PAXMAN



INSTRUCTIONS FOR USE

The Paxman Neuropathy | 800-16-04

EU Issue 1 | 2026-09-18

CE UKCA

paxmangroup.com

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1. Device Description and Identification

Description of the Device and System Overview

The Paxman Neuropathy is a compact, mobile refrigeration device designed to circulate a temperature-controlled coolant through specially designed accessories to achieve localized cooling of the limbs.

The refrigeration device cools the Orbis C coolant and pumps it through the coolant lines to the accessories. The coolant circulates through the accessories (gloves and boots) that are applied to the patient's hands and feet. The Paxman Neuropathy also incorporates an integrated pneumatic compression module that provides gentle, cyclic compression during the cooling period to enhance comfort.

Models, Variants, Accessories and Consumables

The Paxman Neuropathy

A small, compact refrigeration device and power supply unit.

Coolant Line

Two Paxman Neuropathy coolant lines with quick release couplings.

Gloves and Boots

- 2x Pair of small Paxman gloves (L&R)
- 1x Pair of large Paxman gloves (L&R)
- 2x Pair of small Paxman boots
- 1x Pair of large Paxman boots

The gloves and boots are type BF applied parts

Coolant

3 x 1-litre coolant cubes, coolant top-up kit

Trolley

A bespoke mobile trolley with coolant line support arms.

2. Intended Purpose and User Information

Intended Purpose

Paxman cooling devices are intended to reduce side effects caused by chemotherapy. They are worn by the patient during treatment and reduce the temperature of the local anatomy by means of controlled cooling.

Indications

The indications for the Paxman Neuropathy are as follows:

- Chemotherapy induced peripheral neuropathy (CIPN).

Clinical Benefits

The use of The Paxman Neuropathy to administer controlled cryocompression to the hands and feet during chemotherapy results in a 95% relative reduction in risk of CTCAE grade ≥2 CIPN and a 70% relative reduction in incidence of any grade CIPN when compared to no treatment in adult cancer patients receiving systemic neurotoxic chemotherapy.

CIPN reduction rates vary from patient to patient and with different drug regimens being administered. Patients cannot be guaranteed that they will not develop neuropathy.

Intended Patient Population

The Paxman Neuropathy is intended to be used to treat patients undergoing chemotherapy.

Intended Users including Training Requirements & User Qualifications

The Paxman Neuropathy is intended to be used by a suitably qualified healthcare professional or a Paxman certified, trained representative.

Intended Environment and Locations of Use

The Paxman Neuropathy is intended to be used in a healthcare facility in the following conditions:

Operational Conditions

Temperature: 10-28 °C / 50-82 °F
Atmospheric Pressure: 70-106 kPa
Relative Humidity: 30-75 %

Transport and Storage Conditions

Temperature: 0-50 °C / 32-122 °F
Atmospheric Pressure: 50-106 kPa
Relative Humidity: 30-85 %

The Paxman Neuropathy does not contain any magnetically sensitive components however it is not expected to be used in locations that contain equipment which generate strong magnetic fields.

Shelf Life and Device Lifetime

The shelf life of the Gloves and Boots is two (2) years. The device lifetime of the Gloves and Boots (after first use) is one (1) year.

Note: Shelf life is inclusive of device lifetime

The device lifetime of The Paxman Neuropathy is five (5) years or ten (10) years with annual Paxman Servicing.

3. Contraindications, Warnings and Precautions

Contraindications

- Paediatric Patients
- Hematological malignancies (leukemia, non-Hodgkin and other generalized lymphomas) or hematological malignancies that are being treated for cure
- Imminent bone marrow ablation chemotherapy
- 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
- Solid tumors that have a high likelihood for metastasis in transit
- Patients with a history of skin or limb metastases
- Patients with Raynaud's phenomenon, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia, post-traumatic cold dystrophy, or peripheral arterial ischemia
- Open skin wounds or ulcers of the limbs

Side Effects

- Discomfort (numbness, shivering) due to feeling cold.
- Headache
- Light-headedness or dizziness
- Nausea
- Transient erythema

General Warnings and Precautions

WARNINGS

(Indicates a potentially hazardous situation which could result in serious injury or harm)

Use by trained personnel only:

- The device must only be operated by appropriately trained healthcare professionals.

Electrical safety:

- Disconnect the mains supply before servicing or maintenance.
- The mains plug is the primary isolation device and must remain accessible during use.
- Do not use extension leads; connect directly to a mains outlet.

Use of non-approved components:

- Use of accessories, cables, or components not specified by the manufacturer may result in improper operation, increased electromagnetic emissions, or reduced immunity.

Thermal injury risk:

- Improper fitting or use outside of intended purpose may result in thermal skin injury (e.g. mild to moderate injury). Patient monitoring is required.

Flammable refrigerant:

- The system contains R1234yf refrigerant (A2L, mildly flammable).
- Do not expose the device to open flames, sparks, or high heat sources.

Liquid exposure hazard:

- Do not allow liquids to contact the device or touchscreen, as this may cause damage or unsafe operation.

Unauthorised servicing:

- Servicing must be performed by authorised Paxman personnel.

Removal of Gloves and Boots:

- The Gloves and Boots MUST be removed prior to the patient standing and/or becoming mobile. Failure to do so could result in damage to the device and/or a trip or fall hazard.

CAUTIONS

(Indicates a potentially hazardous situation which could result in minor or moderate injury or device damage)

Device Operation and Environment:

- Do not operate in ambient temperatures above 28°C (82°F).
- Do not cover or obstruct ventilation grills during operation.
- Keep the device upright at all times.

Electromagnetic Compatibility:

- Avoid using the device adjacent to or stacked with other equipment; if unavoidable, verify correct operation.
- Portable RF communication equipment must be kept at least 30 cm from the device and cables.
- This device is CISPR 11 Class A and may cause interference in residential environments.

Handling and Transport:

- Disconnect power, coolant lines, and wearables before moving the device.
- Exercise care when moving over uneven surfaces; move slowly and engage trolley brakes when stationary.
- Ensure coolant is drained if the device is carried by its handle.

Connections and Components:

- Do not apply excessive force when connecting or disconnecting quick-release couplings.
- Ensure all components are free from obstruction and damage prior to use.

Cleaning and Care:

- Do not allow liquids to contact the touchscreen.
- Clean the touchscreen using a soft material with horizontal or vertical motion only (no circular motion).
- Do not apply excessive pressure to the touchscreen.

Coolant Handling:

- Although not classified as hazardous, it is recommended to wear protective gloves when handling coolant.

NOTES

(Provides additional information to ensure safe and effective use)

The device operates using a low voltage DC supply provided by an approved Class II (double insulated) power supply; no protective earth connection is required.

It is extremely unlikely that overcooling will occur due to system design (minimum coolant temperature approx. 8°C).

Treatment outcomes vary:

- Prevention of chemotherapy-induced peripheral neuropathy (CIPN) are not guaranteed
- Effectiveness depends on patient factors and chemotherapy regimen

The system is not validated for user disinfection or sterilisation; contact the manufacturer before attempting such procedures.

Fault Handling

In the event of a fault the system should be isolated from the mains by unplugging the system from the wall.

To report a complaint to Paxman, complete the Paxman Complaint Form using the QR code or paxmanscalpcooling.com/complaints-form

Any serious incident that has occurred in relation to the device should be reported to the manufacturer (Paxman Coolers Limited) and the competent authority of the Member State in which the user and/or patient is established.

4. Safety and Performance Characteristics

Essential Performance

The Paxman Neuropathy does not have any essential performance requirements.

Safety and Performance Characteristics

The Paxman Neuropathy

PARAMETER	SPECIFICATION
Weight	Approx. 17.3 kg (filled), approx. 15.0 kg (empty)
Dimensions	H 310 mm x W 280 mm x D 540 mm
Power Supply	24V DC via approved external power supply
Coolant Temperature Range	10-12°C
Coolant Flow Rate	10-40 mL/s
Coolant Pressure	12 psi / 82.7 kPa
Air Pressure	<1 psi / 52 mmHg / 6.9 kPa

Gloves and Boots

PARAMETER	SPECIFICATION
Weight	Between 415 g and 440 g
Dimensions	Gloves and Boots are available in a small and large and are designed to cover the full range of hand and foot sizes

Classification

REQUIREMENTS	CLASSIFICATION
CE marked in accordance with Annex VIII of the Medical Devices Regulations 2017/745	IIa
USA device classification	2*
Electrical classification of double insulated external power supply	2
Applied parts classification	Type BF
Ingress protection	IP 20
Electromagnetic compatibility classification	Professional Healthcare Facility

**Product code for classification in the USA is PMC*

Applicable standards and accreditations

Biocompatibility

The system passed biocompatibility testing in accordance with the requirement for ISO 10993-1 and FDA Guidance. Specifically, Cytotoxicity testing per ISO 10993-5, Sensitization testing per ISO 10993-10, and Intracutaneous Reactivity testing per ISO 10993-10. The accessories are the only part of the system that comes into direct contact with the skin. All material used in the construction of the a are designed to comply with the requirements of the Medical Devices Biocompatibility standard ISO10993 for Category A applied parts. The contact duration category as defined in ISO 10993-1:2018 as Surface Device with Long Term Contact (>30 days) for the gloves and boots.

Electrical Safety

The system has been designed to comply with electrical safety testing in accordance with requirements for IEC 60601-1 medical electrical equipment. The device operates from 24Vdc powered by an external medical grade power supply.

Electromagnetic Compatibility

The system has been designed to comply with the requirements of IEC 60601-1-2 medical electrical equipment. There is no known equipment within the intended operational environment of the system that will interfere with or be affected by the Paxman System. No further precautions are needed to prevent adverse events to the Patient and Operator due to Electromagnetic Disturbances.

Software

Verification and validation testing were conducted on the Paxman System software per IEC 62304 and FDA Guidance. All tests were completed successfully with respect to stated pass/fail criteria thereby deeming the device and software appropriate for its intended use.

Source of Power

- Power to the device is provided by a specific 24V, 300W external power supply.
- Only use an appropriately rated and approved power cord for the country of use.
- Electrical input: 100 to 240 Vac, 50 to 60 Hz, 5 to 2.5 A
- Protected against Short circuit / Over voltage / Over current / Over temperature
- Input connector: IEC C18, Output connector: Neutrik NAC3FXXA

Electromagnetic Compatibility

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTRONMAGNETIC EMISSIONS		
The Paxman Neuropathy is intended for use in the electromagnetic environment specified below. The customer or user of the Paxman Neuropathy should assure that it is used in such an environment.		
INTERNATIONAL	**FOR EU**	
Test	Test	Test Levels
IEC 61000-4-2:2025 - Electrostatic Discharge Immunity	EN 61000-4-2:2025 - Electrostatic Discharge Immunity	± 2 kV, ± 4 kV, , ± 6 kV, ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
IEC 61000-4-3:2020 - Radiated RF Immunity	EN 61000-4-3:2020 - Radiated RF Immunity	3 V/m 80 MHz - 6 GHz 80 % AM at 1 kHz
IEC 61000-4-3:2020 - Proximity fields from RF wireless communications equipment	EN 61000-4-3:2020 - Proximity fields from RF wireless communications equipment	According to table 9 of IEC 60601-1-2:2014 +A1:2020 EN 60601-1-2:2015 +A1:2021
IEC 61000-4-4:2012 - Electrical Fast Transients Immunity	EN 61000-4-4:2012 - Electrical Fast Transients Immunity	± 2 kV 100 kHz repetition frequency
IEC 61000-4-5:2014+A1:2017 - Voltage Surge Immunity	EN 61000-4-5:2014+A1:2017 - Voltage Surge Immunity	AC Line common mode: ± 0,5 kV, ± 1 kV, ± 2 kV AC Line differential mode: ± 0,5 kV, ± 1 kV
IEC 61000-4-6:2023 - Conducted RF Immunity	EN 61000-4-6:2024 - Conducted RF Immunity	3 V 0,15 MHz - 80 MHz 6 V in ISM bands 80 % AM at 1 kHz
IEC 61000-4-8:2009 - Power Frequency Magnetic Field Immunity	EN 61000-4-8:2010 - Power Frequency Magnetic Field Immunity	30 A/m, 60 Hz
IEC 61000-4-11:2020 - Voltage Dips and Short Interruptions Immunity	EN 61000-4-11:2020 - Voltage Dips and Short Interruptions Immunity	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 30 and 25 cycles Single phase: at 0 % 0 % UT; 300 and 250 cycles
IEC 61000-4-39:2017 - Proximity magnetic fields in the frequency range 9 kHz to 13.56MHz	EN 61000-4-39:2017 - Proximity magnetic fields in the frequency range 9 kHz to 13.56MHz	134.2 kHz with 2.1 kHz pulse at 65 A/m 13.56 MHz with 50 kHz pulse at 7.5 A/m

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Radiated emissions CISPR 11:24 / EN IEC 55011:2025	Group 1 Class A 230 Vac, 50 Hz	The Paxman Neuropathy System uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
Conducted emissions on AC power ports CISPR 11:24 / EN IEC 55011:2025		
Mains harmonic emissions IEC 61000-3-2:2019+A2:2024	Class A 230 Vac, 50 Hz	The Paxman Scalp Cooling System is suitable for use in all establishments including those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Mains voltage fluctuations/flicker emissions IEC 61000-3-3:2013+A2:2021	230 Vac, 50 Hz Dmax limit = 6%	

The built in NFC reader has an operating frequency of 13.56 MHz and an operating range up to 50mm.

5. Cybersecurity and Software-Related Information

Cybersecurity Information

The Paxman Neuropathy is a standalone medical device that does not connect to the internet, hospital networks, or external systems. The device does not store, process, or transmit patient or confidential data.

Device Connectivity

The Paxman Neuropathy has no active network connections. Wireless communication functions (Wi Fi and Bluetooth) are disabled and are not used during operation.

Access Control

A 5 digit PIN code is required to access the engineering settings screen. Only trained and authorized service personnel should access the device's internal components. Access to internal hardware requires the use of tools.

Software Update

Software updates, if required, are performed only by authorized service engineers by physically replacing the internal SD card. Users and operators cannot update, modify, or install software on the device.

Data Handling

The Paxman Neuropathy does not store or transmit patient data. The only data generated is an internal system status log used for service diagnostics. This log contains no patient or user information and is accessible only to authorized service engineers.

User Responsibilities

- Do not attempt to modify the device software or hardware.
- Do not remove the device cover or access internal components.

- Report any unexpected device behaviour to Paxman or your authorized distributor.
- Ensure that only trained personnel perform servicing or repairs

Cybersecurity-Related Safety Information

Software operation cannot affect patient safety because dedicated hardware, independent of the software, manages temperature safety cutoffs. Any software malfunction cannot cause overcooling or thermal injury.

Information Signals and User Notifications

Information Signals During Use

- Visual indicators for incorrect parameters or faults can be monitored from the 'Treatment' screen
- A trained professional should monitor the working status of the device on the 'Treatment' screen, by pressing the bottom of the screen, below the grey line, that will cause the System Status information to be displayed.
- After 20 seconds, the system status will be hidden.
- To return to the 'Coolant Times' screen, press the green Return button. If treatment is running, the Return button will be greyed out and have no function.

Information Signals for Troubleshooting

No Flow:

- If the flow rate is below 7ml/s while treatment is running or paused, the "NO FLOW" indication is displayed.
- If no flow is recorded for more than 8 minutes, the "NO FLOW – 8 MINUTES!" indication is displayed and an audible buzzer sounds.
- If this information signal appears, there could be an airlock or a kink in the wearables or coolant lines.
- If flow is detected or treatment is stopped (by pressing the red Stop button), the 8-minute No Flow timer is reset.

Low Coolant:

- If the coolant level drops below the level sensor, the "LOW COOLANT" warning is displayed, and the treatment pump will stop completely.
- Treatment will then stop (same as the red Stop button being pressed).
- The System Status will indicate "Coolant: REFILL". If this information signal appears, follow the steps for coolant top off in Section 9.
- When the coolant is filled above the level sensor, the level will return to normal, and the System Status will indicate "FULL".

Information Signals that Require Contacting Paxman:

- High temperature: If the coolant temperature rises more than 3 °C above the setpoint, the "TEMPERATURE HIGH" message is displayed. This may be displayed when warm gloves and boots are initially connected to the system and treatment started. This should disappear after a few minutes. It is recommended that gloves and boots are pre-cooled by connecting to the system and waiting a minimum of 10 minutes before starting treatment.
- Low temperature: If the coolant temperature drops more than 3 °C below setpoint, the "TEMPERATURE LOW" message is displayed, and the treatment pump stops.
- Incorrect temperature: If the temperature measures below -15 °C or above 45 °C, the "INCORRECT TEMPERATURE" message is displayed, and the treatment pump stops

6. Preparation and Setup

Selection and fitting of Gloves and Boots

Please refer to The Paman Neuropathy training materials for guidance on correct fitting of the gloves and boots.

Equipment Preparation

Disconnect wearables from coolant and compression lines using the quick-release couplings prior to fitting.

Hang coolant lines on support arms to prevent contact with the floor and reduce contamination risk.

Connecting the Wearables

Align and connect quick-release couplings:

- Push each coupling firmly until a click is heard.
- Hold the device handle for stability during connection.

Connect coolant lines to appropriate ports:

- Hand symbol → gloves
- Foot symbol → boots

Once connected:

- Secure coolant lines with Velcro to minimise condensation.
- Confirm all connections are fully engaged before use.

Pre-Use Checks

Before switching on, verify:

- Device is upright
- Coolant level is within the indicator range (via sight glass)
- Power cable is connected
- Air vents are unobstructed
- Trolley brakes are engaged

Switching on the Device

Press the green ON/OFF switch (illuminates when active).

Ensure coolant lines and wearables are connected in advance to allow sufficient cooling time prior to treatment.

System Start-Up and Operation

For detailed operating instructions, refer to the Paxman Neuropathy training materials.

Start-Up:

- Device displays boot screen followed by “Cooling – Please Wait”.
- Coolant reaches operating temperature within 20 minutes (temperature displayed on screen).
- Confirm flow indicators are spinning on all connected wearables.

Cooling Time Selection:

Once cooled, the “Cooling Times” screen appears:

- Pre-infusion: 30 or 45 min
- Post-infusion: 20, 30, 60, or 90 min

Controls and Operation

- Green Arrow: Proceed to Treatment screen
- Play Button: Starts treatment (changes to Pause)

- Pause Button: Pauses treatment (timer stops; flashing separators indicate pause)
- Skip Forward: Advance to next stage (paused state)
- Stop Button: Ends treatment, resets timer and returns to stage 1
- Shutdown (Red): Powers down software
- Settings (Blue): Access restricted settings (PIN required)

Display Information

- Left: Treatment stage and total elapsed time
- Right: Countdown timer and treatment status
- Software version shown in top-left

7. Use of the Device

Stage 1 – Pre-Infusion Cooling

Wearables are applied prior to chemotherapy infusion to achieve optimal limb temperature and compression.

Default duration: 30 minutes (adjustable as per Section 6.6).

Operation:

Upon entering the Treatment screen, Stage 1 is automatically selected.

'Total Elapsed Time' = 00:00:00; 'Remaining Time' reflects the selected pre-infusion duration.

Press Play to initiate treatment:

- Cooling and compression commence
- Pump speed increases to treatment level
- 'Remaining Time' counts down; 'Total Elapsed Time' increases
- Notes:
- Pre-medication may be administered during this stage.
- Treatment cannot be paused or skipped during Stage 1 (Pause and Skip Forward button inactive).

Stage 2 – Infusion Cooling

Wearables remain in place during chemotherapy infusion.

Duration is determined by the infusion regimen.

Operation

Automatically starts when Stage 1 completes, or manually via Skip Forward.

Press Play to begin:

- Treatment indicated by rotating blue arrows
- 'Total Elapsed Time' continues to increase

Stage 3 – Post-Infusion Cooling

Wearables remain in place after infusion completion.

Default duration: 20 minutes (adjustable as per Section 6.6).

Operation

Access via automatic progression or Skip Forward from Stage 2.

Press Play to begin:

- 'Remaining Time' counts down
- 'Total Elapsed Time' continues

Monitoring:

Periodic checks should be performed to ensure:

- Patient comfort
- Correct system operation

Completion:

When countdown ends, "Treatment complete" is displayed.

Cooling circulation continues unless stopped manually.

System Status

Tap below the grey line on the Treatment screen to display system status.

Displayed parameters:

- Coolant temperature
- Coolant level
- Flow rate (left/right)
- Pump speed (0–100%)
- Compressor speed (0–100%)
- Air pump status

Controls:

- Shutdown (red) – software shutdown
- Return (green) – returns to Cooling Times (disabled during active treatment)
- Status screen auto-closes after 20 seconds.

Completion of Treatment

Removal of Wearables

Disconnect wearables using quick-release couplings (press release buttons).

Leave wearables in place for ~5 minutes to allow warming.

Remove gently by releasing Velcro fastenings.

Possible temporary effects post treatment:

- Cold sensation
- Redness
- Numbness
- Light-headedness or dizziness
- Patient should remain seated or lying down for at least 10 minutes or until symptoms resolve.

Device Shutdown

After completing all sessions:

- Shut down the software using on-screen controls.
- Switch off using the green ON/OFF switch at the rear.
- Disconnect power from mains.
- Store cables safely on support arms.

8. Cleaning, Disinfection and Infection Control

Cleaning Instructions for Glove and Boot Cooling inners

- Remove the cooling inner from the cover
- Wash the internal and external surface of the cooling inner with warm soapy tap water (100-110 °F or 37–43 °C) for a minimum of 1 minute. It is recommended to use enzymatic detergent diluted as per the detergent instructions.
- Rinse the cooling inner with tap water to remove soap residues for a minimum of 1 minute.
- Dry the wearable thoroughly with a lint-free cloth for a minimum of 1 minute.
- Use a 70% ethanol alcohol wipe to thoroughly wipe down the cooling inner for a minimum of 1 minute.
- Allow the cooling inner to air dry, for a minimum of 1 minute.

Disinfection Instructions for Glove and Boot Cooling inners

- Remove the cooling inner from the cover.
- Use a 10% bleach/water solution made fresh daily or equivalent hospital grade disinfection wipe to thoroughly wipe down the cooling inner for a minimum of 3 minutes.
- Rinse the cooling inner with water for a minimum of 1 minute, ensuring all of the bleach is washed off.
- Allow the cooling inner to air dry.
- Wipe over the internal and external surface of the cooling inner with 70% ethanol alcohol wipe, for a minimum of 1 minute.
- Allow the cooling inner to air dry, for a minimum of 1 minute.

Cleaning and Disinfection for Coolant Lines and Covers

The covers can be cleaned by hand or via machine using the following instructions:

- Rinse for 3 minutes using cold water
- Wash in water at 40 °C/104 °F for 10 minutes using standard mild detergent
- Rinse with water for 2 minutes
- Allow to air dry fully prior to use

The glove/boot cover and coolant lines contain a wipeable outer layer for easy disinfection. Use hospital-grade alcohol sanitising cloth or wipes and allow to air dry.

Approved Cleaning and Disinfection Agents

- Cleaning validation of the glove and boot covers has been performed using an enzymatic detergent (Triple-Zyme – Serchem).
- Disinfection validation of the cooling inners was performed using 10% bleach/water solution and a 70% ethanol alcohol wipe.

Cleaning and Disinfection Frequency

- The cooling inners should be cleaned and disinfected when soiled.
- The glove and boot covers should be cleaned and disinfected between patients.
- The coolant lines should be cleaned and disinfected when soiled.

9. Preventative Maintenance and Servicing

Preventative Maintenance Requirements

Maintenance Instructions

Coolant Level:

- Check via sight glass when the device is switched off.
- Top up as required using the blue coolant top-off valve.

Wearables and Couplings:

- Inspect regularly for wear and damage
- Inspect regularly for bulging in wearables
- Inspect for cracking or damage around quick-release couplings

Coolant Lines:

- Inspect for signs of wear or deterioration.

Cleaning:

- Clean wearables and coolant lines only in accordance with the specified cleaning procedure.
- Clean quick-release couplings using hospital-grade alcohol wipes and ensure they are free from obstructions.
- Clean external device surfaces (including trolley) with hospital-grade wipes, ensuring no liquid contacts the touchscreen.
- Clean touchscreen using a soft, absorbent material with vertical or horizontal motions (do not use circular motion).

Airflow Maintenance:

- Keep ventilation grills clean and unobstructed.
- Remove dust build-up using a vacuum cleaner.

Maintenance Restrictions

Servicing must be performed only by Paxman authorised technical service personnel.

Unauthorised servicing is not permitted.

Replacement of the 15A mains fuse must only be carried out by qualified personnel.

Service Intervals

The Paxman Neuropathy has a recommended service interval of 2 years

Replacement of Parts

All internal components must be serviced or replaced only by an authorised Paxman service representative.

Coolant Top-Up

Coolant Level Checks

Coolant levels should be checked using either method:

Sight glass (preferred):

- Check when device is OFF and wearables are disconnected.
- Top up if below indicated level.
- System alert:
- ‘LOW COOLANT’ message displayed on screen.

Coolant Top-Up Procedure

- Switch off device and disconnect from mains power.
- Insert air relief tube into connector until a click is heard.
- Position tube into a container to capture any overflow.

- Obtain a 1L coolant cube.
- Connect coolant cube to the blue top-off valve until it clicks (seal pierced).
- Lift and hold the cube upright to allow coolant flow.
- Monitor coolant level via sight glass.

Once the correct level is reached:

- Return valve to original position
- Disconnect cube using the release button
- Note: The full 1L volume may not be required.

Further Information

Detailed electrical schematics, circuit diagrams, components lists and fault finding information will be made available on request for suitably qualified and authorised service personnel.

The coolant is made up of an organic salt-based solution complete with inhibitors. The coolant is not classified as dangerous or hazardous under EC criteria and is deemed completely safe for use in its intended purpose. The Material Safety Data Sheet can be found in Section 10.

10. Disposal

Wearables & Coolant Lines

In the event of the wearable or the coolant lines becoming damaged or contaminated such that the user deems the component unfit for use, the component should be removed from use, drained of coolant and disposed of in line with local regulations. Alternatively, please contact Paxman to arrange for the component(s) to be collected from the site.

Coolant

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

Should spillage of coolant occur wipe affected area with a disposable cloth or absorbent paper and place in a suitable waste container. Wash affected area with soap and water or a suitable floor cleaner. The product is biodegradable and it is recommended to wear surgical gloves while handling.

The safety data sheet is available via the following QR code link:

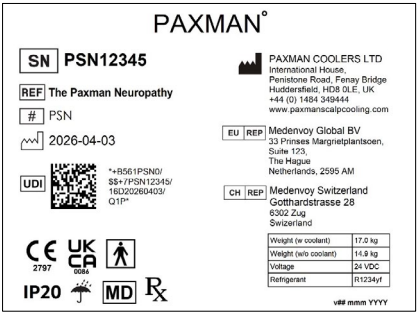
The Paxman Neuropathy

If the whole system is to be taken out of use, please ensure that local regulations are adhered to, such as WEEE and F-gas regulations. Please contact Paxman for further advice or to arrange for the device(s) to be collected from the site for disposal.

Corrosion, aging, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable risk.

11. Labelling, Symbols and Packaging Information

Device Label



Symbols

⚠	Warnings are directions which, if they are not followed can cause the device to mis-function or cause serious injury
⚠	Cautions are directions which if not followed can cause damage to the system described in this manual
	Advise please read the Instructions for Use
	Product information; Information point
	Must not be disposed of in household waste
CE	Indicates the medical device is approved to be sold within European Community
UKCA	Indicates the medical device is approved to be sold within the United Kingdom and Northern Ireland
	Indicates that the medical device contains a Type BF applied part
	Indicates a medical device needs to be protected from moisture
	Earth (Ground)
IP20	Indicates the applicable ingress protection of the device.
EU REP	Indicates the authorized representative in the European Community/European Union
CH REP	Indicates the authorized representative in Switzerland
R_x Only	The Rx symbol (or "R_x only") used on medical device labelling to indicate prescription-only.
	Indicates the medical device manufacturer
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified
#	Indicates the model number or type number of a product
	Indicates the date when the medical device was manufactured
MD	Indicates the item is a medical device
UDI	Indicates a carrier that contains unique device identifier information

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PAXMAN

A DEGREE OF CONTROL®

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EU Issue 1 | 2026-09-18

Any serious incident that has occurred in relation to the device should be reported to the manufacturer (PAXMAN) and the competent authority of the Member State in which the user and/or patient is established.