THE PAXMAN
SCALP COOLING
SYSTEM

Caution: Federal law restricts this
device to sale by or on the order
of a Physician.

SYSTEM OVERVIEW, CLINICAL EFFICACY, & SAFETY
Published experiences with Paxman Scalp Cooling System efficacy and patient tolerability data

The Paxman Scalp Cooling System is globally recognized as the leading product for hair-loss prevention during chemotherapy treatment.¹

The Paxman Scalp Cooler is indicated to reduce the likelihood of chemotherapy-induced alopecia (CIA) in women with breast cancer.
When Sue Paxman lost her hair while receiving chemotherapy for breast cancer, her family shared her distress. Sue’s husband, Glenn, founded Paxman on the back of this experience and to this day we remain a close family business. Knowing first-hand the effects that both cancer and its treatment can have on patients, friends, and families, our business is much more than just a job. We aim to make a difference in people’s lives by raising awareness about scalp cooling and establishing it as a common practice for patients undergoing chemotherapy.

As the leading global manufacturer and supplier of scalp-cooling equipment, we work in partnership with medical professionals, research centers, cancer support groups, charities, and patients to continually improve our technology and expert knowledge base. Investing in scientific testing and development has allowed us to attain outstanding technical precision and the highest levels of clinical efficacy. We strive to gain further knowledge and understanding of hair-loss prevention for cancer patients receiving chemotherapy.

We are committed to giving patients a degree of control during chemotherapy treatment. We have made it our responsibility to offer advice, support, and access to scalp cooling for patients with breast cancer no matter where they are in the world. Having been through the same journey as many patients and their families, we are dedicated to empowering people by giving them the choice to keep their hair.

WATCH THE PAXMAN STORY
paxmanUSA.com
A Simple Definition

Scalp cooling is a simple procedure that can prevent alopecia caused by certain chemotherapy drugs. The use of scalp cooling is proven to be an effective way of combating CIA and can result in a high level of retention or can completely preserve the hair. For patients, this means the opportunity to regain some control, maintain their privacy, and encourage a positive attitude toward treatment.
Why Chemotherapy Makes Hair Fall Out

Chemotherapy works by targeting all rapidly dividing cells in the body. Hair is the second fastest dividing cell in the body and this is the reason why many chemotherapy drugs cause hair loss. The hair follicles in the growth phase are attacked resulting in hair loss approximately 2 weeks after the commencement of the chemotherapy treatment.

The basic principle of chemotherapy is to damage the mitotic and metabolic processes in cancer cells. The reason this also affects hair follicles is because as many as 90% of them will be in an active growth phase (anagen).

Chemotherapy induces keratinocyte apoptosis and hair follicle regression, as well as the impaired metabolic and mitotic processes in anagen hair follicles, all of which results in rapid and extensive alopecia.

How Scalp Cooling Works

The damage that chemotherapy causes to the hair follicle can be alleviated by using scalp cooling. It works by reducing the temperature of the scalp by a few degrees immediately before, during, and after the administration of chemotherapy. This in turn reduces the blood flow to hair follicles, which may prevent or minimize hair loss.

Cooling causes blood-vessel vasoconstriction, which has been shown to reduce blood flow in the scalp to 20% to 40% of the normal rate, resulting in less chemotherapeutic drug being delivered to the hair follicles.

The rate of drug diffusion across a plasma membrane is reduced by cooling, and thus lower effective drug doses may enter the cells.

Cell division is metabolism-driven—this process is decelerated by cooling.

Also, a decrease in the metabolic activity of the cells in the hair follicle could cause a more general reduction in the cytotoxicity of chemotherapy drugs localized to the scalp.
The Paxman Scalp Cooling System is globally recognized as the leading product for hair-loss prevention during chemotherapy treatment for breast cancer.\(^1\) Tested and developed for more than 20 years, the system features the highest levels of clinical efficacy, hospital safety, and patient comfort.\(^1-3\)

Used by patients with breast cancer, with most commonly used chemotherapy drug regimens, the Paxman Scalp Cooling System is specifically designed to meet the needs of both patients and nursing staff. A compact unit means the system can be easily operated, quickly transported, and efficiently stored. Single or dual patient units mean greater flexibility for your center.

Our advanced system delivers a high level of technology, service, and best practices across the board.

### World-class reasons to use Paxman:

- Clinically proven success rates\(^2,3\)
- Requires little nursing time
- Each patient will receive a personal, single-patient-use cap packaged with other items
- Lightweight, comfortable cap is easy to use, and the system is low maintenance
- Paxman Hub has case managers who help patients with information and cap access
- Paxman training videos (on the website) clearly explain cap fitting
- Cleared by the FDA
- Serviced in the United States
- Extensive global experience\(^1,3,5-8\)
THE PAXMAN SCALP COOLING SYSTEM

MEET PAXMAN

The Paxman Scalp Cooling System is available in 2 models to allow either 1 patient to be treated or 2 patients to be independently treated at the same time. The Paxman Scalp Cooling System offers many benefits for use in hospitals, chemotherapy clinics, or healthcare facilities.

Providing the leading scalp-cooling technology for hair-loss prevention, the system consists of a compact refrigeration unit containing a coolant that is circulated through specially designed cooling caps. The coolant lines are supported by a raised, adjustable arm to offer maximum comfort for the patient.
Features

- Small, compact size, which is easily maneuvered
- Single or dual patient unit, which are independently controlled
- Easy-to-read, touch-screen visual display with system-status graphics
- One-touch switch operation for simple ease of use
- Scientifically developed, low-temperature, nonviscous coolant with ultraefficient heat transfer properties
- Instant cooling capability once connected to the system to allow immediate use
- Visual and audible alarms for restricted and no-flow coolant conditions
- High-ambient-temperature warning alarm
- Countdown timer with touch-screen access and visual display
- System-diagnostics access for operators
- Coded access for service engineers
- Telephone technical support
- Pay-for-use token in the cap gets scanned, which starts the Paxman Scalp Cooling System machine. The session cost is then depleted from the patient’s account (set up through the Paxman Hub)
THE PAXMAN SCALP COOLING SYSTEM

PAXMAN SCALP COOLING CAPS

Designed for Flexibility

The most important feature of the Paxman Scalp Cooling System is the lightweight design of the personal single-patient-use cap. Manufactured from medical-grade, soft-silicone material, the cap is light, yet flexible and strong, and easy to use. The Paxman Cap provides a close fit around the patient’s head. After extensive anthropometric research regarding head shapes, 3 different cap sizes were developed to meet the needs of all patients.

Personal Paxman Scalp Cooling Cap covers have a logo that is color coordinated by size:

Each personal cap package will include:

- The Paxman Scalp Cooling Cap
- The neoprene cooling cap cover
- A head band for protection of the ears and forehead
- Spray bottle to moisturize hair prior to putting on cap
- A wide-toothed comb
- Conditioner
- Patient brochure with instructions and specific hair-care–related information
- Towel to dry the hair and to dry the cap after the session

One of the adverse side effects can be a transient headache. Some patients may require mild pain-relief medication to reduce this side effect. As patients may feel cold from time to time, blankets should be made available for extra patient comfort.

Cools Efficiently

As coolant passes through the cap to extract heat from the patient’s scalp, inline temperature sensors ensure the cap maintains the scalp at an even, constant temperature. A neoprene cover is provided with the Paxman Cap to assist in the efficiency and operation of the system. Insulating it and protecting it from high room temperatures, the cover absorbs condensation and ensures good contact with the scalp—an essential factor for successful treatment.

Connects and Disconnects Easily

Paxman Caps are attached to the Scalp Cooling System with easily operated, quick-release, nondrip plastic couplings. Once the treatment is finished, the cap can be disconnected from the coolant line.

For successful hair-loss prevention, the scalp needs to be maintained at a constant temperature. This is achieved by the correct fitting of the cap.

Switch on the machine and allow it to reach operating temperature. This takes up to 30 minutes and indicates when the system is ready to use on the touch-screen display. Scan the pay-for-use token on the back of the cap so the session number can be recorded.

Prior to placing the cap on her head, some water and conditioner will need to be put on the patient’s hair (this is shown and explained in Paxman videos on the website). The patient will bring her personal cap and, after the initial use, she should be able to place it on her head. The nurse can then help put the neoprene cover over the cap. Alternatively, the cap can be placed in the cover and then fit to the head. Ensure the headband is in place, too. Connect the cap to the system.

Pre-cooling of the scalp takes 30 minutes prior to commencement of drug infusion. This ensures the scalp is at the required temperature before chemotherapy is administered. Premedication and patient preparations can take place during the pre-cooling period.

The cap should be worn throughout the administration of the chemotherapy drugs and for 90 minutes after.

The system requires minimal nursing supervision so that it works well for both patients and healthcare professionals.
Patient Flexibility
Due to the lightweight nature of the caps, patients can relax during the cooling process, engage in a number of activities, and visit the bathroom without affecting their treatment.

Nursing Flexibility
The system is simple to operate with easy-to-read displays. It is compact and maneuverable; therefore, post-infusion cooling does not need to be carried out in the infusion chair.

Termination of Cooling
A nurse should assist with cap removal initially, but the patient should then become comfortable removing her personal cap. After removal, the patient should remain seated for approximately 5 minutes so that her head temperature adjusts to room temperature. The system can be left on for continuation of a second patient or while awaiting a new patient, or it can be simply switched off.

Post-Infusion Cooling Solution
Since infusion-chair time is often limited, Paxman will work with your center to supply additional equipment, which can be used in another area in your center. Once chemotherapy has been completed, patients can be disconnected from the Paxman Scalp Cooling machine and moved, making the infusion chair available to others.
A prospective investigation was recently published in *JAMA* evaluating the benefits of scalp cooling to prevent chemotherapy-induced alopecia.\(^2\)

- Efficacy results: scalp cooling was associated with prevention of significant hair loss in approximately 50% of women
  - Higher success rates were shown in patients receiving taxane-based regimens
- Scalp cooling was generally well tolerated with no severe adverse events. In a minority of patients, scalp cooling was associated with headache

**Scalp Cooling Alopecia Prevention (SCALP) trial: Study Design\(^2\)**

- This was a multicenter, randomized, nonblinded study testing scalp cooling among 182 women with early-stage breast cancer who were receiving chemotherapy with a taxane, anthracycline, or both
- The mean age of patients was 52.6 years; 36% (n=51) received anthracycline-based chemotherapy and 64% (n=91) received taxane-based chemotherapy
- Primary endpoint was success in hair preservation after the fourth cycle of chemotherapy. Secondary endpoints included wig use and scores on the EORTC Quality of Life Questionnaire-Core 30, Hospital Anxiety and Depression Scale, and a summary score of the Body Image Scale

**There were 7 trial sites across the United States\(^2\)**

- Baylor College of Medicine
- Cleveland Clinic
- Memorial Sloan Kettering Cancer Center
- Hematology & Oncology Associates of Northern NJ (now Summit Medical Group-MD Anderson Cancer Center)
- Baylor Sammons Cancer Center
- Texas Oncology-Medical City Dallas
- Texas Oncology-Houston Memorial City
RESULTS FROM THE SCALP TRIAL

• At the time of interim analysis, 142 patients were evaluable. Among the patients who were randomized and completed 4 cycles of chemotherapy, 48 of 95 women in the scalp-cooling group had successful hair preservation 50.5% (95% CI, 40.7%-60.4%) compared with 0 of 47 women in the control group 0% (95% CI, 0%-7.6%) (success rate difference, 50.5% [95% CI, 40.5%-60.6%; P<.001])²

• In an exploratory post hoc analysis that accounted for site effects, the estimated rate of hair preservation with anthracycline-based chemotherapy was 16% (95% CI, 4%-46%), and with taxanes was 59% (95% CI, 27%-84%)²

Patients with Paxman Scalp Cooling were significantly more likely to have less than 50% hair loss after the fourth chemotherapy cycle vs those with no scalp cooling²

Hair preservation with Paxman Scalp Cooling vs a control group and with chemotherapy regimens²

- Patients receiving anthracycline-based chemotherapy
- Patients receiving taxane-based chemotherapy

This trial was stopped early for superiority of hair retention²
Hair preservation in the scalp cooling group was statistically greater than that in the control group (P<.001 by Cochran-Mantel-Haenszel test).
Patient-Reported Outcomes/Quality of Life Results

There were no significant differences between the scalp-cooling group and the control group in the patient-reported outcome of changes in scores on quality-of-life scales from baseline to the end of treatment.

Safety Findings

- Of the 101 participants in the scalp-cooling group, 28 (27.7%) had at least 1 adverse event. The most common adverse device effects included headache, nausea, dizziness, chills, paresthesia, pruritus, sinus pain, skin and subcutaneous tissue disorders, and skin ulceration. Only adverse events related to device use were collected; 54 adverse events were reported in the cooling group, all were grades 1 (n=46) and 2 (n=8). Of the grade 2 events, 7 patients had headaches and 1 had scalp pain. There were no serious adverse device events.

- In this study, no patients developed scalp metastases. Because of the concern of the potential to develop scalp metastases, study participants will have routine post-study follow-up visits for 5 years to assess safety and overall survival.

Conclusions

Among women receiving adjuvant chemotherapy for early-stage breast cancer, use of scalp cooling vs no scalp cooling was associated with less hair loss. Additional studies will be necessary to assess the long-term efficacy and safety profile associated with scalp cooling.
**EXTENSIVE GLOBAL EXPERIENCE**

- **100,000+** patients treated worldwide
- Available in **32 markets** globally
- Used extensively for more than **20 years**
- More than **20 studies** since 2003 conducted in 17 countries: Australia, Austria, Canada, Denmark, France, Germany, Greece, India, Italy, Japan, Lebanon, Netherlands, Norway, Sweden, Switzerland, UK, US
Will Scalp Cooling Work for Your Patient?
Many thousands of patients throughout the world have retained their hair using the Paxman Scalp Cooling System when receiving their chemotherapy treatment.

Indication for use:
The Paxman Scalp Cooler is indicated to reduce the likelihood of chemotherapy-induced alopecia (CIA) in women with breast cancer.

Intended Use
The Paxman Scalp Cooling System is intended for use by appropriately qualified healthcare professionals who have been trained in correct operation of the device by a Paxman representative.

Patients and healthcare professionals should be aware of the following:
- Hair loss is a possible side effect of chemotherapy
- The treatment success rates vary from patient to patient and with different drug regimens being administered
- Patients cannot be guaranteed they will not lose any or all of their hair
- Patients may experience a headache during treatment
- Some patients may experience feeling cold during the treatment
- Some patients may experience feeling light-headed after the Paxman Scalp Cooling Cap has been removed
- Patients may visit the restroom during the treatment

Contraindications
Scalp cooling is contraindicated for:
- Patients with 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, tumor 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 hematologic malignancies (leukemia, non-Hodgkin and other generalized lymphomas)
- Patients with imminent skull irradiation

### Warnings and Precautions

- It cannot be guaranteed that scalp cooling will prevent all patients undergoing chemotherapy from losing any or all of their hair. The success rate of scalp cooling in reducing chemotherapy-induced alopecia varies from patient to patient and according to the chemotherapy regimen administered
- Long-term effects of scalp cooling and scalp metastasis have not been fully studied
- The Paxman Scalp Cooler should only be used by appropriately qualified healthcare professionals who have been trained in the operation of the device
- Do not allow any liquids to be placed on the scalp cooler or near the touch-screen controller, including drips from the cooling caps
- Avoid use in ambient temperatures above 86°F/30°C
- Do not touch the side ventilation grills while the device is in use

### Side Effects

Known side effects associated with scalp-cooling therapy include:

- Discomfort due to feeling cold
- Headache
- Light-headedness or dizziness
- Nausea
How Will My Patient Receive Her Paxman Scalp Cooling Cap?

The cap comes in the specially designed Paxman Personal Cap Kit, and is sent directly to each patient from the Paxman Hub.

The Paxman Hub is a call center with case managers who will work with each patient to discuss their situation and to quickly secure access. Patients will be encouraged to continue their scalp cooling throughout their treatment to maximize hair preservation. The Hub will provide continued support and reminders so that patients bring their kits to all visits. And should a patient not use all sessions, the remainder will be refunded. Many services and referrals (such as, referrals to The Hair to Share Foundation) are also provided at the Paxman Hub.

The Paxman Process: Facilitated by the Paxman Hub

- **Patient and HCP meet and discuss chemo and hair preservation**
  - Paxman Scalp Cooling is explained and, if chosen, cap is fit and Rx for Paxman Scalp Cooling is given. Cost is also discussed.

- **Enrollment form and Rx are faxed to the Paxman Hub**
  - Patient contacts the Paxman Hub. Case manager discusses services, logistics, and payment.

- **Paxman Personal Cap Kit is delivered**
  - Cap is quickly sent to patient’s home.

- **Patient receives package**
  - Patient reviews items in the kit, reads brochure, and is prepared for treatment visit. Hub will remind patient to bring kit. Patient is encouraged to view videos on the Paxman website.

- **Treatment day**
  - Patient brings Paxman Personal Cap Kit to center.
| WEIGHT          | Refrigeration unit 79.4 lbs (36 kg)  
|                | Caps between 28 oz (795 g) and 31.7 oz (900 g), includes coolant and cover |
| DIMENSIONS     | Height 25.2 in (640 mm) x Width 12.6 in (320 mm) x Depth 16.5 in (420 mm)  
|                | Extended height 64.9 in (1650 mm) |
| POWER SUPPLY   | 100-120 v or 230 v (50/60 Hz) single phase 850 VA  
|                | All electrical circuits earthed and protected with fused system  
|                | All fuses are Bussmann quick-blown fuses—10 A at 250 Vac with F-speed |
| CONDITION OF USE | Temperature: 50°F to 86°F (10°C to 30°C)  
|                | Atmospheric pressure: 70-106 kPa  
|                | Relative humidity: 30% to 75% |
| TEMPERATURE CONTROL | Electronic thermostat with touch-screen controller  
|                | Coolant flow rate and temperature continuously monitored in line |
| ALARMS         | Visual and audible for high temperature conditions  
|                | Loss of coolant flow |
| INLET PRESSURE OF COOLANT FLOW | Pressure into cap – 17 psi  
|                | Flow rate of coolant 0.3-1.7 fluid oz/s (10-50 ml/s) |
|                | REFRIGERATION - Hermetically sealed unit. CFC-free R134A refrigerant  
|                | COOLANT - Orbis C. See data sheet section 10 |
| DEVICE CLASSIFICATION | CE marked in accordance with annex V of the Medical Devices Directive 93/42/ EEC for a Class IIa Device. Body No. CE 0473 |
| ELECTRICAL CLASSIFICATION | BS EN 60601-1: 2006 + IEC60601-1-2006 for medical electrical equipment,  
|                | BS EN 60601-1-2: 2007 + IEC60601-1-2006 electromagnetic compatibility  
|                | Class 1 type BF  
|                | Product specifications are subject to continued evaluation and improvements and subject to change without prior notification. |

If you require any further technical information on scalp cooling or the Paxman system, please contact Paxman at the telephone number listed on the back cover.

In the United States, call 888-5PAXMAN