



Essential care before, during and after surgery.

# Convective Warming Machine



## CWS 4000 OPERATOR MANUAL



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## 1. INTRODUCTION

This device should only be operated under the guidance/supervision of qualified medical/nursing personnel or other paramedical staff trained in the use of Convective Patient Warming Systems.

It is a pre-requisite for all persons using this medical device to understand the information contained in this Manual. Read and understand this Manual and all precautions prior to operating the Cocoon Convective Warming System.

When used with Care Essentials patient warming blankets, the Care Essentials CWS4000 provides a continuous method of warming patients intended for preventing and treating hypothermia. The Cocoon Convective Warming System consists of a CWS4000 and a warming blanket. A connecting hose conducts heated air from the CWS4000 to the warming blanket.

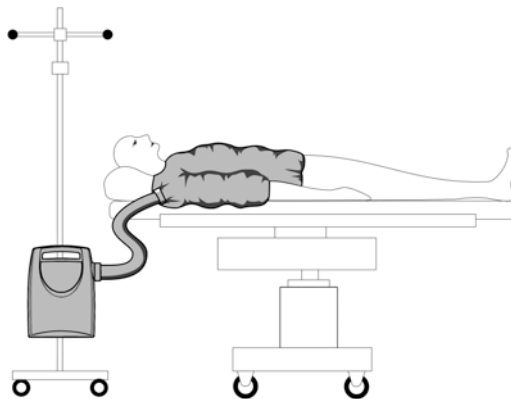


Figure 1 Convective Warming System

Care Essentials recommend that a program of regular routine maintenance, electrical safety and performance inspections be instituted for the CWS4000 as described in Section 4.3 below.

The CWS4000 is a mains-powered, microprocessor-controlled device that delivers a continuous flow of temperature-controlled air through a flexible hose to the warming blanket. The temperature of the air delivered to the blanket can be set to one of six settings ambient, 34°C, 37°C, 40°C, 43°C, or 46°C. When a temperature of 46°C is selected, the setting automatically drops to 43°C after 10 minutes. The CWS4000 will not cool the air delivered to the blanket below the ambient temperature of the room.

Air is drawn into the sides of the CWS4000 and passes through a bacteriological HEPA filter. The CWS4000 includes a number of over-temperature prevention systems and in a temperature fault condition it automatically shuts down and signals an alarm.

This Manual presents all the relevant operation information for the Care Essentials CWS4000 Cocoon Warming System. This information is intended for the fair purposes of operation and maintenance of the CWS4000. It is provided as Commercial-In-Confidence material to the Care Essentials Distributor or CWS4000 owner and shall not be made available to any other organization or person without the specific written permission of Care Essentials.

While every attempt has been made to ensure this manual is accurate and complete, no responsibility is taken for any errors or omissions. Care Essentials has a policy of continuous product improvement and product specifications and component types are subject to change without notice.

If you, as a user of this manual, have any relevant comments or questions about the CWS4000 or this Manual, your communication with Care Essentials would be welcomed. Our contact details are located on the first page of this Manual.

## 2. OPERATION

### 2.1. Unit Setup

The CWS4000 may be placed on the floor, mounted on the foot of the bed using the foldout brackets, or clamped to an IV pole using the IV pole clamp. When using an IV pole, do not mount the CWS4000 higher than 1 metre or it could tip over. Do not place the CWS4000 on a bed surface. Note that if the CWS4000 is placed on the floor, increased levels of dust and lint could reduce filter life.

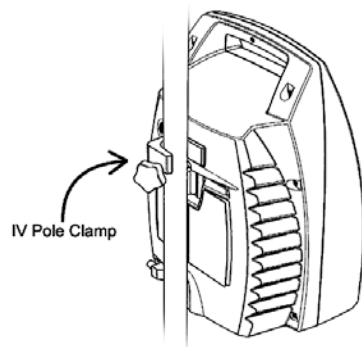


Figure 2 IV pole or stand mounted

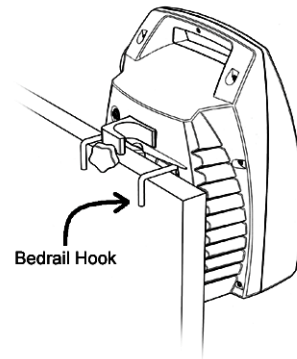


Figure 3 Bed rail mounted

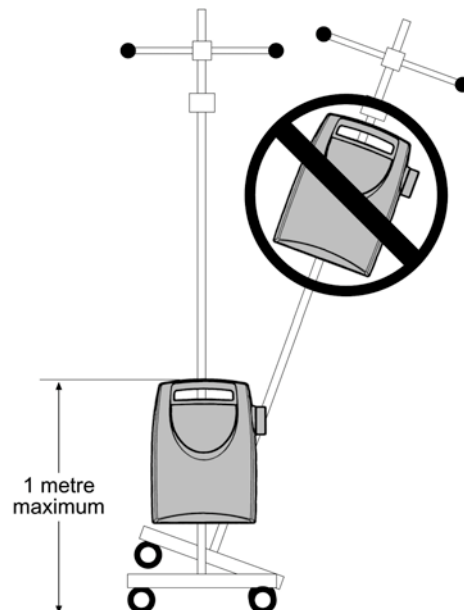


Figure 4 Pole mounting height limit

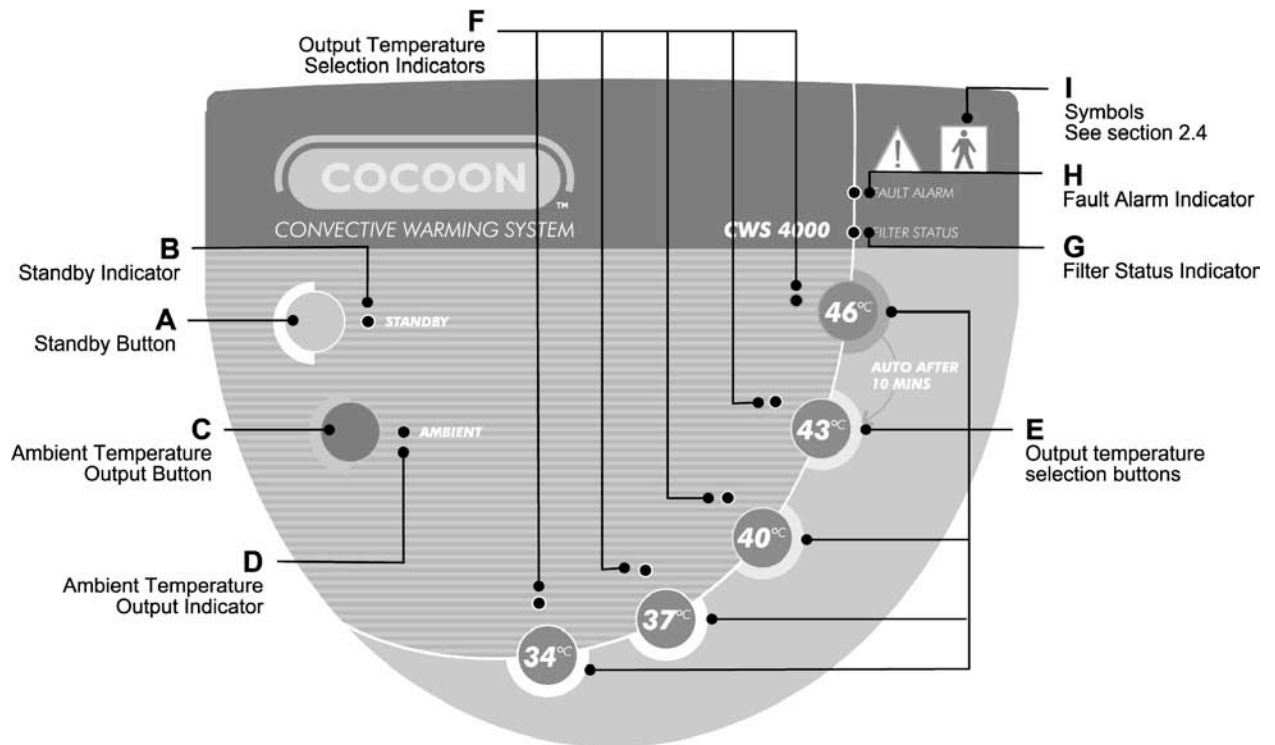


Figure 5 Operator control panel

## 2.2. Getting Started

Plug the mains cable into a conventional, properly earthed 240 Volt 10 Amp mains power socket-outlet and switch it on. The green **Standby indicator (B)** will illuminate and the CWS4000 will beep when power is connected.

Ensure that air is not prevented from entering the inlet slots at the sides by blankets or other objects.

Remove the CE Marked warming blanket from its packaging. Unfold the warming blanket and place it over the patient. Connect the air delivery hose to the warming blanket by pushing the plastic fitting into the air inlet port and secure firmly. Please note that when using the CWS4000 warming unit with a Bair Hugger™ blanket a delivery hose nozzle adaptor is required (Part Number CWS203); please contact your Care Essentials representative or agent. Refer to Section 7 below for commingling information relating to the use of Cocoon warming unit and/or blankets with other manufacturer's warming units and blankets.

## 2.3. Unit Operation Procedure

Select the desired temperature on the control panel pressing either one of the **Output temperature selection buttons (E)** or **Ambient Temperature Output Button (C)**. The appropriate green or yellow light (**D or F**) will indicate the selected temperature setting. Another temperature may be selected at any time. When using the 34°C, 37°C, 40°C, 43°C, or 46°C temperature settings, place your hand under the warming blanket to confirm that the CWS4000 is supplying warm air. Placement of a blanket, sheet or drape over the inflated warming blanket maybe undertaken to maximize the efficiency and minimize the heat loss from the system. In using additional covers it is important to ensure air flow through the convective warming blanket is not disrupted.

The internal timer will automatically decrease the temperature setting from 46°C to 43°C after 10 minutes. This timer can be reset by momentarily selecting another setting and then re-selecting 46°C.

Switch the unit off by pressing the **Standby Button (A)**. The green **Standby indicator (B)** will illuminate when the unit is off.

The unit will automatically switch off in an alarm condition and the green **Standby indicator (B)** will illuminate together with the red **Fault Alarm indicator (H)**. In the event the **Fault Alarm indicator (H)** illuminates, disconnect the CWS4000 from the patient and from the mains power supply and have it serviced by trained personnel.

The **Filter Status indicator (G)** provides the user with information on remaining filter life. This indicator is interpreted as follows:

Indication	Description
Steady green indicator	Filter status normal
Steady orange indicator	Filter life has reached 950 hours
Flashing orange indicator	Filter life has reached 990 hours
Steady red indicator	Filter life has exceeded 1000 hours and requires replacing

#### 2.4. Practical issues to consider when selecting and using warming blankets

- Select correct style and size of blanket
- Ensure hose is attached securely
- Secure the position of the blanket on the patient– tapes and ties
- Place convective warming blanket directly against patients skin
- If placing additional covers, eg sheets, blankets or drapes over patient ensure air flow is not disrupted
- Inflate convective warming blanket before adding additional covers.
- Monitor temperature setting on warming unit.

## 2.5. Symbols

The following symbols are used on the CWS4000:



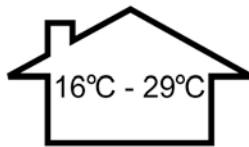
Attention: consult accompanying documents



Dangerous voltage



Type BF applied part



Ambient operating temperature range, indoor use only



Do not free hose

### 3. SAFETY PRECAUTIONS

Review the following safety precautions prior to servicing the CWS4000.

#### 3.1. Danger

- Explosive hazard. Do not use in the presence of flammable anaesthetic agents.
- Risk of electric shock. Disconnect mains power before servicing the CWS4000.

#### 3.2. Warning

- No free hosing – use of convective warming machine without a compatible convective warming blanket may cause thermal injury.
- Ensure that no direct or indirect contact is made between the patient and the communications connector located on the rear of the CWS4000.
- The CWS4000 must only be opened or serviced by qualified personnel such as certified biomedical electronics technicians or certified clinical engineers familiar with repair practices for servicing medical devices, and in accordance with the Service Manual. Damage to the CWS4000 or malfunction could otherwise result.
- Ensure the unit is subjected to the specified routine electrical safety and performance inspections.
- In the event of excess fluid contact with the CWS4000 it is recommended that the unit be disconnected from the mains power supply and checked by qualified personnel.
- Use only in accordance with Operator Manual instructions.

#### 3.3. Caution

- Operate the CWS4000 only in the specified supply voltage range and environmental conditions and as detailed in Section 9 below.
- When using an IV pole, do not mount the CWS4000 higher than 1 metre or it could tip over.
- The 46°C temperature setting is not recommended for patients who are non-responsive or with impaired circulation.
- It is not recommended that the unit be operated after the filter has exceeded the specified life period.

#### 3.4. Electromagnetic Interference

The CWS4000 has been designed to comply with IEC 601-1-2:1993 (Medical electrical equipment – Part 1: General requirements for safety. 2. Collateral standard: electromagnetic compatibility – Requirements and tests) but this does not guarantee that other equipment in the vicinity will not be affected by the electromagnetic emissions from the CWS4000. Similarly, other equipment in the vicinity may affect the operation of the CWS4000.

It is recommended that all equipment used near the CWS4000 comply with the relevant electromagnetic compatibility requirements for that equipment and to check before use that no interference is evident or disruptive. Increasing the distance between offending devices, and keeping interconnecting leads as short as possible will help reduce the effect.

## 4. PREVENTATIVE MAINTENANCE

### 4.1. Cleaning

- Clean the CWS4000 control panel, enclosure exterior, and hose with a soft cloth lightly dampened with a non-staining hospital disinfectant.
- Clean accumulated dirt and lint from the air inlet slots using a vacuum cleaner.

### 4.2. Filter Service

Only qualified service personnel may change filters. Refer to the CWS4000 Service Manual for instructions on replacing the filter. Under normal use, replace the HEPA filter inside the CWS4000 every 1000 operating hours or 12 months, whichever occurs first. The FILTER STATUS indicator will warn of the need for filter replacement.

### 4.3. Electrical Safety and Performance Inspection

Care Essentials recommend that the CWS4000 receive regular electrical safety inspections. Information on the type and frequency of inspections may be obtained from locally published technical standards.

In Australia, the relevant technical standards are:

- AS3511 Technical management programs for medical devices.  
This standard specifies procedures required to develop equipment management programs for medical devices. Some of these include procedures for acceptance, fault management and routine testing of medical devices. This standard specifies electrical safety, essential safety and performance testing.
- AS2500 Guide to the safe use of electricity in patient care.  
This standard provides a comprehensive guide to the safe use of electrically operated equipment used in health care facilities. Measures are detailed to provide and maintain patient and operator safety, including details of the classes of equipment and electrical installations to be used for particular medical procedures.

Programmed electrical safety inspections are essential to confirm continued operator and patient safety. Mandatory, statutory requirements for electrical safety inspections may also apply.

Care Essentials also recommend that the CWS4000 receive at least an annual performance inspection as described in the CWS4000 Service Manual.

## 5. TROUBLESHOOTING

### 5.1. Warming Blanket Will Not Inflate

- Make sure the CWS4000 is plugged in to an energized mains power socket-outlet.
- Check both ends of the delivery hose for proper connection.
- Check the delivery hose and warming blanket inlet for kinks.
- Check that there are no obstructions to the air inlet slots.
- Check the warming blanket for damage. If air is flowing from the hose, try another warming blanket. Small rips or tears in the warming blanket may be temporarily repaired with adhesive tape.
- Request qualified service personnel check for a clogged or dirty filter.
- Check for fault alarm.

### 5.2. Standby Indicator Will Not Light

- Extremely high storage temperatures (such as those found motor cars on hot summer days) can cause the temperature limit thermostats in the CWS4000 to actuate. Should this occur, the STANDBY indicator will fail to light when the CWS4000 is connected to mains power. If this occurs, simply wait for the CWS4000 to cool down and eventually the thermostats will automatically reset and the STANDBY indicator will light.
- Request qualified service personnel check for blown mains power fuses.

### 5.3. Equipment Repairs

Repairs to the CWS4000 should be performed by qualified personnel such as certified biomedical electronics technicians or clinical engineers familiar with repair practices for servicing medical devices, and in accordance with the CWS4000 Service Manual. Damage to the CWS4000 or malfunction may otherwise result.

## 6. ACCESSORIES

### 6.1. Warming Blankets

Use only warming blankets recommended by Care Essentials. Failure to do so may result in thermal injury. Care Essentials supply a variety of warming blankets.

### 6.2. Stand

An optional stand for the CWS4000 is available.

### 6.3. User Training

In-service training is available from Care Essentials or nominated distributor.

## **7. COMMINGLING WARMING UNITS AND BLANKETS**

Commingling refers to the use of Cocoon warming units and/or blankets with other manufacturer's Class 11B Convective Warming Systems. Care Essentials recommend that you consider the following recommendations and warnings when commingling.

### **7.1. Commingling Recommendations**

- Use warming units that regulate the air temperature at the end of the delivery hose.
- Use warming units with audible and visual over temperature alarms.
- Ensure that bends in the delivery hose are minimised when in use. Excessive bends in the delivery hose may affect the temperature performance.
- Refer to tables in section 7.3 below for instructions about connecting warming systems.
- To compare the Cocoon Convective Warming System with other manufacturers, please refer to the CWS 4000 Product Information chart in Appendix 1.

### **7.2. Commingling Warnings**

- Ensure the connection of the delivery hose and blanket is secure and that air is not escaping.
- A delivery hose nozzle adaptor (Part Number CWS203) is required when using the CWS4000 warming unit with Bair Hugger™ blankets.
- Consider individual manufacturer's recommendations and warnings when commingling.

### 7.3. Commingling Recommended Instructions

#### Cocoon CWS4000 Warming Unit

Brand of Blanket	Recommended Instructions
Tyco WarmTouch™ Blankets	<ul style="list-style-type: none"> <li>• Insert the CWS4000 delivery hose nozzle well into the WarmTouch blanket.</li> <li>• Secure the blanket to the nozzle with adhesive tape.</li> <li>• Inflate the blanket and ensure that there is no air leakage.</li> <li>• Refer to Figure 6 below.</li> </ul>
Arizant Bair Hugger™ Blankets	<ul style="list-style-type: none"> <li>• Ensure that the Care Essentials CWS203 adaptor is attached to the CWS4000 delivery hose nozzle.</li> <li>• Insert the adaptor into the connection point of the Bair Hugger blanket. The adaptor should fit securely and be held in place by the blanket connection.</li> <li>• Inflate the blanket and ensure that there is no air leakage.</li> <li>• Refer to Figure 7 below.</li> </ul>



*Figure 6 Cocoon CWS4000 warming unit attached to WarmTouch™ blanket*



*Figure 7 Cocoon CWS4000 warming unit attached to Bair Hugger™ blanket*

### Cocoon Blankets

Brand of Warming Unit	Recommended Instructions
Tyco WarmTouch™ Warming Unit	<ul style="list-style-type: none"> <li>• Insert the WarmTouch™ delivery hose nozzle into the Cocoon blanket until it covers half of the nozzle.</li> <li>• Secure the blanket to the nozzle with the Cocoon blanket ties in a manner resembling tying a shoelace.</li> <li>• Inflate the blanket and ensure that there is no air leakage.</li> <li>• Refer Figure 8 below.</li> <li>• Cocoon reusable - ensure the hose nozzle is securely inserted into the blue ribbed hose inlet. Refer Figure 10 below</li> </ul>
Arizant Bair Hugger™ Warming Unit	<ul style="list-style-type: none"> <li>• Insert the Bair Hugger™ delivery hose nozzle into the Cocoon blanket until it covers half of the nozzle.</li> <li>• Secure the blanket to the nozzle with the Cocoon blanket ties in a manner resembling tying a shoelace.</li> <li>• Inflate the blanket and ensure that there is no air leakage.</li> <li>• Refer to Figure 9 below.</li> <li>• Cocoon reusable - ensure the hose nozzle is securely inserted into the blue ribbed hose inlet. Refer Figure 11 below</li> </ul>



Figure 8 Cocoon Disposable blanket attached to WarmTouch™ warming unit



Figure 9 Cocoon Disposable blanket attached to Bair Hugger™ warming unit



Figure 10 Cocoon Reusable blanket attached to WarmTouch™ warming unit



Figure 11 Cocoon Reusable blanket attached to Bair Hugger™ warming unit

## **8. WARRANTY**

The CWS4000 is warranted free of defects in material and workmanship under normal use and operation for a period of two years, under the terms and conditions of the Care Essentials warranty in place at time of purchase. During the warranty period, Care Essentials will repair or replace at its sole option, free of charge, any defective parts or products returned with prior authorization prepaid to Care Essentials. Consumable items such as filters are excluded. The full warranty is available from Care Essentials upon request.

This warranty does not cover products abused, misused, or altered outside the factory. There are no obligations on the part of Care Essentials for consequential damages arising out of or in connection with the use or performance of the product. Care Essentials disclaims all implied warranties including but not limited to, the implied warranties of merchantability and of fitness for a particular purpose.

This warranty does not cover the following accessories or consumables; filters, hose covers, power cords, or accessory blankets.

## 9. SPECIFICATIONS

<b>ELECTRICAL</b>	
Supply Voltage	230 – 240 Vac
Supply Frequency	50 Hz
Supply Power	1100 Watts Maximum
External Fuses	2 x 6.3 Amp 250V Time Lag (T) 5x20mm
Heater	1000 Watt heating element
Fan Motor	45 Watt
<b>CLASSIFICATION</b>	
Applied Parts	Warming Blanket & Delivery Hose
Applied Part classification	Type BF
Device classification	Class 1
Mode of operation	Continuous
Degree of protection against ingress of liquid	No protection against ingress of liquid
Degree of safety in the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide	Not designed for use in the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide.
Environmental conditions required for operation	16°C to 29°C, Less than 90% relative humidity, non-condensing
Environmental conditions required for transport and storage	10°C to 40°C, 45% to 95% relative humidity, non-condensing
Method of disinfection	Surface disinfection is possible using a cloth moistened with a mild, non-staining, disinfectant solution.
<b>PERFORMANCE</b>	
Temperature settings indicate the average air temperature at the end of the delivery hose	Ambient, 34°C, 37°C, 40°C, 43°C or 46°C Note: The air temperature around the patient is affected by the ambient air temperature, the warming blanket type and the use of an insulating blanket placed on top of the warming blanket.
Temperature accuracy of delivered air, except for the ambient temperature setting	± 2°C with delivery hose cover. Not specified without delivery hose cover.
Environmental conditions required to achieve the specified temperature accuracy	20°C to 22°C, 30% to 70% relative humidity, non-condensing
Time required to attain the specified temperature accuracy of delivered air following a change in temperature setting	2 minutes
<b>SAFETY SYSTEMS</b>	
Dual temperature limit thermostats	Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature.
Heater temperature limit devices	A 98°C thermal fuse and 104°C self-resetting thermostat protect the filter from excessive temperatures.
Temperature limit alarm	Continuous temperature monitoring guarantees that the temperature of the delivered air maintains its specified accuracy.
Control system failure alarm	Continuous self-monitoring by the control system ensures that it always functions predictably.
<b>PHYSICAL</b>	
Dimensions	29 cm x 22 cm x 40 cm
Weight	6 Kilograms
Enclosure	Flame-Retardant ABS-PC Plastic
Filter type/Life	Bacteriological HEPA filter/ 1000 hours

## 10. APPROVALS

The CWS4000 has achieved the following medical device approvals.

<b>Certifying Body</b>	<b>Title</b>	<b>Standard</b>
Wakefield Laboratories Report No. 21977	Medical Electrical Equipment Part 1: General requirements for safety	IEC 60601 – 1: 1988 + Amendments 1 and 2 (AS/ NZS 3200.1.0:1998)
EMC Technologies Report No. M050325	Medical Electrical Equipment Part 1: General requirements for safety Section 2. Collateral Standard: Electromagnetic Compatibility – Requirements and tests	IEC 60601 – 1 – 2: 2004
Therapeutic Goods Administration ARTG No. 76807	TGA Certificate of Device Listing	

## 11. Appendix 1. Cocoon CWS 4000 Product Information

### Response

Model	Care Essentials Pty Ltd, Cocoon CWS 4000
Where Marketed	Australia, Asia, Middle East and Europe
FDA Clearance	No
CE Mark	Yes, CE 0120
Configuration	Mobile, portable, pole or bed mounted, trolley
Applications	Operating Theatre, Intensive/Critical Care Area, Recovery, Emergency/Trauma, Ward
Controls	Touchpad
Display Type	LED
Function Indicators	Standby, Filer Status, Fault Indicator, six temperature settings plus ambient setting. Ambient to 46 degrees Celsius
Line Power, VAC	230-240VAC
Heater Power, W	1100 watts maximum
Blanket	Full range disposable and reusable
Hose Length	1.5 metres
Temp Settings C	Ambient, 34, 37, 40, 43, 46 degrees Celsius
Safety Thermostats	53 degrees C +/- 3 degrees C
Automatic overheat Shutoff	Yes
Alarm Conditions	High temperature safety cut out fuse, visual and audible
Noise Level, dB	<55dB
Warm Up Time	2 minutes
Fan Speed, cfm	38 CFM
Filtration System	Yes, Hepa Filtration
H x W x D	40cm x 29cm x 22cm
Weight	6 kg
Warranty	2 years
Delivery Time	2/3 weeks
Other Specifications	Heater Element – single shot fuse, test port through windows Hyper-terminal communications program