

PRODUCTS  
MILLENNIUM

paxman  
coolers limited



CE  
0473

MODEL PSC-1

INSTRUCTIONS FOR USE

BEFORE OPERATING THE PAXMAN SCALP COOLING SYSTEM,  
IT IS IMPORTANT THAT THIS MANUAL BE FULLY READ AND  
UNDERSTOOD BY ALL OPERATORS OF THE SYSTEM.

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## DEVICE FUNCTION AND DESCRIPTION

Hair loss is undoubtedly one of the most distressing side effects of chemotherapy. Preventing or reducing alopecia by scalp cooling can result in a patient's increased self confidence and positive attitude - widely recognised as beneficial in the fight against cancer.

The Paxman Scalp Cooler is a device which is offered to selected cancer patients receiving cytotoxic chemotherapy to help prevent or reduce hair loss. The system uses a small refrigeration unit that circulates a coolant through an insulated cooling cap. The scalp is cooled by placing a cap onto the patient's head, which remains in place for the duration of the treatment.

The Paxman Scalp Cooler comprises of a powerful refrigerated cooling system which rapidly reduces the temperature of a liquid coolant to a pre-set temperature. When this temperature has been reached, electronic sensors monitor and control the coolant between -5°C and -6°C. The coolant is pumped, at low pressure, through a scalp cooling cap. The scalp temperature is reduced to an optimum level. The device is simple to operate and is safe for the patient.

## INDICATIONS

Patients and users/operators 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 cooling cap has been removed
- Patients may visit the bathroom during the treatment

Information on the above indications is available for users and patients

## CONTRA-INDICATION

- Haematological malignancies (leukaemia, non Hodgkins and other generalised lymphomas)
- Cold allergy
- Cold agglutinins
- Manifest scalp metastases
- Imminent bone marrow ablation chemotherapy
- Imminent skull irradiation

## SECTION 1

### 1. EQUIPMENT SUPPLIED WITH THE PSC-2



Equipment Consists of:

- 1.1 Electronically operated refrigeration unit c/w power cable
- 1.2 2 sets of coolant lines with quick release couplings, covered with neoprene shroud
- 1.3 Four standard cooling caps. 1 small, 2 medium and 1 large  
Complete with insulation covers and quick release couplings.\*
- 1.4 Adjustable coolant line support arm
- 1.5 1 litre of coolant (top up)
- 1.6 Plastic storage bin (UK only)
- 1.7 Instructions for use manual
- 1.8 Guidance for use notes.
- 1.9 Recommended cooling periods information sheets.
- 1.10 Patient information leaflets
- 1.11 Technical Data and specification file.

\* It is optional to have any combination of caps.

## SECTION 2

### 2. CONTROLS INDICATORS AND CONNECTIONS

- 2.1 Power cable connection.
- 2.2 Fuses.
- 2.3 Coolant line support arm - height adjustment.
- 2.4 Coolant filling point.
- 2.5 Coolant level gauge.
- 2.6 Coolant line connections.
- 2.7 Re-circulation ports.
- 2.8 Temperature controller.
- 2.9 Power switch (illuminates green).
- 2.10 Pump switch (illuminates green).
- 2.11 HI-Temp alarm / return coolant temp/flow indicator.



## SECTION 3

### 3. DEVICE HANDLING AND SAFETY

#### 3.1 DEVICE HANDLING



##### CAUTION

If the device has to be lifted it should be performed by two people using the lifting handles provided. When device is in use ensure brakes on the front castors are engaged.

When manoeuvring the device, the mains cable must first be removed. Pushing the device can be performed from either the front or the back of the device. EXTREME CAUTION must be taken whilst moving the device over uneven floors or surfaces with obstructions, undulations, ramps or slopes. A slow manoeuvre is recommended.

##### WARNING

Do not manoeuvre the device with the support arm. Tipping can cause the device to become unstable.

#### 3.2 DEVICE SAFETY

The device has been tested and complies with British Standard BS EN ISO 60601-1-1990 including amendments A1, A2, A11, A12 and A13 general requirements for safety for Medical Electrical Equipment. Our certificate number is DUR22211/AC/00. Classification: Class 1 Type BF

##### WARNING: Potential effects of electromagnetic radiation

The device has been tested for EMC emissions and meets with the standard BS EN ISO 60601-2:2002 for a Group 1 Class A device. Our certificate number is C/00/096.

Awareness however should be made to the potential of electromagnetic radiation and advice to reduce the potential of this occurring. We would typically advise users to consider increasing the distance between potentially offending equipment, switching off non-critical equipment and consider shortening connecting leads.

#### 3.3 APPLIED PARTS

The scalp cooling caps are applied parts and are covered under Applied Parts classification 'Type BF' for protection against electrical shock.



## SECTION 4

### 4.1 SYSTEM OPERATION

#### SYSTEM PREPARATION PROCEDURE (prior to commencing scalp cooling)

4.1.1 With the PSC-2, two caps can be selected and cooled simultaneously. Alternatively if only one patient is receiving scalp cooling, the spare cooling line must be connected into the recirculation port. This will ensure the system circulates coolant continuously and works to its most optimum level.



4.1.2 Check coolant level - ensure it is at operating level - top up if necessary.

4.1.3 Plug the unit into mains power supply ensuring both of the cable ends are fully inserted.

4.1.4 Press POWER ON, switch will illuminate GREEN. Temperature controller LCD will illuminate and in a few seconds the coolant temperature will be indicated.



4.1.5 Press PUMP ON switch. Switch will illuminate GREEN. The Hi Temp/Alarm LCD will illuminate indicating the return coolant temperature. The LCD will also alternate between the temperature display and a high temperature warning 'HI'. An audible warning buzzer will also sound. This should be muted by pressing the mute button. The buzzer will be muted but HI will continue to flash until the pre-set temperature is reached. The controller will re-set automatically. When the coolant return temperature is below 5.1°C the 'HI' temperature warning will stop flashing.

4.1.6 The unit will continue to run until the pre-set temperature is achieved. This will take approximately 1hr to 1 1/2 hrs dependent on the ambient room temperature it is operating in.

Note - The system can be switched on without the pump operating. This will reduce the temperature of the coolant in the holding tank, but the system will not be ready for use as the coolant in the coolant lines and caps will not be at the correct temperature and will require cooling prior to use.

**WARNING - DO NOT OPERATE THE SYSTEM WITHOUT COOLANT IN THE TANK.  
THIS WILL DAMAGE THE CIRCULATOR PUMP**

MUTE



## 4.2 OBSERVE

- The noise of the refrigeration system running.
- Small airflow from front of unit.
- Temperature readouts slowly decreasing.
- The cap is starting to get cold (inside) after several minutes of operation.

### APPROXIMATE TIMES FOR SYSTEM TO REACH OPERATING TEMPERATURE IN DIFFERENT ROOM TEMPERATURES

Ambient Room Temperature	Time
Up to 18°C	1 hr to 1 hr 10 mins
18°C - 22°C	1 hr 10 mins to 1 hr 20 mins
22°C - 26°C	1 hr 20 mins to 1 hr 40 mins

BOTH WITH CAP(S) ATTACHED

## 4.3 AFTER 15 MINUTES

- 4.3.1 Temperature read outs should be slowly decreasing.
- 4.3.2 Cooling caps should be feeling cold.

## 4.4 READY FOR USE

The refrigeration unit will automatically stop (switches and LCD's remain illuminated) when the pre-set operating temperature has reached -6°C. The system has now reached its operating temperature. The temperature on the controller will start to rise slowly. When approximately -5°C is reached the refrigeration unit will automatically start running again. The system has been designed to cycle on and off continually whilst in use. The temperature will rise and fall between approximately -5°C to -6°C. (This will vary slightly dependant on room temp) The equipment is ready for use and scalp cooling can commence.

4.4.1 The HI Temp/Alarm LCD should be indicating a temperature between approx -4°C and +4°C. This will be dependent on room temperatures and if there are one or two caps connected to the system.

NOTE - If the coolant lines have been connected into the recirc ports, follow 4.5 before commencing scalp cooling for a second patient.



## 4.5 UNCOOLED CAPS - NEW PATIENT/NEW CAP



To use an uncooled cap for either a new patient or to change to a cap which has not been cooled, it will be necessary to allow a further cooling period of 10 - 15 minutes (dependent on room ambient temperature to allow the cap to reach operating temperature) before the cap can be used. When a new cap is connected, both temperature controllers will show an increase in temperature. This is normal. The HI Temp alarm will be activated if the temperature rises above 5.1°C. Press the mute if warning buzzer is activated. The temperature will soon fall and the HI visual warning will stop flashing. Check to ensure cap is becoming colder. When the temperature controller reaches approx. -4°C (not -6°C) and when the HI visual warning stops flashing, the cap will be ready for use.

## 4.6 PATIENT CHANGEOVER



Patients can begin and terminate scalp cooling at any time independently of each other. The system has been designed to allow any patient to commence and terminate cooling without effecting the other patient being treated.

When a patient terminates scalp cooling, they should be disconnected and the coolant lines re-connected to the recirculation ports. The cap should be cleaned and made ready for use for the next patient. A cap can be re-connected at any time.



### 5. COOLING CAP ASSEMBLY

#### 5.1 SCALP COOLING CAP

The cap assembly has 3 distinct components:

- A colour coded silicone cap - Red (Small), Purple (Medium), Blue (Large).
- Adjustable insulating cover, colour coded to match cap
- Quick release couplings - Male (Small)

#### 5.2 CONNECTING AND DISCONNECTING COOLING CAPS WITH QUICK RELEASE COUPLINGS

**IMPORTANT - ALWAYS SWITCH OFF PUMP BEFORE CONNECTING OR DISCONNECTING**

5.2.1 Before connection or disconnection of couplings, it will be necessary to pull apart the velcro neoprene cover to expose the male and female couplings.

NOTE: There is no left or right coupling, connecting to either is possible.

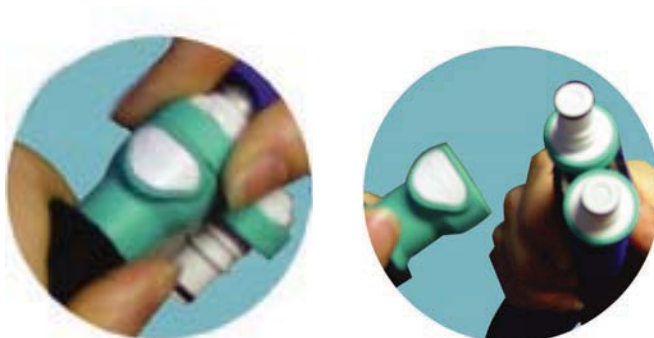
5.2.2 Connection - (see page 11) To connect the cooling caps to the coolant lines, push the male coupling into the female coupling, a little pressure needs to be applied, a click will be heard when couplings are engaged.

5.2.3 Disconnecting - (see page 11) Hold the male and female couplings in each hand (as shown on page 11). Press the release button on the female coupling which will cause the male coupling to partially eject from the female coupling by approximately 10mm. Gently pull the couplings apart, a little force may be needed.

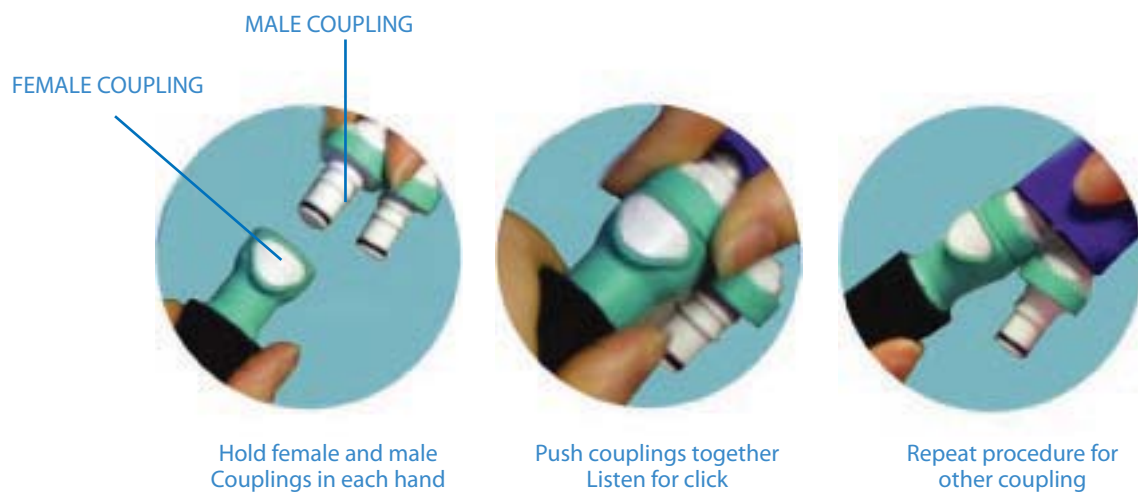
NOTE - Do not pull apart by holding the silicone tubing.

NOTE - It is recommended to wear protective gloves when handling the coolant.

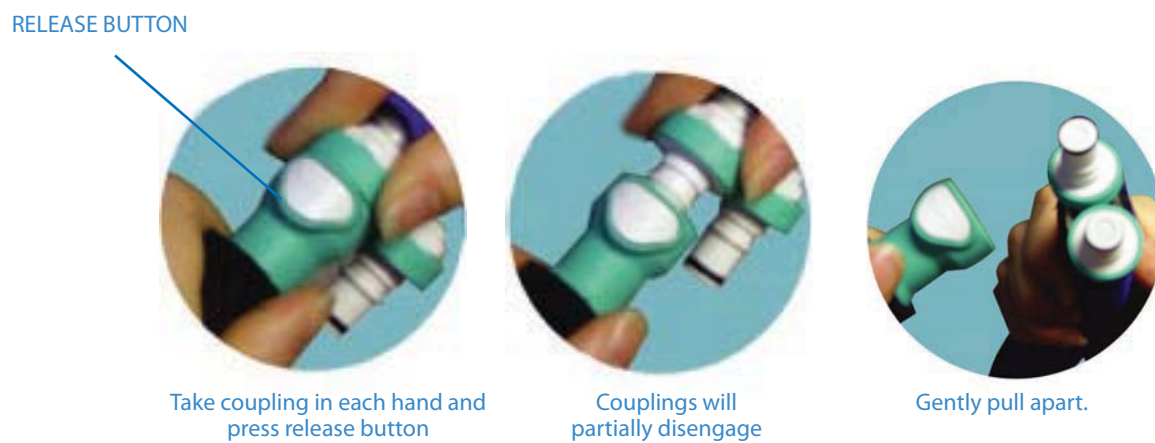
NOTE - Do not forget to turn on the pump after connection.



## TO CONNECT COUPLINGS



## TO DISCONNECT COUPLINGS



NOTE: Do not pull apart by holding silicon tube

## SECTION 6

### 6.1 PATIENT PREPARATION AND PROCEDURE FOR SCALP COOLING

Prior to commencement of scalp cooling procedures, it is advised that the scalp cooling time applicable to the drug regimen being administered is assessed and recorded. This can be obtained from our recommended cooling periods information sheets.

### 6.2 NEW PATIENTS

Before scalp cooling can commence, it will be necessary to select a cap which fits the patient. Patients head shape, ear position, hair lines and hair quantity will affect the fitting. The selected cap should not be overtight or too loose. It is essential to have good scalp contact for most effective cooling. A cap which is too tight will cause discomfort and may lead to patients discontinuing with the procedure.

6.2.1 New patients should be offered all the caps to determine the best fit. This procedure should be undertaken as soon as practical to allow the pre-cooling of the cap which may be required, and to prevent any delay in commencement of scalp cooling. Caps which have not been previously connected to the system and require cooling will take between 10 and 15 minutes to reach operating temperature (see section 4.5).

6.2.2 When the correct size of cap has been selected and pre-cooled the system is ready for use. CHECK INSIDE OF CAP IS COLD. It is recommended that a record of the patient's cap size is made for future reference.

6.2.3 Before scalp cooling commences with a NEW patient, it is important to explain the procedure fully. The patient should understand that scalp cooling can be discontinued at any time and that it will not jeopardise the chemotherapy treatment.

6.2.4 It is recommended that the Paxman Cooler patient information leaflet is offered to patients who are having scalp cooling for the first time.



## 6.3 PROCEDURE

### HAIR TYPES



The effectiveness of scalp cooling is dependent on having a good scalp to cap contact. Although the cap is very efficient in cooling the scalp, the patient's hair acts as an insulation barrier. It is recommended to minimize the insulation effect of hair and allow for better cap to scalp contact by wetting and applying a ph neutral or natural / herbal type hair conditioner to the patients' hair. For patients with thick and afro caribbean hair who do not use this option it is recommended that the pre-cooling time is increased by 10-15 minutes to allow sufficient cooling of the scalp prior to drug infusion.

6.3.1 The patient should be seated prior to the fitting of the cooling cap. Ask patient to assist in placing the cap on their head, ensuring the cap cover is fitted and the trailing feed lines are positioned down the left side of the patient. Ensure the cap fits correctly and the cap cover is not rolled up inside the cap.

6.3.2 The patient's ears are normally outside the cap but if necessary can be positioned inside the cap if this is more comfortable for the patient. If ears are inside the cap ensure they are protected from the cold.

6.3.3 Where necessary cover forehead/brow and ears with cotton wool or gauze. Try to position the cap to just below the hairline on the patient's forehead. (Adjust the cap to ensure it does not cover the forehead as this could cause headache). To assist in correctly positioning the cap turn up the cap cover to expose the profile of the cap.

6.3.4 When correctly positioned turn down the cap cover and pull down the chin strap. Ask the patient to place in a comfortable position on chin.

Note: Hold the cap at the front when positioning the chin strap to avoid pulling the cap forward and onto the patient's forehead.

6.3.5 Gently pull down on each strap to tighten the cap onto the patient's scalp,

Caution: Do not over tighten as this may cause discomfort.

6.3.6 Adjust height of support arm to remove any drag effect of coolant lines (see section 2.2.3). Place coolant lines in position to avoid kinking of coolant lines.

6.3.7 Ensure patient is comfortable. The cap should not be over tight but also not too loose. If in doubt, try another size of cap.

6.3.8 Check coolant lines are not kinked or twisted.

6.3.9 Ensure inlet and outlet tubes on the cap are not kinked or twisted.

6.3.10 Pre-cooling of the patients scalp can now commence.

## 6.4 PRE-COOLING

IMPORTANT - IT IS RECOMMENDED TO CANULATE PATIENTS PRIOR TO SCALP COOLING TO MINIMISE THE RISK OF POOR VENOUS ACCESS.

PLEASE REFER TO THE RECOMMENDED COOLING TIMES TABLE PROVIDED WITH YOUR GUIDANCE FOR USE.

6.4.1 Check the pre cooling time. A minimum of 30 minutes is required for pre-cooling the patient's scalp prior to infusion of chemotherapy drugs. (See the recommended cooling times data sheets). Other patient preparations can now commence prior to infusion.

6.4.2 Ensure patient is comfortable - pillows and blankets should be offered for extra comfort.

6.4.3 Reassure patient that although there is an initial cold feeling, this will become much less noticeable after 10-15 minutes. To avoid distress it is advisable for first time users to be comforted and distracted during this initial cooling period.

## 6.5 COMMENCE DRUG ADMINISTRATION

NOTE: Drug administration should not commence before minimum recommended pre cooling time has elapsed.

After administration of the alopecia causing chemotherapy drugs, check the time and calculate a post-cooling time for completion of scalp cooling. Inform the patient of the length of time of cooling and the actual time the cap can be removed. This will allow patients to remove the cap by themselves in the event that the nursing staff are unavailable to assist in the removal of the cap.

PLEASE REFER TO THE RECOMMENDED COOLING TIMES TABLE PROVIDED

## 6.6 TEMPORARY DISCONNECTION FROM THE SYSTEM

SWITCH OFF PUMP BEFORE DISCONNECTION

6.6.1 Patients can be disconnected from the system for a temporary period without effecting the treatment, a maximum of 5 minutes is recommended. This will allow patients to visit the bathroom, or move as required by the medical staff. Disconnection procedures must be followed.

NOTE: COOLING CAP MUST REMAIN ON PATIENTS SCALP DURING TEMPORARY DISCONNECTION FROM THE SYSTEM.

6.6.2 Whenever disconnection is required the pump must be switched off. Dependent on the number of patients and caps connected to the system will determine the action required. If two patients are connected the coolant lines of the disconnected patient must be connected to the recirculation ports and the pump switched on whilst the patient is absent.

6.6.3 When both patients require to be disconnected together both sets of coolant lines must be connected to the recirculation ports and the pump remains switched on. On return of the first patient the coolant lines are reconnected to the cap and the second patient's coolant lines remain connected to the recirculation ports. Switch on the pump to recommence cooling. When the second patient returns switch off pump, disconnect coolant lines from recirculation ports, re-connect to the cooling cap and switch on pump to recommence cooling.

6.6.4 If the system is in use for a single patient with the spare coolant lines connected into the recirculation ports, switch off the pump, disconnect coolant lines from the cap and connect to the re-circulation port and switch pump on. On return reconnect to the cooling cap and switch on the pump to recommence cooling.





## 6.7 ALARMS

Patients should be advised what to do in the event of hearing the Hi-Temp Alarm. They should immediately draw it to the attention of a member of the nursing staff. Long delays can result in the treatment being ineffective.

NOTE - If the alarm sounds, check the male and female couplings have been correctly connected as this is the usual cause for alarm activation.

## 6.8 COMPLETION OF TREATMENT

6.8.1 On completion of scalp cooling treatment the cap can be removed.

6.8.2 Release chin straps by pulling up on the toggle fasteners.

6.8.3 Assist the patient to remove cooling cap using both hands pushing up and back from the front.

6.8.4 Important - Try to encourage patient to rest if desired before attempting to move in case dizziness is experienced.

6.8.5 Disconnect cap from coolant lines ensuring pump is first switched off. Connect coolant lines into recirculation ports if applicable and switch on pump to continue cooling of 2nd patient.

6.8.6 Remove the cap cover then rinse and wipe the inside of cap. This can be done in the sink after disconnecting the cap from the coolant lines. The cap is ready for immediate use on the next patient.

## 7. SYSTEM SAFETY FEATURES

### 7.1 TEMPERATURE CONTROLLER

The Temperature Controller is factory set to display a normal operating temperature between -7°C and -4°C. The LCD temperature read-out shows the coolant temperature in degrees Celsius and has a low temperature alarm. An alarm will sound and the LCD will flash low if the coolant reaches the low temperature alarm setting of -14°C. The system has been designed to ensure the temperature does not go below -14°C. Even at this temperature the system will be inherently safe with no danger to patients or users. Other safety cut outs will prevent any risk of super cooling.



### 7.2 HI-TEMP ALARM

The LCD temperature read-out gives an indication of coolant temperature on its return from the cooling caps. If the temperature rises above 5.1°C an alarm will sound (Buzzer) and temperature indicator will flash HI. This can be due to a restriction in the flow of coolant and / or one of the following conditions may apply:

- Quick release couplings have not been connected correctly
- Kinked flow lines.
- Low coolant level.
- Pump failure.
- Fused connection.



## SECTION 8

### 8.1 ALARM CONDITIONS/FAULT FINDING/FUSES

Fault	Action
8.1.1 Cap not cold	<ol style="list-style-type: none"><li>1. Check couplings fully engaged</li><li>2. Coolant lines not kinked</li><li>3. Ensure 2 caps are connected or coolant lines are connected to recirculation port</li><li>4. Check pump switch is on</li></ol>
8.1.2 HI-temp - Alarm (buzzes)	<ol style="list-style-type: none"><li>1. Check all couplings are fully engaged</li><li>2. Check if cap or flow lines are kinked</li><li>3. Check coolant level</li><li>4. Check coolant has reached correct operating temperature and LCD is between -5°C - -6°C</li></ol>
8.1.3 All controls work but no cooling	<ol style="list-style-type: none"><li>1. Check couplings fully engaged</li><li>2. Coolant lines not kinked</li><li>3. Ensure 2 caps are connected or coolant lines are connected to recirculation port</li><li>4. Check coolant level and top up if required (see maintenance)</li></ol>
8.1.4 Circulator pump fails to operate	<ol style="list-style-type: none"><li>1. Check fuse F2</li></ol>
8.1.5 When Mains power is switched on, The compressor does not operate and the green light fails to illuminate	<ol style="list-style-type: none"><li>1. Check fuse in mains power plug</li><li>2. Check fuse F1 and F4</li><li>3. Check power plug in back of unit is fully inserted</li><li>4. If all above check OK, Contact Service Help Desk</li></ol>
8.1.6 Temperature controller alarms (buzzes) - pump is switched on	<ol style="list-style-type: none"><li>1. Switch off unit</li><li>2. Contact Service Help Desk</li></ol>
8.1.7 Hi-temperature alarm controller not illuminated when pump switched on	<ol style="list-style-type: none"><li>1. Contact Service Help Desk</li></ol>
8.1.8 Temperature controller not illuminated when main power switch is on	<ol style="list-style-type: none"><li>1. Check fuse F3</li><li>2. If all above check OK, Contact Service Help Desk</li></ol>
8.1.9 Temperature controller does not decrease in temperature after 20 mins	<ol style="list-style-type: none"><li>1. Check fuses, if these are OK, Contact Service Help Desk</li></ol>

NOTE - THE CHANGING OF FUSES MUST BE CARRIED OUT BY QUALIFIED TECHNICAL PERSONNEL. REMOVE POWER CABLE FROM UNIT BEFORE CHANGING FUSES.

### 8.2 FUSES

F1 - Type F 10amp - Mains Power Live Feed, F2 - Type F 10amp - Coolant Pump  
F3 - Type F 10amp - Refrigeration Compressor, F4 - Type F 10amp - Mains Power Neutral Feed

### 8.3 SERVICE HELP DESK

TELEPHONE NUMBER: 01484 349444

## SECTION 9

### 9.1 GENERAL PERIODIC MAINTENANCE RECOMMENDATIONS



- Check coolant level - top up as necessary. Pour coolant into receptacle. Fill through filling point to maximum level.
- Check cooling caps for wear and tear. Check for bulges and cracking around couplings. Cut back and replace as necessary.
- Check coolant lines for wear and tear. It is advised that coolant lines be replaced every 24 months.
- Keep caps clean and wash as necessary.



- Keep front and rear grills clear and free from dust. Use a vacuum cleaner to suck out any build up of dust or dirt especially on the condenser coil at the rear of the device.
- Wash couplings with liquid detergent and check they are free from obstructions.
- If couplings become sticky use Molykote 111 silicon lubricant to lubricate the rubber 'O' ring on the male coupling.

NOTE - IT IS RECOMMENDED THAT WHILST HANDLING COOLANT, SURGICAL GLOVES ARE WORN.

### 9.2 ANNUAL SERVICING

It is recommended that the Paxman Scalp Cooling System is annually serviced. Paxman Coolers can provide a comprehensive annual service and maintenance contract. Information is available upon request.

### 9.3 IN-HOUSE REPAIRS & SERVICE

Component part lists, circuit diagrams, descriptions, instructions and / or information is available to assist USER's appropriately trained and qualified technical personnel to replace those parts of the EQUIPMENT designated replaceable. Equipment repairs should only be undertaken by the company's authorised representative or other competently trained personnel.



## 9.4 RECOMMENDED SPARES

- Silicone Caps
- Cap insulation covers
- Couplings male and female
- Coolant
- Coolant Line Assembly
- Cable Ties
- 10 amp fuses
- Molykote 111 Silicon lubricant

## 9.5 COOLING CAP MAINTENANCE

9.5.1 The silicone cooling cap should be cleaned with soap or a mild detergent and warm water after each treatment session. The insulating cap cover should be completely removed before cleaning. The silicone cap should be dried inside and out after cleaning and the cap cover re-fitted. Ensure when refitting the cap cover it is placed on the cap the correct way.

9.5.2 Periodically the cap cover may require cleaning. Remove the cover from the silicone cap prior to cleaning. Cleaning can either be by hand or using a washing machine on a 40°C cycle wash program. Any standard washing powder or detergent can be used. Leave the cover to dry naturally before re-fitting to the silicone cap. Ensure when refitting the cap cover it is placed on the cap the correct way.

9.5.3 Periodic checks for bulges, splits, wear and tear around couplings should be made.

## 9.6 RE-FITTING COUPLINGS

The inlet and outlet tubes on the cap do wear from time to time. The worn perished part of the inlet and outlet tubes can be removed and the cap continued to be used.

- Carefully cut the plastic fixing cable tie.
- Pull the connector out of the tube.
- Cut back silicone tube to remove worn part with a sharp knife.
- Insert coupling into tube.
- Attach new plastic fixing cable Tie.
- Repeat for other coupling.

Note - We recommend the above procedure is undertaken by a competent maintenance engineer.

Note - Quick release couplings will be inspected and re-fitted by a maintenance engineer on the annual service visit (only if maintenance contract is in force) and should not normally have to be re-fitted. However, in the unlikely event they do, the above procedure must be followed.

## 9.7 DRAINING COOLING CAPS OF COOLANT

- Remove couplings from the inlet and outlet tubes as described in 9.6 above.
- Using a large surgical syringe (without needle) insert into the inlet/outlet tube, drain off coolant.
- Coolant can be either returned directly to the cooler via the filler point, put into the coolant top up bottle or disposed of in accordance with waste disposal and water authority regulations.
- When all coolant is removed, the cap should be flushed out with tap water using the syringe.
- Procedure should be performed over a sink and surgical gloves should be worn.

# DISINFECTION AND STERILISATION

## 10.1 SILICONE CAP

The silicone cap and its accessories are supplied non-sterile and are not subject to disinfection or sterilisation protocols. Should the user hospital deem that the silicone cap and its accessories be contaminated and unfit for continued use then the contaminated silicone cap and its accessories should be removed from use and disposed of by the preferred method of incineration. Before disposal, ensure that the coolant inside the silicone cap is removed by follow the procedure detailed in section 9.7

## 10.2 REFRIGERATION UNIT

The refrigeration unit and its accessories are supplied non-sterile and are not subject to disinfection or sterilisation protocols. Should disinfection or sterilisation of the refrigeration system and its accessories be deemed necessary by circumstances arising in the individual hospital, please contact our help desk and provide details of the method of disinfection or sterilisation that is to be used. Advice then can be provided as to what effect this may have on the refrigeration system. It is advised that any contaminated coolant line assemblies be replaced and the contaminated coolant line assemblies be disposed of by the preferred method of incineration. Before disposal ensure any coolant is drained from the coolant lines.

For further information and advice please contact our Customer Help Desk.

## SECTION 11

# 11. MATERIAL SAFETY AND DATA SHEETS

## 11.1 COOLANT



Diluted Monopropylene Glycol - USP and Tap Water. Mix Ratio 30% - 70%. This product is NOT classified as dangerous or hazardous under EC criteria and is deemed completely safe for use in its intended purpose.

### 11.1.1 SPILLAGE

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

### 11.1.2 DISPOSAL

Coolant can be disposed of by following the manufacturers instructions detailed in the Materials Safety Data Sheets or returned to Paxman Coolers for disposal

## 11.2 MONOPROPYLENE GLYCOL

Listed below is an abbreviated version of the Material Safety Data Sheet. The manufacturers complete version is provided in the Technical Data & Specification File. This product is NOT classified as dangerous or hazardous under EC criteria and is deemed completely safe for use in its intended purpose.

Product Name: Monopropylene Glycol - USP.  
Chemical Name: Propan-1, 2-Diol  
Formula: C<sub>3</sub>H<sub>8</sub>O<sub>2</sub>  
Hazard Classification Information Secondary Risk  
Risk Phrases: NONE Conveyance Class: NOT ALLOCATED  
Safety Phrases: NONE ADR HIN: NONE  
Primary Risk: NON-HAZARDOUS EINECS No.: 200-338-0  
S.I. Number: NOT ALLOCATED IMCO Class: NONE  
ADR Class: NONE Packing Group: NOT ALLOCATED  
Tremcard No.: NONE  
UK Customs Number: CUS 22430  
IATA Special Provisions: NOT APPLICABLE UN Number: NOT ALLOCATED  
CAS Number: 57-55-6  
Hazchem Code: NOT ALLOCATED



## 11.2 MONOPROPYLENE GLYCOL CONT...

### TOXICITY

This product has a high flash point and is not regarded as hazardous for transport purposes. Under ordinary conditions it is stable but at high temperature it tends to become oxidised. It can also react with oxidising agents. The product has low toxicity but splashes on the skin and in the eyes can cause minor irritation.

The following toxicological information is recorded :-

LD 50 (oral) 20 gm/kg (rat)

LD 50 (skin) 5000 gm/kg (rabbit)

### FIRST AID

Eyes : Wash thoroughly with plenty of clean water. While unlikely, if irritation persists, obtain medical attention. Skin : Wash affected areas with clean water. Ingestion : Wash out mouth with water and give plenty of water to drink. Obtain medical attention.

### HANDLING PRECAUTIONS

No special handling precautions are required but it is good practice to wear rubber or PVC gloves. Eyewash bottle with clean water should be readily available.

### STORAGE

Store in a cool, dry place apart from oxidising agents.

### FIRE

The product does not give rise to any great fire risk but if it becomes involved in an established fire, it may provide further fuel for the fire. Use water fog, water spray, foam, carbon dioxide or dry chemical powder to fight the fire.

### SPILLAGE

Contain, if possible, flush the contaminated area with plenty of water and possibly detergent.

DISPOSAL: Dispose of waste material in accordance with waste disposal and water authority regulations.

This information has been prepared from the best sources of knowledge available to us but we shall not be liable for any inaccuracy or any insufficiency in this information whatsoever. AUGUST 2007



## 11.3 SILICONE LUBRICANT

Product Name: Dow Corning - 111 Silicone Compound.

This product is deemed NOT hazardous according to Council Directive 1999/45/EC and its subsequent amendments and is safe to use in its intended purpose.

### Composition

Silicone Oil

Inorganic Thickener

Additives

### How to Use

Dow Corning 111 Silicone Compound can be applied by hand, specially designed automated equipment, brushing or wiping.

### Solubility

Dow Corning 111 Silicone Compound is insoluble in water, methanol, ethanol, or mineral oil, and is soluble in Chloroethene NU, perchloroethylene, mineral spirits and methyl ethyl ketone.

### Chemical Resistance

Dow Corning 111 Silicone Compound is not greatly affected by mineral oils, vegetable oils or air. It is generally resistant to dilute acids and alkalines and to most aqueous solutions.

Dow Corning 111 Silicone Compound is quite resistant to a wide variety of organic and inorganic chemicals.

Dow Corning 111 Silicone Compound is not to be used with liquid oxygen and should not be used in applications requiring LOX compatibility.

### Usable life and Storage

When stored at or below 20°C (68°F) in the original unopened containers, this product has a usable life span of 60 months from date of production. Handling Precautions Dow Corning 111 Silicone Compound may cause temporary discomfort when in direct contact with eyes. In case of eye contact, flush eyes with water.

PRODUCT SAFETY INFORMATION REQUIRED FOR SAFE USE IS NOT INCLUDED. BEFORE HANDLING, READ PRODUCT AND SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE SAFETY DATA SHEETS ARE LOCATED IN THE TECHNICAL DATA AND SPECIFICATION FILE.

## SECTION 12

### UK CONTACT ADDRESS AND TELEPHONE/FAX NUMBER

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### OVERSEAS CONTACT - DISTRIBUTOR

Name: .....

Address: .....

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Telephone Fax: .....

E.mail: .....

### OVERSEAS CONTACT - SERVICE AGENT

Name: .....

Address: .....

.....

.....

Telephone Fax: .....

E.mail: .....