June 7, 2018

Paxman Coolers Limited
% Heather Crawford
Senior Consultant, Quality and Regulatory
Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, Texas 78746

Re: K173032
Trade/Device Name: Paxman Scalp Cooler
Regulation Number: 21 CFR 878.4360
Regulation Name: Scalp Cooling System
Regulatory Class: Class II
Product Code: PMC
Dated: May 2, 2018
Received: May 7, 2018

Dear Heather Crawford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173032

Device Name
Paxman Scalp Cooler

Indications for Use *(Describe)*
The Paxman Scalp Cooler is indicated to reduce the likelihood of chemotherapy-induced alopecia (CIA) in cancer patients with solid tumors.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Paxman Scalp Cooler

K173032

1. Submission Sponsor

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3. Date Prepared

June 03, 2018

4. Device Identification

Trade/Proprietary Name:	Paxman Scalp Cooler
Common/Usual Name:	Scalp Cooling System
Classification Name:	Scalp Cooling System to Reduce the Likelihood of Chemotherapy-Induced Alopecia
Regulation Number:	878.4360
Product Code:	PMC, Scalp Cooling System
Device Class:	Class II
Classification Panel:	General and Plastic Surgery

5. Legally Marketed Predicate/Reference Devices

Predicate Device: K163484, Paxman Scalp Cooler, Paxman Coolers Limited
Reference Device: K170871, DigniCap Scalp Cooling System, Dignitana AB

6. Device Description

The Paxman Scalp Cooler is a scalp cooling system used to reduce the likelihood of chemotherapy-induced alopecia previously cleared by FDA in women with breast cancer (K163484). The only change from the previously cleared device is the update in the indication for use from "women with breast cancer" to use in "cancer patients with solid tumors." There are no changes to the hardware or software in the subject device when compared to the device cleared under K163484.

The Paxman Scalp Cooler is a self-contained, mobile, electrically-powered refrigeration unit that circulates a refrigerated liquid coolant, at a pre-set temperature and flow rate, through a cooling cap, which is fitted to the top of the patient's head and connected to the refrigeration unit by a pair of coolant lines. A touchscreen controller with a menu-driven, graphical user interface, integrated into the refrigeration unit, allows the healthcare professional to initiate, monitor, and complete the scalp cooling process.

The touchscreen displays a menu-driven Graphical User Interface (GUI) that provides information to the user concerning the operational status of the scalp cooling unit; it also prompts the user to initiate some actions regarding the scalp cooling procedure and provides a timer count-down function for scalp cooling sessions. The GUI does not, however, directly control the scalp cooling process as there are pre-established programs for the scalp cooling administration.

The touchscreen controller provides feedback to the user concerning the status of the Paxman Scalp Cooler as it relates to the achievement of the pre-set temperature of the coolant, operation of the recirculation pump and connection of a cooling cap to the system. The software also

provides a timer count-down function for the initiated pre- and post-infusion cooling procedure. At the end of the pre-set time, a message is displayed on the touchscreen, and a buzzer sounds to alert the user to the fact that the scalp cooling time is complete.

7. Indication for Use Statement

The Paxman Scalp Cooler is indicated to reduce the likelihood of chemotherapy-induced alopecia (CIA) in cancer patients with solid tumors.

8. Limitations

The sale, distribution, and use of Paxman Scalp Cooler are restricted to prescription use in accordance with 21 CFR §801.109.

Limitations on device use are also achieved through the following contraindications, warnings and precautions included in the instructions for use.

9. Contraindications

Scalp cooling is contraindicated in pediatric patients.

Scalp cooling is contraindicated in patients with:

- An existing history of scalp metastases or the presence of scalp metastasis is suspected.
- Cancers of the head and neck.
- CNS malignancies (either primary or metastatic).
- Cold sensitivity, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia, cold migraine, cold urticaria, and post-traumatic cold dystrophy.
- Hematological malignancies (leukemia, non-Hodgkin and other generalized lymphomas) or hematological malignancies that are being treated for cure.
- Imminent bone marrow ablation chemotherapy.
- Imminent skull irradiation.
- Previously received, or scheduled to undergo skull irradiation.
- 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.
- Severe liver or renal disease from any etiology who may not be able to metabolize or clear the metabolites of the chemotherapeutic agent.
- Skin cancers including melanoma, squamous cell carcinoma, and Merkel cell carcinoma.

- Small cell carcinoma of the lung.
- Solid tumors that have a high likelihood for metastasis in transit.
- Squamous cell carcinoma of the lung.

10. Warnings and Precautions

Scalp and/or cutaneous metastases have been reported in patients with non-small cell lung cancer, colon cancer, renal cell carcinoma, ovarian cancer, and bladder cancer. Patients with advanced forms of these tumors may be more likely to experience scalp metastases with the scalp cooling system.

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 hair loss varies from patient to patient and according to the chemotherapy regimen administered.

Long-term effects of scalp-cooling and scalp metastasis have not been thoroughly studied.

Use of scalp cooling in the palliative setting in patients with metastatic cancer may also increase the risk for scalp metastases.

Use of scalp cooling with Taxanes plus anthracyclines when used together or in sequence has not been shown to be successful in preventing chemotherapeutic drug induced alopecia. The Paxman Scalp Cooler should not be used in these patients.

The effectiveness of this device in patients who have received previous chemotherapy has not been evaluated.

Clinical studies have demonstrated variable success rates in patient reduction of chemotherapy-induced alopecia with scalp cooling since the outcome is dependent on multiple factors including chemotherapy regimen, dose, duration of drug infusion, chemotherapy drug metabolism, and concomitant comorbidities. Data have shown that women who experience hair loss despite using scalp cooling might have worse quality of life than women who did not have scalp cooling.

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 at ambient temperatures of over 30°C/86°F.

Do not touch the side ventilation grills whilst the device is in use.

11. Substantial Equivalence Discussion

Aside from the change in the Indications for Use, the Paxman Scalp Cooler is identical in technological characteristics, design, and performance to the predicate.

The following table compares the Paxman Scalp Cooler to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

	Subject Device	**Predicate Device**	**Significant Differences**
Manufacturer	**Paxman Coolers Limited**	**Paxman Coolers Limited**	
Trade Name	**Paxman Scalp Cooler**	**Paxman Scalp Cooler**	
510(k) Number	K173032	K163484	Not applicable
Product Code	PMC	PMC	Same
Regulation Number	878.4360	878.4360	Same
Regulation Name	Scalp Cooling System	Scalp Cooling System	Same
Indications for Use	The Paxman Scalp Cooler is indicated to reduce the likelihood of chemotherapy-induced alopecia (CIA) in cancer patients with solid tumors.	The Paxman Scalp Cooler is indicated to reduce the likelihood of chemotherapy-induced alopecia (CIA) in women with breast cancer.	The subject device is identical in technological characteristics to the predicate device K163484 apart from the indications for use, which are being broadened from “in women with breast cancer” to “in cancer patients with solid tumors.” The subject device indications for use are identical to DigniCap,

	Subject Device	**Predicate Device**	**Significant Differences**
Manufacturer	**Paxman Coolers Limited**	**Paxman Coolers Limited**	
Trade Name	**Paxman Scalp Cooler**	**Paxman Scalp Cooler**	
			K170871.
Mechanism of Action	The unit is a compact, mobile refrigeration unit which circulates liquid coolant at low pressure through a special cooling cap on the patient's head. The circulation of the refrigerated coolant through the cap extracts heat from the patient's scalp maintaining temperature.	The unit is a compact, mobile refrigeration unit which circulates liquid coolant at low pressure through a special cooling cap on the patient's head. The circulation of the refrigerated coolant through the cap extracts heat from the patient's scalp maintaining temperature.	Same
Technology Overview	The unit is composed of the main unit that contains the refrigeration components, touch screen controller, and coolant tank. There are detachable coolant lines with covers, detachable cooling cap with covers, and proprietary coolant.	The unit is composed of the main unit that contains the refrigeration components, touch screen controller, and coolant tank. There are detachable coolant lines with covers, detachable cooling cap with covers, and proprietary coolant.	Same
Patient Population	Cancer patients with solid tumors	Women with Stage I – II breast cancer undergoing neoadjuvant or adjuvant chemotherapy.	Differs – The expanded patient population includes all cancer patients with solid tumors, which includes women with breast cancer.
Set Cooling Time	Yes	Yes	Same
Pre/Post Cooling Time	Yes	Yes	Same

	Subject Device	**Predicate Device**	**Significant Differences**
Manufacturer	**Paxman Coolers Limited**	**Paxman Coolers Limited**	
Trade Name	**Paxman Scalp Cooler**	**Paxman Scalp Cooler**	
Material of Cooling Cap	Silicone; Primasil Sil 100 silicone from 20 – 80 Shore Duromater	Silicone; Primasil Sil 100 silicone from 20 – 80 Shore Duromater	Same
Size of Cooling Cap	Small, Medium, Large	Small, Medium, Large	Same
Number of Cooling Caps/Lines	2	2	Same
Quick Disconnect	Yes	Yes	Same
Coolant Temperature Range	-15°C to 5°C	-15°C to 5°C	Same
Refrigerant Type	OrbisC (organic salt based)	OrbisC (organic salt based)	Same
Coolant Refilling	Yes	Yes	Same
Sterile	No	No	Same
Single-Use	No	No	Same
Main Unit Dimensions	Height: 640 mm Width: 320 mm Depth: 420 mm	Height: 640 mm Width: 320 mm Depth: 420 mm	Same
Weight	29.5 kg	29.5 kg	Same
AC Powered	100 – 120 V, 50/60 Hz	100 – 120 V, 50/60 Hz	Same
Touch Screen Interface	Yes	Yes	Same
Software Controlled	Yes	Yes	Same
Complies with	Yes	Yes	Same

	Subject Device	**Predicate Device**	**Significant Differences**
Manufacturer	**Paxman Coolers Limited**	**Paxman Coolers Limited**	
Trade Name	**Paxman Scalp Cooler**	**Paxman Scalp Cooler**	
ISO 10993-1			
Electrical Safety Testing Passed	Yes	Yes	Same

12. Non-Clinical Performance Data

No additional testing was conducted for this 510(k) to support substantial equivalence. The device in this submission is identical to the previously cleared device, as the purpose of this application was for the expansion of the treatment population only. Testing of the predicate device included biocompatibility, shelf-life, shipping and packaging, electromagnetic compatibility and electrical safety, software, and bench testing. All tests met the pre-determined specifications and acceptance criteria and demonstrated the Paxman Scalp Cooler to be safe and effective as labeled.

13. Clinical Performance Data

Published and non-published clinical data support use of the Paxman Scalp Cooling System in cancer patients with solid tumors. Clinical data in this application comprises registry data, a manufacturer-sponsored clinical study, clinical literature and non-published studies as described below.

Dutch Scalp Cooling Registry

The Dutch Scalp Cooling Registry has enrolled over 6000 cancer patients, including multiple cancer types and varies chemotherapy regimens. Seventy-one percent of all solid tumor patients wore no head cover at their last cooling session ($p < 0.05$) compared to 50% of all breast cancer patients at their last cooling session. Registry data demonstrate some subgroups, e.g. patients treated with certain chemotherapeutic agents, including AC, DAC and Irino mono, as well as patients with Asian or chemically-colored hair may be least likely to benefit from scalp cooling.

Paxman Coolers Limited SCALP study

The Paxman Coolers Limited SCALP (Scalp Cooling to Prevent Chemo-induced Hair Loss) clinical study (ClinicalTrials.gov identifier: NCT01986140) was initiated to evaluate the safety and efficacy of the Paxman Scalp Cooler, in support of its initial indication to reduce the likelihood of CIA in women with breast cancer (K163484).

Successful hair preservation was demonstrated in 69 of 130 women with cooling (53.1%; 95%CI, 44.5%-61.4%) compared with 0 of 54 women in the no cooling (control) group (0%; 95%CI, 0%-

6.6%) (success rate difference, 53.1%; 95%CI, 44.5%-61.7%). Seventy-one device-related adverse events were reported in the cooling group, all grades 1 and 2. No serious device-related adverse events occurred.

Primary and secondary study endpoints are complete. Enrolled subjects are currently in long-term follow-up for disease status and survival.

Clinical literature and non-published studies

The performance and/or safety of scalp cooling with the Paxman Scalp Cooler is reported in the clinical literature and non-published studies. These documents report the effects of scalp cooling on a range of cancer types, chemotherapeutic agents and regimens, and patient characteristics. Scalp cooling treatments appear well-tolerated and were infrequently discontinued by patients. The sensation of cold was sometimes reported, no serious adverse events occurred, and patient ratings of cooling therapy were generally favorable.

Findings from the clinical literature include:

- No unfavorable development of disease due to scalp cooling has been documented in patients with solid tumors, scalp cooling can safely be offered to patients treated with alopecia-inducing chemotherapy;
- Among women with stage I to II breast cancer receiving chemotherapy with a taxane, anthracycline, or both, those who underwent scalp cooling were significantly more likely to have < 50% hair loss after the 4th chemotherapy cycle compared with those who received no scalp cooling; and
- Solid tumor cancer patients undergoing docetaxel chemotherapy with Paxman scalp cooling had a lower occurrence of alopecia compared to patients without cooling. Alopecia occurrence among Paxman Scalp Cooler patients in the 3-weekly docetaxel regimen group was 23% compared with 74% in no cooling (control) patients. Similarly, alopecia occurrence was 7% among Paxman Scalp Cooler patients undergoing weekly docetaxel treatments compared with 17% in the no cooling patient group.

Findings from non-published studies include:

- An observational multi-center study of patients with several types of cancers reported a head cover was used by 51% of scalp-cooled patients; 38% of scalp-cooled patients were thought to have needlessly purchased a wig;
- A multi-center trial of breast, prostate and lung cancer patients demonstrated no head cover or wig was required in 88% of patients following 45 minutes of post-infusion cooling after 3-weekly docetaxel, compared with 74% of patients after 90 minutes post-infusion cooling; and
- A multi-center observational study of Lebanese patients reported a 91% success rate including 6 of 6 (100%) patients undergoing treatment with TAC who showed no signs of hair loss.

Table 5B and Table 5C, respectively, summarize published and non-published studies using the Paxman Scalp Cooling System on patients receiving chemotherapy.

14. Statement of Substantial Equivalence

The Paxman Scalp Cooler described in this application is unchanged from the device previously cleared in K163484. This application is limited to a revision of the indications for use. The clinical data from the Dutch Scalp Cooling Registry, Paxman Coolers Limited SCALP study, clinical literature and non-published studies provided in this application demonstrate the Paxman Scalp Cooler can be used to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.

Table 5B – Published Clinical Studies of the Paxman Scalp Cooler

Author	Type of Study/ Method	Patients	Chemotherapy Agents	Objective	Results (Performance and Safety)	Conclusion
van den Hurk, CJ, et al. (2012) Note: Study data is included 2006-2010 Dutch registry data and Paxman Netherlands Clinical Study of Efficacy/3	Registry, multi-center (28) Nurses and patients completed questionnaires on patients, chemotherapy and scalp cooling; logistic regression analysis was used to examine associated characteristics of the scalp cooling result	n=1411 Male n=50 (4%), female n=1357 (96%), missing n=4 Types of cancer: breast n=1216 (86%), female genital n=65 (5%), gastrointestinal/ colorectal n=63 (4%), lung n=19 (1%), prostate n=27 (2%), other n=16 (1%), missing n=5	A60C600 (AC) (n=74), A60C600/D100 (ACD) (n=16), ACT overall (n=50), D75A50C500 (TAC) (n=66), D overall (n=120), F500A50C500 (FAC) (n=39), FEC overall (n=752), F500E100C500/D100 (FE100CD) (n=46), TCarbo overall (n=68), T70-90 (42), Irino 250 (n=42), other (n=64)	To estimate the results of scalp cooling for currently used chemotherapies to provide patient information and identify characteristics associated with the results.	Overall, 50% of the 1411 scalp-cooled patients did not wear a head cover during their last chemotherapy session. Patients were satisfied with the results in 8% of cases after TAC chemotherapy and up to 95% after paclitaxel treatment. Besides the type of chemotherapy, higher dose and shorter infusion time, older age, female gender and non-West-European type of hair significantly increased the proportion head cover use. Hair length, quantity, chemical manipulation (dyeing, waving, coloring), wetting hair before scalp cooling, and treatment with chemotherapy ever before did not influence the degree of head covering among	Scalp cooling results as recorded in this open patient registry were positive for most regimens, justifying its use by all eligible patients, except for those needing TAC. Lengthening infusion time may improve the results.

Author	Type of Study/ Method	Patients	Chemotherapy Agents	Objective	Results (Performance and Safety)	Conclusion
					patients.	
van den Hurk, CJ, et al. (2013)	Review of observational studies, autopsy studies and Munich cancer registry	Studies of skin and scalp skin metastases in patients with breast cancer without scalp cooling: studies of scalp skin metastases in scalp-cooled patients with (mainly) breast cancer	Diverse	Using frequency data on metastases in breast cancer to discuss the risk of whether scalp cooling might facilitate hiding and disseminating scalp skin metastases and thus decrease survival.	The incidence of scalp skin metastases in breast cancer patients seems to be comparable for scalp-cooled (0.04-1%) and for non-scalp-cooled (0.03-3%) patients.	In patients with solid tumors, an unfavorable development of the disease due to scalp cooling has never been documented. Scalp cooling can safely be offered to patients treated with alopecia-inducing chemotherapy.
Lemieux J, et al. (2015)	Retrospective cohort	n=1370 women with non-metastatic breast carcinoma who received chemotherapy in neoadjuvant (n=140) or adjuvant setting (n=1230) n=553 used scalp cooling; n=817 were treated in facilities where scalp cooling was not routinely available	Not reported	To compare overall survival according to whether or not scalp cooling was used during neoadjuvant or adjuvant chemotherapy for non-metastatic breast cancer.	Median follow-up was 6.3 years for scalp-cooled group and 8.0 years for non-scalp-cooled group. No difference in overall mortality was observed between scalp-cooled patients and non-scalp-cooled patients (adjusted hazard ratio 0.89, 95% confidence interval 0.68-1.17, p=0.40).	Among women undergoing neoadjuvant or adjuvant chemotherapy for non-metastatic breast cancer, scalp cooling used to prevent CIA had no negative effect on survival.

Author	**Type of Study/ Method**	**Patients**	**Chemotherapy Agents**	**Objective**	**Results (Performance and Safety)**	**Conclusion**
Nangia J, et al. (2017) Clinicaltrials.gov identifier NCT01986140	Randomized, multi-center (7) A comfort scale was administered after each treatment in scalp-cooling group. Alopecia assessments using Common Terminology Criteria for Adverse Events (CTCAE) v4.0 at baseline and after chemotherapy cycle by a blinded clinician, patient's clinician and patient; participants	n=182 women with stage 1 or II breast cancer undergoing chemotherapy from December 2013 to September 2016 Randomized to receive scalp cooling (n=119) or no cooling (n=63) Each patient underwent scalp cooling for 30 minutes pre-infusion, during infusion and 90 minutes post-infusion	Planning to receive at least 4 cycles of taxane-(n=91, 64%) and/or anthracycline-based chemotherapy for curative intent (n=51, 36%)	To assess whether use of the Orbis Paxman Hair Loss Prevention System is safe and effective in reducing CIA in woman with breast cancer undergoing neoadjuvant or adjuvant chemotherapy.	Publication reports on interim analysis (n=142 patients); patients will be followed for 5 years for safety (time and site of first recurrence) and overall survival. 48 of 95 (50.5%) in cooling group had successful hair preservation (95% confidence interval 40.7%-60.4%) compared to 0 of 47 (0%) in the control group (95% confidence interval, 0%-7.6%). Success rate difference was 50.5% (95% confidence interval, 40.5%-60.6%). The trial was stopped early for superiority (p=0.0061). No statistically significant differences in changes in any of the quality-of-life (QOL) scales from baseline to chemotherapy cycle 4 were observed between the scalp cooling and control groups. 54 adverse events (all grades 1 and 2) were reported in the	Among women with stage I to II breast cancer receiving chemotherapy with a taxane, anthracycline, or both, those who underwent scalp cooling were significantly more likely to have < 50% hair loss after the 4th chemotherapy cycle compared with those who received no scalp cooling.

Author	Type of Study/ Method	Patients	Chemotherapy Agents	Objective	Results (Performance and Safety)	Conclusion
	were asked if they needed to use a wig and/or a head wrap				cooling group. There were no serious adverse device events.	
Massey C (2004) Note: Data is included in Paxman UK Clinical Study of Efficacy	Open, non-randomized, observational, multi-center (8) Alopecia was assessed using the World Health Organization (WHO) grading system; patient acceptability assessed by questionnaire; results compiled by Scalp Cooling Assessment Groups	n=94 breast cancer patients who underwent treatment 1997-2000	5-fluorouracil, epirubicin and cyclophosphamide (FEC) regimen	To assess the efficacy of scalp cooling to reduce alopecia for women undergoing treatment for breast cancer using the Paxman Scalp Cooler. To assess patient views on the comfort and acceptability of scalp cooling using the Paxman Scalp Cooler.	Use of the Paxman Scalp Cooler was judged a success for 89% of all patients using the WHO grading system for alopecia and for 87% of patients being specifically administered the commonly used 5-fluorouracil, epirubicin and cyclophosphamide (FEC) regimen. When asked about degrees of comfort during the scalp-cooling process, 85% of patients described it as very comfortable, reasonably comfortable or comfortable, with only 15% of patients reporting a description of uncomfortable or very uncomfortable.	Scalp cooling using the Paxman Scalp Cooler was found to be an effective technique with minimal side-effects for patients treated with commonly prescribed alopecia-inducing chemotherapy drugs.
Bini M, et al.	Observational,	N=47 breast cancer	70% of patients	To verify effectiveness of	Median number of the	The Paxman scalp cooler

Author	Type of Study/ Method	Patients	Chemotherapy Agents	Objective	Results (Performance and Safety)	Conclusion
(2004)	single-center Nurses completed questionnaire on patients, chemotherapy and scalp cooling characteristics during each session; results were evaluated indicating the severity of hair loss per CTCAE 3.0 during each chemotherapy session and patient's satisfaction during last treatment	patients who underwent treatment from June 2013-March 2014 Mean age: 53 years (range 35-72) 46 female, 1 male 80% were treated in the adjuvant setting and chemotherapy naïv e	received anthracycline-based polychemotherapy (AC or FEC 75 every three weeks), and 30% received monotherapy with taxanes on a weekly schedule	Paxman concerning alopecia in the sample group; evaluate patients' expectation and degree of final satisfaction with regard to its use.	cooling session: 5 (range 1-12). Alopecia G0 and G1 were registered at the end of chemotherapy in 62% of the patients, irrespective of the type of treatment. 100% of patients reported being satisfied in terms of hair preservation during their last session. 27% of patients discontinued scalp cooling treatment because of severe alopecia (G2); all these patients were receiving an anthracycline. Scalp cooling was stopped because of intolerance in 11% of patients mainly due to discomfort and longer time of infusion.	was found to be an effective technique with moderate side-effects for patients treated with commonly prescribed alopecia-inducing chemotherapy drugs. Lengthening infusion time seems to be the main limit of this system.
Falanga M, et al. (2010)	Observational, single-center	n=5 patients with breast or non-small cell lung cancer Patients complete	Single agent docetaxel	To determine efficacy and patient compliance of scalp cooler Paxman of patients subjected to single agent	The pilot study is ongoing with 5 patients enrolled to date and 9 chemotherapy cycles with the scalp cooler	Providing a means to reduce alopecia is important for patients for whom this is a distressing

Author	Type of Study/ Method	Patients	Chemotherapy Agents	Objective	Results (Performance and Safety)	Conclusion
		patient priority scale for chemotherapy-related side effects at baseline; patients treated with Paxman Scalp Cooler for 30 minutes pre-infusion and 45 minutes post-infusion; patient questionnaire following each treatment; hair loss evaluated by nurses applying WHO criteria at each chemotherapy cycle		docetaxel for breast cancer or non-small cell lung cancer; to report on first Italian experience.	support. Treatment has been well tolerated, with 1 case of refusal at treatment onset and all others continuing with successive chemotherapy cycles.	and feared side effect, and studies are warranted. Early data on patient acceptance to therapy are encouraging. Data on patient symptom priority, efficacy and further data on tolerance will be presented.
El-saka RO, et al. (2009)	Randomized Paxman Scalp Cooler was applied 20 minutes pre-infusion, during infusion and for 2 hours	n=120 female breast cancer patients treated in adjuvant setting, July 2007-August 2008 Patients were randomized for scalp cooling during	Doxorubicin (50 mg/m^2), 5-FU (500 mg/m^2) and cyclophosphamide (500 mg/m^2) for 6 cycles	To evaluate the role of scalp cooling in reducing anthracycline-induced hair loss and its impact on QOL.	After 4 cycles, 61.7 % of patients in the scalp cooling group had grade 4 hair loss compared to 81.7 % of patients in control group. After 6 cycles, 85% of patients in scalp cooling group experienced grade 4 hair loss compared to 100%	The role of scalp cooling is limited at the total dose of 300 mg/m^2 doxorubicin. It may be more effective with fewer cycles or less aggressive drug combination. Hair loss affects various aspects of QOL, especially

Author	Type of Study/ Method	Patients	Chemotherapy Agents	Objective	Results (Performance and Safety)	Conclusion
	post-infusion; hair loss assessed using WHO criteria at each cycle and after 6 chemotherapy cycles; QOL was assessed using the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and BR23	chemotherapy (n=60) or not (n=60)			of patients in the control group. 9 patients (15%) in the scalp cooling group developed grade 1-2 hair loss. No significant relation was found between degree of hair loss and liver function tests. 73.3% of patients were comfortable during cooling. QOL scores were comparable between groups except for emotional functioning and body image. In the hair loss group, 71.2% of patients showed severe disturbance of emotional functioning and 54.1% of patients had moderate disturbance in body image. In hair preservation group (9 patients), 77.8% developed moderate disturbance of emotional functioning and all patients had mild disturbance	emotional functioning and body image. More time is needed to assess the long-term effect of hair loss on QOL and the incidence of scalp metastasis in the two study groups.

Author	Type of Study/ Method	Patients	Chemotherapy Agents	Objective	Results (Performance and Safety)	Conclusion
					in the body image.	
Betticher DC, et al. (2013) Note: Study data is reported in Paxman Swiss Clinical Studies of Efficacy Clinicaltrials.gov identifier NCT01008774	Open-label, prospective, non-randomized	n=238 patients with solid tumors receiving chemotherapy in a palliative setting Patients allocated per their preference; n=128 Paxman, n=77 cool cap, n=39 no cooling Types of cancer: breast n=76, lung n=38, prostate n=86, other n=38	Docetaxel (55–60 mg/day on weekly therapy, 135–140 mg/day on 3-weekly therapy)	To investigate whether two different methods of scalp cooling can prevent hair loss, i.e. Paxman PSC-2 machine and cold cap. Primary endpoint was incidence of WHO grade III or IV alopecia as assessed by treating physician or wearing a wig. Additional endpoints consisted of discontinuation of initially chosen alopecia prevention method, number of cycles of chemotherapy received in each subgroup, patient perception of scalp cooling procedures, well-being, and tolerability/side effects of scalp cooling systems.	Median number of cycles and median docetaxel doses were similar across groups. Alopecia occurrence under 3-weekly docetaxel - Paxman: 23% - Cold cap: 27% - No cooling: 74%. Alopecia occurrence under weekly docetaxel - Paxman: 7% - Cold cap: 8% - No cooling: 17%. Cooling (Paxman and cold cap combined) reduced alopecia risk by 78% (hazard ratio 0.22, 95% confidence interval 0.12-0.41). 5% patients reported adverse events (most frequently sensation of cold). 30 (13%) patients discontinued cooling measures after 1 cycle.	Both Paxman scalp cooling and cold cap offer efficacious protection against hair loss, in particular when docetaxel is administered in a 3-weekly interval. There appears to be no difference between scalp cooling with Paxman or cold cap in terms of efficacy and tolerability.

Author	Type of Study/ Method	Patients	Chemotherapy Agents	Objective	Results (Performance and Safety)	Conclusion
Kurbacher CM, et al. (2017)	Retrospective analysis	n=99 female patients who underwent sensor-controlled scalp cooling alongside chemotherapy from 2014-2016 Types of cancer: breast n=78, epithelial ovarian carcinoma n=15, other n=6 Curative intent n=72, palliative setting n=27 Chemotherapy naïve n=66, prior chemotherapy n=33 Pre-menopausal n=48, post-menopausal n=51	Anthracycline-based n=4, taxane-based n=29; AT-based n=51, other n=15	To obtain detailed information about the effectiveness and safety of sensor-controlled scalp cooling using the Paxman system in female patients exposed to CIA-inducing chemotherapy for breast cancer or genital tract malignancies in the clinical routine.	69 (69.7%) patients completed sensor-controlled scalp cooling, of which 58 (58.6%) experienced complete hair preservation (DS 0) and 11 (11.1%) showed partial success (DS 1–2). 30 (30.3%) patients discontinued sensor-controlled scalp cooling. 21 (21.2%) patients discontinued for CIA, 4 (4.0%) headache, 3 (3.0%) local discomfort/"feeling cold", 2 (2.0%) unknown. Side effects were all not severe and resolved completely after cessation of sensor-controlled scalp cooling.	In the clinical routine, sensor-controlled scalp cooling to prevent CIA in patients with breast or female genital tract cancer is feasible, safe, and effective. Study success rate is in good agreement to previous reports although more patients in the palliative setting or with a history of prior chemotherapy have been included.
Silva G, et al. (2016)	Observational Photography and assessment of hair loss by CTCAE v4.0;	n=20 female patients followed since 2015 Median age: 51 years Types of cancer:	Most common treatments were docetaxel-cyclophosphamide (25%) and doxorubicin and cyclophosphamide followed by paclitaxel -	To evaluate scalp cooling results in preventing CIA in a private clinic in Brazil, using the Paxman Orbis scalp cooling machine.	7 (35%) patients had success with alopecia G1. 5 (25%) patients discontinued scalp cooling; of these, 3 of 5 patients discontinued secondary to hair loss, all	Scalp cooling is tolerable and has been showing good results in preventing CIA in our patients. Patients AC/T receivers remain challenging.

Author	Type of Study/ Method	Patients	Chemotherapy Agents	Objective	Results (Performance and Safety)	Conclusion
	discomfort was assessed by Pain Visual Analogue Scale	breast (90%), n=2 patients had metastatic tumors	AC/T (25%)		from AC/T group. 7 patients (35%) are still under scalp cooling treatment; 2 of 7 patients with alopecia G2. 56% of patients complained of headache with a median visual analog pain score of 4.	
Boyle F, et al. (2015)	Focus group or semi-structured interview Participant perceptions and experiences of scalp cooling were discussed as part of patients' overall chemotherapy experience and a thematic analysis	n=17 women with breast cancer Scalp-cooled (Penguin Cold Caps®, Dignitana Dignicaps® or Paxman Orbis® caps) and non-scalped-cooled participant views were sought	Largely adjuvant TC or FEC-D	To explore breast cancer patients' perceptions and experience of scalp cooling, and their needs for information. Provide first exploration of Australian patient attitudes to scalp cooling.	Scalp cooling was perceived as a proactive way of managing hair loss. 5 main themes: (1) scalp cooling in the context of treatment decision-making discussions (2) hair loss expectations vs experiences (3) treatment expectations vs experiences (4) potential for faster regrowth, and (5) satisfaction with scalp cooling. Accurate information during treatment decision-making was primary factor influencing patient expectations and satisfaction. Faster regrowth was a	Evidence-based information during treatment decision-making is essential to ensure patient expectations are consistent with current treatment outcomes. Additional information and education tools are needed to assist patients and health care professionals manage scalp cooling, and will be developed.

Author	Type of Study/ Method	Patients	Chemotherapy Agents	Objective	Results (Performance and Safety)	Conclusion
	conducted				motivator to continue treatment. Efficacy and tolerability of scalp cooling influenced future hypothetical treatment decision-making for all participants. Information regarding tolerability and hair care during treatment influenced anxiety.	
Kinoshita T, et al. (2015)	Case review Hair loss was graded using the WHO classification scheme	n=21 female breast cancer patients AC therapy n=11, TC therapy n=10	Patients were scheduled to receive 4 cycles of post-operative adjuvant chemotherapy using either AC (60/600mg/m^2) or TC (75/600mg/m^2)	To confirm the efficacy of hair loss prevention and the safety of scalp cooling equipment, and thus enhance patient recovery and QOL. The primary outcome was the proportion of patients able to complete 4 cycles of post-operative adjuvant AC or TC therapy. Secondary outcomes were the degrees of comfort, satisfaction, and hair loss prevention, as well as the rates of adverse events and metastases to the scalp in	9 (81.8%) cases in the AC therapy group and 10 (100%) cases in the TC therapy group completed the protocol. WHO grades: - AC therapy, Grades 0-4: 0, 3, 2, 5, 1 - TC therapy, Grades 0-4: 0, 3, 3, 4, 0 11 of 21 (52.4%) patients experienced Grade 1-2 hair loss, i.e. 5 of 11 (45.5%) patients in the AC group and 6 of 10 (60%) patients in the TC group.	We will continue studying the effects of scalp cooling in breast cancer patients undergoing chemotherapy, and work to improve on the design of the original scalp cooling equipment.

Author	Type of Study/ Method	Patients	Chemotherapy Agents	Objective	Results (Performance and Safety)	Conclusion
				patients who used the scalp cooling equipment, i.e. Paxman Cooler.	Scalp cooling resulted in greater hair loss prevention during TC therapy than AC therapy.	
Hussain O, et al. (2015)	In vitro testing	Not applicable HaCaT cells cultured in serum free conditions were treated with chemotherapy agents; drug-induced cytotoxicity following treatment at physiological temperature (37°C) and cooling conditions (max 22°C) was determined at 72 hours post-treatment	Range of concentrations of 5-fluorouracil, epirubicin and paclitaxel; TAC (docetaxel, doxorubicin and cyclophosphamide), FAC [5-fluorouracil (5-FU), doxorubicin and cyclophosphamide] and FEC (5-FU, epirubicin and cyclophosphamide) as combinatorial treatments	To use in vitro keratinocyte models to study the effect of TAC, FAC and FEC on cell viability and determine whether cooling can protect from combinatorial drug-induced cytotoxicity.	Combinatorial drug treatments TAC, FEC and FAC are more cytotoxic in comparison to individual chemotherapy drugs. Cooling demonstrated the ability to protect very well from individual drug-induced cytotoxicity (e.g. 5-FU associated toxicity), whilst showing differential ability to protect from combinatorial drug-induced cytotoxicity.	The similarity of our in vitro data with clinical observations provides biological support for the cytoprotective role of scalp cooling as well as evidence that, despite their reductive nature, our in vitro models are biologically relevant.
Letchford DB, et al. (2016)	Ongoing prospective cohort Degree of hair loss was assessed using	n=20 consenting patients who underwent scalp cooling using the Paxman Orbis II device during	11 varying chemotherapy regimens including FEC, FEC-D, pacitaxel, carboplatin/paclitaxel and TCH	To report preliminary results from ongoing prospective cohort study of scalp hypothermia in the prevention of CIA.	Six patients withdrew due to grade 2/3 alopecia. 3 patients that completed treatment with scalp cooling developed grade 2 alopecia.	Interim results suggest scalp hypothermia using modern scalp cooling systems represents a safe and effective method of reducing rates of CIA.

Author	Type of Study/ Method	Patients	Chemotherapy Agents	Objective	Results (Performance and Safety)	Conclusion
	the WHO and Deans alopecia scale, digital photography and patient self-reporting questionnaire	treatment Each patient underwent scalp cooling for 30 minutes pre-infusion, during infusion and 90 minutes post-infusion			6 patients treated so far with FEC (as part of the FEC-D protocol) or weekly paclitaxel developed grade 2/3 alopecia. 4 patients treated with carboplatin/ paclitaxel or TCH completed treatment with either grade 1 or no alopecia. 5 patients withdrew due to discomfort, but otherwise no adverse effects were associated with scalp cooling.	Further clinical trials are required to indicate which patients/chemotherapy regimens will obtain maximal efficacy from scalp hypothermia in preventing CIA.

Table 5C – Non-Published Clinical Studies of the Paxman Scalp Cooler

Study Description	**Type of Study / Method**	**Patients**	**Chemotherapy Agents**	**Scalp Cooling Times**	**Results**
Dutch Registry (presented at 2017 MASCC/ISOO International Meeting) Note: 2006-2010 registry data is included in van den Hurk et al. (2012) and Paxman Netherlands Clinical Study of Efficacy/3	Registry	2006-2010: n=1411 (4% male) 2010-2015: n=4864 (14% male) 2015-2017: n=827 (19% male) Types of cancer: breast 75%, prostate 8%, ovarian 6%, stomach/colon/liver 5%, lung 3%, other 2%	AC/AC-T/AC-D 2006-2010: 140/1411 (10%) 2010-2015: 941/4864 (19%) 2015-2017: 329/827 (40%) FEC/FEC-D/ FEC-T 2006-2010: 798/1411 (57%) 2010-2015: 1386/4864 (28%) 2015-2017: 66/827 (8%) Jevtana 2006-2010: 0/1411 (0%) 2010-2015: 42/4864 (1%) 2015-2017: 6/827 (1%) Eribuline 2006-2010: 0/1411 (0%) 2010-2015: 0/4864 (0%) 2015-2017: 6/827 (1%)	Not reported	Results of 2006-2013 registry Chemotherapy agent (s) / No. patients / Positive result of scalp cooling AC/AC-T/AC-D 1079 61% Docetaxel 843 87% FEC/FEC-D/FEC-T 2192 44% FAC 101 46% Taxol(wkl/3wkl) 556 82% TAC 167 11% TCar 475 57% Irinotecan 267 31%
Paxman UK Clinical Study of Efficacy Note: Data is included in Massey CS, et al. (2004)	Open, non-randomized, observational, multi-center (8) Patients completed questionnaires related to	n=95 breast cancer patients being treated with chemotherapy in adjuvant or palliative setting between 1997-2000 Mean age: 44 years	Epirubicin as monotherapy (n=10), FEC combination therapy used 1997-2000 (n=62), doxorubicin as monotherapy or combination (n=11), docetaxel single agent (n=5), CMF (n=5), not reported (n=2)	Pre-infusion: 15-20 minutes During infusion: cooling was maintained Post-infusion: 120 minutes for majority of patients	5 of 95 (5.3%) total patients observed grade 3 hair loss 1 of 95 (1.1%) total patients observed grade 4 hair loss 5 of 95 (5.3%) patients discontinued scalp cooling treatment 2 of 62 (3.2%) patients receiving FEC observed grade 3 hair loss 1 of 62 (1.6%) patients receiving FEC observed grade 4 hair loss

Study Description	**Type of Study / Method**	**Patients**	**Chemotherapy Agents**	**Scalp Cooling Times**	**Results**
	comfort and acceptability of scalp cooling	(range 28-61)			11% of 95 total patients and 13% of 62 patients treated specifically with FEC required wigs 85% of patients reported that they were comfortable, reasonably comfortable, or very comfortable during the scalp cooling period 12% of patients reported they were uncomfortable with an additional 3% very uncomfortable Only 5% of patients discontinued scalp cooling before the end of chemotherapy treatment, with discontinuation because of discomfort seen in one patient Headaches at some time during treatment cycles were reported in 32% of patients
Paxman Norwegian Clinical Study of Efficacy	Observational, single-center Patients views related to comfort and acceptability of scalp cooling were collated by contact nurse	n=54 breast cancer patients treated in neo-adjuvant, adjuvant or palliative settings between 2000-2001 Mean age: 44 years (range 28-61)	FEC/FAC – epirubicin or paclitaxel	Pre-infusion: - FEC/FAC: median 20 minutes (range 15-50) - Paclitaxel: median 20 minutes (range 15-120) During infusion: cooling was maintained Post-infusion: - FEC/FAC: median 120 minutes (range 120-150)	8% of patients experienced significant hair loss 89% of patients described scalp cooling as acceptable, with minimal discomfort caused by the longer treatment period 15% of patients considered coldness to be a major problem 2% of patients considered headaches to be a major problem One patient discontinued treatment because of discomfort Authors concluded scalp cooling is an effective method for avoiding alopecia in patients receiving FEC or weekly paclitaxel

Study Description	**Type of Study / Method**	**Patients**	**Chemotherapy Agents**	**Scalp Cooling Times**	**Results**
				- Paclitaxel: median 60 minutes (range 60-120)	
Paxman Netherlands Clinical Study of Efficacy/1	Observational, multi-center (13 of which 2 did not have scalp cooling available) Patients completed questionnaires related to comfort and acceptability of scalp cooling; observational study was scored using the WHO & visual analogue scale systems	Scalp-cooled (n=160) and non-scalp-cooled (n=86) patients with several types of cancers	Taxane and/or anthracycline-based chemotherapy (n=184) FEC regimen used 1997-2002 (n=62)	Pre-infusion: 30 minutes During infusion: cooling was maintained Post-infusion: 90 minutes for majority of patients	A head cover was used by 51% of scalp-cooled patients 38% of scalp-cooled patients were thought to have purchased a wig needlessly 40% reduction in the use of head covers
Paxman Netherlands Clinical Study of	Non-randomized (Phase I),	n=166 cancer patients	3-weekly docetaxel	Pre-infusion: 30 minutes	A reduction in scalp cooling time to 45 minutes, did not reduce the effectiveness of the Paxman Scalp Cooling System in preventing hair loss in docetaxel treated cancer

Study Description	**Type of Study / Method**	**Patients**	**Chemotherapy Agents**	**Scalp Cooling Times**	**Results**
Efficacy/2	randomized (phase II), multi-center (11) Patients views related to comfort and acceptability of scalp cooling were collated by contact nurse	Types of cancer: breast 49%, prostate 33%, lung 23% Mean age: 44 years (range 35-79)		During infusion: cooling was maintained Post-infusion: - Phase I: 90 minutes - Phase 2: 90 vs. 45 minutes	patients No head cover or wig required in 88% of patients following 45 minutes post-infusion cooling after 3-weekly docetaxel, compared with 74% after 90 minutes post-infusion cooling Headaches were only reported in 20% of patients, with only 5% of patients discontinuing scalp cooling Visual analogue scale: mean score = 69 (0 = bad, 100 = good) Headache: 80% no headaches; 13% mild headaches and 7% moderate/severe headaches 5% of patients discontinued scalp cooling because of intolerance
Paxman Netherlands Clinical Study of Efficacy/3 Note: Study data is included in van den Hurk, CJ, et al. (2012)	Observational	n=1411 patients with range of cancer types	A60C600 (AC) (n=74), A60C600/D100 (ACD) (n=16), ACT overall (n=50), D75A50C500 (TAC) (n=66), D overall (n=120), F500A50C500 (FAC) (n=39), FEC overall (n=752), F500E100C500/D100 (FE100CD) (n=46), TCarbo overall (n=68), T70-90 (42), Irino 250 (n=42), other (n=64)	Not reported	Success rates (no wig or head cover required) varied according to regimen 48% mean success rate (range 8-80%) Study demonstrates effectiveness of the Paxman Scalp Cooling System in the prevention of chemotherapy induced hair loss with widely used chemotherapy dosages and regimens High levels of comfort and patient acceptability were reported in all trials, with low numbers of patients discontinuing scalp cooling Besides the type of chemotherapy, higher dose and shorter infusion time; older age, female gender and non-western

Study Description	**Type of Study / Method**	**Patients**	**Chemotherapy Agents**	**Scalp Cooling Times**	**Results**
					European types of hair increased the proportion of head cover Hair length, quantity, chemical manipulation and treatment with chemotherapy ever before, did not influence degree of head covering among patients
Paxman Swiss Clinical Studies of Efficacy Note: Data is included in Betticher et al. (2013)	Non-randomized, prospective, controlled, multi-center (27)	n=238 patients with several types of cancer including breast, lung, prostate, others who underwent treatment July 2009-October 2011 n=128 patients treated with Paxman Scalp Cooling System; n=71 treated with gel caps (cold caps); n=39 received no cooling treatment	All patients except 1 received docetaxel chemotherapy, alone or in combination with other agents	<u>Paxman Scalp Cooling</u> Pre-infusion: 15 minutes During infusion: cooling was maintained Post-infusion: 90 minutes (45 minutes according to amended temperature) <u>Cold cap</u> Pre-infusion: 15 minutes During infusion: cooling was maintained Post-infusion: 90 minutes (45 minutes according to amended temperature) Gel caps have to be exchanged after the	Kaplan-Meier estimate to reach the combined end point (alopecia WHO III/IV and/or wearing a wig) showing Paxman Scalp Cooling Systems and gel caps have a significantly reduced risk of alopecia by 78% On a six-point scale (1=good to 6=bad) with respect to global impression of therapy, patients at study end reported the following: Paxman 4.5 ± 1.6, gel cap 4.6 ± 1.4, no cooling 4.1 ± 1.9; respective grading marks were similar in the three groups Risk of alopecia is significantly reduced (70%) when using either the Paxman Scalp Cooling System or gel cap compared to no cooling In particular, alopecia is reduced by these two cooling devices when docetaxel is administered every 3 weeks

Study Description	**Type of Study / Method**	**Patients**	**Chemotherapy Agents**	**Scalp Cooling Times**	**Results**
				first 25 minutes of treatment, after another 45 minutes, and every 60 minutes thereafter	
Paxman Lebanese Clinical Studies of Efficacy	Open, non-randomized, observational, multi-center (10)	n=91 cancer patients who underwent treatment March 2012-April 2013	Docetaxel 80-130mg as monotherapy or combination; TAC; Doxorubicin 100mg/Endoxan 1000mg; Taxotere 100mg + Herceptin; Taxol 120-140mg; Taxol 120mg/Carboplatin; FEC; Alimta 700mg + Carboplatin 300mg; FAC; TCH; VP 16 Etoposide; Taxol/Cisplatin, Herceptin; MTX 100mg - Doxorubicin 80mg; Doxorubicin 50mg, Dacarbazine 550mg; Gemzar 1600mg + Carboplatin	Pre-infusion: 90 minutes During infusion: cooling was maintained Post-infusion: dependent upon drug dosage (range 120-360 minutes)	91.21% overall scalp cooling had excellent results 6 of 91 patients underwent treatment with TAC, 6/6 (100%) patients showed no signs of hair loss Severity of chemotherapy-induced alopecia has been reduced greatly by using the Paxman Scalp Cooling System, with only 5 of 91 (5.5%) patients not responding well to head cooling Study demonstrates effectiveness of the Paxman Scalp Cooling System on a variety of anti-cancer treatments It should be noted that the difference in climate, nature of skin and types of hair amongst European and Mediterranean, makes a difference with pre/post-infusion times

Chemotherapy and Abbreviations

A: doxorubicine
Carbo: carboplatin
C: cyclophosphamide
CMF: cyclophosphamide, methotrexate and 5-fluorouracil
D: docetaxel
E: epirubicine
F: 5-fluorouracil (5-FU)
H: herceptin
Irino: irinotecan
MTX: methotrexate
T: paclitaxel

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