

PAXMAN^o

Scalp Cooling Guide

Training Manual
UKROW

Issue 1 03/2025



Contents

Module 01 Company history

- 1.1 The Paxman story
 - 1.2 Global growth
 - 1.3 Research & development
-

Module 02 Scalp cooling

- 2.1 The importance of scalp cooling and the impact of CIA
 - 2.2 How scalp cooling works
 - 2.3 Efficacy of scalp cooling
 - 2.4 Faster hair regrowth - benefits of scalp cooling beyond hair retention
-

Module 03 The Paxman Scalp Cooler

- 3.1 System description & function
 - 3.2 Moving the device
 - 3.3 Switching on the device & operational check
 - 3.4 Device handling & safety
-

Module 04 The Paxman caps, cap sizing, hair preparation & cap fitting

- 4.1 Introduction to the caps & cap sizes
 - 4.2 How to size a patient for a cap
 - 4.3 Patient preparation
 - 4.4 Fitting the cap to the patient
 - 4.5 Connecting the cap to the system
-

Module 05 Operation of the Paxman Scalp Cooler

- 5.1 Scalp cooling treatment stages & system operational options
 - 5.2 Stage 1 - pre-infusion cooling
 - 5.3 Stage 2 - infusion cooling
 - 5.4 Stage 3 - post-infusion cooling
 - 5.5 Temporary disconnection/bathroom breaks
 - 5.6 Ending treatment
 - 5.7 Switching off the device
-

Module 06 Post treatment information

- 6.1 Cap removal
 - 6.2 Post-treatment information - immediately after treatment in clinic
 - 6.3 Post-treatment information - immediately after treatment at home
-

Module 07 Paxman Scalp Cooler maintenance

- 7.1 Cleaning the Paxman Scalp Cooling System & caps
 - 7.2 Cap storage, handling & cap rotation
 - 7.3 Coolant top up
-

Module 08 Other important information

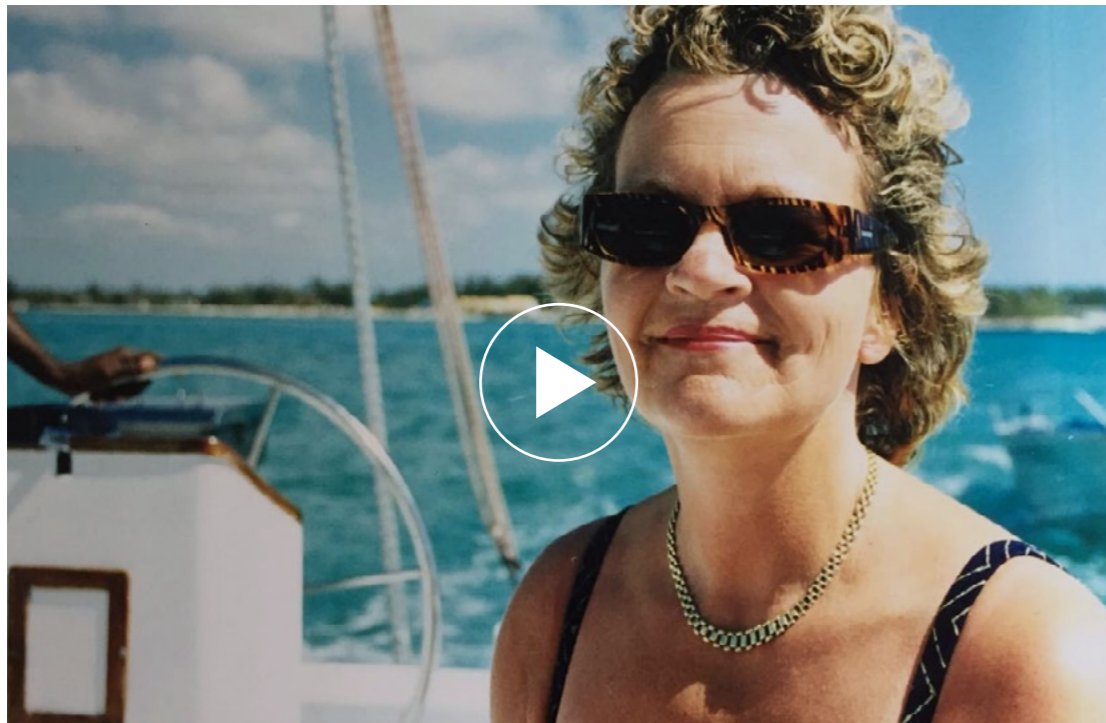
- 8.1 Safety, side effects & tolerability
 - 8.2 Contraindications
 - 8.3 Key clinical data
 - 8.4 Haircare
 - 8.5 Paxman resources
-

01

Module 01

Company history

- 1.1 The Paxman story
- 1.2 Global growth
- 1.3 Research & development



1.1 The Paxman story

Paxman is a family company.

The Paxman Scalp Cooling System exists because of Sue – Our Original Pioneer

Sue was the wife of our founder Glenn, and mum to Curtis, Claire, our Director of Global Training, Richard, our CEO, and James. She is the heart and motivation behind everything that happens at Paxman.

Sue was diagnosed with breast cancer in the early 90's aged 36 and tried a rudimentary scalp cooling system during her chemotherapy treatment. Sadly, it did not work, and Sue lost her hair. The trauma of losing her hair had an enormous impact on Sue and her young family of four children. This is when our founder and chairman, Glenn decided he needed to do something to stop anyone else from having to go through this horrible experience.

Glenn Paxman used his knowledge and expertise in the refrigeration industry (his father Eric Paxman invented the first type of ice bank beer cooler in the 1950's) to pioneer a scalp cooling system that enables people going through chemotherapy treatment to maintain their hair without the discomfort for patients and laborious task for clinicians of changing caps, like the methods used at the time.

We thought it was important to share with you the wonderful woman who sits at the centre of everything at Paxman. Her experience has helped us to understand what patients are facing. Sue was bright, warm, funny, and full of life. She didn't let her diagnosis stop her or slow her down, at least not in front of her children or the outside world. Eventually, she was diagnosed a second time and died of cancer in 2000 aged only 44. But she did not die in vain. The Paxman Scalp Cooling System's impact on thousands of patients worldwide is Sue's legacy. We could not be prouder that there is a small part of the mother, wife, and daughter that meant so much to us, reaching every one of the people who uses our system and gives cold capping a try.

Sue overflowed with personality and determination. It is this unwavering forward motion that has become an innate part of the Paxman approach, and the family's mission to ensure that anyone who wants scalp cooling can access the treatment.

Please scan the QR code to watch this video of the Paxman family talking about their memories of our 'Original Pioneer' who has inspired so much.

1.2 Global growth

The Paxman System was launched in 1997 with first systems being installed in the UK. Now, over 20 years later, we are incredibly proud to be the global leaders in the scalp cooling industry.

To date, there are over 5,000 systems installed worldwide in over 65 markets. More than 1,000 of these are installed in the UK, with Paxman systems accessible in more than 98% of UK National Health Service and private hospitals, as well as being offered in the home through Home Healthcare businesses. A defining moment for Paxman was achieving US FDA clearance for use with breast cancer in April 2017 following a 5-year US multicentre trial using the Paxman system.

Further FDA clearance for use with all solid tumour cancers was granted in 2019. We now have over 950 systems in over 460 locations across 41 states which includes the world-renowned cancer centres such as MSKCC, MD Anderson, Dana Farber and the Mayo Clinic.

We are incredibly proud to have treated hundreds of thousands of people across the world. Paxman's ultimate goal is to ensure that no matter who you are, where you are in the world, regardless of your ethnicity, gender or financial situation that patients will have access to scalp cooling.



Distributed in over 60 markets internationally



Research & development

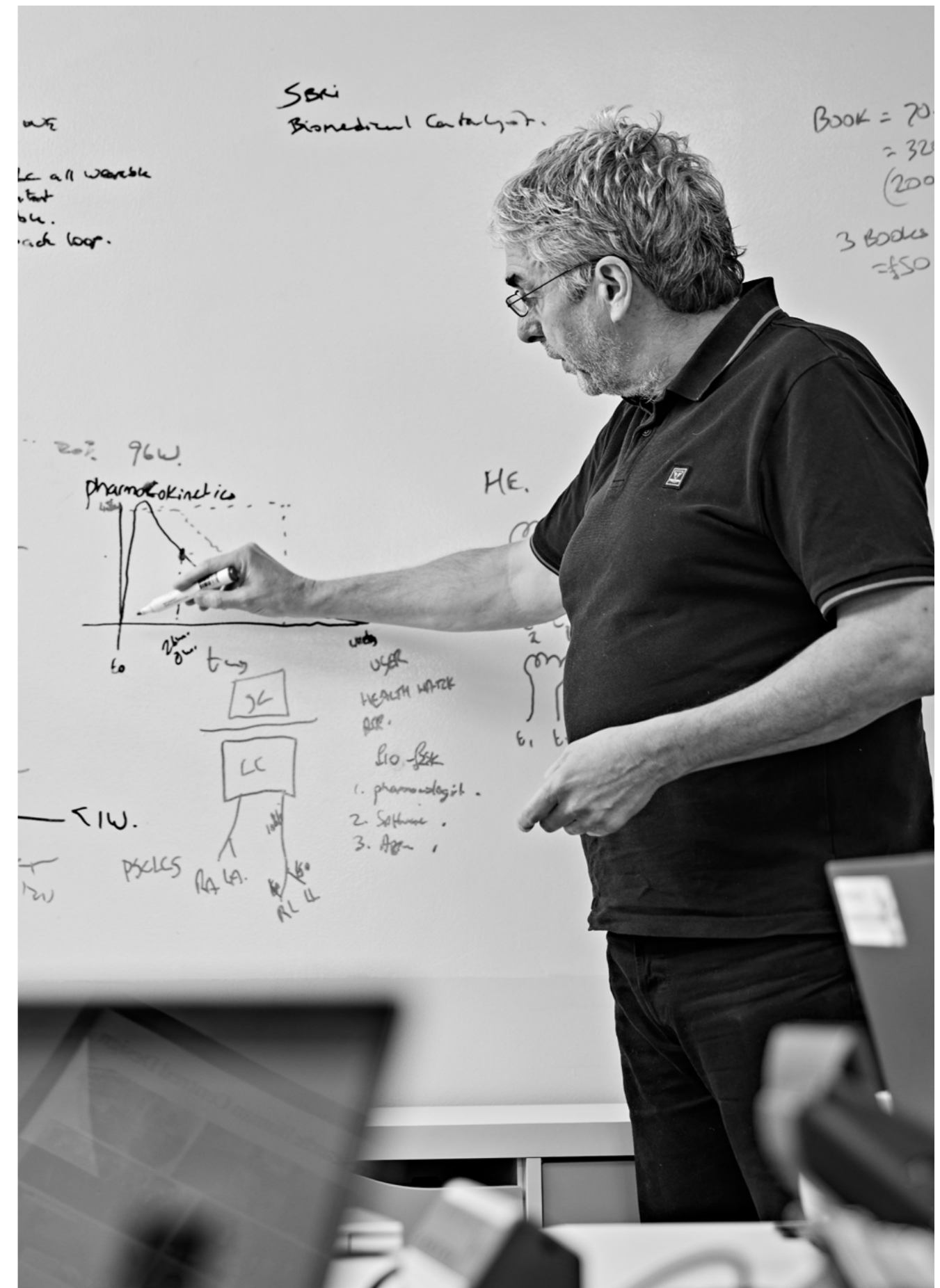
Development of systems, caps, scalp cooling treatment and efficacy has always been a central commitment for Paxman. We have long-standing collaborative relationships with several universities including the National University of Singapore, Kings College London, the University of Leeds and the University of Huddersfield, where we collectively produced the first-ever paper on cellular response to cold protection from chemotherapy, showing that cold exposure to the hair follicle helps to reduce hair loss. Ongoing product design research with the University of Huddersfield was awarded 4 stars by the Research Excellence Framework, who define the research as of a "quality that is world-leading in terms of originality, significance, and rigour".

Current biological research is also developing topical agents that will enhance the effect of scalp cooling, providing added resistance to chemotherapy at the hair follicle with the intention of vastly improving scalp cooling efficacy.

Our new cap and cover design work features the use of bespoke recyclable materials with an innovative manufacturing approach to achieve improved comfort and fit. This is managed through the unique 3D-formed shape of the cap material and the novel mechanism by which the cover applies pressure in the most important areas.

Finally, we are also developing a new approach to combinatorial treatment of peripheral neuropathy and scalp cooling. Nerve damage through chemotherapy is a well-documented side effect of cancer treatment and one that Paxman are committed to providing a solution for. The system that has been developed is in the final stages of clinical trialling. Patient-centred design and development runs through Paxman's core, honing sustainable innovation approaches supported by over 25 years of experience in the field of scalp cooling.

"Quality that is world-leading in terms of originality, significance, and rigour."



- 2.1 The importance of scalp cooling and the impact of CIA
- 2.2 How scalp cooling works
- 2.3 Efficacy of scalp cooling
- 2.4 Faster hair regrowth - benefits of scalp cooling beyond hair retention

Module 02

Scalp cooling

The importance of scalp cooling and the impact of CIA

Many people consider hair loss as the most feared and common side effect of chemotherapy treatment.

Chemotherapy-induced alopecia is considered:

- The most feared side effect of treatment for more than 75% of patients.
- The most traumatic side effect of chemotherapy treatment.
- To lead to social isolation.
- To affect a patient's self-image more than breast surgery.
- The most visible indicator of diagnosis, removing a patient's privacy and feeling of normality.

Patient's Motivations & Drivers

A patient's reasons for choosing to scalp cool can be complicated and diverse, but the majority fall into the following categories:

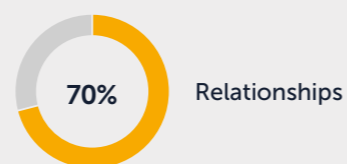
- A desire to protect their **family**.
- An attempt to maintain **normality**.
- To provide some **privacy**.
- To retain **identity** and feeling of self.
- To retain some **control** during treatment.

Patient Experience and the Psychosocial Impact of Scalp Cooling

Scalp cooling can have a profound effect on a patient's experience of treatment. Hair loss is known to have a debilitating impact on a patient's life and livelihood. When asked if scalp cooling had an impact on different aspects of their lives, a positive effect was felt by patients in the following areas:

- 93% Emotional wellbeing
- 84% Social Activities
- 77% Work Activities
- 70% Relationships
- 60% Physical/Sporting

Up to 10% of people will refuse or request a less efficacious treatment in order to retain their hair during treatment



Patient stories



"I feel so happy and grateful. It allowed me to feel normal and enjoy normal things all summer. It gave me so much more confidence to have my hair. I was able to keep my cancer private when I wanted to and share when I felt comfortable."

Carmen



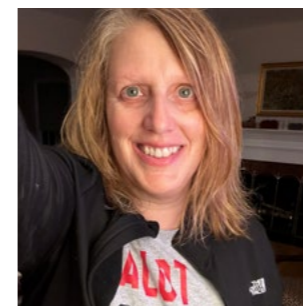
"I am eternally grateful. My motivations were not wanting to be bald and feeling like I had some kind of control in a situation where most of the decisions were made for me by doctors. To me it was worth trying even if it didn't work. I was and am so thankful to have had the option."

Kia



"Even if I lost all my hair, I feel like it helped prevent permanent hair loss and will make it grow back faster."

Kim



"I had a great experience and retained about 60% of my hair. I had a nurse tell me it would not work and I felt defeated but decided to try anyway. I'm so happy I did and want to make sure women know this is a real option."

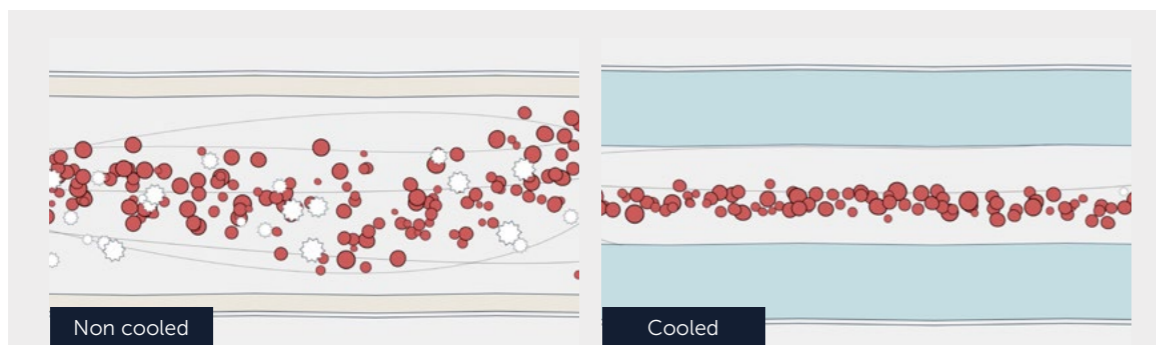
Anya

How scalp cooling works

Why does chemotherapy cause hair loss?

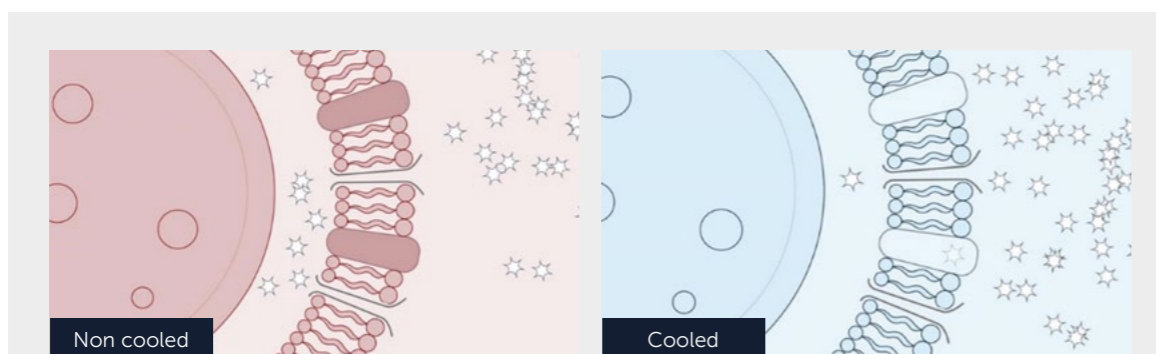
- Chemotherapy works by targeting **all** rapidly dividing cells, however, it cannot identify the difference between healthy fast dividing cells and the cancerous ones that make up a tumour.
- Hair is the second-fastest dividing cell in the body. 90% of the time, hair is in its 'anagen stage' or active growth stage.
- By cooling the scalp to a temperature of 18 to 22° Celsius /64 to 72° Fahrenheit a number of biological mechanisms occur;

Proposed mechanisms to explain the cytoprotective effects of scalp cooling



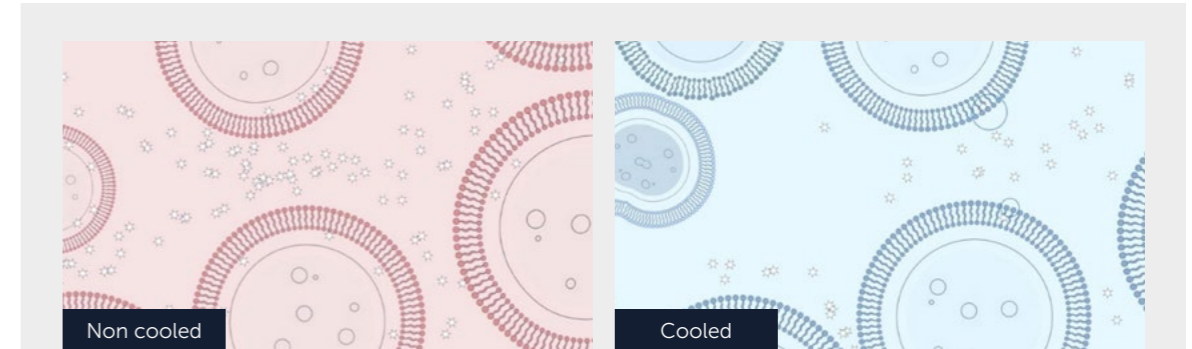
Vasoconstriction

- Cooling causes vasoconstriction.
- Blood vessels contract, reducing blood flow to 20-40%.
- Less blood flow means less chemotherapy drug reaches the follicle.



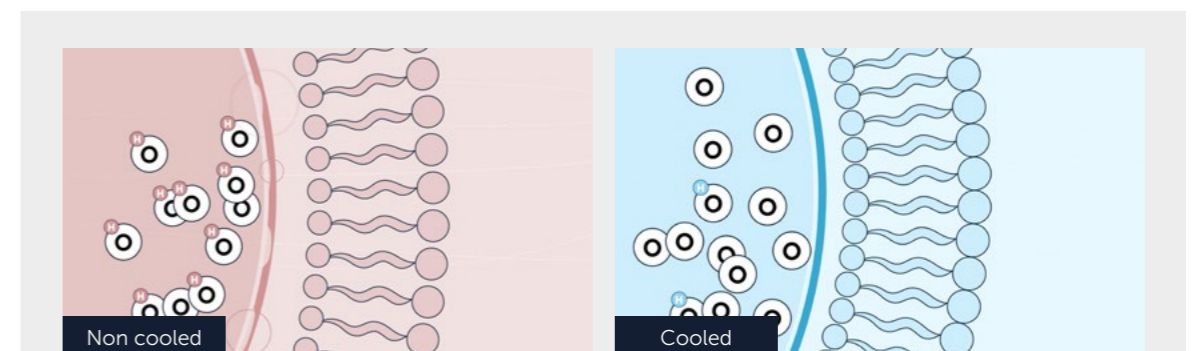
Reduced drug uptake into the hair follicle cell

- Cooling means that it is more difficult for chemo to enter cells.
- There are several ways that the chemo enters cells; all are significantly reduced by cooling.
- Plasma membrane changes reduce the ability of chemo to enter the cell.



Reducing rate of hair follicle cell division

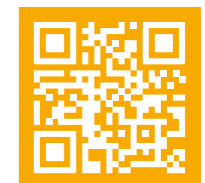
- Hair cells are fast dividing like a cancer and therefore are targeted by chemo.
- Hair follicle cells become dormant through cooling, which means the chemo bypasses them.



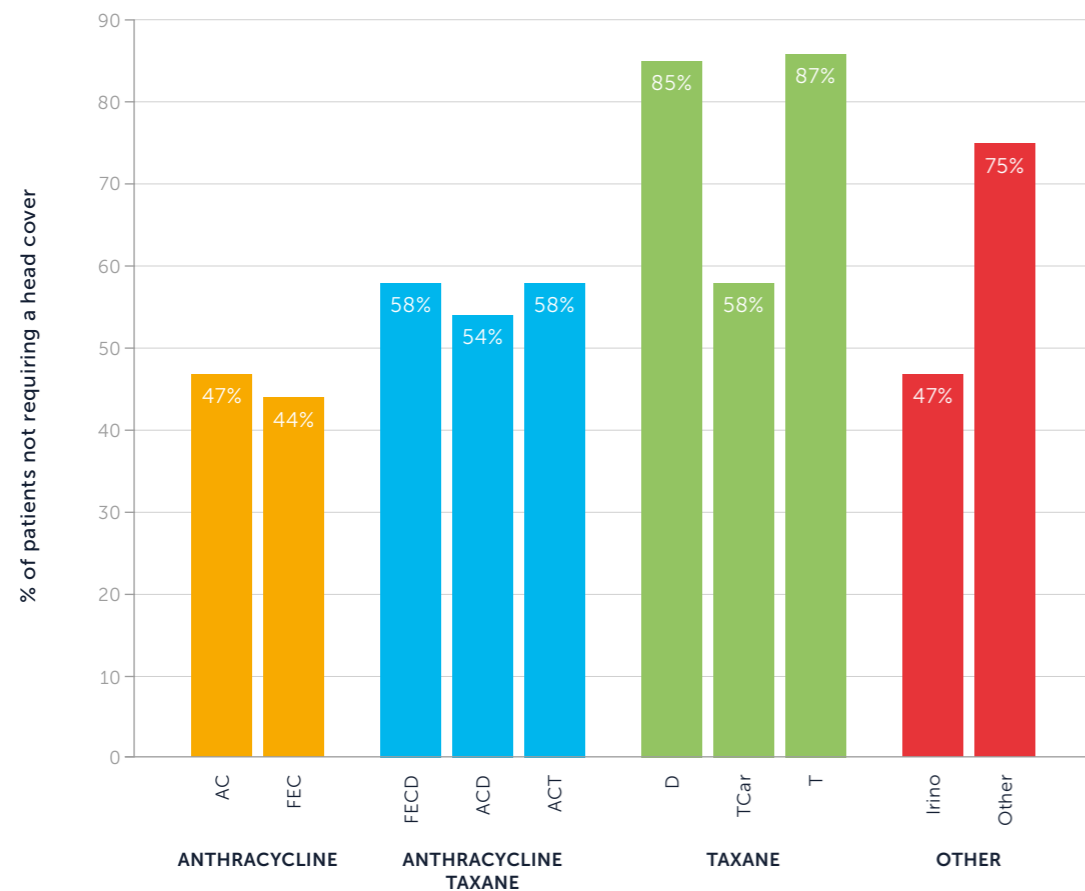
Reduces metabolic activity

- Cells behave differently when cold and a lot of biological processes slow down, making the chemo less damaging to the hair follicle cell.

- Most likely it is a combination of these mechanisms that renders scalp cooling cytoprotective.
- Cooling may protect cells by a direct mechanism and not merely by vasoconstriction, as was previously believed.
- Cooling reduces the entry of chemotherapy drugs into human keratinocytes.



Watch the video on [how scalp cooling works](#)



Main variances in scalp cooling efficacy are related to the type and dosage of chemotherapy. Data outlined here is taken from the 2013-2019 cohort from the Dutch Scalp Cooling Registry. The Registry comprises of over 7000 patient's data.

2.3 Efficacy of scalp cooling

The efficacy of scalp cooling varies based on a series of factors, with drug regimen being the primary influence.

Taxane-based regimens see the highest rates of hair retention. Anthracycline regimens on average see a lower level of efficacy, but scalp cooling is still beneficial.

On average, there is a 56% chance of patients retaining half of their hair with scalp cooling.

With most regimens, dosage can also have an effect on hair retention, with higher dosages making hair retention more challenging.



For an indication on possible hair retention rates with specific drug regimens please visit the [Scalp Cooling Outcomes Calculator](#)

Managing expectations

There are no guarantees when it comes to scalp cooling. Outcomes can vary significantly from person to person. Three people receiving the same treatment plan for the same diagnosis, are likely to see different rates of hair retention with scalp cooling, due to individual biological response.

Scalp cooling success is subjective – one person's success can be another person's failure. It is important that the patient decides if scalp cooling is a valuable addition to their treatment plan or not.

Shedding is an inevitable part of the scalp cooling process – It is important to be mindful that scalp cooling will likely be challenging, and even those with the highest rates of retention will see levels of shedding hair and hair loss – this is a normal part of the process and not a sign that it isn't working. While any hair loss can be difficult, it is important to remember that for the majority of chemotherapy drugs, the alternative to scalp cooling is complete hair loss.

Managing patient's expectations is fundamental to a positive outcome – The more familiar the patient is with the scalp cooling process and is realistic about what to expect, the more likely they are to be comfortable with their outcome.

Factors that influence outcomes

There are various elements that can affect the outcome of scalp cooling on hair retention - some can be managed, and others cannot.

Can't be influenced

1. Chemotherapy drug regimen and dosage.
2. Individual biological response – each person's body will respond differently as with any drug or medical intervention.

Can be influenced

3. Cap fit - a consistent close fit across the scalp will ensure the best possible outcome.
4. Cooling times - the appropriate pre- and post-infusion cooling times according to chemotherapy drug administered is important for the best possible outcomes.

Adapted haircare approaches are an important element of good scalp cooling practice.

Appropriate haircare approaches will not improve hair retention outcomes but can have a significant impact on a patient's experience in between treatments, and can improve the condition of their retained hair, which can make their transition to life post treatment easier.

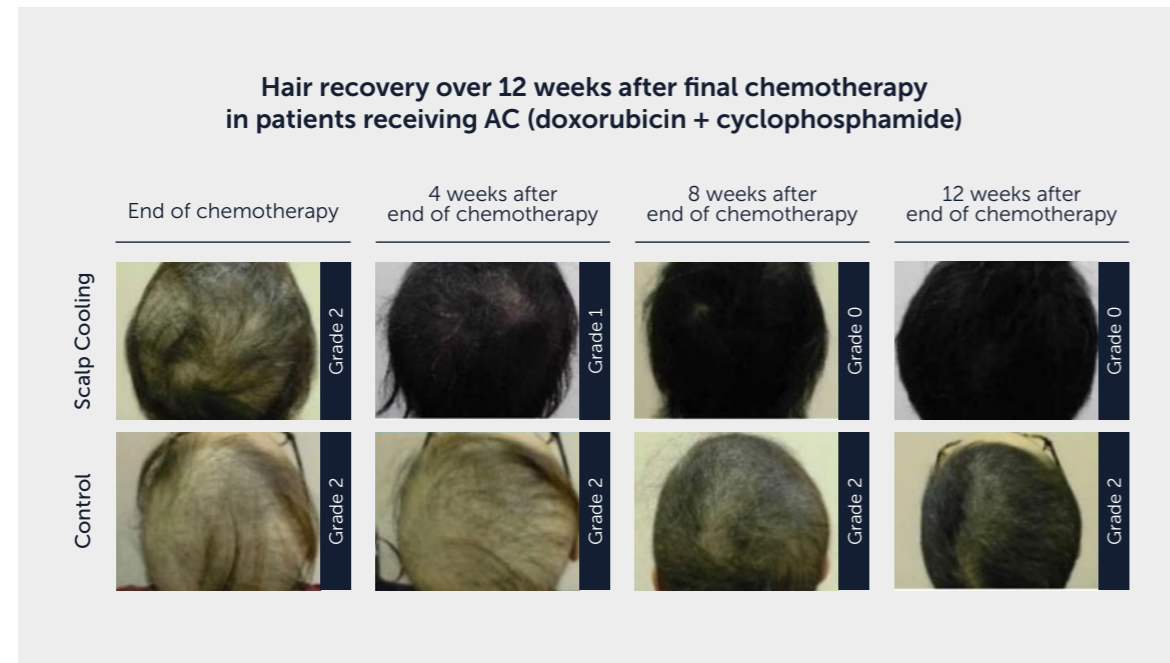
Faster hair regrowth - benefits of scalp cooling beyond hair retention

Most people choose scalp cooling to try and retain their hair through chemotherapy, however, scalp cooling has now been clinically proven to increase the rate of hair regrowth. Faster regrowth is a true benefit to anyone who chooses to scalp cool, even when a considerable amount of hair has been lost.

A study conducted in Japan in 2019 called 'Efficacy of Scalp Cooling in Preventing and Recovering from Chemotherapy-Induced Alopecia in Breast Cancer Patients: The HOPE Study', concluded that scalp cooling resulted in faster recovery of hair volume within 12 weeks of chemotherapy, even in patients where scalp cooling failed to prevent chemotherapy-induced alopecia.

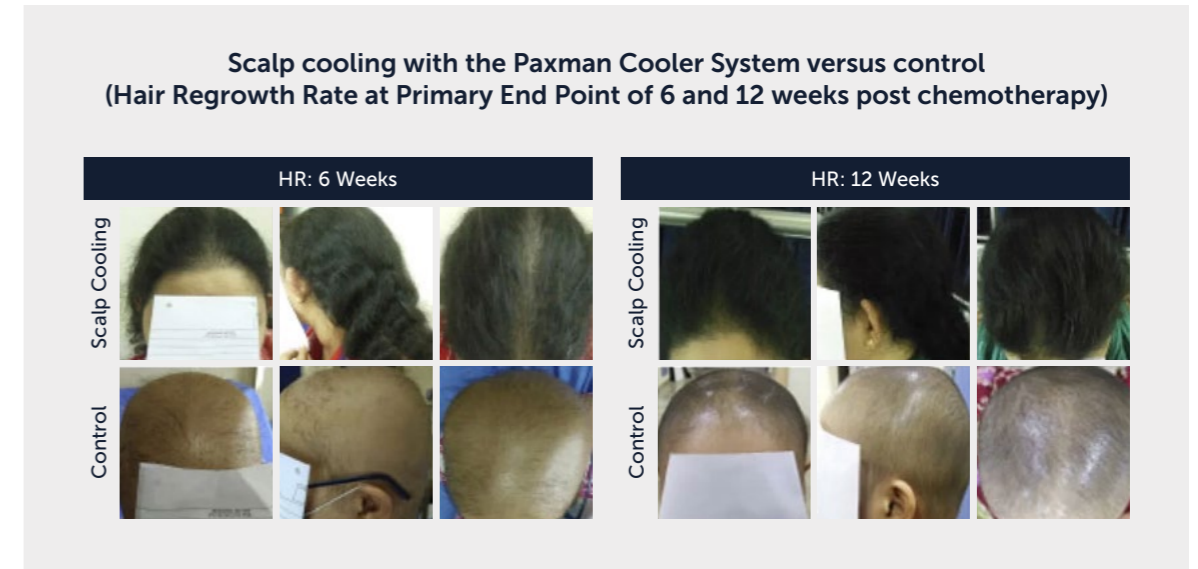
This was particularly important for the patients in the trial who received TC (docetaxel and cyclophosphamide), or AC (doxorubicin and cyclophosphamide), both of which are particularly challenging regimens when it comes to hair retention.

As you can see from the photos, not only were the hair retention rates higher for patients who scalp cooled, but the rate of hair regrowth was notably faster for patients in the scalp cooling group in comparison to the control group who did not scalp cool.



A study conducted in 2020 in India – 'Randomized Control Trial of Scalp Cooling for the Prevention of Chemotherapy Induced Alopecia' – concluded that scalp cooling patients saw **significant hair regrowth at both 6 and 12 weeks** post their final chemotherapy treatment.

At 6 weeks, 89% of the patients who had scalp cooled saw grade 0/1 alopecia (less than 50% or no noticeable hair loss), whereas the control group who didn't scalp cool saw 12% of patients with grade) 0/1 alopecia. By week 12, this had increased to 100% of the scalp cooling group and 60% of the control group.



As you can see from these study images, faster regrowth is important for those with good levels of hair retention, but even more important for those that see significant hair loss. Hair regrowth will happen naturally, but scalp cooling can help speed that process up, from a timescale of months to weeks.

It is also worth noting, that it is not uncommon for patients to see regrowth occurring before the end of their chemotherapy treatment with some drug regimens.

Continuing or starting scalp cooling with significant hair loss

When do you need to use a theatre/surgical cap?

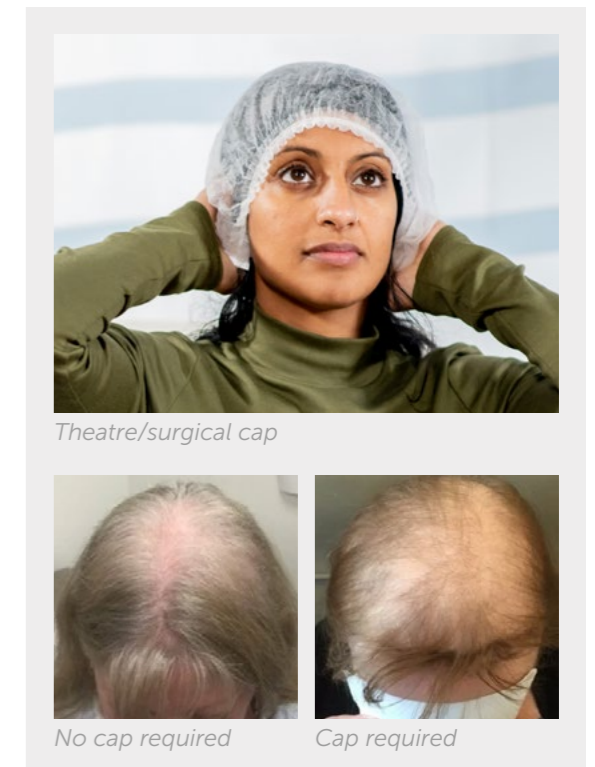
You only need to use the theatre cap if you have exposed scalp. If your hair has thinned but there aren't specific areas of hair loss, you won't need a theatre cap.

How to use a theatre/surgical cap

Prepare your hair as shown in the hair preparation How-to video, then place the theatre/surgical cap over your head so that it is positioned correctly for the inner cooling cap to fit on top. The material of the disposable cap is thick enough to provide protection to any exposed scalp and make the scalp cooling more tolerable, but not thick enough to compromise the cooling process.

If you have patchy hair loss and you still have hair that is long enough, you can arrange your hair over the exposed scalp once it is dampened and conditioner is added. This is a simple but effective way of protecting exposed scalp without additional items.

As long as any exposed scalp is protected, it is completely safe to continue to scalp cool.



Patient regrowth stories



"I experienced thinning, mostly on the crown. The regrowth is fast! I am now 4 weeks post final chemo and if you didn't know I had just gone through chemo, you would just think I had thin hair. I have been very surprised at the regrowth of my hair, especially comparing it to my eyelashes and eyebrows."

Jo



"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."

Emma



"It's worth a go. If it works for you, you get to keep your hair (at least some of it anyway), and if you do still end up losing your hair or shaving it, then you can feel assured that it will help to protect your hair follicles which means quicker and healthier re-growth!"

Julie





Module 03

The Paxman Scalp Cooler

- 3.1 System description & function
- 3.2 Moving the device
- 3.3 Switching on the device & operational check
- 3.4 Device handling & safety

Introduction to the Paxman Scalp Cooler

The Paxman Scalp Cooling System is a small, compact mobile refrigeration unit which rapidly cools a special liquid coolant down to a required temperature. The system maintains it at this temperature as long as it is switched on. The coolant is pumped from the system, through the coolant lines, into the cap and back again with a continual flow. The cap remains on the patients head during treatment and doesn't need to be changed.

There are two different models of the Paxman System - a single unit and a double unit. The single patient system allows just one patient to be treated, whereas the double unit allows either one patient to be treated on their own, or two patients to be treated completely independently of one another.

With a very simple and intuitive touch screen to operate the system, minimal nursing supervision is required.

Parts of the system

PSCS I – Single Patient System

1. Small Compact mobile Refrigeration Unit
2. Simple Intuitive Touchscreen
3. Coolant Line
4. Quick Release Couplings
5. Cap Support – To place the cap on before and after treatment to avoid placing the cap on the system or hanging from the support lines
6. Support Arm for Coolant lines - To hold the coolant line and prevent it from kinking, twisting or dragging on the floor. This can be raised or lowered for patient comfort to ensure the cap, or coolant lines, are not dragging or feeling heavy – See Instructions below
7. Power On/Off Switch (Illuminates Green)
8. Coolant Top up Valve
9. Mains Power Connection & Lead
10. Coolant Line Support Arm Height Adjustment
11. Handle at the back – To safely move the device



PSCS II – Dual Patient System

1. Small Compact mobile Refrigeration Unit
2. Simple Intuitive Touchscreen
3. Coolant Line
4. Quick Release Couplings
5. Cap Supports – To place the caps on before and after treatment to avoid placing the caps on the system or hanging from the support lines
6. Support Arm for Coolant lines - To hold the coolant line and prevent it from kinking, twisting or dragging on the floor. This can be raised or lowered for patient comfort to ensure the cap, or coolant lines, are not dragging or feeling heavy – See Instructions below
7. Power On/Off Switch (Illuminates Green)
8. Coolant Top up Valve
9. Mains Power Connection & Lead
10. Coolant Line Support Arm Height Adjustment
11. Handle at the back – To safely move the device



How to raise or lower the support arms for patient comfort

There is a handle at the rear of the system to enable the support arms to be raised or lowered. Pull the coolant lines through the support arms and unscrew the handle to enable you to raise or lower the pole. Tighten the handle then depress the grey button or pull out to straighten the handle.



3.2 Moving the device

The Paxman Scalp Cooling System has 4 swivel castors on the base of the refrigeration unit to facilitate easy relocation of the System. All castors feature a foot-operated brake lever designed to prevent unwanted movement of the unit during operation.

- Switch the system off.
- Disconnect the power supply before moving.
- Use the handle at the rear of the System to move it, not the support arms.
- The lever on the castors can be raised by foot to release the break.
- Once in position activate the brake, use the foot to depress the lever on all sets of castors.

Warnings and precautions

- The Paxman Scalp Cooling System should only be lifted using appropriate lifting equipment.

- Ensure the brakes are engaged before switching on the Paxman Scalp Cooling System.
- When moving the Paxman Scalp Cooling System, always push it from the rear.
- Do not move the Paxman Scalp Cooling System using the support arm or cap holders.
- Always disconnect the power cable before moving the Paxman Scalp Cooling System.
- Ensure there is easy access to the power lead or mains plug during operation of the Paxman Scalp Cooling System
- Exercise care when moving the Paxman Scalp Cooling System over uneven floors or surfaces with obstructions, undulations, ramps or slopes. A slow manoeuvre is recommended.
- Ensure the Paxman Scalp Cooler is always kept upright.

3.3 Switching on the device & operational check

The following checks should be performed before switching on the Paxman Scalp Cooling System.

Check the power cable is firmly inserted into the back of the machine

Check the plug is inserted into a wall socket and the socket is **switched on**

- Switch on the system by pressing the power switch located at the rear of the machine. The switch will illuminate green (Fig 3.1).
- After 30 seconds, the touchscreen display will show the startup screen (Fig 3.2).
- The refrigeration system will begin reducing the temperature of the coolant which can take up to 30 minutes. During this time the engineering screen is accessible for fault diagnosis.
- Once the coolant has reached operating temperature the system will move onto the main screen (Fig 3.3).

Software version

- The touch screen will briefly show the software version when the startup screen is displayed (Fig 3.2).

Information

It will take approximately 30 minutes for the Paxman Scalp Cooling System to reduce the temperature of the coolant to the appropriate to the operating temperature.

We advise switching the system on in the morning to ensure that they are ready for when your patients arrive.

A patient's treatment will not be able to start whilst the 'System Cooling Please wait...' screen is displayed.



Fig 3.1

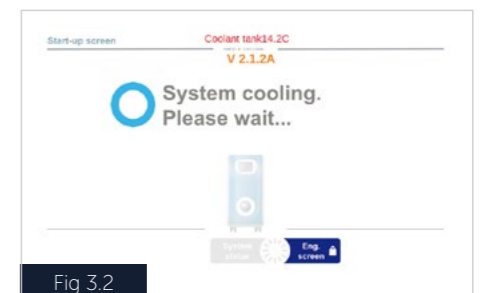


Fig 3.2

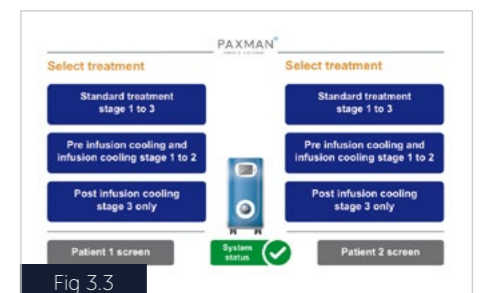


Fig 3.3

Device handling & safety

Touch screen controller care

- Do not allow liquids to come into contact with the touchscreen.
- Lightly wipe the surface with absorbent cotton or other soft material. Always wipe horizontally or vertically and not in a circle.
- Immediately wipe off water drops to prevent damage to the touchscreen.
- When using the touchscreen controller press gently, use of excessive pressure may damage the touchscreen.

Overcooling

It is extremely unlikely that overcooling can occur due to the inherent design of the device. The refrigeration system and coolant are designed so that the coolant cannot cool below -15°C .

Coolant lines

- Do not pull or use excessive force to access the quick release connectors within the coolant lines.

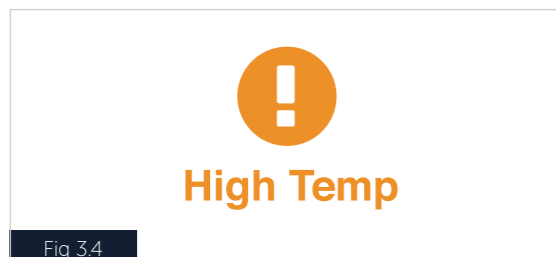


Fig 3.4

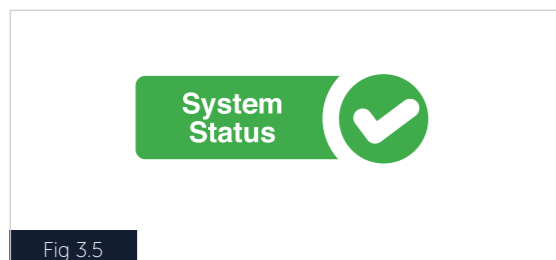


Fig 3.5

Visual warnings

- The coolant temperature in the Paxman Scalp Cooling System is continuously monitored.
- If the temperature is observed to be above $3^{\circ}\text{C}/37^{\circ}\text{F}$ the Status Symbols will show the exclamation symbol ! (Fig 3.4) and the text will read 'High Temp'.
- The status symbol will be green and show a tick (Fig 3.5) if treatment can be carried out.
- If the temperature is observed to be more than 3°C below the setpoint, the treatment pumps will stop, the temperature too low warning (Fig 3.6) will be displayed and a buzzer will sound. Switch off the System and contact the service provider to arrange for an Engineer to investigate.
- If the temperature is observed to be below -15°C (5°F) or above 45°C (113°F) the treatment pumps will stop. The incorrect temperature reading warning (Fig 3.7) will be displayed and a buzzer will sound. Switch off the system and contact the service provider to arrange for an Engineer to investigate.

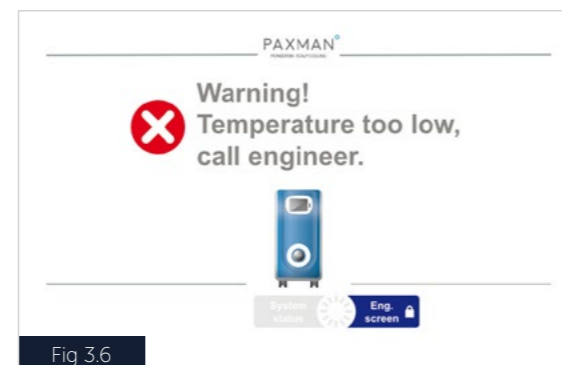


Fig 3.6

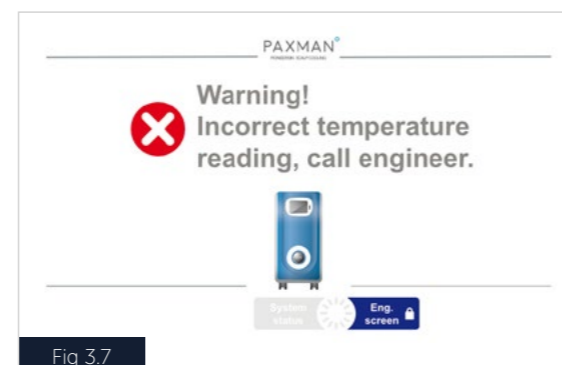


Fig 3.7

Insufficient flow warning

- The coolant flow rate in the cooling cap is continuously monitored.
- Visual and audible signals are employed to alert the user if the flow of the coolant becomes obstructed during the scalp cooling treatment.
- Check if the coolant line has become obstructed/kinked anywhere as this could affect the flow rate.
- Disconnect and reconnect the couplings following the procedure in section 10 if the coolant line does not appear to be trapped.
- If the fault persists, please contact the service provider.

Power loss warning

- If the power is lost or switched off while treatment is taking place, a power loss warning screen will be displayed when the system is next powered on. Press OK to continue to the cooling screen. To avoid this message, ensure the power lead is firmly attached and that treatment is stopped before power is switched off.

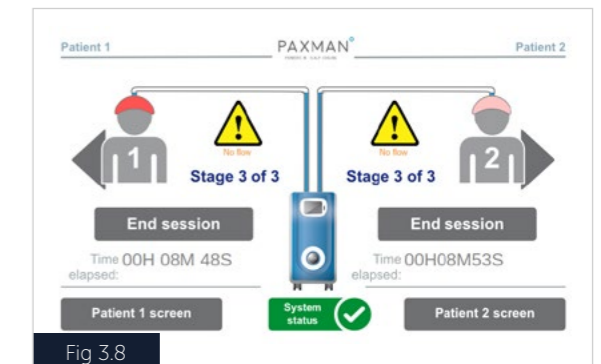


Fig 3.8

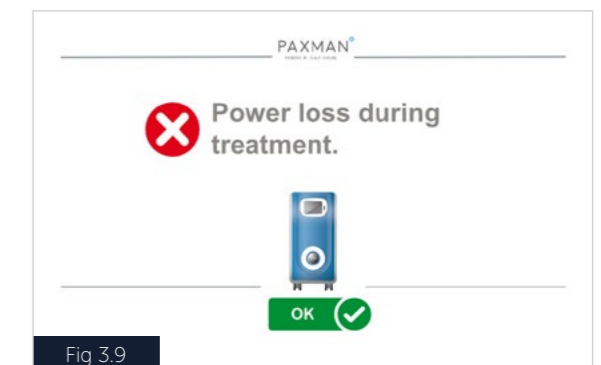


Fig 3.9

4

Module 04

The Paxman caps, cap sizing, hair preparation & cap fitting

- 4.1 Introduction to the caps & cap sizes
- 4.2 How to size a patient for a cap
- 4.3 Patient preparation
- 4.4 Fitting the cap to the patient
- 4.5 Connecting the cap to the system



Fig 4.11

4.1 Introduction to the caps & cap sizes

Patients' heads vary enormously in shape and size. We have developed a number of different sized caps to accommodate these varying sizes.



Each silicone cap has a serial number on it which can also be used to identify the size of the cap as the first letter(s) of this serial number will be either S, M, or L depending on its size.

The caps are made from medical grade soft silicone. They are light in weight but flexible and strong.

The silicone caps are supplied with a neoprene cover. The purpose of this cover is to absorb condensation from the external surface of the cap during use and prevent it from running down the back of patients' necks.

The neoprene cover also acts as an excellent insulator helping with the efficiency of the cooling cap.

The bungee cord and chin strap also ensure a tight fit of the cooling cap. The colour of the Paxman logo on the cap cover corresponds with the size as shown in the example above.

4.2 How to size a patient for a cap

There are 3 key points to consider to ensure that a patient is provided with the correct size of cooling cap for them, which is crucial for the best possible hair retention when scalp cooling.

It is recommended to allow time for the pre-consultation appointment prior to the commencement of chemotherapy treatment for the fitting of the correct cap size.

Selection of cap size should always be performed with the cap cover removed.

There are **3 key areas** to consider when measuring a patient for a cap;

Information

The following are indicative of an incorrect cap size:

Crown hair loss:
Cap too small - use a larger cap

Hair loss from the back of the head:
Cap too big - use a smaller cap

View instructional cap fitting videos:
www.coldcap.com

Cap not too Small

Ensure the cap is not too small – it is important that top of the cap is touching the crown of the patient's head and that there is no bounce to avoid crown hair loss. Also, if any amount of force is required to push the cap down on the head, this is also an indication that the cap is too small. This could be both painful for the patient and the cap could rise up away from the scalp during treatment.



Hairline

The cap should cover the whole of the hairline from the front to the back. If a patient has longer hair, please ensure you lift this up so that you can see beneath the hair and to check the cap is covering the hairline. NB: It is not imperative that the hairline in front of the ears is covered.



Caps too large

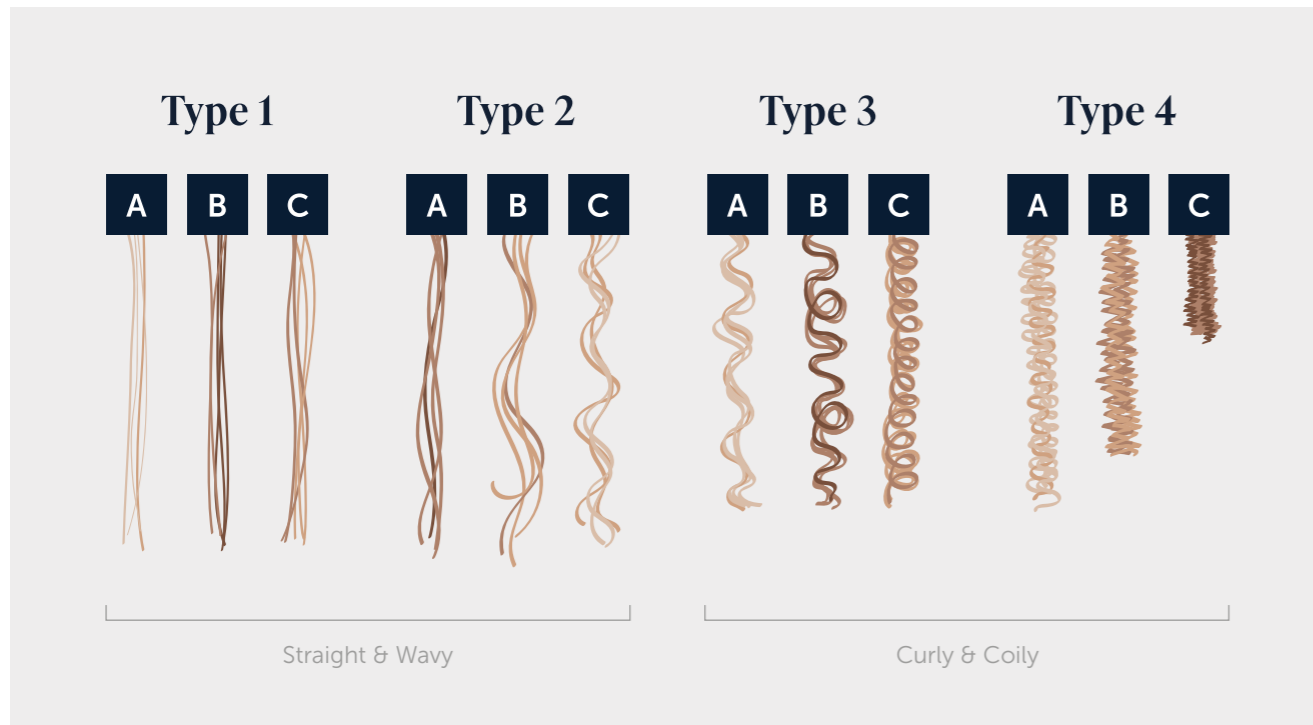
If the cap is too large there will be a gap at the back above the neck which would fit two hands or in some cases an entire fist. A further indication that a cap is too large is if the cap can be moved easily when placed on the head.



Important

A medium (M) inner silicone cap and a small (S) outer cap cover should be used for any patient considered to be in between the small and medium cap sizes.





4.3

Patient preparation

- It is recommended that any cannulation of the patient is performed prior to the commencement of scalp cooling as vasoconstriction caused by scalp cooling can impair venous access.
- Place a towel around the patient's shoulders.
- Prepare the hair according to hair type.

Hair preparation principles – all hair types

It is important that the patient's hair is prepared before the cold cap is put on the patient on treatment day.

By prepping the hair, we are aiming to:

- **Get the hair as flat to the scalp as possible/volume reduction** - This prevents any air pockets that can have insulative properties.
- **Improve conductivity** - Water assists the process of heat transferring away from the scalp
- **Prevent the hair from sticking to the cap for easy removal of the cap after treatment** - Conditioner should be smoothed over the hair.

Hair preparation methods vary between hair type.

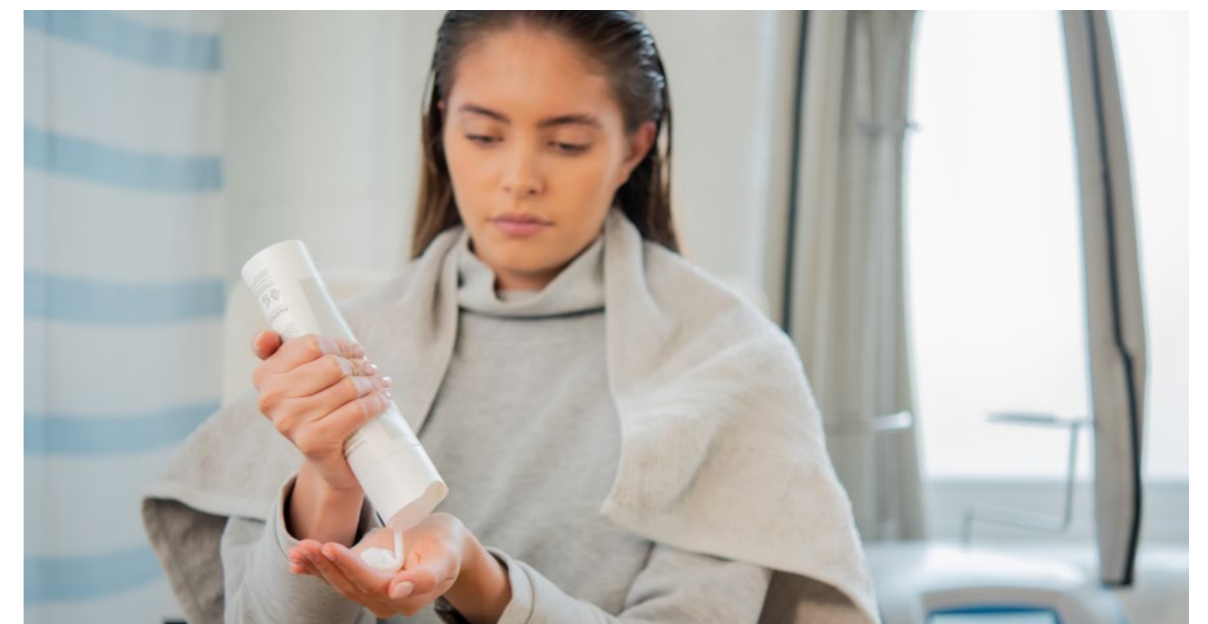
Hair preparation type 1 & 2 – straight & wavy

Use a spray bottle to dampen the patient's hair. There is no specific amount of water required, as each person's hair is different. The hair will need to be damp enough to slick back, but not so it is drenched.

There is no need to dampen the lengths of the hair if it is long, just the hair that will be under the cap.

Once the patient's hair is dampened, push it back and away from the forehead, particularly if the patient has a fringe or bangs, so that you can see the hairline. If a patient has thick hair, it is advisable to add a centre parting to ensure there are no dense sections of hair that could obstruct the cooling.

Use a small amount of conditioner, about the size of a coin, and smooth over the surface of the dampened hair. A huge amount of conditioner is not needed as the conditioner is only there to aid the removal of the cap once the patient's treatment is complete.



Hair preparation type 3 & 4 – curly & coily



Parting/sectioning the hair

Spreading the hair evenly across the scalp is important to achieve an even cooling process. Sectioning or parting the hair is the easiest way to achieve this with thick hair.

- Section the hair at the crown in to four or more sections.
- Sectioning the hair can also aid in distributing water and conditioner through the hair.



Using water

Important - Using water in hair prep is important to aid conductivity, allowing heat to more easily leave your scalp. Though, of course, adding water to type 3 and 4 hair is more likely to make it curlier and more voluminous.

- Option 1 for adding water - work a thick conditioner through the hair, then add some water with a spray bottle to create an emulsion, this can allow the hair to be slicked down.
- Option 2 for adding water - get the hair wet, then add conditioner. If your patient has high porosity hair, it may be challenging to keep their hair wet, but the conditioner will help to retain the moisture.

Note: Whichever option is used, ensure that water is used at the roots of the hair.



Twists or braids

- Small and loose twists or braids can be another way of getting the hair as flat as possible if smoothing the hair flat is not possible.
- Braids or twists should be done lightly (avoiding any tension at the roots) allowing them to compress under the cap- this will avoid dense sections of hair that might block the scalp.



Forehead protection

Please ensure that the patient's forehead is **always** protected during treatment by creating a barrier between the cap and the patient's skin. This will reduce the discomfort.

Important

For gentlemen using scalp cooling who have a receding hairline, please ensure that additional protection is provided. This can be in the way of gauze or cotton rounds as per the picture.

There are a number of ways in which you can protect the forehead;

1. Paxman Forehead Protector – A specific adhesive protector positioned on the forehead.
2. Elasticated cotton headband – positioned on the forehead, below the hair line and below each ear.
3. Cotton rounds or gauze – push up inside the cap after it has been fitted.



Ear protection



Important – Please note if needed that the ears should be protected from the cap. This is to ensure that bare skin does not come into contact with the cap to avoid any discomfort.

Fitting the cap to the patient

Here you will find 2 different options for fitting the cap to the patient. It is really important that you achieve the **3 C's** Close, Consistent, Contact. That there is no tenting on the cap cover and no blue cap showing. Below you find the guidance on how to achieve the best cap fit.

Option 1: cap complete with cap cover

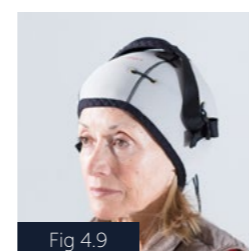
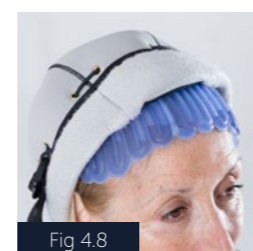
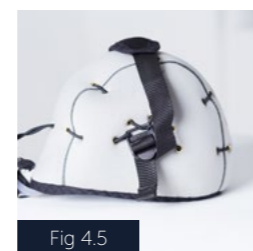
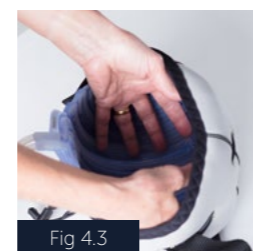
Cap cover application

- Remember to outstretch the cap cover before every application – see section 7.1 for full guidance on this.
- Pinch together the edges of the silicone cap (Fig 4.1).
- Insert the pinched cap inside the cap cover (Fig 4.2).
- Pull the silicone cap sides outwards to fill the cap cover (Fig 4.3).
- Pull the cap cover up over the silicone cap so that the cover fully covers the external surface of the silicone cap (Fig 4.4).
- Ensure that there is a snug fit between the cap cover and the silicone cap. (Fig 4.5 - 4.6).

Cap fitting to the patient (including cover)

Please note that all the standard protocols of patient preparation should be carried out before fitting the cap. It is also important to utilise a forehead protector, headband or medical gauze with the cap to prevent direct contact between the silicone cap and bare skin.

- Lift the front part of the cap cover up so that the silicone cap is visible.
- Fit the cap to the patient's head whilst standing directly in front of them to ensure the cap is on straight. Align the front of the silicone cap with the hairline and around the ears (Fig 4.8).
- Lower the front of the cap cover once the cap is in the right position (Fig 4.9).
- Keep one hand on top of the cap cover and then with the other hand pull down and smooth down the cap cover. This will eliminate any tenting. Don't be afraid to pull hard but do not use two hands at once, as this will be unnecessarily uncomfortable for the patient and will only move the inner silicone cap from side to side. (Fig 4.13)
- Fully tighten the chin strap to set the cap in position and activate the bungee chords. (Fig 4.16)
- Pull tight on the bungee cord at the back of the cap and lock in place utilising the bungee cord toggle. (Fig 4.18)
- Loosen of the chin strap to ensure a more comfortable fit – the patient should be able to talk and eat! (Fig 4.19)



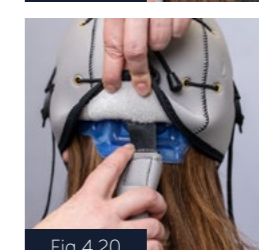
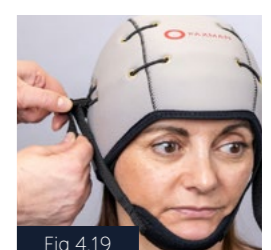
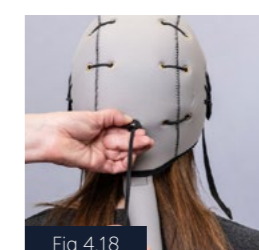
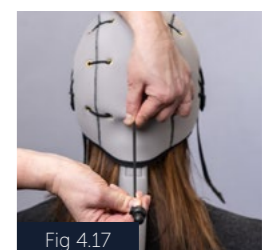
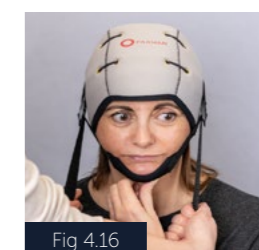
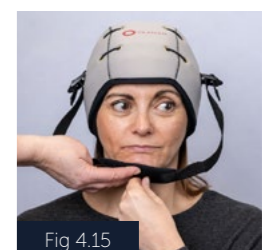
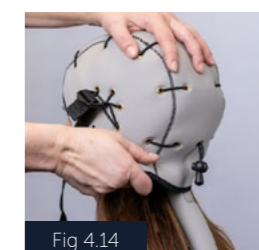
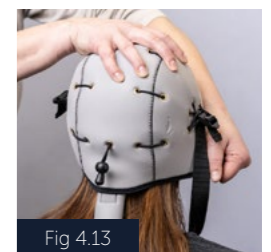
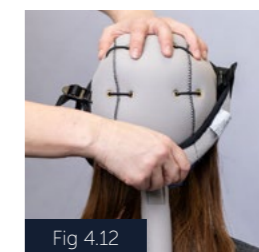
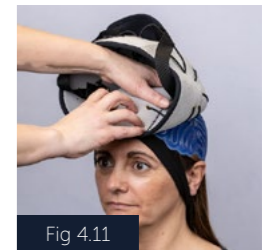
- Fix the velcro tab at the back of the cap inside the cap cover to ensure the cap tail coolant lines are protected. (Fig 4.20)
- Finally, apply the all important lacing technique as per the below instructions.

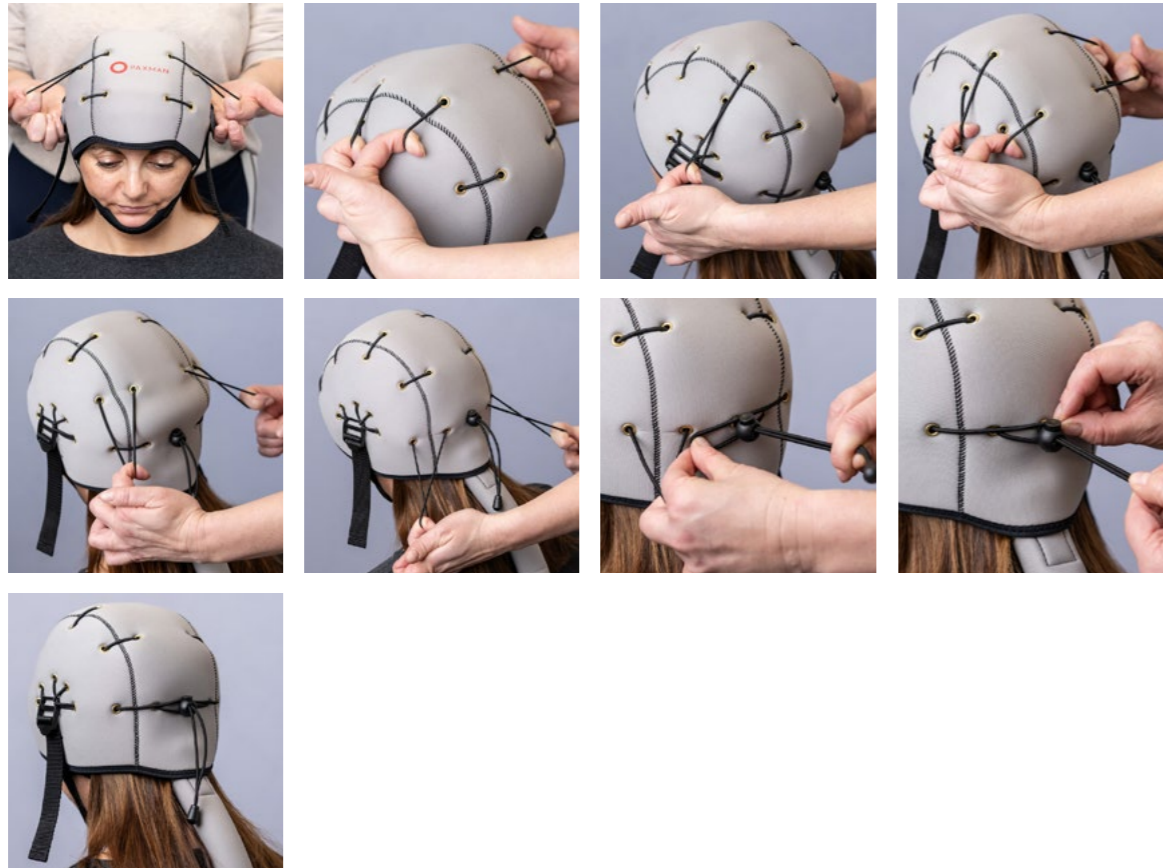
Option 2: fitting the cap excluding the cap cover

Remember to outstretch the cap cover before every application – see section 7.1 for full guidance on this.

Please note that all the standard protocols of patient preparation should be carried out before fitting the cap. It is also important to utilise forehead protector, headband or medical gauze with the cap to prevent direct contact between the silicone cap and bare skin.

- Standing in front of the patient, fit the required inner silicone cap to the patients head. Line the front of the silicon cap up with the hairline and around the ears. (Fig 4.10)
- Turn the cap cover inside out
- With the Paxman logo to the front, line the front of the edge of the cap cover up to the edge of the silicon cap with one hand and then place the other inside the cap on the top of the head like a spider. (Fig 4.11)
- Roll down the cap cover ensuring all the inner silicone cap is totally covered. (Fig 4.12)
- Keep one hand on top of the cap cover and then with the other hand pull down and smooth down the cap cover. This will eliminate any tenting. Don't be afraid to pull hard but do not use two hands at once, as this will be unnecessarily uncomfortable for the patient and will only move the inner silicone cap from side to side. (Fig 4.13)
- Fully tighten the chin strap to set the cap in position and activate the bungee chords. (Fig 4.16)
- Pull tight on the bungee cord at the back of the cap and lock in place utilising the bungee cord toggle. (Fig 4.18)
- Loosen of the chin strap to ensure a more comfortable fit – the patient should be able to talk and eat! (Fig 4.19)
- Fix the velcro tab at the back of the cap inside the cap cover to ensure the cap tail coolant lines are protected. (Fig 4.20)
- Finally, apply the all important lacing technique as per the below instructions.





Lacing technique

- Standing behind the patient, starting with the **second set** at the front of the cap, pull the bungee cords at each side out and down (so they look like bunny ears).
- Whilst still holding this set, then take the next set and pull out and down, then let go of the first set.
- Repeat this 4 times until you reach the final set.
- With the remaining bungee cord from the final set, cross this over the toggle at the back on each side to secure in place.



What are the important things to note to ensure the best fit?

1. The inner cap has consistent all over contact with the scalp.
2. Inner cap & outer cap are positioned centrally on the head.
3. The bungee cords and the chin strap are tightened – but not so tight that the patient cannot speak, eat or drink.
4. If a patient is having a cap fitted for them, the person fitting the cap must stand in front of the patient for best visibility.
5. Before fitting the cap cover for either method, ensure it is turned inside out and loosen those bungee cords, to ensure the cover isn't distorted before fitting.
6. Keep one hand on top of the cap to pull down and smooth the cap cover. Don't be afraid to pull hard, do not use two hands at once!
7. Use the lacing technique to achieve a better fit.



Cap Fitting is critical to success!

For more information and help with Cap Sizing, Hair Preparation and Cap Fitting, please follow the link to our 'How-To' videos on Coldcap.com



Our Big Sister of Scalp Cooling

Claire Paxman, Our Big Sister of Scalp Cooling, also has some useful cap fitting tips and helpful videos on her social media.

Connecting the cap to the system

The system is designed for ease of use when connecting and disconnecting caps and coolant lines. The system incorporates simple to operate, quick-release couplings. The design of the couplings is such that no spillage of coolant will occur.

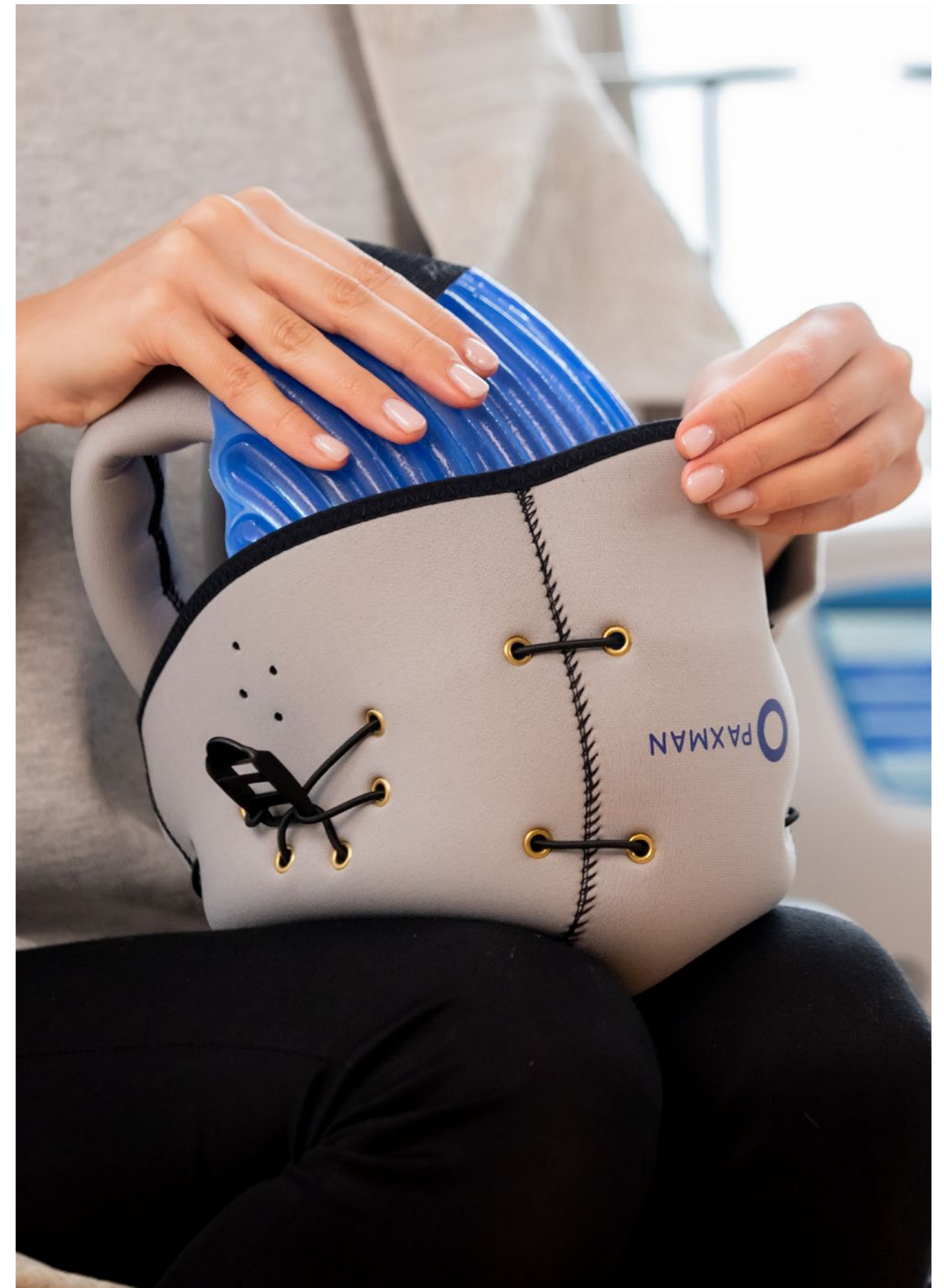


When connecting the couplings, the male and female connectors should be held with one in each hand, and simply pushed firmly together to connect as shown above. A click will be heard when the couplings are successfully connected.



When disconnecting the couplings, simply hold the couplings in both hands and press the white release button as shown above. The couplings will spring apart. Continue to pull the couplings apart to complete the disconnect procedure.

When the cap has been fitted correctly and connected to the system, the patient is ready to commence scalp cooling treatment.





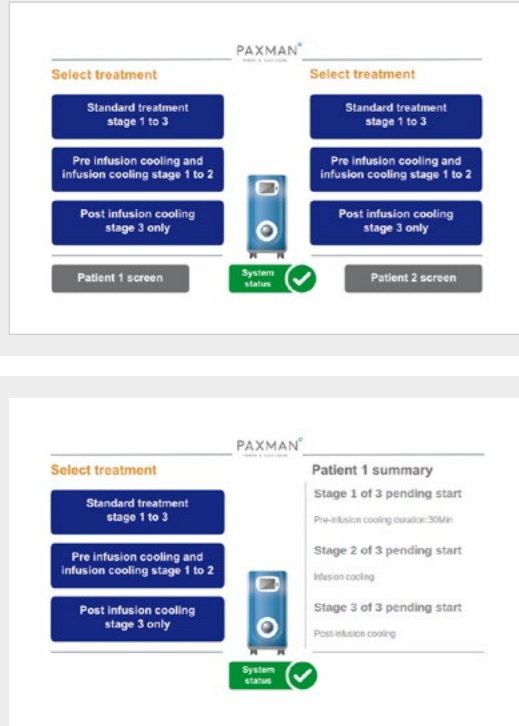
Module 05

Operation of the Paxman Scalp Cooler

- 5.1 Scalp cooling treatment stages & system operational options
- 5.2 Stage 1 - pre-infusion cooling
- 5.3 Stage 2 - infusion cooling
- 5.4 Stage 3 - post-infusion cooling
- 5.5 Temporary disconnection/bathroom breaks
- 5.6 Ending treatment
- 5.7 Switching off the device

Stages of scalp cooling treatment and system operational options

Stages of scalp cooling treatment



Please note the 'Home Screen' on the Paxman Scalp Cooling System. It has operational options for both Patient 1 and Patient 2.

A single patient system will only have the operational options on the left-hand side and a 'Patient Summary' on the right.

There are 3 stages to the scalp cooling treatment

Stage 1

Pre-Infusion Cooling; this is the time that the patient wears the cap before the chemotherapy infusion, to ensure the scalp is at the required temperature before infusion starts.

Stage 2

Infusion cooling; this is the time the patient continues to wear the cap during their chemotherapy infusion.

Stage 3

Post Infusion Cooling; this is the time that the patient continues to wear the cap following the chemotherapy infusion, ensuring that the scalp remains at the required temperature while the chemotherapy drugs are at their most potent in the patient's body.

System operational options

The home screen (Fig 5.1), has 3 operational treatment type options;

Option 1

Stage 1 through to Stage 3 – select this treatment type option if the patient is to remain in the same infusion chair throughout their whole scalp cooling treatment.

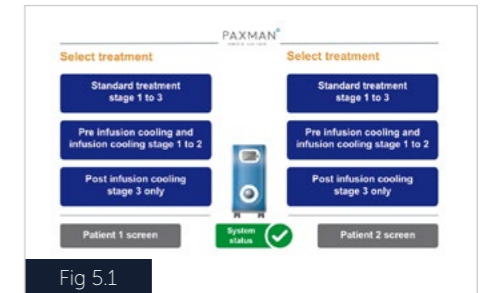
Option 2

Stage 1 and Stage 2 Only – select this option if the patient is to be moved from the infusion chair to a post cooling area and/or system for stage 3.

Option 3

Is Stage 3 Only – select this treatment type after the patient has been moved to commence Stage 3 Post Infusion Cooling only.

Select the option which is appropriate to how you will be treating you patient.



Stage 1 Pre-infusion cooling

- To start pre-infusion cooling press the **Continue** button (Fig 5.5). This will activate the pump and start the flow of coolant through the cap. The cap will inflate slightly and the temperature of the cap will start to decrease. It will start to feel cold quite quickly. For the first 10 minutes the patient may experience some cold discomfort, but this will pass when the patient acclimatises to the cooling sensation.
- A countdown timer will be activated depicting the time remaining for Stage 1 (Fig 5.6). The duration of Stage 1 cooling is standardized at 30 minutes. **Extend Stage 1 Cooling for patients with thick hair.**
- There is an option to extend the Stage 1 cooling time by 15 minutes for patients with thick hair. The nurse will advise the patient if this is necessary.
- If required, extended cooling is achieved by pressing the **Extend** button.
- Upon completion of Stage 1 pre-infusion cooling the screen will indicate cooling complete (Fig 5.7).

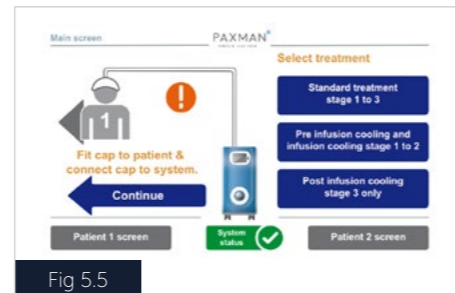


Fig 5.5



Fig 5.6

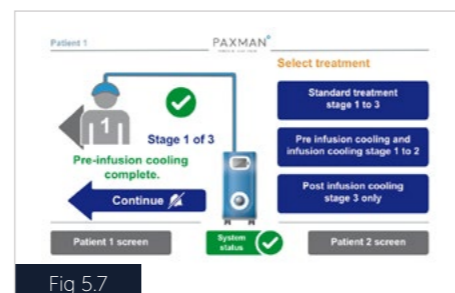


Fig 5.7

Note: The system will continue to circulate the coolant through the cap continuously during all Stages 1 to 3. Coolant circulation will be terminated when the yes button is pressed in response to the end treatment prompt. This process ensures that scalp cooling is not compromised or disrupted due to any delays being incurred between treatment stages.

Patient comfort during treatment and takeaways

The first 15 minutes are tough! But the discomfort is transient and will pass.

- Patients may benefit from pain relief and should try distraction techniques such as; deep breathing, meditation, reading, listening to music, having a conversation, watching a film, drinking a hot drink.
- Patients should wear layers and warm clothing including thick socks.
- Patients should bring something to help pass the time such as a tablet to watch TV/ Films or a book.
- Bring plenty of water and snacks.
- Try not to look at the extra time in the infusion as a negative! How often do people get to just sit and relax, read that book or catch up with that box set?

Stage 2 Infusion cooling

- Chemotherapy infusion can now commence. The scalp is at optimum temperature to help prevent chemotherapy-induced alopecia.
- The User should press the **Continue** button and commence with the chemotherapy infusion. The screen will now show (Fig 5.8).
- When all the chemotherapy agents have been infused, the infusion complete button should be pressed (Fig 5.8).
- Stage 2 is now complete.

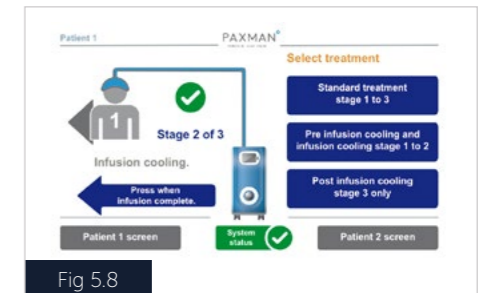


Fig 5.8

Protocol if a patient has a reaction to chemotherapy whilst scalp cooling

If a patient has a reaction to the chemotherapy, leave the scalp cooling cap on whilst immediately responding to the reaction with hospital protocol medication. Leave the cap on the patient for 30 minutes before re-challenging the infusion of chemotherapy. Continue with normal scalp cooling protocols once the reaction has been managed.

Stage 3 Post infusion cooling

Option 1 with timer

- Post Infusion Cooling can be carried out with or without a timer (Fig 5.9).
- Pressing the **Set Timer** button on the screen brings up the screen shown in Fig 5.10.
- Select the Hour and/or minute display when highlighted and then use the arrows to set.
- Press **Start** to begin the timer.
- For more information on post-infusion cooling times, please refer to the Scalp Cooling Guide: Efficacy, Data & Cooling Times.

Option 2 without timer

- Press the 'Without Timer' button on the screen.
- This will now show the 'Time Elapsed' (Fig 5.11).
- For more information on post-infusion cooling times, please refer to the Scalp Cooling Guide: Efficacy, Data & Cooling Times.

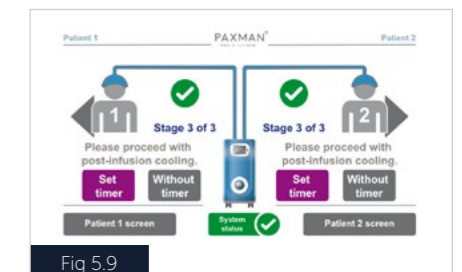


Fig 5.9

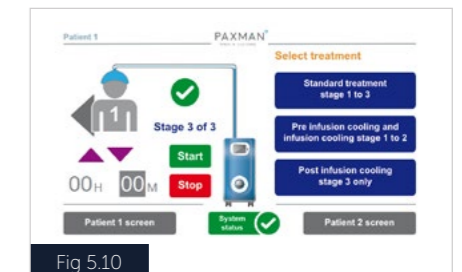


Fig 5.10



Fig 5.11

Paxman cooling times

For a comprehensive list of the Post Cooling Times please refer to the Scalp Cooling Guide: Efficacy, Data and Cooling Times.



Download our [Scalp Cooling Guide: Efficacy, Data and Cooling Times](#)

Patient summary screen

The Patient Summary Screen advises which treatment stages are 'pending' and which have 'completed' (Fig 5.12-5.13).

On a single patient Paxman Scalp Cooling System this remains on the screen at all times on the right hand side as per above (Fig 5.14).

On a dual patient Paxman Scalp Cooling System to access the Summary Page you must press the Patient 1 Screen or Patient 2 Screen dependant on which side the patient is being treated on (Fig 5.14).

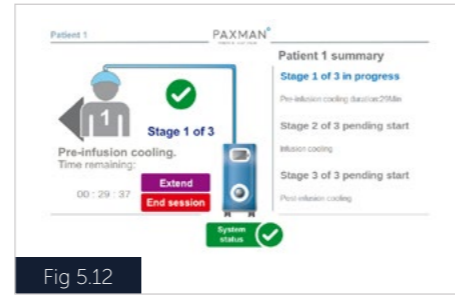


Fig 5.12

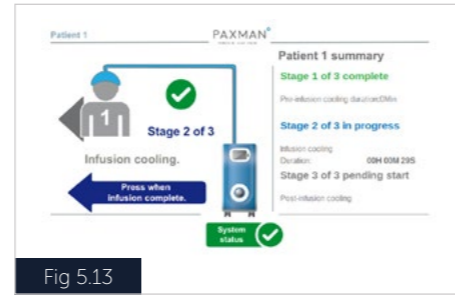


Fig 5.13

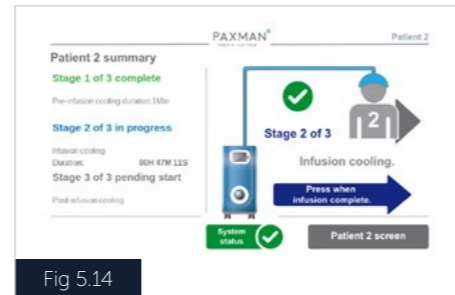




Fig 5.14

5.5

Temporary disconnection/bathroom breaks

Scalp cooling may be temporarily interrupted for patient bathroom visits. This involves disconnecting the cooling cap from the coolant line. The patient is then free to visit the bathroom while wearing the cooling cap.

- Disconnect the cap from the coolant line following the procedure in section 4.5 for disconnecting the couplings.
- An orange exclamation symbol  will appear (Fig 5.15).
- If the cap is not connected within 8 minutes a no flow warning symbol  will appear (Fig 5.16), and flash between connect cap and no flow and a buzzer will sound to alert the user or patient.

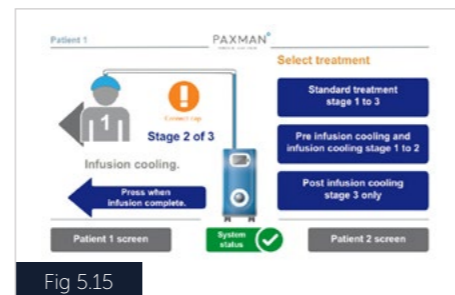


Fig 5.15

- When ready, reconnect the cooling cap, making sure that an audible 'click' is heard.

It is recommended a maximum of 10 minutes is taken for a bathroom visit or disconnection, any longer than this could lead to an increased chance of hair loss.

It is recommended that patients are NOT disconnected in the pre-infusion cooling stage. If this is unavoidable then the pre-infusion cooling time must start again.

If disconnection is carried out in the post-infusion cooling time then no additional scalp cooling time is required, scalp cooling can be terminated at the end of the timer countdown.

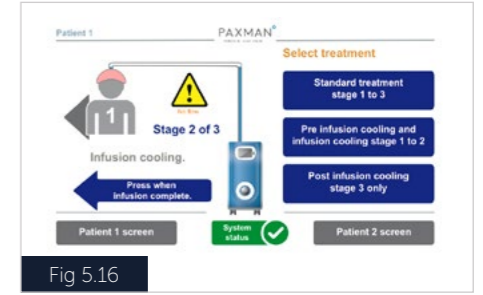


Fig 5.16

5.6

Ending treatment

With timer

- When the timer has completed the screen will ask for confirmation of the end of treatment (Fig 5.17). Press **YES**.
- The screen will return to the home screen.

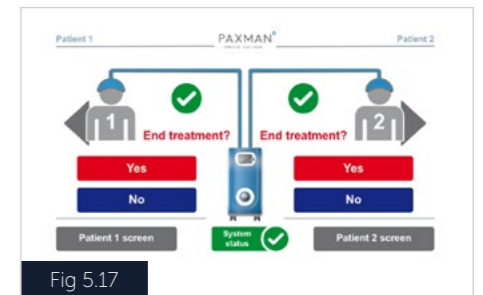


Fig 5.17

Without timer

- When Post-Infusion Cooling is complete press the **End Session** button (Fig 5.18).
- Then press the **End Treatment** button and confirm to end treatment (Fig 5.19).
- Then press **YES** as a final confirmation to end the treatment (Fig 5.17).
- The screen will return to the home screen.

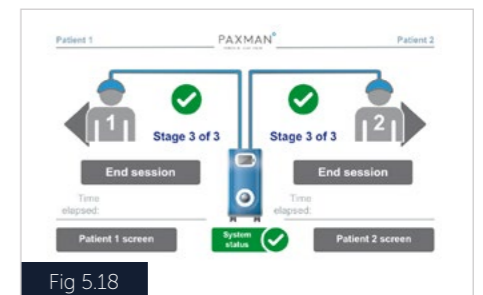


Fig 5.18

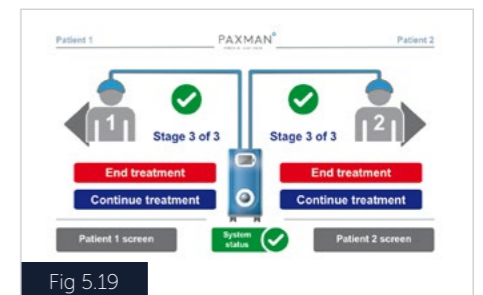


Fig 5.19

Cap disconnection

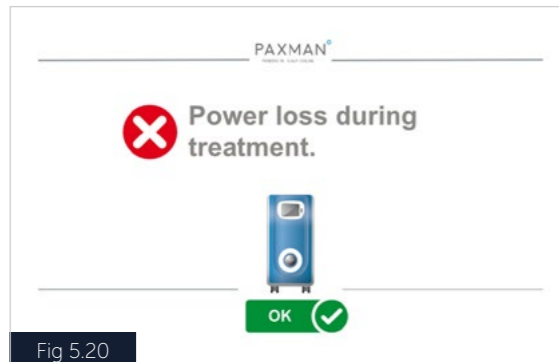
Disconnect the cap from the coolant line following the instructions in section 4.5

5.7

Switching off the device

If the Paxman Scalp Cooling System is not required for some time or once you have completed all your patients' treatments for the day, switch off the device using the power **on/off** switch on the back of the unit.

Ensure that there is no treatment in progress before switching power **off**. If power is switched off while treatment is taking place, a message (Fig 5.20) will be displayed when the system is next powered on.

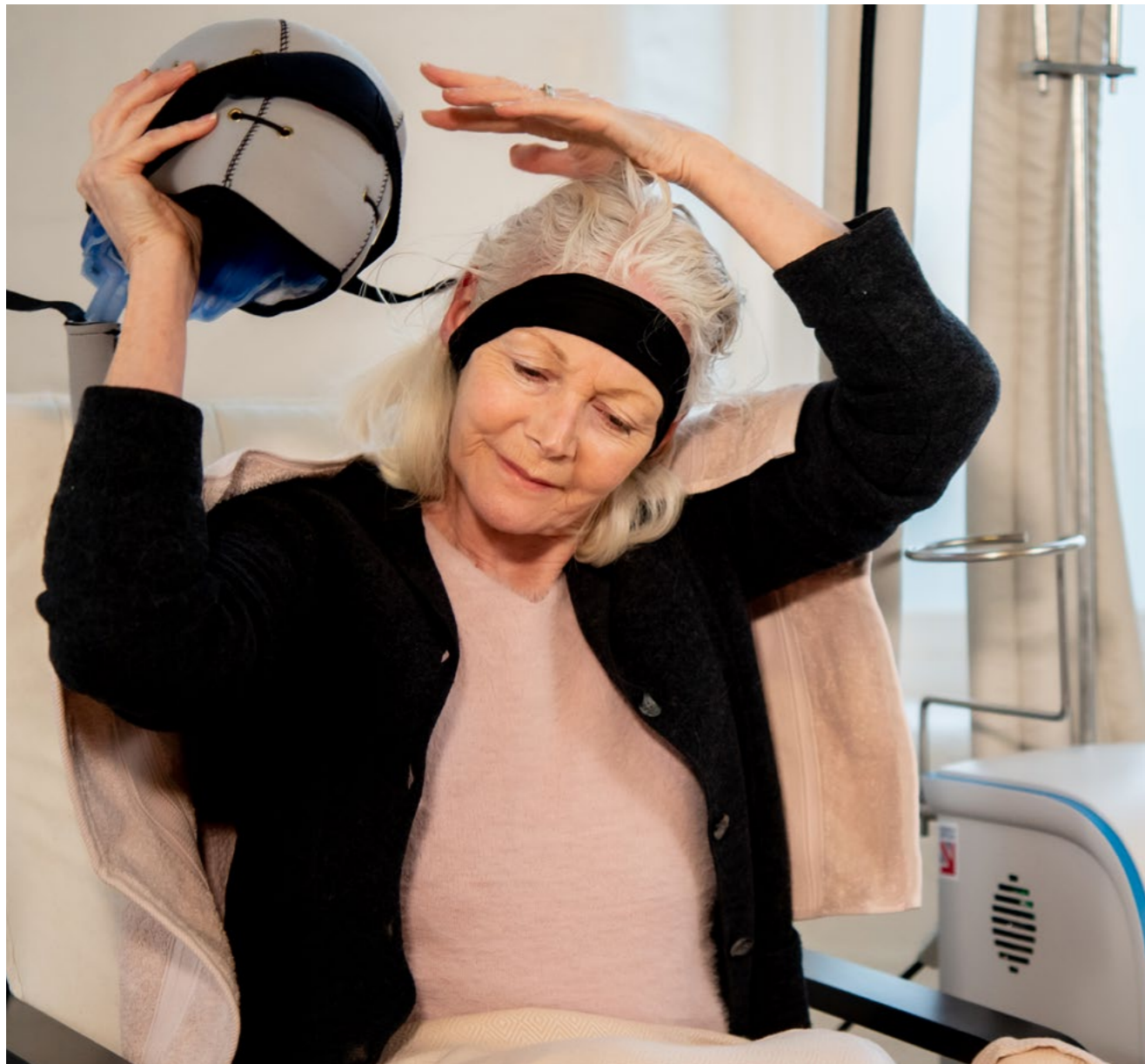




Module 06

Post treatment information

- 6.1 Cap removal
- 6.2 Post-treatment information - immediately after treatment in clinic
- 6.3 Post-treatment information - immediately after treatment at home



6.1 Cap removal

- With the patient now disconnected from the Paxman Scalp Cooling System, loosen the cooling cap chin strap and release the bungee cord.
- Do not remove the cooling cap at this stage.
- With the cap loosened, leave it in place on the patient's head for 5 to 10 minutes before removing the cap to allow the cap to warm up. This makes it easier to remove the cap and is more comfortable for the patient.
- Remove the cap from the patient's head by gently rocking it from side to side, so not to pull the patient's hair.
- If the patient can feel the hair pulling, stop the cap removal process and leave the cap on the patient's head for 5 more minutes before reattempting cap removal.

6.2 Post treatment information – immediately after treatment in clinic

- Once the cap has been removed, ensure the patient remains seated and allow them to acclimatise for 5 to 10 minutes as it can make them feel light headed when the cap is removed.
- If the hair has crystallised, allow the patient to gently finger touch the hair to alleviate this.
- Ensure that the patient leaves the clinic for the journey home with some form of head covering, either a hoodie, scarf or loose-fitting hat as their hair is damp.

6.3 Post treatment information – immediately after treatment at home

- For patients with Type 3 & 4 hair who have applied loose braids or twists; these should be removed within 24 hours to avoid any possible matting.
- The conditioner should be rinsed out of the hair for ALL hair types on treatment day or within 24 hours as the hair will be less manageable if it is left any longer.
- There is no need to shampoo unless the patient wants to, just rinse the conditioner out.
- Be very gentle when washing the hair – do not pile hair on top of the head.
- Gently pat dry the hair if using a towel or any other drying item used for curly/coily hair then allow to dry naturally.
- Brush hair with a detangling brush very gently.

For more information on general haircare guidance based on hair type please see Module 8.4.

- 7.1 Cleaning the Paxman Scalp Cooling System & caps
- 7.2 Cap storage, handling & cap rotation
- 7.3 Coolant top up

Module 07

Paxman scalp cooler maintenance

Cleaning of the Paxman scalp cooling system & caps

- Use the infection control procedure of the facility.
- The Paxman Cooling Cap should be thoroughly cleaned and disinfected before and after use.

Cleaning

- Remove cap cover from the silicone cap
- Wash the internal and external surface of the cap with warm soapy tap water.
- Rinse the cap with tap water to remove soap residues.
- Dry the cap thoroughly with a lint-free cloth.
- Use a 70% isopropyl alcohol (IPA) wipe to thoroughly wipe down the cooling cap.
- Allow the cooling cap to air dry.

Disinfecting

- Use a 10% bleach/water solution made fresh daily or purchase a bleach cloth/disinfecting wipe (e.g., Super Sani-Cloth® & Sani-Cloth® HB Germicidal) to thoroughly wipe down the cooling cap.
- Allow the cooling cap to air dry.
- Wipe over the internal and external surface of both the silicone cap and the cap cover (including the chinstrap) with a sanitising wipe. Any hospital-grade range of disinfectant / cleaning wipes is suitable for use with the cap and cap cover.
- In the event of the cap cover becoming soiled, the cap cover can be hand or machine washed in water no warmer than 40°C/104°F using standard mild detergent.
- Clean the external surfaces of the Paxman Scalp Cooling System machine using wipes dampened with soapy water of no more than 20°C/68°F or hospital-grade disinfecting wipes, ensuring liquid does not come into contact with the touchscreen display.
- When the caps are not in use they should be stored in the plastic box provided.

Reshaping the Cap Cover

To ensure the durability of the cap cover and to ensure that it fits properly to the patient, it is important to reshape the cap cover after and before each use. Follow the below guidance:

- Loosen the bungee cord toggle at the back of the cap cover and loosen the chin strap
- Turn the cap cover inside out
- In no order, pull out each of the internal bungee cords one by one until all of them have been pulled
- Stretch out the cap cover using both your hands
- Turn back inside out and perform a final stretch again using your hands
- Your cap cover is now back to it's normal shape



Examples of Poorly Shaped Cap Covers

Cap storage, handling & cap rotation

To ensure maximum effectiveness of the Paxman Cold Caps and durability it is important that good handling and storage practices are carried out to ensure the cap is not inadvertently damaged.

Correct storage of caps

The below instructions ensure that no sharp kinking or excessive strain is applied to the tail tubing when removing the caps from storage.

- The cap covers should be replaced back on to the cap once it has been used and cleaned, this maintains the shape of the cap cover and protects the silicone cap. Fig 7.1.
- Ensure the cap tail sleeve covers the silicone tubing and the Velcro is attached to the inside of the cover. Fig 7.2.
- Coil/fold the cap tail inside the cap Fig 7.3.
- Tighten the chin strap to neatly hold everything in place Fig 7.4.
- If caps are stored in the plastic tubs/boxes provided, please ensure they are neatly stacked next to each other upright Fig 7.5.
- If caps are stored in cupboards or on shelves, please ensure they are neatly stored with the cap covers in place, and cap tails coiled and secured inside as Fig 7.6.



Fig 7.1



Fig 7.2



Fig 7.3



Fig 7.4



Fig 7.5



Fig 7.6

Poor storage of caps

Further guidance, please see detailed below some incorrect and bad examples of storage methods.

- Cap tails bent at a sharp angle Fig 7.7. - The stress on the tail tubes can eventually lead to splitting of the tubing and coolant leaks.
- Caps without covers and poorly placed in the tubs/box with bent or sharp angled tail tubes, parts of the cap can get trapped resulting in punctures to the silicone. Caps may be picked up by the tail resulting in excessive strain on the cap tail tube. Fig 7.8.
- Caps stored in cupboards incorrectly with cap tails hanging loose or bent at sharp angles can result in part of the cap getting trapped in doors/cupboards resulting in punctures to the silicone. Caps may be picked up by the tail resulting in excessive strain on the cap tail tubing. Fig 7.9.



Fig 7.7



Fig 7.8

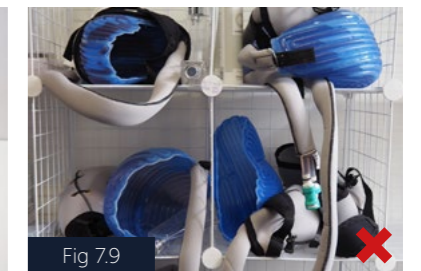


Fig 7.9

Handling of caps

Please always ensure that caps are handled with due care and attention.

- Do not pull a cap out from storage via the tail tube (this should be coiled inside the cap).
- Do not carry the cap via the tail tube.
- Do not carry the cap via the cap cover chin strap.
- Do not hang caps on the system support arms via the cap cover chin strap - please use the cap holders provided.
- Do not place the silicon cap on the support arms - please use the cap holders provided.

Cap rotation

Paxman continue to strive to ensure that our device and products remain state of the art. A part of this process is analysing post-market surveillance and updating our guidance and recommendations.

The Paxman cold caps have a 2-year device lifetime, however we are aware that some hospital sites have a larger uptake for scalp cooling. Please carry out appropriate cap rotation procedures to ensure the caps work optimally for patients and the hospital site.

Coolant top up

It is important that an adequate level of coolant is maintained within the device to ensure successful operation of the device. There are two level sensors in the coolant tank. One that monitors when the coolant has dropped below the higher level and one that monitors when the coolant has dropped below the lower level. When coolant drops below the higher level then the user is alerted to top-up the coolant level. When the coolant drops below the lower level the device will shut down and the user is advised to consult a service engineer.

Low coolant

- When the coolant drops below the high-level sensor an action box (Fig 7.10), will appear on the screen. The device will continue to operate normally. However the action screen will remain until the acknowledgment button is pressed. Once the button is pressed, the screen will return to normal.
- The device will continue to function normally until:
 - Either the device is switched off.
 - Or the coolant level drops below the lower level
- The system should be topped off after patient treatment has been completed.

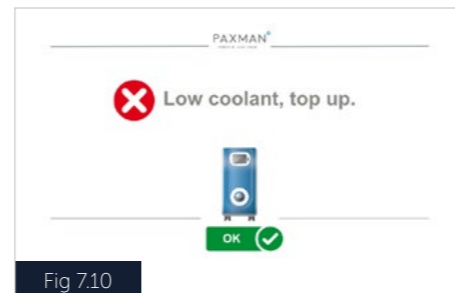


Fig 7.10



Fig 7.11

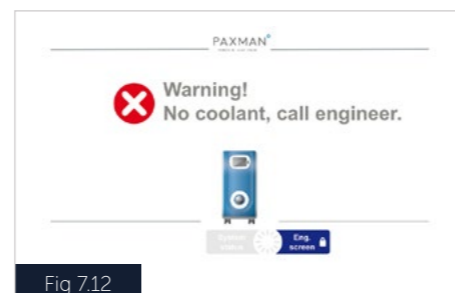


Fig 7.12

For full General Periodical Maintenance instructions and Technical Description for the Paxman Scalp Cooling System please refer to the [Instruction for Use Manual](#)

Switched off

If the device is switched off, it will remember it had low coolant. When it is switched on again it will not function, and it will display the warning screen (Fig 7.11).

Note the acknowledgement button is now disabled (Fig 7.11).

Adding 1lt of coolant following the process below will return the device to its normal status.

Coolant falls below lower level

The screen shown in Fig 7.12 is displayed. Call a Service Engineer.

Topping up the coolant level

The 'Coolant Top Up Valve' can be located at the back of the device Fig 7.13. This has a non return valve to minimize spillage. This should be unclipped to attach the 1 litre Bag or Cube (Fig 7.14 & 7.15)

The 1 litre Bag or cube had a membrane on the top of the dispenser. Push the bag/cube dispenser into the Top Up Valve until you hear it click to break the membrane and securely connect to the valve.

Lift the Bag/cube in the upwards position and the coolant will automatically flow into the device. (Fig 7.16 & Fig 7.17)

When the dispenser is empty, turn the top up point back to its original position with the valve pointing down whilst leaving the dispenser connected. Allow any residual coolant to flow back into the dispenser before removing it. This will close the valve and seal the device.

Secure the valve in its original position in the clip.

Coolant spillage

Should spillage of coolant occur wipe affected area with a disposable cloth or absorbent paper and place in a suitable waste container. Wash affected area with soap and water or a suitable floor cleaner. The product is biodegradable and no special handling is required.

Disposal

Coolant can be disposed of by following the manufacturer's instructions detailed in the Materials Safety Data Sheets or returned to Paxman for disposal.

Material Safety Data Sheet

The manufacturer's material safety data sheet is provided in the IFU. This product is NOT classified as dangerous or hazardous under EC criteria and is deemed completely safe for use in its intended purpose.



Fig 7.13

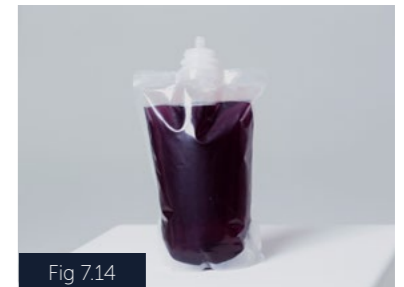


Fig 7.14



Fig 7.15



Fig 7.16



Fig 7.17

Information

The device can be topped up with coolant when it is switched on or when it is switched off



Module 08

Other important information

- 8.1 Safety & side effects & tolerability
- 8.2 Contraindications
- 8.3 Key clinical data
- 8.4 Haircare
- 8.5 Paxman resources

Safety, side effects & tolerability

Group	No. of Patients	Cases of Scalp Metastases	Incidence Rate
Scalp Cooling	1959	12	0.61% 95% CI / (0.32 - 1.1%)
Non-scalp Cooling	1238	5	0.41% 95% CI / (0.13 - 0.9%)

Safety

A study carried out by Dr Hope Rugo et al. in 2017, showed that there was no statistical difference in the incidence of scalp metastases between patients who have and have not received scalp cooling.

Scalp cooling with adjuvant/neoadjuvant chemotherapy for breast cancer and the risk of scalp metastases: systematic review and meta-analysis. Hope S. Rugo | Susan A. Melin | Jeff Voigt

Side effects

Below are a list of known and reported side effects of scalp cooling. It is important to note that all of these side effects are transient or temporary in duration.

- Discomfort due to feeling cold.
- Headache.
- Light-headedness or dizziness.
- Nausea.

Tolerability

Less than 5% of patients discontinue scalp cooling due to discomfort or intolerability.

A lot of patients don't find scalp cooling to be as cold as they expected, and the majority would describe the overall experience to be acceptable or tolerable.

Please refer to the guidance in Section 5.2 for tips and advice to help patients with any discomfort in the first 15 minutes.

Contraindications

Scalp cooling is contraindicated for:

- The subject has an existing history of scalp metastases, or the presence of scalp metastasis is suspected.
- Patients with cold sensitivity, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia, and post-traumatic cold dystrophy.
- Scalp metastases have rarely been reported in the literature, but caution regarding their development has been a limitation for the broad-scale application of scalp cooling during chemotherapy. Theoretically, tumour cells that have seeded in the scalp might not receive adequate chemotherapy during hypothermia, thus allowing them to grow at a later date.
- Patients with severe liver or renal disease from any etiology who may not be able to metabolize or clear the metabolites of the chemotherapeutic agent.
- Patients with haematological malignancies (leukaemia, non-Hodgkin and other generalised lymphomas).
- Patients with imminent skull irradiation.

Key clinical data & scalp cooling guidelines

The Dutch Registry found the following results on overall efficacy

56%

Patients did not require a head cover

53%

Patients reported good hair retention at the start of their final treatment

(WHO score 0/1)

Results of the Dutch scalp cooling registry in 7424 patients: analysis of determinants for scalp cooling efficacy

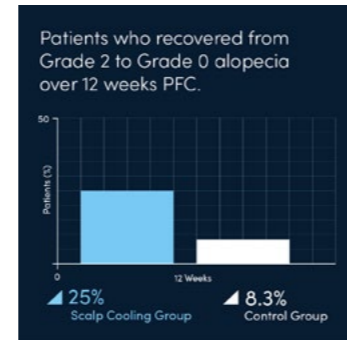
The Dutch Scalp Cooling Registry stands as the largest real-world, multicentre study focused on identifying the determinants of scalp cooling efficacy. Spanning over thirteen years (2006-19), this extensive registry includes data from 7,424 patients who underwent scalp cooling across 68 hospitals in The Netherlands. By examining patient outcomes across 24 different chemotherapy regimens, the study aims to provide valuable insights into the determinants that affect efficacy of scalpcooling to mitigate chemotherapy-induced alopecia (CIA). To date, it is the best snapshot we have of scalp cooling in the real world and a significant number of patients from this study used the Paxman Scalp Cooling System.

Visit scalpcoolingstudies.com/dutchregistry

Toni S Brook, Tanja Seetsen, Marcus W Dercksen, Annemarie van Riel, Veerle A Derleyn, Johan van den Bosch, Johannes W R Nortier, Andrew Collett, Nikolas T Georgopoulos, Jarek Bryk, Wim P M Breed, Corina J G Van Den Hurk.

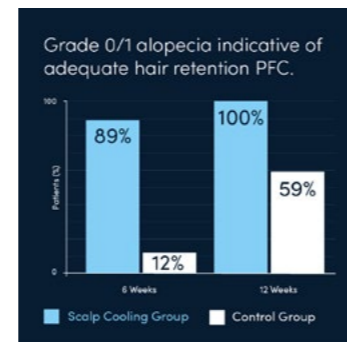


Calling for an international registry
Sign up to join the registry



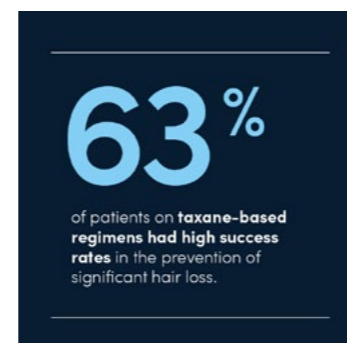
Efficacy of Scalp Cooling in preventing and recovering from Chemotherapy-Induced Alopecia in Breast Cancer Patients. The HOPE Study.

Takayuki Kinoshita et al



Randomized controlled trial of scalp cooling for the prevention of chemotherapy-induced alopecia

J. Bajpai et al



Effect of scalp cooling on alopecia in women undergoing chemotherapy for breast cancer. The SCALP trial

Julia Nangia et al

Persistent chemotherapy-induced alopecia (PCIA)

What is PCIA?

Persistent chemotherapy-induced alopecia, or PCIA, is hair loss that continues for more than six months after chemotherapy treatment ends. In a small number of cases, this can be permanent.

What causes PCIA?

Incomplete or altered hair growth can sometimes occur when receiving drugs such as paclitaxel, docetaxel¹, cyclophosphamide and epirubicin due to damage to the hair follicles.² It is estimated that PCIA will affect between 10-30% of patients receiving these treatment regimens, however the exact causes are not yet known.³

In a recent study, titled Scalp Cooling in Preventing Persistent Chemotherapy-Induced Alopecia: A Randomized Controlled Trial, researchers found that scalp cooling was effective at preventing PCIA⁴. The trial compared the outcomes of two patient groups receiving drugs known to cause persistent or permanent hair loss. One group scalp cooled, one group did not. Out of the 89 patients that scalp cooled, only 13.5% developed PCIA. Researchers also found that the scalp cooling patients had thicker hair and a greater hair density at the end of the study.

Living with PCIA

Both Shirley Ledlie and Jo Knight, two incredible and influential women living with PCIA, use their experiences with the condition to help others. We spoke to both of them individually about PCIA.



Watch Shirley's video



Watch Jo's video

It is important that we are making patients aware of this and allowing them to make an informed decision as to if they want to scalp cool or not to protect the hair follicles and the risk of PCIA.

Resources

aheadofourtime.org
alopecia.org.uk

Clinical papers

scalpcoolingstudies.com/ohsumi
scalpcoolingstudies.com/bhoayrul
scalpcoolingstudies.com/martin

References

¹ Kang D, Kim IR, Choi EK, Im YH, Park YH, Ahn JS, Lee JE, Nam SJ, Lee HK, Park JH, Lee DY, Lacouture ME, Guallar E, Cho J. Permanent Chemotherapy-Induced Alopecia in Patients with Breast Cancer: A 3-Year Prospective Cohort Study. *Oncologist*. 2019 Mar;24(3):414-420. doi: 10.1634/theoncologist.2018-0184. Epub 2018 Aug 17. PMID: 30120165; PMCID: PMC6519756.

² Permanent scalp alopecia related to breast cancer chemotherapy by sequential fluorouracil/epirubicin/cyclophosphamide (FEC) and docetaxel: a prospective study of 20 patients Kluger, N. et al. *Annals of Oncology*, Volume 23, Issue 11, 2879 - 2884

³ Persistent Alopecia and Docetaxel – Low Incidence, High Impact – Conversation led by patient advocate Shirley Ledlie with Dr Bevin Bhoayrul, Dr Albane Lhuillier, and Dr Dominique Spaeth. April 2022. Scalp Cooling Summit. <https://scalpcoolingsummit.com/wp-content/uploads/2023/03/Persistent-Alopecia-and-Docetaxel-Scalp-Cooling-Summit-Whitepapers.pdf>

Scalp Cooling Guidelines



US National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in oncology for breast cancer (Version 1.2019) update in 2019 and ovarian cancer, fallopian tube cancer and primary peritoneal cancer (Version 1.2020) update in 2020 to include scalp cooling as a Category 2A recommendation.

Cancer Australia Guidelines published in 2020, contains a list of recommendations and practice points that have been developed to assist health professionals in the management and care of early breast cancer.

The European Society for Medical Oncology (ESMO) Guidelines the leading professional organisation for medical oncology. With more than 25,000 members representing oncology professionals from over 160 countries worldwide, ESMO is the society of reference for oncology education and information.

Association Francophone des Soins Oncologiques de Support (AFSOS) an association founded in 2008 by oncologists to promote the knowledge and implementation of supportive cancer care. Its aim is to share knowledge, research, training and protocols between the French-speaking oncology community and the various players in supportive care.

UK Oncology Nursing Society (UKONS) has included scalp cooling in their Systemic Anti-Cancer Therapy (SACT) Competency Passport.

German Guideline Program in Oncology (GGPO) Guidelines The Association of the Scientific Medical Societies in Germany, the German Cancer Society and the German Cancer Aid jointly launched the German Guideline Program in Oncology in 2008. The program aims to foster the development, implementation and evaluation of evidence based clinical practice guidelines in oncology.



8.4

Haircare

Haircare during scalp cooling is likely to be different from usual haircare approaches, but doesn't need to be difficult.

It is important to be very gentle with the hair, focusing on keeping the hair as manageable as possible. It is good practice to brush the hair daily to remove any shed hairs that can lead to tangling, to wash hair less frequently than before treatment started, and to focus on conditioning products that will help maintain the hair's quality.

Good haircare won't improve hair retention rates, but it can make the experience more pleasant and ensure that retained hair is in the best possible condition.

We have a very useful booklet in conjunction with coldcap.com which includes lots of information to make patients day-to-day haircare during chemotherapy and scalp cooling as simple as possible. The booklet will guide patients through the following:

1. Getting your hair ready for scalp cooling
2. Scalp cooling haircare guides
 - Type 1 & 2 guidance
 - Type 3 & 4 guidance
3. Scalp cooling haircare FAQs
4. Post scalp cooling haircare guides

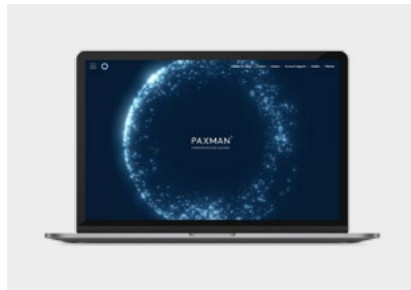


Download a copy of the [Scalp Cooling Haircare Guide](#)

Paxman resources

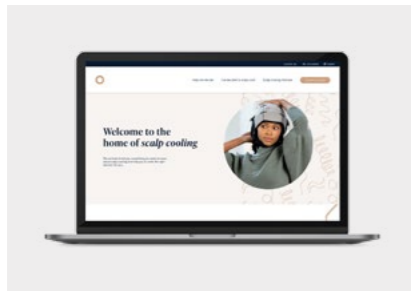
Please see detailed below all the helpful resources that Paxman offer and provide for you and your patients.

Websites



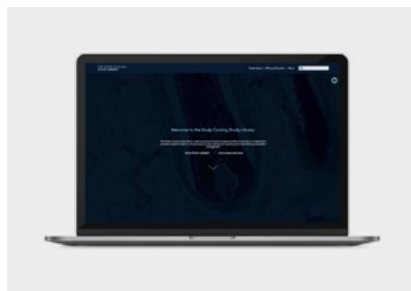
paxmanscalpcooling.com

For information on the Paxman Scalp Cooling System, clinical data summaries and Paxman across the globe.



coldcap.com

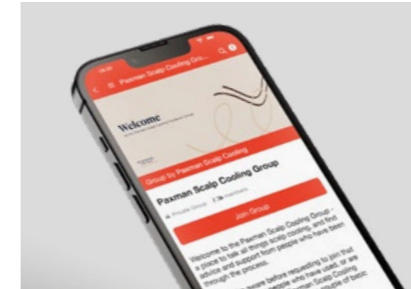
The home of scalp cooling information for patients to ensure that they are able to make informed decisions about the treatment.



scalpcoolingstudies.com

The Scalp Cooling Study Library highlights key clinical research studies and data to provide a platform for discussion, and provides an independent overview of global research and practice on scalp cooling and cryotherapy for chemotherapy side effect management.

Further items



Facebook Group

The Paxman Facebook Group is a private community where patients can find advice, guidance and support from those also going through scalp cooling.



Awareness resources

Items that can be put in place at cancer centres to ensure scalp cooling is front of mind for patients.



Desktop Aid

A comprehensive resource that can aid clinical teams in introducing and talking through scalp cooling with patients.

Patient literature



Help me decide - an introduction to scalp cooling

Everything you need to know to make an informed decision about scalp cooling.



Tell me what I need to know - scalp cooling patient manual

All the information you will need to get the most from scalp cooling.



Scalp cooling haircare guide

Everything you need to know to look after your hair while you are scalp cooling.



Information for hairdressers

Share with your hairdresser so they can help to support you through scalp cooling.



All of the above are available in a comprehensive pack encompassing information that will support the patient through scalp cooling from diagnosis to the end of chemotherapy treatment and beyond. To be given to all newly diagnosed patients

All literature is available in printed version and can be ordered for **free** by scanning the QR code.



10 things to know about scalp cooling

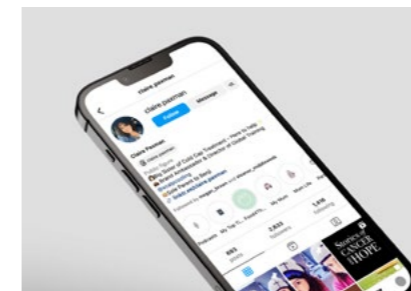
A succinct summary of the key factors to know about scalp cooling. A useful overview or introductory piece to be shared with newly diagnosed patients.



Diagnosis leaflet

A one-page summary of scalp cooling and available supportive resources. Can be shared with newly diagnosed patients as an introduction to scalp cooling.

The Big Sister of Scalp Cooling



Social media

Whether you are a patient going through treatment or a clinician providing treatment - **Claire Paxman is here to support you.**

You will find lots of information, helpful videos, top tips and myth busting on her social media channels.



Postcard

To be shared with patients who may need additional support when going through scalp cooling.



Find out more about Claire, your big sister of scalp cooling, by scanning the QR code.

PAXMAN^o

Contact info

Paxman Scalp Cooling

Tel: +44 (0)1484 349 444

Email: info@paxmanscalpcooling.com

Paxman Coolers Limited

International House, Penistone Road,

Fenay Bridge, Huddersfield, West Yorkshire HD8 0LE

United Kingdom