxman is addressing manufacturing and sustainability challenges through innovative approaches such as a focus on eco-design and circular economy principles to advance technological limitations and help reach the outlined targets. Paxman also undertakes building and renovation works where possible to improve energy efficiency and accessibility to manufacturing and office premises.

# England's third investment

In November 2023, the UK government designated West Yorkshire as its third Investment Zone, an initiative intended to create new jobs, offer skills training, and support businesses in the area over the next 5 years.

With government-backed funding and tax relief, Paxman is investing £5 million to bring our innovative healthcare products to the global market and to help turn West Yorkshire into a centre of MedTech advancement. Both the Chancellor of the Exchequer and the Mayor of West Yorkshire launched the Investment Zone at the Paxman offices in Huddersfield.

This regional and national recognition places Paxman at the forefront of MedTech innovation in West Yorkshire.



Paxman is investing £5 million to bring our innovative healthcare products to the global market and to help turn West Yorkshire into a centre of MedTech advancement.

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# THE PEOPLE BEHIND PAXMAN

All holdings refer to current holdings at the time of publication for this annual report.

# **Management Team**

Introducing the Paxman Management Team





# Richard Paxman, OBE Emelie Gustafsson

CEO and member of the board since February 10th, 2017

from global market development, including design of clinical studies and regulatory approvals specifically related to scalp cooling. He has worked for the company since 2009. Before Richard Paxman started his assignment at Paxman double bachelor's degree in economics Coolers Ltd he held a leading position at Brewfitt Ltd.

CFO since March 1st, 2020

Richard Paxman has extensive experience Since 2015, Emelie Gustafsson is the CFO of the CIMON group, one of PAXMAN's largest shareholders, and she is also a board member of several companies in the CIMON Group. She has a solid academic background with a and tax law at Kristianstad University.

Born: 1983

Holding: 1,268,000 shares

Born: 1980 Holding: 2,000 shares

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Our People

# **Board of Directors**

Introducing the Paxman Board of Directors



# **Per-Anders Johansson**

Chairman of the board since December 1st, 2016

Per-Anders Johansson has extensive experience from technology and development companies and is an active investor through CIMON AB. CIMON AB has invested in and developed several successful companies. Per-Anders Johansson also has long industrial experience from the Karlshamns group, Nordico and Ellos where he has held leading positions.



# **Robert Kelly**

Member of the board since January 10th, 2017

Robert Kelly is a lawyer specialised in corporate law.He is also an authorized accountant and has extensive experience from management of both private and public companies before his career as a lawyer. Robert Kelly has also been CFO and later CEO of the technology company, Minorplanet Systems plc, that was listed on the London Stock Exchange. Before that he held leading positions at Caudwell Group and Kinuck



# **Björn Littorin**

Member of the board since December 1st, 2016

Björn Littorin has extensive experience as a management consultant, business leader and board member of both manufacturing and service-based companies as well as 20 years' experience as Investment Manager and board member of technology and development companies, mostly within medical technology. Some of the companies where he has been CEO or board member have been listed on the Stockholm Stock Exchange. He has also been a board member of Paxman Group Ltd and its subsidiary Paxman Coolers Ltd since 2001.



Holding: 1,286,992 shares via CIMON Venture Trust AB, 5,000 shares privately held, 310,000 shares via NOMIC AB. Born: 1961

Holding: 111,250 shares

Born: 1947

Holding: 465,076 shares



# Glenn Paxman

Member of the board since January 10th, 2017

Glenn Paxman is the founder of Paxman and responsible for the design and development of the scalp cooler. He has over 40 years of business experience including management strategy and product design of medtech products, and over 25 years of experience in developing manufacturing processes for the pharmaceutical and chemical industry sectors. Glenn is also the founder and chairman of Brewfitt Ltd. Currently, his role in the company is to support the board and management in strategic matters and assist in growth-stimulating projects on the American market.



# Richard Paxman, OBE

CEO and member of the board since February 10th, 2017

Richard Paxman has extensive experience from global market development, including design of clinical studies and regulatory approvals specifically related to scalp cooling. He has worked for the company since 2009. Before Richard Paxman started his assignment at Paxman Coolers Ltd he held a leading position at Brewfitt Ltd.



# Maria Bech

Member of the board since January 10th, 2017

Maria Bech has extensive experience from several companies in the biotech and pharmaceutical sector, and has held leading positions including Clinical Project Manager and Study Delivery Director at AstraZeneca, Director Clinical Operations and Principal Project Manager at Karo Bio AB and Chief Scientific Officer at Smartfish AB. Maria is a board member in Neuronano AB and Iconovo AB, and CEO in EpiEndo Pharmaceuticals.

Born: 1956

Holding: 5,757,395 shares

Born: 1983

Holding: 1,268,000 shares

Born: 1968

Holding: 4,200 shares held directly and 4,500 held through the company Bech Pharma Consulting AB

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Directors Report

# DIRECTORS REPORT 2023

The Board of Directors and the Chief Executive Officer of Paxman AB (publ), hereby submit the annual accounts and consolidated accounts for the financial year 1 January—31 December 2023.

Amounts in the annual report are reported in thousands of Swedish kronor (TSEK), unless otherwise stated.

# MULTI-YEAR SUMMARY FOR THE GROUP

	2023	2022	2021	2020
Total operating income	220,608	156,745	104,708	85,478
EBITDA <sup>1)</sup>	31,229	16,175	2,882	-1,045
Operating profit/loss	12,619	-1,243	-10,587	-11,690
Profit/loss after net financial items	7,969	-8,562	-12,670	-20,096
Balance sheet total	167,124	173,960	166,341	77,011
Assets as percentage of equity <sup>2)</sup>	73.4%	65.6%	75.6%	14.2%
Number of employees at end of period	91	78	56	51

# MULTI-YEAR SUMMARY FOR THE PARENT COMPANY

	2023	2022	2021	2020
Total operating income	2,207	1,295	244	
EBITDA <sup>1)</sup>	-3,851	-4,042	-4,171	-3,622
Operating profit/loss	-3,874	-4,065	-4,179	-3,622
Profit/loss after net financial items	-1,151	-2,850	-4,676	-5,284
Balance sheet total	160,716	162,320	165,010	73,799
Assets as percentage of equity <sup>2)</sup>	99.6%	99.3%	99.3%	53.8%
Number of employees at end of period	1	1	1	-

1) Earnings before interest income, interest expenses, tax and depreciation.

2) Adjusted equity as a percentage of total assets.

# **Corporate Information**

# The Company

Paxman AB (publ), with corporate registration number 559079-3898, was established in October 2016. Its current name and operations were registered on 14 December 2016. Paxman AB is a public limited liability company, and its legal form is thus regulated by the Swedish Companies' Act (2005:551). The parent company has its registered once in Karlshamn, at Pirgatan 13, SE-374 35 KARLSHAMN. Production and sales are handled by the UK subsidiary Paxman Coolers Ltd, International House, Penistone Road, Fenay Bridge, HD8 OLE HUDDERSFIELD, England. The group also has a

subsidiary in the US, Paxman US, Inc. with its registered office in Houston, Texas and in Canada, Paxman Canada, based in Toronto. Paxman Coolers Ltd as well as Paxman US, Inc. are wholly owned subsidiaries of Paxman Group Ltd, in its turn a fully owned subsidiary of Paxman AB (publ).

Paxman AB has appointed FNCA Sweden AB (tel +46.8 - 528.003.99, info@fnca.se) its Certified Adviser.

# **Earnings and Financial Position**

- The group's turnover amounted to 210,117 (145,921) TSEK.
- The group's net profit/loss was 8,330 (-10,324) TSEK, with profit/loss per share amounting to 0.44 (-0.54) SEK.
- Consolidated equity as of 31 December totalled 122,616 (114,198) TSEK. The equity/assets ratio for the group was 73.4 (65.6)%
- The cash and bank balances for the group was 24,981 (38,092) TSEK.
- At year end, the group had 17,531 (16,985) TSEK in external interest bearing liabilities, of which 11,038 (12,728) TSEK were current.
- Cash flow from operating activities amounted to 15,632

   (2,686) TSEK, and this year's net investments affecting cash flow to -25,329 (-36,691) TSEK. Cash and cash equivalents decreased by 13,111 (34,174) TSEK during the year.

# The Parent Company

- The company's turnover amounted to 2,207 (1,295) TSEK.
- The parent company's cash and bank balances amounted to 18,013 (36,400) TSEK on 31 December.
- Cash flow from operating activities was -1,664 (-2,832)
   TSEK. Net investments affecting cash flow for the year amounted to 0 (0) TSEK.
- The parent company had 1 (1) employee on the balance sheet date.

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# Significant developments in 2023

In the beginning of the year Paxman announced that it received EU Medical Device Regulation (MDR) certification from its Notified Body, the British Standards Institution (BSI). Paxman is amongst the latest companies to achieve MDR approval, reaffirming its commitment to the market, its customers and, most importantly, the patients who will continue to benefit from the use of the Paxman Scalp Cooling System.

In January, the company incorporated Paxman Canada Inc., as a corporation in the province of Ontario. Following a successful pilot of the business through 2021 and 2022 the decision was taken to fully launch the company and incorporate. The company shall operate a hybrid business model offering pay for use services through Paxman personnel in large academic and high volume cancer centres and the sale of capital equipment to smaller regional cancer centres.

Paxman attended its first exhibition in relation to the promotion and marketing of the company and its products in China. Paxman, along with it's partner Concord Medical was exhibiting at BEYOND 2023 International Technology Innovation Expo in Macau. The exhibition took place at the Venetian Macao Convention and Exhibition Centre for 3 days from May 10-12 2023.

Paxman have shipped its first clinical trial Paxman Limb Crycocompression Systems (PLCS) to the USA in the months of April and May for the initiation of the ICE COMPRESS: Randomized Trial of Limb Cryocompression versus Continuous Compression versus Low Cyclic Compression for the Prevention of Taxane-Induced Peripheral Neuropathy. Sites among the first to participate include Columbia University Medical Center, University of Washington Medical Center and Caromont Regional Medical Center.

In June Paxman announced that the Palmetto Medicare Administrative Contractor (MAC) had issued a Proposed Local Coverage Determination (LCD) to provide coverage guidance for

Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia. The draft policy recommends coverage be considered reasonable and necessary for FDA cleared devices as long as the patient does not have any of the listed contraindications. This is the first LCD that has been proposed for scalp cooling. The proposed scalp cooling LCD was discussed at two open meetings of the Palmetto GBA in July. Palmetto GBA is soliciting comments on these proposed LCDs from physicians, manufacturers, suppliers and other professionals involved in the ordering and/or provisioning of these items. If approved, the Palmetto LCD would provide a pathway for successful reimbursement of Medicare scalp cooling claims for patients in the seven-state service area early in 2024.

In June Richard Paxman was Honoured in the British King's first Birthday Honours list. Richard has been honoured with an OBE for services to International Trade. Special honours such as OBE, MBE and CBE are given to recognise people's amazing achievements and service to the country. The awards are handed out twice a year in the UK. It is the second highest ranking Order of the British Empire Award and stands for Officer of the Order of the British Empire, awarded to someone for making a great impact in their line of work.

In August Paxman signed a further agreement with Concord Medical, China. Both parties have decided to cooperate in introducing the scalp cooling system before it officially obtains the medical device registration license issued by NMPA, in order to facilitate market research, customer interest data collection, and product promotion in the early stages - a further step in developing the company's profile in Asia.

Also in August Paxman signed an agreement with TACRO in China. TACRO provides medical device manufacturing companies with NMPA registration services and is headquartered in Wuhan, with branches in Beijing, Suzhou, Shenzhen, and Shanghai. Now, the total employee number is 170+. They have more than 30 regulatory consultants

assisting companies to access China's fast growing market.

Later in August Paxman signed its first Buy & Bill agreement in the state of New York, which adds a further 12 locations to its newest business model. A large initial order for cooling caps was received equating to over 2.5 MSEK.

Following the incorporation of Paxman Canada Inc. earlier in the year, the company has now officially onboarded its first Canadian employees based in Ontario. The company welcomes its new employees to the global team.

In early October Paxman passed its
Medical Device Single Audit Program
(MDSAP) surveillance audit with BSI, The
British Standards Institution. The Medical
Device Single Audit Program allows an
MDSAP recognized Auditing Organization
to conduct a single regulatory audit
of a medical device manufacturer that
satisfies the relevant requirements of the
regulatory authorities participating in the

At the beginning of October Paxman announced that the Palmetto GBA Medicare Administrative Contractor (MAC) has issued a Local Coverage Determination (LCD) to provide coverage guidance for Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia. According to the final LCD guidance from Palmetto GBA, "the use of a scalp hypothermia device that has been approved by the United States (U.S.) Food and Drug Administration (FDA) for the prevention of chemotherapy-induced alopecia (CIA) shall be considered reasonable and necessary for patients with solid tumors." In addition, there were no changes between the Proposed LCDand the Final LCD. This is the first LCD that has been approved for scalp cooling and is a result of a request made to Palmetto GBA in February 2023 by PAXMAN. This important Palmetto LCD provides a pathway for reimbursement of Medicare scalp cooling claims for patients in the seven-state service area, effective November 12, 2023. PAXMAN currently serves 55 locations within the Palmetto GBA jurisdiction.

On the 10th October our CEO, Richard Paxman, attended his OBE Investiture ceremony. Richard was presented with his OBE insignia award (medal) for services to international trade by Her Royal Highness The Princess Royal in the Grand Reception Room at Windsor Castle.

In early November Paxman announced that the US Centers for Medicare & Medicaid Services (CMS) had published the OPPS Final Rule, which continues to support scalp cooling but decreases the average rate from \$1850.50 to \$1250.50 under the Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgery Center (ASC) payment system for Calendar Year (CY) 2024

In early November, Paxman's Regional R&D Manager, Dr Aishwarya Bandla, was awarded 1 of 12 Outstanding Young Alumni Awards from the National University of Singapore, honouring her achievements and contributions in her field and recognising the impact of her work on society and the world.

Paxman conducted its annual employee engagement survey in November 2023 with a 95% completion rate, making it one of the most engaged employers on the survey platform. Survey results were highly positive, with 98% of respondents proud to work for Paxman and 97% would recommend Paxman as a great place to work. The employee engagement survey helps Paxman to gauge the internal success of its company initiatives and culture overall.

On 23rd November, Paxman, alongside 40+ Nordic companies in the life sciences sector attended Redeye Life Science Day 2023. CEO, Richard Paxman, introduced the company in a live broadcast to investors, businesses, and experts in the industry. The live stream included an initial pitch followed by an interview with Redeye research analyst, Mats Hyttinge.

Richard Paxman then visited Stora Aktiedagen in Stockholm on November 28th, where he gave a presentation to stakeholders with updates on the company's operations and development in addition to an overview on finanicals, global adoption, reimbursement, and research and development. Richard then answered questions on the company in a live Q&A session.

At the end of November, the 2023 Forward Ladies Leadership Summit and Awards brought together some of the country's most successful and influential businesswomen for a celebration of remarkable leadership and impact across the UK and the globe. Claire Paxman was awarded the Disruptor/Innovator of the Year Award.

On the 6th December, Paxman attended the Franco-British Trade & Innovation Awards in Paris, winning SME of the Year 2023 in recognition of our growth in France. The award was presented to the company by His Majesty's Ambassador to France, Dame Menna Rawlings. Charlotte Fraser, Head of French-speaking markets, and Clément Achard, User Development and Training Officer for France received the award.

From 5th to 9th December, Paxman attended the SABCS conference in San Antonio. The San Antonio Breast Cancer Symposium is designed to provide state-of-the-art information on the experimental biology, aetiology, prevention, diagnosis, and therapy of breast cancer and premalignant breast disease. With an international audience of academic and private physicians and researchers, Paxman was able to reinforce established relationships and forge new ones.

# **Employees**

As of 31 December 2023, the Group had a total of 91 employees, 1 by Paxman AB 68 by Paxman Coolers Ltd, 12 by Paxman US Inc and 10 by Paxman Canada Inc.

As of 31 December 2022, the Group had a total of 78 employees, 1 by Paxman AB, 65 by Paxman Coolers Ltd and 12 by Paxman US, Inc

### Incentive programmes

At the Annual General Meeting on May 23, 2019, it was resolved to issue warrants to employees of the subsidiary Paxman Coolers Ltd. A total of 68,478 warrants have been issued, with the right to subscribe for a maximum of 68,478 new shares in Paxman AB. The warrants entitle the holder to subscribe for shares from June 2020 until June 2029, at a subscription price of SEK 65.37 per share. Upon full subscription, the dilution effect amounts to 0.4% of the total number of shares in the company. The warrants have been issued free of charge and the benefit has therefore, according to current accounting principles, been valued at market value.

In total, The group's personnel costs have been charged with 1.4 MSEK over three years (without any cash flow effect) with the last adjustment date 2022-06-30.

# Environment

The Paxman group conducts no operations covered by, or requiring concessions in accordance with, the Environmental Code.

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# Proposed Appropriation of Retained Earnings

Retained earnings at the disposal of the annual general meeting

161,211
Retained earnings (TSEK)

-1,151
Profit/loss for the year (TSEK)

The board of directors and the CEO proposes that the retained earnings are to be appropriated as follows

160,060
Caried forward (TSEK)

Paxman's net profit/loss for the accounting year 2023, as well as the company's financial position as at 31 December 2023, are disclosed in the following income statements, balance sheets and cash flow statements.

# CONSOLIDATED INCOME STATEMENT

TSEK	JAN-DEC 2023	JAN-DEC 2022
Operating income		
Net sales	210,117	145,920
Work performed by the company for	10,491	10,825
Total operating income	220,608	156,745
Operating expenses		
Raw materials and consumables	-74,189	-55,310
Other operating costs	-55,849	-35,788
Personnel costs	-59,341	-49,472
Depreciation and write-downs	-18,610	-17,418
Total operating costs	-207,989	-157,989
Operating profit/loss	12,619	-1,243
Results from financial investments		
Other interest income and similar profit/loss items	13	27
Interest expense and similar profit/loss items	-4,663	-7,346
Total result from financial investments	-4,650	-7,319
Profit/loss after financial items	7,969	-8,562
Тах	361	-1,762
Net profit/loss for the year	8,330	-10,324
Earnings per share*	0.44	-0.54

<sup>\*</sup>The calculation of net profit/loss per share is based on the average number of shares during the year.

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# CONSOLIDATED BALANCE SHEET

TSEK	31-DEC-2023	31-DEC-2022
Assets		
Fixed Assets		
Intangible fixed assets		
Development expenditure	34,157	22,701
Total intangible fixed assets	34,157	22,701
Tangible fixed assets		
Plant and machiner	35,878	40,020
Equipment, tools, fixtures and fittings	7,207	7,802
Total tangible fixed assets	43,085	47,822
Financial fixed assets		
Deferred tax asset	7,072	7,378
Shares in associated companies and jointly controlled companies	49	48
Long-term receivable	2,108	-
Total financial fixed assets	9,229	7,426
Total Fixed Assets	86,471	77,949
Current Assets		
Inventories etc		
Finished products and goods for resale	19,999	27,161
Total inventories etc	19,999	27,161
Current Receivables		
Accounts receivable - trade	27,060	19,146
Receivables from associated companies	1,282	1,292
Other reeiveables	2,141	3,707
Prepayments and accrued income	5,190	6,613
Total current receivables	35,673	30,758
Cash and bank balances	24,981	38,092
Total current assets	80,653	96,011
Total assets	167,124	173,960

TSEK	31-DEC-2023	31-DEC-2022
Equity and Liabilities		
Equity		
Share capital (19,012,500 shares)	19,012	19,012
Non-restricted equity	95,274	105,510
Profit/loss for the year	8,330	-10,324
Total equity	122,616	114,198
Provisions		
Provisions for taxes	1,660	1,451
Total provisions	1,660	1,451
Liabilities		
Non-current liabilities		
Liabilities to credit institutions	2,532	4,257
Accrued costs and prepaid income	3,961	-
Total non-current liabilities	6,493	4,257
Current liabilities		
Liabilities to credit institutions	11,038	12,728
Accounts payable - trade	15,145	24,170
Income tax liability	-	2,121
Other liabilities	2,971	2,088
Accrued costs and prepaid income	7,200	12,947
Total current liabilities	36,355	54,054
Total liabilities	42,848	58,311
Total equity and liabilities	167,124	173,960

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# CONSOLIDATED STATEMENT OF CASH FLOWS

TSEK	JAN-DEC 2023	JAN-DEC 2022
Cash Flow from Operating Activities		
Results before financial items	13,028	-1,243
Financial items	-4,650	-7,319
Income tax paid	555	-1,287
Adjustments for:		
Depreciation and write-downs	18,610	17,418
Other non-cash items	-	-1,196
Cash flow before changes in working capital	27,543	6,373
Cash flow from changes in working capital:		
Inventories, etc	7,162	-9,050
Current receivables	-7,025	-13,470
Current debts	-12,048	18,833
Cash flow from operating activities	-11,911	-3,687
Cash flow from operating activities	15,632	2,686
Investing Activities		
Investments in intangible fixed assets	-13,605	-8,352
Investments in tangible fixed assets	-11,724	-27,340
Investments in financial fixed assets	-	-999
Cash flow from investment activities	-25,329	-36,691
Financing Activities	_	_
Loans taken (+)/repayment of loans (-)	-3,414	-169
Cash flow from financing activities	-3,414	-169
Cash flow for the year	-13,111	-34,174
Cash flow for the year	-13,111	-34,1/4
Cash and cash equivalents, opening balance	38,092	72,266
Cash and cash equivalents, closing balance	24,981	38,092

# PARENT COMPANY INCOME STATEMENT

TSEK	JAN-DEC 2023	JAN-DEC 2022
Operating income		
Net sales	2,207	1,295
Total operating income	2,207	1,295
Operating expenses		
Raw materials and consumables	-932	-455
Other external expenses	-3,736	-3,875
Personnel costs	-1,390	-1,007
Depreciation and write-downs	-23	-23
Total operating costs	-6,081	-5,360
Operating profit/loss	-3,874	-4,065
Results from financial investments		
Interest income and similar profit/loss items	2,735	1,215
Interest expenses and similar profit/loss items	-12	-
Total result from financial investments	2,723	1,215
Profit after financial items	-1,151	-2,850
Tax	-	-
Net profit/loss for the year	-1,151	-2,850

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# PARENT COMPANY BALANCE SHEET

Assets		
Fixed Assets		
Tangible fixed assets		
Machinery and other technical facilities	16	39
Total tangible fixed assets	16	39
Financial assets		
Participations in group companies	26,937	26,937
Receivables from group companies	114,586	97,864
Total financial assets	141,523	124,801
Total fixed assets	141,539	124,840
Current Assets		
Current receivables		
Accounts receivable	631	65
Other receivables	464	722
Prepayments and accrued income	70	293
Total current receivables	1,165	1,080
Cash and bank balances	18,013	36,400
Total current assets	19,178	37,480
Total assets	160,717	162,320

TSEK	31-DEC-2023	31-DEC-2022
Equity and liabilities		
Equity		
Restricted equity		
Share capital (19,012,500 shares)	19,012	19,012
Total restricted equity	19,012	19,012
Non-restricted equity		
Share premium reserve	142,199	145,049
Profit/loss for the year	-1,151	-2,850
Total non-restricted equity	160,060	142,199
Total equity	160,060	161,211
Liabilities		
Current liabilities		
Accounts payable - trade	60	87
Accounts payable - group companies	83	327
Other liabilities	41	31
Accrued costs and deferred income	473	664
Total current liabilities	657	1,109
Total liabilities	657	1,109
Total equity and liabilities	160,717	162,320

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# PARENT COMPANY CASH FLOW ANALYSIS

TSEK	JAN-DEC 2023	JAN-DEC 2022
Cash Flow from Operating Activities		
Profit/loss before financial items	-3,874	-4,065
Adjustments for:		
Financial items	2,723	1,215
Depreciation and write-downs	23	23
Cash flow from changes in working capital:		
Current receivables	-84	71
Current liabilities	-452	-76
Cash flow from operating activities	-1,664	-2,832
Investing Activities		
Investments in intangible fixed assets	-	-
Cash flow from investment activities	-	-
Financing Activities		
Loans to group commpanies	-16,722	-30,187
Cash flow from financing activities	-16,722	-30,187
Change in Liquid Funds	-18,386	-33,019
Cash and cash equivalents at the beginning of the period	36,400	69,419
Cash and cash equivalents at the end of the period	18,013	36,400

# CHANGES IN EQUITY

# The Group

TSEK	Share capital	Non-restricted equity	Profit/loss for the year	Total equity
Total equity as of 2021-12-31 (19,012,500 shares)	19,012	119,519	-12,776	125,755
Profit/loss carried forward	-	-12,776	12,776	-
Translation gains/losses on consolidation	-	-1,233	-	-1,233
Profit/loss for the year			-10,324	-10,324
Total equity as of 2022-12-31 (19,012,500 shares)	19,012	105,510	-10,324	114,198
Profit/loss carried forward	-	-10,324	10,324	-
Translation gains/losses on consolidation	-	88	-	88
Profit/loss for the year	-	-	8,330	8,330
Total equity as of 2023-12-31 (19,012,500 shares)	19,012	95,274	8,330	122,616

### **Parent Company**

TSEK	Share capital	Share premium reserve	Profit/loss for the year	Total equity
Total equity as of 2021-12-31 (19,012,500 shares)	19,012	149,489	-4,676	163,825
Profit/loss carried forward	-	-4,676	4,676	-
Share related remuneration regulated by equity instruments	-	236	-	236
Profit/loss for the year	-	-	-2,850	-2,850
Total equity as of 2022-12-31 (19,012,500 shares)	19,012	145,049	-2,850	161,211
Profit/loss carried forward	-	-2,850	2,850	-
Change in translation difference regarding subsidiaries	-	-	-	-
Share related remuneration regulated by equity instruments	-	-	-	-
Profit/loss for the year	-	-	-1,151	-1,151
Total equity as of 2023-12-31 (19,012,500 shares)	19,012	142,199	-1,151	160,060

### The Share

Paxman has issued a total number of 19,012,500 shares, all fully paid for. Each share has a quota value of 1 SEK, and a voting right of 1. There are no pre-emption clauses, refusal clauses or other restrictions on the transfer of shares in the company. Up to 12 March 2018, the company's four original shareholders were bound by a so-called lock-up agreement, entered into in connection with Paxman's listing on Nasdaq First North Growth Market. By this agreement, these shareholders committed themselves to refrain from selling shares (directly or indirectly) in a nine-month period from the first day of trading on Nasdaq First North. In all, 12,810,000 shares were bound by the lock-up agreement. Prior to the listing this corresponded to 100% of all issued shares; after the listing and the new shareissue to 80%.

### The Share Price

The listing price for Paxman's share on 12 June 2017 was SEK 9.50. The closing price at year-end was SEK 36.8 (2022: SEK 43.1. 2021: SEK 65.00, 2020: SEK 25.40, 2019: SEK 60.00, 2018: SEK 24.10, 2017: SEK 19.50).

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# SHAREHOLDERS

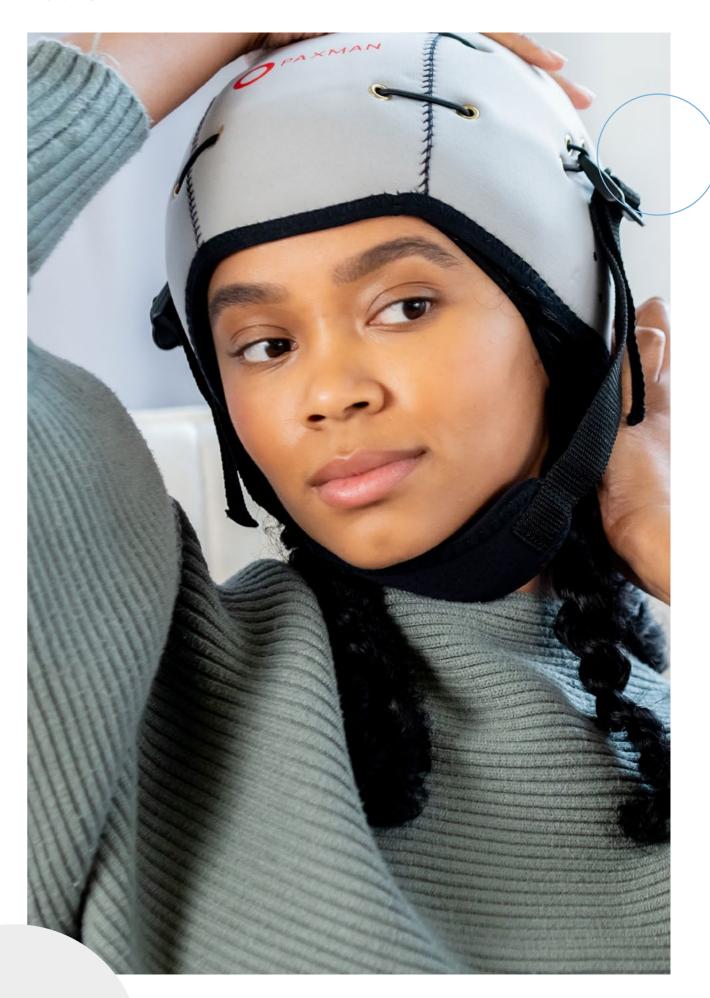
The company's 10 largest shareholders as of 2023-12-29 (Source: Euroclear 2023-12-29).

Name	Number of shares held	Shareholding in %
Paxman, Glenn	5,757,395	30.28
Försäkringsaktiebolaget Avanza Pension	2,187,830	11.51
CIMON Venture Trust AB	1,286,992	6.77
Paxman, Richard	1,268,000	6.67
BNY Mellon SA/NV	1,031,364	5.42
Alcur Grow	674,825	3.55
Länsförsäkringar Blekinge	585,000	3.08
Länsförsäkringar Kalmar län	545,185	2.87
Littorin, Björn	465,076	2.45
Andra AP-fonden	456,617	2.40

On 31 December 2023, Paxman had a total of 1,163 (2022: 1,179) shareholders. The 10 largest of these held 75 (76.6)% of all issued shares.

Data per share	2023	2022
Earnings per share, SEK <sup>1)</sup>	0.44	-0.54
Earnings per share at full dilution, SEK <sup>2)</sup>	0.44	-0.54
Equity per share, SEK , <sup>11</sup>	6.45	6.01
Cash flow from operating activities per share, SEK <sup>1)</sup>	0.82	-0.09
Share price at the end of the period, SEK	36.8	43.10
Number of shares at the end of the period	19,012,500	19,012,500
Number of shares at the end of the period at full dilution <sup>2)</sup>	19,080,978	19,080,978
Number of shares, weighted average during the year	19,012,500	19,012,500
Number of shares, weighted average during the year at full dilution <sup>2)</sup>	19,080,978	19,080,978

<sup>1)</sup> Earnings and cash flow per share are based on the weighted average number of shares during the period. Equity per share is based on the total number of issued shares on balance sheet day.



<sup>2)</sup> As of December 31, 2023, the company implemented an incentive program for employees in the subsidiary Paxman Coolers Ltd. The decision to issue warrants was made at the Annual General Meeting on May 23, 2019, and the warrants were issued immediately thereafter. In total, 68,478 warrants have been issued, which entitles to subscription for a maximum of 68,478 new shares in the company. The warrants entitle the holder to subscribe for shares from June 2020 until June 2029, at a subscription price of SEK 65.37 per share. Upon full subscription, the dilution effect amounts to 0.4% of the total number of shares in the company. As of December 31, 2023, there was no dilution effect to report.









paxman.se
paxmanscalpcooling.com
scalpcoolingstudies.com
coldcap.com