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ARTG LISTED PRODUCTS

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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.

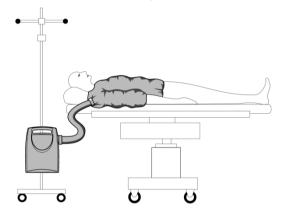


Figure 1 Convective Warming System

Care Essentials recommend that a program of regular routine maintenance, electrical safety and performance inspections be instituted for the CWS4000 as described in Section 5.3 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.

1. **OPERATION**

1.1. **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.

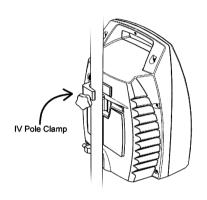


Figure 2 IV pole or stand mounted

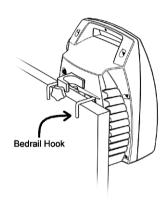


Figure 3 Bed rail mounted

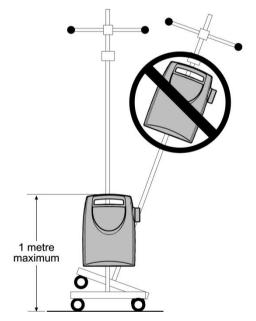


Figure 4 Pole mounting height limit

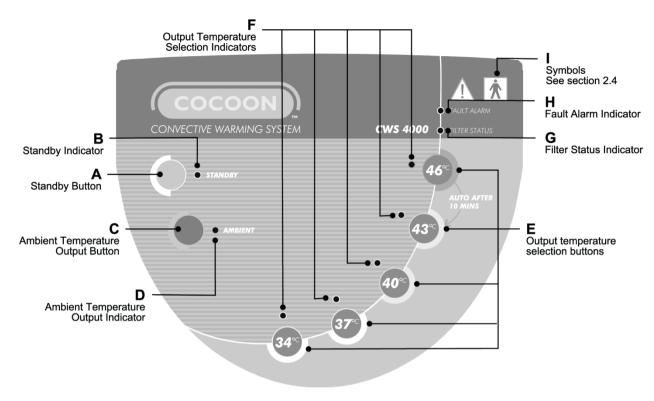


Figure 5 Operator control panel

1.2. 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. Refer to Section 2 below for more detailed instructions on warming blankets. Connect the air delivery hose to the warming blanket by pushing the plastic fitting into the air inlet port and securing it 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 8 below for commingling information relating to the use of Cocoon warming unit and/or blankets with other manufacturer's warming units and blankets.

1.3. Unit Operation Procedure

Select the desired temperature on the control panel by pressing the **ambient temperature output button (C)** or one of the **output temperature selection buttons (E)**. 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 may be undertaken to maximize the efficiency and minimize the heat loss from the system. When 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 re-selecting the 46°C temperature setting.

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 that 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 replacement

2. PATIENT WARMING BLANKETS

Care Essentials manufactures both Cocoon single-use and reusable (available Australia only) patient warming blankets. In addition, the CWS4000 can be used with blankets supplied by other manufacturers. Refer to Section 8 below for commingling information relating to the use of Cocoon warming unit and/or blankets with other manufacturer's warming units and blankets. Use only patient warming blankets recommended by Care Essentials. Failure to do so may result in thermal injury.

2.1. Cocoon Disposable Patient Warming Blankets

Features of Cocoon disposable patient warming blankets include:

Warm, soothing, cocooning design.

Single use. This product is not for reuse due to the risk of cross infection.

Universal inlet port ensures hose stays firmly in the blanket.

Full range of blankets. Refer to www.careessentials.com.au for details.

Latex free.

Model CLM0101, CLM0102, CLM0103, CLM0104, CLM0118, CLM0108 Instructions

Remove the yellow Cocoon blanket from its plastic wrapper.

Place the Cocoon blanket over the patient with the white side down.

Insert and secure the CWS4000 delivery hose in the blanket inlet port.

Inflate the Cocoon blanket according to the CWS4000 instructions, refer Section 1.3 above.

Do not use plastic head covers unless the patient is intubated and ventilated.

Model CLM0105, CLM0107, CLM0106, CLM0122, CLM0125 Instructions

Place Cocoon blanket on the bed with the white side facing upwards.

Position patient on top of the blanket.

Insert and secure the CWS4000 delivery hose in the blanket inlet port.

Secure the position of the blankets by using the tapes and ties where provided.

Inflate the Cocoon blanket according to the CWS4000 instructions, refer Section 1.3 above.

Do not use plastic head covers unless the patient is intubated and ventilated.

Model CLM0112 Instructions

Place the Cocoon blanket alongside the patient

Insert and secure the CWS4000 delivery hose in the blanket inlet port.

Inflate the Cocoon blanket according to the CWS4000 instructions, refer Section 1.3 above.

2.2. Cocoon Reusable Patient Warming Blankets

Features of Cocoon reusable patient warming blankets include:

Technically advanced smart fabric, which conforms to the patient's body.

Antistatic and non-linting.

Oil and water repellent.

Universal air inlet is designed for ease of use and offers a secure fitting to all convective warming machines.

Cocoon reusable blankets are an environmental friendly alternative to disposable blankets.

Full range of blankets: refer www.careessentials.com.au for details.

Instructions

Place the Cocoon blanket on the patient with the purple side down.

Insert and secure the CWS4000 delivery hose in the blanket inlet port.

Inflate the Cocoon blanket according to the CWS4000 instructions, refer Section 1.3 above.

This is a reusable product, which should be laundered between patient uses following the washing instructions as detailed in APPENDIX 2. COCOON REUSABLE BLANKET WASHING AND FOLDING INSTRUCTIONS.

Care Essentials will review the blankets, with the intention of removing them from use, two years following the date of issue.

2.3. Practical Issues to Consider When Selecting and Using Blankets

Select the correct style and size of blanket.

Ensure the CWS4000 delivery hose is attached securely.

Secure the position of the blanket on the patient using tapes and ties.

Place the convective warming blanket directly against the patient's skin.

When using additional covers over the patient, e.g. sheets, blankets or drapes, it is important to ensure air flow through the convective warming blanket is not disrupted.

Inflate the blanket before adding additional covers.

Monitor the temperature setting on the CWS4000.

3. SYMBOLS

The following symbols are used on the Cocoon Convective Warming System:



Attention: Refer Section 2.1 Operator Manual



Dangerous voltage



Type BF applied part



Do not free hose



Single patient Use



The device has not been sterilised



Latex free

4. SAFETY PRECAUTIONS

Review the following safety precautions prior to servicing the CWS4000.

4.1. Danger

Explosive hazard. Do not use in the presence of flammable anaesthetic agents.

Risk of electric shock. Disconnect mains power before servicing the CWS4000.

4.2. Warning

No free hosing – use of the CWS4000 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 CWS4000 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.

Do not to position the CWS4000 so that it is difficult to operate the appliance plug and socket.

4.3. Caution

Operate the CWS4000 only in the specified supply voltage range as detailed in Section 11 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.

4.4. Electromagnetic Interference

The CWS4000 has been designed to comply with IEC 60601-1-2:2007 (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.

5. PREVENTATIVE MAINTENANCE

5.1. 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.

5.2. 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 (G)** will warn of the need for filter replacement.

5.3. 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:

AS/NZS3511 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.

AS/NZS2500 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.

6. TROUBLESHOOTING

6.1. 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.

6.2. 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 (B)** 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 (B)** will light.

Request qualified service personnel check for blown mains power fuses.

6.3. 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.

7. ACCESSORIES

7.1. Stand

An optional stand for the CWS4000 is available.

7.2. User Training

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

8. 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.

8.1. 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 8.3 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.

8.2. 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.

Only use Convective warming machines that have that have passed safety and electrical testing

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8.3. Commingling Recommended Instructions

Cocoon CWS4000 Warming Unit

Brand of Blanket	Recommended Instructions
	Insert the CWS4000 delivery hose nozzle well into the WarmTouch blanket.
Tyco	Secure the blanket to the nozzle with adhesive tape.
WarmTouch™ Blankets	Inflate the blanket and ensure that there is no air leakage.
	Refer to Figure 6 below.
	Ensure that the Care Essentials CWS203 adaptor is attached to the CWS4000 delivery hose nozzle.
Arizant	Insert the adaptor into the connection point of the Bair Hugger blanket. The adaptor should fit securely and be held in place
Bair Hugger™ Blankets	by the blanket connection.
	Inflate the blanket and ensure that there is no air leakage.
	Refer to Figure 7 below.



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
	Insert the WarmTouch™ delivery hose nozzle into the Cocoon blanket until it covers half of the nozzle.
Tues	Secure the blanket to the nozzle with the Cocoon blanket ties in a manner resembling tying a shoelace.
Tyco	Inflate the blanket and ensure that there is no air leakage.
WarmTouch™ Warming Unit	Refer Figure 8 below.
	Cocoon reusable blanket – ensure the delivery hose nozzle is securely inserted into the blue ribbed hose inlet. Refer Figure 10 below.
	Insert the Bair Hugger™ delivery hose nozzle into the Cocoon blanket until it covers half of the nozzle.
Arizont	Secure the blanket to the nozzle with the Cocoon blanket ties in a manner resembling tying a shoelace.
Arizant	Inflate the blanket and ensure that there is no air leakage.
Bair Hugger™ Warming Unit	Refer to Figure 9 below.
	Cocoon reusable blanket – ensure the delivery hose nozzle is securely inserted into the blue ribbed hose inlet. Refer Figure 11 below.



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



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

to WarmTouch™ warming unit

9. 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.

10. RETURNING OF UNIT FOR REPAIR

Tools/Equipment

Cocoon CWS 4000 carton (or similar)

Tape Dispenser

Shipping label

Method

Call Customer Service (03 5277 1455) to request a Return for Repair Form QFP 018, otherwise available from our web site www.careessentials.com.au

The Cocoon CWS 4000 must be cleaned and disinfected (by wiping over with Chlorhexidine 0.5% in Alcohol 70% solution) prior to return to Care Essentials.

The Cocoon CWS 4000 must be packaged with suitable packaging to protect the machine in transit. (Preferably the Cocoon carton and foam packaging, as supplied with the machine.)

Apply the shipping label addressed to Care Essentials Pty Ltd.

SPECIFICATIONS 11.

Supply Voltage 230 – 240 Vac Supply Frequency 50 Hz 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 45 Watt CLASSIFICATION 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 Degree of safety in the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide. Method of disinfection Surface disinfection is possible using a cloth moistened with a mild, non-staining, disinfectant solution. PERFORMANCE Temperature settings indicate the average air temperature accuracy of delivered air, except for the ambient temperature secting Environmental conditions required to achieve the specified temperature accuracy of delivered air following a change in temperature accuracy of delivered air following a change in temperature accuracy of delivered air following a change in temperature accuracy of delivered air following a change in temperature accuracy of delivered air following a change in temperature accuracy of delivered air following a change in temperature accuracy of delivered air following a change in temperature accuracy of delivered air following a change in temperature accuracy of delivered air following a change in temperature accuracy of delivered air following a change in temperature accuracy of delivered air following a change in temperature accuracy of delivered air following a change in temperature setting Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature limit devices Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature limit alarm Continuous temperature monitoring guarantees that the temperature of the delivered air maintains its specified accuracy. Continuous self-monit	-	
Supply Frequency 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 CLASSIFICATION Applied Parts Warming Blanket & Delivery Hose Applied Part classification Degree of protection against ingress of liquid Degree of safety in the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide Method of disinfection DEFFORMANCE Temperature settings indicate the average air temperature at the end of the delivery hose Interperature 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 accuracy of delivered air, except for the ambient temperature setting Environmental conditions required to achieve the specified temperature accuracy Time required to attain the specified temperature accuracy of delivered air following a change in temperature setting SAFETY SYSTEMS Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature. Continuous temperatures monitoring guarantees that the temperature of the delivery limit air memperature accuracy. Continuous self-monitoring by the control system ensures that it always functions predictably.	ELECTRICAL	
Supply Power External Fuses 2 x 6.3 Amp 250V Time Lag (T) 5x20mm Heater 1000 Watt heating element Fan Motor 45 Watt CLASSIFICATION Applied Parts Warming Blanket & Delivery Hose Applied Part classification Type BF Device classification Class 1 Continuous 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. Surface disinfection is possible using a cloth moistened with a mild, non-staining, disinfectant solution. PERFORMANCE Temperature settings indicate the average air temperature at the end of the delivery hose and the delivery hose cover. Temperature at the end of the delivery hose and the use of an insulating blanket placed on top of the warming blanket. Temperature accuracy of delivered air, except for the ambient temperature settings required to achieve the specified temperature accuracy Time required to attain the specified temperature accuracy Time required to attain the specified temperature accuracy Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature ilmit thermostats Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature ilmit alarm Continuous temperature monitoring guarantees that the temperature of the delivered air maintains its specified accuracy. Continuous self-monitoring by the control system ensures that it always functions predictably.	Supply Voltage	230 – 240 Vac
External Fuses 2 x 6.3 Amp 250V Time Lag (T) 5x20mm Heater 1000 Watt heating element Fan Motor 45 Watt CLASSIFICATION 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 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. Surface disinfection is possible using a cloth moistened with a mild, non-staining, disinfectant solution. PERFORMANCE Temperature settings indicate the average air temperature at the end of the delivery hose at temperature at the end of the delivery hose of the ambient temperature settings indicate the average air temperature accuracy of delivered air, except for the ambient temperature setting to the achieve the specified temperature accuracy of delivered air continuous Environmental conditions required to achieve the specified temperature accuracy of delivered air following a change in temperature setting SAFETY SYSTEMS Dual temperature limit thermostats Either of two independent 53°C self-resetting thermostats removes power from the CW\$4000 if the delivered air exceeds a preset limit temperature. Continuous self-monitoring by the control system ensures that it always functions predictably.	Supply Frequency	50 Hz
Heater 1000 Walt heating element 45 Watt CLASSIFICATION 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 Not designed for use in the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide. Method of disinfection Surface disinfection is possible using a cloth moistened with a mild, non-staining, disinfectant solution. PERFORMANCE Temperature settings indicate the average air temperature at the end of the delivery hose in the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide. 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 accuracy of delivered air, except for the ambient temperature setting Temperature accuracy of delivered air, except for the ambient temperature setting Environmental conditions required to achieve the specified temperature accuracy of delivered air following a change in temperature setting SAFETY SYSTEMS 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. A 98°C thermal fuse and 104°C self-resetting thermostats protect the filter from excessive temperatures. Continuous self-monitoring by the control system ensures that it always functions predictably.	Supply Power	1100 Watts Maximum
Fan Motor CLASSIFICATION Applied Parts Applied Parts Warming Blanket & Delivery Hose Applied Part classification Device classification Class 1 Mode of operation Degree of protection against ingress of liquid Degree of safety in the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide Method of disinfection Surface disinfection is possible using a cloth moistened with a mild, non-staining, disinfectant solution. PERFORMANCE Temperature settings indicate the average air temperature at the end of the delivery hose In the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide. Ambient, 34°C, 37°C, 40°C, 43°C or 46°C Note: The air temperature around the patient is affected by the ambient temperature accuracy of delivered air, except for the ambient temperature setting Temperature accuracy of delivered air, except to the ambient temperature setting Environmental conditions required to achieve the specified temperature accuracy of delivered air following a change in temperature setting SAFETY SYSTEMS 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. A 98°C thermal fuse and 104°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature limit alarm Control system failure alarm Control system failure alarm Control osystem failure alarm Assignment appearature sucuracy of delivered air control system ensures that it always functions predictably.	External Fuses	2 x 6.3 Amp 250V Time Lag (T) 5x20mm
Applied Parts Applied Parts Applied Parts Applied Part classification Device classification Class 1 Continuous Degree of 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. Method of disinfection PERFORMANCE Temperature settings indicate the average air temperature at the end of the delivery hose Degree of the end of the delivery hose Temperature accuracy of delivered air, except for the ambient temperature setting Fenvironmental conditions required to achieve the specified temperature accuracy of delivered air following a change in temperature accuracy of delivered air following a change in temperature setting SAFETY SYSTEMS Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature. A 89°C thermal fuse and 104°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature. Control system failure alarm Control system failure alarm Control system failure alarm Warming Blanket & Delivery Hose Itage of vuse in the presence of flammable anaesthetic mixtures with air desired or use 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. Not designed for use 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. Not designed for use 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. Sufface disinfection spossible using a cloth moistened of flammable anaesthetic mixtures with air/oxygen/nitrous oxide.	Heater	1000 Watt heating element
Applied Parts Applied Part classification Type BF Device classification Class 1 Mode of operation Continuous Degree of 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. Method of disinfection PERFORMANCE Temperature settings indicate the average air temperature at the end of the delivery hose In the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide. Ambient, 34°C, 37°C, 40°C, 43°C or 46°C Temperature accuracy of delivered air except for the ambient temperature accuracy of delivered air except for the ambient temperature accuracy Fervironmental conditions required to achieve the specified temperature accuracy of delivered air following a change in temperature setting SAFETY SYSTEMS Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature. Agilia the filter of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature. Continuous temperature monitoring guarantees that the temperature of the delivered air maintains its specified accuracy. Continuous self-monitoring by the control system ensures that it always functions predictably.	Fan Motor	45 Watt
Applied Part classification Device classification Class 1 Continuous Degree of protection against ingress of liquid Degree of safety in the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide Method of disinfection PERFORMANCE Temperature settings indicate the average air temperature at the end of the delivery hose Temperature accuracy of delivered air, except for the ambient temperature accuracy Environmental conditions required to achieve the specified temperature accuracy of delivered air achange in temperature accuracy of delivered air following a change in temperature setting SAFETY SYSTEMS Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air excepted for the delivered air maintains its specified accuracy. Control system failure alarm Temperature limit alarm Temperature limit alarm Temperature limit alarm Temperature monitoring by the control system ensures that it always functions predictably.	CLASSIFICATION	
Device classification Class 1 Mode of operation Continuous Degree of protection against ingress of liquid Degree of safety in the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide Method of disinfection PERFORMANCE Temperature settings indicate the average air temperature at the end of the delivery hose Temperature accuracy of delivered air, except for the ambient temperature setting Environmental conditions required to achieve the specified temperature accuracy of delivered air following a change in temperature setting SAFETY SYSTEMS Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air excepts for the delivered limit darm Contrious system failure alarm Contrious self-monitoring by the control system ensures that it always functions predictably.	Applied Parts	Warming Blanket & Delivery Hose
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Degree of protection against ingress of liquid Degree of safety in the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide Method of disinfection Method of disinfection PERFORMANCE 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 accuracy of delivered air, except for the ambient temperature setting Environmental conditions required to achieve the specified temperature accuracy of delivered air following a change in temperature setting Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature. Either of two independent 53°C self-resetting thermostat protect the filter from excessive temperatures. Continuous self-monitoring by the control system ensures that it always functions predictably.	Device classification	Class 1
Degree of safety in the presence of flammable anaesthetic mixtures with air/oxygen/nitrous oxide Method of disinfection Method of disinfection Surface disinfection is possible using a cloth moistened with a mild, non-staining, disinfectant solution. PERFORMANCE Temperature settings indicate the average air temperature at the end of the delivery hose intemperature at the end of the delivery hose intemperature accuracy of delivered air, except for the ambient temperature setting Environmental conditions required to achieve the specified temperature accuracy of delivered air following a change in temperature setting 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. A 98°C thermal fuse and 104°C self-resetting thermostat protect the filter from excessive temperatures. Continuous self-monitoring by the control system ensures that it always functions predictably.	Mode of operation	Continuous
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PERFORMANCE Temperature settings indicate the average air temperature at the end of the delivery hose blanket placed on top of 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 Environmental conditions required to achieve the specified temperature accuracy Time required to attain the specified temperature setting Early SYSTEMS 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. 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. ± 2°C with delivery hose cover. Not specified without delivery hose cover. 20°C to 22°C, 30% to 70% relative humidity, non-condensing temperature accuracy of delivered air following a change in temperature setting SAFETY SYSTEMS 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. Continuous temperature monitoring guarantees that the temperature of the delivered air maintains its specified accuracy. Continuous self-monitoring by the control system ensures that it always functions predictably.	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.
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 accuracy of delivered air, except for the ambient temperature setting Environmental conditions required to achieve the specified temperature accuracy Time required to attain the specified temperature setting SAFETY SYSTEMS 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 Temperature limit alarm 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. ± 2°C with delivery hose cover. Not specified without delivery hose cover. Not specified without delivery hose cover. 20°C to 22°C, 30% to 70% relative humidity, non-condensing 2 minutes 2 minutes 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 Continuous temperature monitoring guarantees that the temperature of the delivered air maintains its specified accuracy. Control system failure alarm Control system failure alarm	Method of disinfection	T
Note: The air temperature around the patient is affected by the ambient air temperature at the end of the delivery hose blanket placed on top of the warming blanket. Temperature accuracy of delivered air, except for the ambient temperature setting Environmental conditions required to achieve the specified temperature accuracy Time required to attain the specified temperature accuracy Time required to attain the specified temperature setting SAFETY SYSTEMS Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature. A 98°C thermal fuse and 104°C self-resetting thermostat protect the filter from excessive temperatures. Continuous temperature monitoring guarantees that the temperature of the delivered air maintains its specified accuracy. Control system failure alarm 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. ± 2°C with delivery hose cover. Not specified without delivery hose cover. Poor to 22°C, 30% to 70% relative humidity, non-condensing a change in temperature setting Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature. A 98°C thermal fuse and 104°C self-resetting thermostat protect the filter from excessive temperatures. Continuous temperature monitoring guarantees that the temperature of the delivered air maintains its specified accuracy. Continuous self-monitoring by the control system ensures that it always functions predictably.	PERFORMANCE	
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Time required to attain the specified temperature accuracy Time required to attain the specified temperature accuracy of delivered air following a change in temperature setting SAFETY SYSTEMS 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 Temperature limit alarm Continuous temperature monitoring guarantees that the temperature of the delivered air maintains its specified accuracy. Continuous self-monitoring by the control system ensures that it always functions predictably.	Temperature accuracy of delivered air, except for the ambient temperature setting	
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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. Continuous temperature monitoring guarantees that the temperature of the delivered air maintains its specified accuracy. Control system failure alarm Control system failure alarm Either of two independent 53°C self-resetting thermostats removes power from the CWS4000 if the delivered air exceeds a preset limit temperature. Continuous temperature monitoring guarantees that the temperature of the delivered air maintains its specified accuracy. Continuous self-monitoring by the control system ensures that it always functions predictably.	Time required to attain the specified temperature accuracy of delivered air following a change in temperature setting	2 minutes
Dual temperature limit thermostats 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. Continuous temperature monitoring guarantees that the temperature of the delivered air maintains its specified accuracy. Control system failure alarm Control system failure alarm Control system failure alarm	SAFETY SYSTEMS	
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the delivered air maintains its specified accuracy. Control system failure alarm Control system failure alarm the delivered air maintains its specified accuracy. Continuous self-monitoring by the control system ensures that it always functions predictably.	Heater temperature limit devices	-
functions predictably.	Temperature limit alarm	The state of the s
PHYSICAL	Control system failure alarm	Continuous self-monitoring by the control system ensures that it always functions predictably.
	PHYSICAL	

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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

APPROVALS 12.

The CWS4000 has achieved the following medical device approvals.

Certifying Body	Title	Standard
Wakefield Laboratories	Medical Electrical Equipment Part 1: General requirements	IEC 60601 – 1: 1988 + Amendments 1 and 2
Report No. 21977	for safety	(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
	Medical Electrical Equipment Part 1: General requirements for safety	IEC 60601 – 1: 2007
Care Essentials	Medical Electrical Equipment Part 1: General requirements for safety Section 2. Collateral Standard: Electromagnetic Compatibility – Requirements and tests	IEC 60601 – 1 – 2: 2007

APPENDIX 1. COCOON CWS4000 PRODUCT INFORMATION

Response

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Model	Care Essentials Pty Ltd, Cocoon CWS4000
Where Marketed	Australia, Asia, Middle East and Europe
FDA Clearance	No
CE Mark	Yes, CE 0805
Configuration	Mobile, portable, pole or bed mounted, trolley
Applications	Operating Theatre, Intensive/Critical Care Area, Recovery, Emergency/Trauma, Ward
Controls	Keypad
Display Type	LED Visual Indicators
Function Indicators	Standby, Filter 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 of disposable and reusable types
Hose Length	1.5 metres
Temp Settings C	Ambient, 34, 37, 40, 43, 46 degrees Celsius
Safety Thermostats	53 degrees Celsius +/- 3 degrees Celsius
Automatic Overheat Shutoff	Yes
Alarm Conditions	High temperature safety cut out fuse, visual and audible
Noise Level	<55dB
Warm Up Time	2 minutes
Air Flow	38 CFM
Filtration System	Yes, HEPA Filtration

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HxWxD	40cm x 29cm x 22cm
Weight	6 kg
Warranty	2 years
Delivery Time	2 – 3 weeks
Other Specifications	Heater Element – thermal fuse, test port through windows Hyper-terminal communications program

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APPENDIX 2. COCOON REUSABLE BLANKET WASHING AND FOLDING INSTRUCTIONS

Care Essentials recommends the following Cocoon reusable blanket washing instructions to laundries.

Washing Instructions

Loading Instructions

Machines should be loaded to no more than 60% of their capacity to reduce friction to the fabric, which will reduce the longevity of the blanket.

Cold rinse, wash at 60 degrees C for 10 minutes using a blended non-ionic surfactant pack detergent at a PH of 10 to 10.5; followed by 6 rinses and then adjust PH to 5 to 6.

Tumble Drying

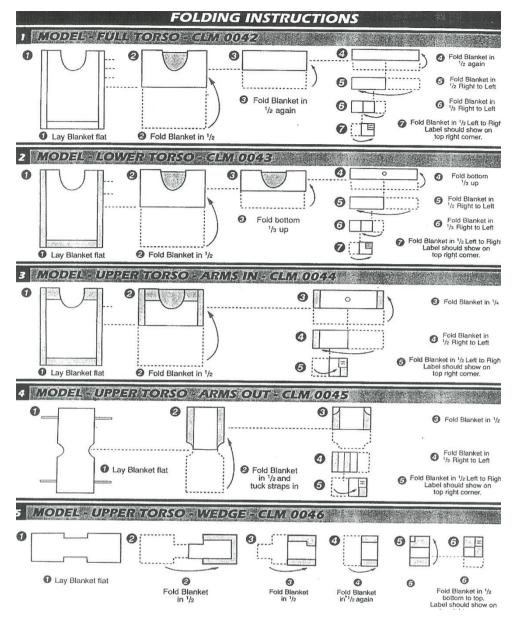
Tumble drying should be carried out in a reduced capacity to ensure complete drying of the blankets.

Folding and Packaging

Sealable plastic bags are provided free of charge to the laundry for packaging each time product is laundered. Plastic bags are clear so product labels can be clearly viewed and included manufacturers name and contact details.

Folding instructions are provided below for laundries to ensure blankets are folded correctly when re-packaged.

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Sterilisation

Reusable blankets can be sterilized in accordance with the sterilizing performance requirements detailed in AS 4187.

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