COCOON™

Essential care before, during and after surgery.

Convective Warming Machine

CWS 5000

OPERATOR MANUAL

CARE ESSENTIALS

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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.

The Cocoon Convective Warming System is indicated for hyper or hypothermic patients or normothermic patients for whom induced hyper or hypothermia or localized temperature therapy is clinically indicated. In addition, the Cocoon Convective Warming System can be used to provide patient thermal comfort when conditions exist that may cause patients to become too cold or too warm. The Cocoon Convective Warming System can be used with adult and pediatric patients.

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.

The Cocoon Convective Warming System consists of a CWS5000 and a warming blanket. A connecting hose conducts heated air from the CWS5000 to the warming blanket.

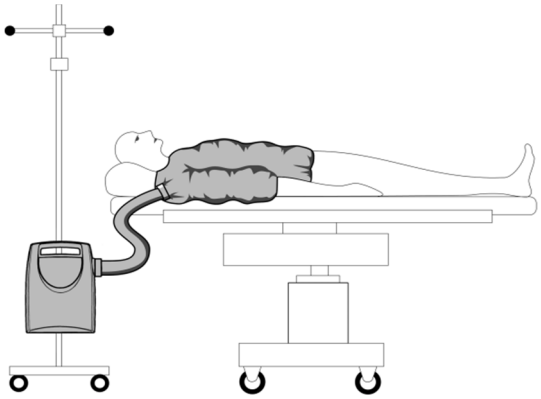

Figure 1 Convective Warming System

Care Essentials recommend that a program of regular routine maintenance, electrical safety and performance inspections be instituted for the CWS5000 as described in section 5.3. The CWS5000 is a mains-powered, microprocessor-controlled device that delivers a continuous flow of temperature-controlled air through a flexible hose to the warming blanket with two air speeds at one temperature setting. The temperature of the air delivered to the blanket can be set to one of four settings - ambient, 34°C (93.2ºF), 40°C (104ºF), 43°C (109.4ºF), or 46°C (114.8ºF). When a temperature of 46°C (114.8ºF) is selected, the setting automatically drops to 43°C (109.4ºF) after 10 minutes.

The CWS5000 will not deliver cool air to the blanket below the ambient temperature of the room. Air is drawn into the sides of the CWS5000 and passes through a bacteriological HEPA filter. The CWS5000 includes a number of over-temperature prevention systems and in a temperature fault condition it automatically shuts down and signals an alarm. The CWS5000 continuously monitors system integrity and performance from the time of start-up.

This Manual presents all the relevant operation information for the Care Essentials CWS5000 Cocoon Warming System. This information is intended for the purposes of operation and maintenance of the CWS5000. It is provided as Commercial-In-Confidence material to the Care Essentials Distributor or CWS5000 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. 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 CWS5000 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 CWS5000 may be placed on the floor, mounted on the bed rails of the bed using the bedrail hooks, or clamped to an IV pole using the IV pole clamp. When using an IV pole, do not mount the CWS5000 higher than 1 metre or it could tip over. Do not place the CWS5000 on a bed surface. Note that if the CWS5000 is placed on the floor, increased levels of dust and lint could reduce filter

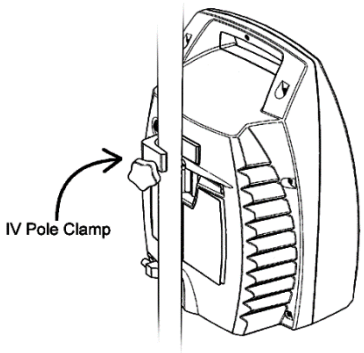

Figure 2 IV pole or stand mounted

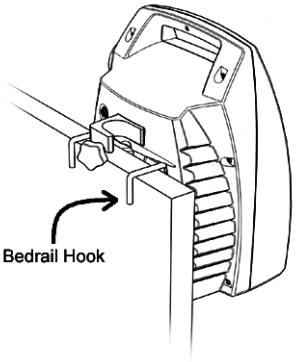

Figure 3 Bed rail mounted

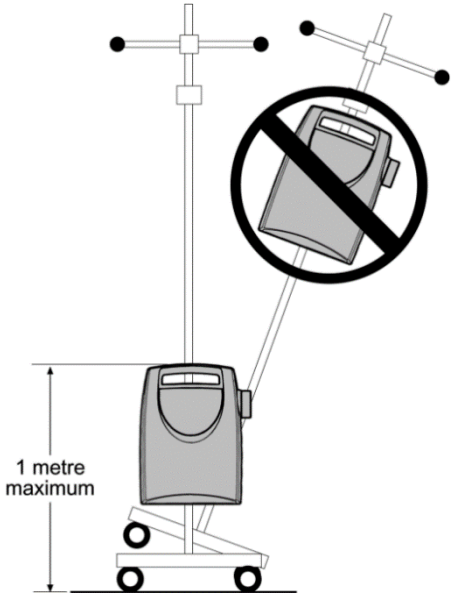

Figure 4 Pole mounting height limit

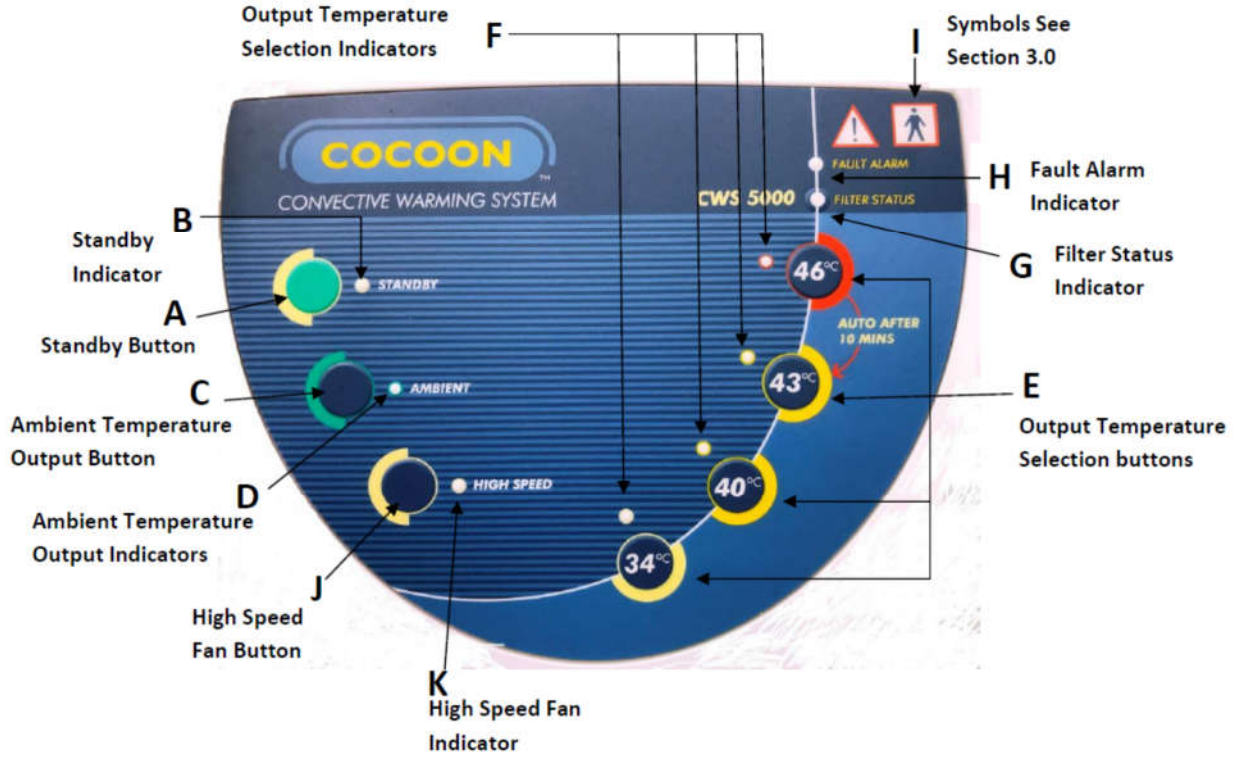

Figure 5 Operator control panel

1.2. Getting Started

Plug the mains cable into a conventional, properly earthed mains power socket-outlet and switch it on. The green **Standby indicator (B)** will illuminate and the CWS5000 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 warming blanket from its packaging. Unfold the warming blanket and place it over or under the patient as per the blanket instruction. Connect the air delivery hose to the warming blanket by pushing the plastic fitting into the air inlet port and securing it firmly.

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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 34°C (93.2ºF), 40°C (104ºF), 43°C (109.4ºF), or 46°C (114.8ºF) temperature settings, place your hand under the warming blanket to confirm that the CWS5000 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. If air flow is not adequate in bigger blankets, select high speed fan button (J) to increase the fan speed, which allows release of more air to the blanket. The flow rate increases by 30%. The orange indicator (K) will illuminate, when the high speed fan is on.

The internal timer will automatically decrease the temperature setting from 46°C (114.8ºF) to 43°C (109.4ºF) after 10 minutes. This timer can be reset by re-selecting the 46°C (114.8ºF) temperature setting.

Switch the unit off by pressing the standby button (A). The green standby indicator (B) will illuminate when the fan 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 CWS5000 from the patient . check the power supply connection from the mains as well as the plug connecting to the machine. Then swtch the unit on. If the fault alarm is still illuminating, switch off the unit 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. Use only patient warming blankets and machines 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.
- Latex free.
- Full range of blankets. Refer to www.careessentials.com.au for details.

2.2. Cocoon Reusable Patient Warming Blankets

Features of Cocoon reusable patient warming blankets include:

- Technically advanced smart fabric.
- 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.

This is a reusable product, which should be laundered between patient uses as per the provided washing instructions with blankets.

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

2.3. Instruction for Use

- Select the correct style and size of blanket.
- Insert and secure the convective warming machine hose into the inlet port. Ensure hose is well inserted and tied on the indicator “TIE HERE”
- Where possible place the convective warming blanket directly patient’s skin. Ensure to touch the white side of the blanket to the patient.
- Follow the convective warming machine instruction for use.
- Do not use head cover unless patient is intubated and ventilated.
- Monitor the patient carefully at all time while using convective warming.

2.4. Practical Issues to Consider When Selecting and Using Blankets

- Select the correct style and size of blanket.
- Ensure the CWS5000 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.
- Select correct fan speed (low or high) for the style and size of the blanket use
- Monitor the temperature settings and fan speed on the CWS5000.
- In the course of temperature monitoring by clinical staff, if the temperature of the patient is still going down, the CWS5000 should be checked for the performance inspection as per section 3.3 of the Service Manual.
- In case the warming through CWS5000 is not found effective, clinicians should consider an alternative warming.
- Select the correct style and size of blanket.

2.5. CWS5000 Operating Mode

The temperature of the air delivered to the blanket can be set to one of four settings ambient, 34°C (93.2ºF), 40°C (104ºF), 43°C (109.4ºF), or 46°C (114.8ºF) and two speed setting for each temperature setting.

Select the desired temperature on the control panel by pressing the ambient temperature output button or one of the output temperature selection buttons 34°C (93.2ºF), 40°C (104ºF), 43°C (109.4ºF), or 46°C (114.8ºF) and press high fan button, if higher air flow is required. The CWS 5000 will deliver air within the specific temperature range given below.

Temperature Mode	Temperature of Delivered air
34°C	34°C±2°C
40°C	40°C±2°C
43°C	43°C±2°C
46°C	46°C±2°C

Ambient air to the blanket at the ambient temperature of the room.

When the temperature mode selected, CWS5000 starts functioning as follows:

- The orange light indicator next to the selected temperature illuminates. If high fan is activated, the orange light next to the high fan illuminates.
- Fan motor operates.
- Heater activation according to temperature settings except in ambient mode where heater does not get activated.
- Hour meter connected on the main PCB gets activated only when the fan is active.

2.6. CWS 5000 Standby Mode

Select the standby button to place the unit in standby mode. When in standby mode, the following events occur;

- standby green indicator light illuminates.
- Turns off heater & fan
- Deactivates hour meter
- Alarm and fault detection functions remains active

3. SYMBOLS

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

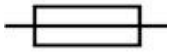
	Follow Operating Instruction
	Attention: Refer website or manual
	Dangerous voltage
	Type BF applied part
	Do not free hose
	Single patient Use
NON STERILE	The device has not been sterilised
STERILE	The device is supplied sterile
	Latex free
	Keep Dry

Date of Manufacture

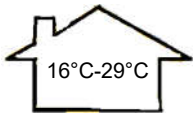
European Authorized Representative

European Conformity

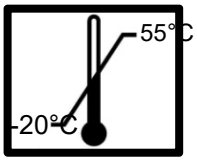
Protective earth ground



Fuse



Ambient operating temperature range, indoor use only



Storage Conditions

4. SAFETY PRECAUTIONS

Review the following safety precautions prior to servicing the CWS5000.

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 CWS5000.

4.2. Contra-indications

- The 46 degree Celsius setting is not recommended for patients who are non-responsive or with impaired circulation.
- Device is only to be used by or under the advice of healthcare professionals.

4.3. Warning

- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Do not apply heat to lower extremities during aortic cross clamping. Thermal injury may occur if heat is applied to ischemic limbs.
-  No free hosing – use of the CWS5000 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 CWS5000.
- Do not use other warming devices in conjunction with CWS5000 unless guided by appropriate qualified clinician.
- The CWS5000 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 CWS5000 or malfunction could otherwise result.
- Ensure the CWS5000 is subjected to the specified routine electrical safety and performance inspections.
- The temperature of the patient should be continuously be monitored at a regular interval.
- In the course of temperature monitoring by clinical staff, if the temperature of the patient is still going down, the CWS5000 should be checked for the performance inspection as per section 3.3 of the service manual.
- In case the warming through CWS5000 is not found effective, senior clinicians should be informed for an alternative warming.
- During the use of the CWS5000 Warming System, ensure no excessive pressure is delivered or contacts the user.
- In the event of excess fluid contact with the CWS5000 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 position the CWS5000 so that it is difficult to operate the appliance plug and socket.
- Do not lay non-porous peach side of the Cocoon blanket touching the patient. Always lay the porous white side of the Cocoon blanket over or under, touching the patient.
- Do not use a Cocoon blanket to transfer or move the patient.
- Only some disposable blankets are supplied sterile, all other disposable and reusable blankets are supplied non-sterile.
- Do not use the sterile blanket if the packaging is damaged/opened.
- Do not use the sterile blanket if the expiry date has passed.
- Do not allow the patient to lie on the warming unit hose or allow the hose directly contact the patient's skin during patients warming, thermal injury may result.
- No modification of this equipment is allowed.
- The unit will automatically switch off in an alarm condition and the green standby indicator will illuminate together with the red fault alarm indicator on the front key pad.
- To avoid injury, do not use the CWS5000 patient warming system for therapy, unless the CWS5000 system is free from mechanical damage, mounted securely or safely placed on a hard surface.
- Do not use material of good conductivity such as water, gel and other similar substances underneath the blanket. If used, it will lead to decrease of effectiveness of warming.
- If a transient high surge of electrical voltage comes though the machine, the machine may go into fault mode evidenced with fault alarm and fault indicator. The machine can be reset by switching off and switching on. Then the machine is ready for further use.
- Patient is not the indented operator of this device and patient is not to service or maintain the device.
- Do not undertake service of the device while in use.

4.4. Caution

- Operate the CWS5000 only in the specified supply voltage range as detailed in Section 10 below or in rear label on the machine.
- When using an IV pole, do not mount the CWS5000 higher than 1 metre or it could tip over.
- Use only with 5 wheel base IV pole with atleast 2 wheels with breaking padels and maximum height of 1m.
- Monitor the temperature and cutaneous response of patients who are incapable of reacting, communicating and/or who are without a sense of feeling according to institutional protocol. Monitor the patient's vital signs regularly. Adjust air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician of vital sign instability immediately.
- Do not leave paediatric patients including infants unattended during therapy.

- It is not recommended that the unit be operated with a filter, which has exceeded the specified life period.
- Federal US law restricts this device to sale by or on the order of a physician.
- To reduce the risks associated with environment contamination, follow applicable regulations when disposing this device along with accessories or any of its electronic components.

4.5. Electromagnetic Interference

The CWS5000 has been designed to comply with IEC 60601-1-2 4th Edition (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 CWS5000. Similarly, other equipment in the vicinity may affect the operation of the CWS5000.

It is recommended that all equipment used near the CWS5000 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.

There is no essentail perforamance fro CWS5000 for the purpose of EMC.

5. PREVENTATIVE MAINTENANCE

5.1. Cleaning

- Do not immerse the device or hose while cleaning. Moisture will damage the components and thermal injury may occur.
- Do not use a dripping wet cloth to clean the device. Moisture may seep into the electrical contacts and damage the components.
- Do not use alcohol or other solvents to clean the labels of the device, strong solvents may damage the labels and other plastic parts.
- Disconnect the device from the power source before cleaning.
- Clean the CWS5000 control panel, enclosure exterior, and hose with a soft cloth lightly dampened with a non-staining hospital disinfectant or mild detergent or antimicrobial spray
- Dry with separate soft cloth.
- Clean accumulated dirt and lint from the air inlet slots using a vacuum cleaner.
- If, after cleaning, there is any visible deterioration of components, device surface or hose, it is to be replaced.

5.2. Filter Service

Only qualified service personnel may change filters. Refer to the CWS5000 Service Manual for instructions on replacing the filter. Under normal use, replace the HEPA filter inside the CWS5000 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 CWS5000 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/NZS 3551 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/NZS 2500 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 recommends that the CWS5000 receive at least an annual performance inspection as described in the CWS5000 Service Manual. As a minimum electrical safety inspection & performance inspection should be performed annually. The temperature limit thermostat test is optional and may be performed at the discretion of those resposible for the technical management of the CWS5000.

6.0 TROUBLESHOOTING

6.1 Warming Blanket Will Not Inflate

1. Make sure the CWS5000 is plugged in to an energized mains power socket-outlet.
2. Check both ends of the delivery hose for proper connection.
3. Check the delivery hose and warming blanket inlet for kinks.
4. Check that there are no obstructions to the air inlet slots.
5. In case of a multi-port blanket, it is possible that both the ports may be opened inadvertently. In that case, change the blanket.
6. Check the warming blanket for damage. If air is flowing from the hose, try another warming blanket.
7. Request qualified service personnel check for a clogged or dirty filter.
8. 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 CWS5000 to actuate. Should this occur, the **standby indicator (B)** will fail to light when the CWS5000 is connected to mains power. If this occurs, simply wait for the CWS5000 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 CWS5000 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 CWS5000 Service Manual. Damage to the CWS5000 or malfunction may otherwise result.

6.4 Fault alram and fault indicator is activated

1. The unit should be switched off and within few seconds it should be switched on.

2. Check the power connecting plug at the back of the unit for tight/secure connection.

3. After doing above, if the fault alarm and fault indicator is still illuminating, request qualified/trained service personnel to check.

7.0 ACCESSORIES

7.1 Stand

An optional stand for the CWS5000 is available with or without basket. Please note the trolley stand has not been tested to IEC 60601-1-3rd Edition.

7.2 User Training

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

8. WARRANTY

The CWS5000 is warranted free of defects in material and workmanship under normal use and operation for a period of one year, 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.

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

9. RETURNING OF UNIT FOR REPAIR

9.1. Australia

Call Customer Service (+61 3 5277 1455) or write to queries@careessentials.com.au, to request a Return for Repair.

The Cocoon CWS 5000 must be cleaned and disinfected (by wiping over with Chlorhexidine 0.5% in Alcohol 70% solution or any other mild, non-staining disinfectant solution) prior to return to Care Essentials.

The Cocoon CWS 5000 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.

9.2. Worldwide

Contact your local distributor/supplier/agent for any warranty repair, replacement or parts requirements. For more details about distributor, please write to queries@careessentials.com.au.

10. SPECIFICATIONS

ELECTRICAL	
Rated input	220-240 VAC, 50/60Hz 110-120 VAC, 50/60 Hz 100VAC, 50/60 Hz
Supply Power	1100 Watts Maximum
External Fuses	2 x 6.3 Amp 250V Time Lag (T) 5x20mm (220-240 VAC) 2 x HBC 10 Amp 250V Time Lag (T) 5x20mm (110-120 VAC) 2 x HBC 12 Amp 250V Time Lag (T) 5x20mm (100 VAC)
Heater	1000 Watt heating element
Fan Motor	50 Watt
Power Cord	5m
Leakage Current	Meets UL 60601-1 -2– 4th edition and IEC 60601-1-2 4th Ed requirements
CLASSIFICATION	
UL Classification	**MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH IEC 80601-2-35, Heating Blankets Pads and Mattresses (2009); (IEC 60601 3rd Edition Affiliated); ANSI/AAMI ES60601-1 (2005+C1+A2); CSA C22.2 No 60601.1 (2008); IEC/EN 60601-1 (2005/2006+C1+C2);** 80601-2-35 Heating Blankets Pads and Mattresses (2009)
Applied Parts	Warming Blanket
Applied Part classification	Type BF
Device classification	Class IIb
Mode of operation	Continuous
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	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	Ambient, 34°±2°C (93.2°±3.6°F), 40°±2°C (104°±3.6°F), 43°±2°C (109.4°±3.6°F), 46°±2°C (114.8°±3.6°F), 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. Recommended operating environment is 16°C (60.8 °F) to 29 °C (84 °F)
Temperature accuracy of delivered air, except for the ambient temperature setting	About ± 2°C (±3.6°F) with delivery hose cover. Not specified without delivery hose cover.
Environmental conditions required to achieve the specified temperature accuracy	16°C (60.8 °F) to 29 °C (84 °F) 30% to 70% relative humidity, non-condensing, maximum altitude of 2000m
Time required to attain the specified temperature accuracy of delivered air following a change in temperature setting including temperature rise from 23±2°C to 37°C	2 – 5 minutes depending on the blanket models
SAFETY SYSTEMS	
Dual temperature limit thermostats	Either of two independent 53°C (127.4 °F) self-resetting thermostats removes power from the CWS5000 if the delivered air exceeds a preset limit temperature.
Heater temperature limit devices	A 98°C(208.4°F) thermal fuse
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.
PHYSICAL	
Dimensions	29 cm x 22 cm x 40 cm
Weight	6.0 Kilograms
Enclosure	Flame-Retardant ABS-PC Plastic
Filter type/Life	Bacteriological HEPA filter/ 1000 hours
Storage conditions	-20°C to +55°C (-4°F to +131°F)
Hose engagement with blanket	A tightly engaged blanket with the hose can withstand over 20N force

11. APPROVALS

The CWS5000 has achieved the following medical device approvals.

Certifying Body	Title	Standard
UL International	Medical Electrical Equipment Part 1: General requirements for basic safety and Essential performance Collateral Standard: Electromagnetic Compatibility	EN 60601-1-2 :2014 (fourth edition) Electromagnetic Compatibility
UL International	Full Safety Evaluation, including: (UL Classification) (cUL Classification) (Informative Test Report),	Particular Standard - ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CAN/CSA C22.2 No. 60601-1:14 **Additional Standards:** IEC 60601-1 Ed.3.0 (2005-12), AM1 (2012-07) - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Adopted IEC 60601-1:2005, third edition, 2005-12 CAN/CSA-C22.2 NO. 60601-1:14 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Adopted IEC 60601-1:2005, third edition, 2005-12, including amendment 1:2012, with Canadian deviations) IEC 80601-2-35:2009/AMD1:2016 - Amendment 1 - Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use

12. APPENDIX 1. COCOON CWS5000 PRODUCT INFORMATION

Model	Care Essentials Pty Ltd, Cocoon CWS45000 (220V-240V/110V-120V, 100V)
Where Marketed	Australia, Japan & Asia, Middle East, Africa, Europe, North America, South America etc
FDA Clearance	510K Approved
CE Mark	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,fourtemperature settings plus ambient setting. Ambient to 46 degrees Celsius, two fan settings for each temperature setting.
Line Power, VAC	100VAC or 110-120 VAC or 220-240VAC
Warmer Power, W	1100 watts maximum
Blanket	Full range of disposable and reusable types
Hose Length	1.8 metres
Temp Settings	Ambient, 34, 40, 43, 46 degrees Celsius (93.2, 104, 109.4, 114.8 degrees Fahrenheit)
Safety Thermostats	53 degrees Celsius ±3 degrees Celsius (127.4 degrees Fahrenheit ± 5.4 degrees Fahrenheit)
Automatic Overheat Shutoff	Yes
Alarm Conditions	High temperature safety cut out fuse, visual and audible
Noise Level	47 dB

Warm Up Time	About 2 -5 minutes
Air Flow	57 CFM at high fan speed, 45.1 CFM at low fan speed
Filtration System	Yes, HEPA Filtration
H x W x D	40cm x 29cm x 22cm
Weight	6.0 kg
Warranty	1 year
Other Specifications	Test port through windows Hyper-terminal communications program

13. 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.

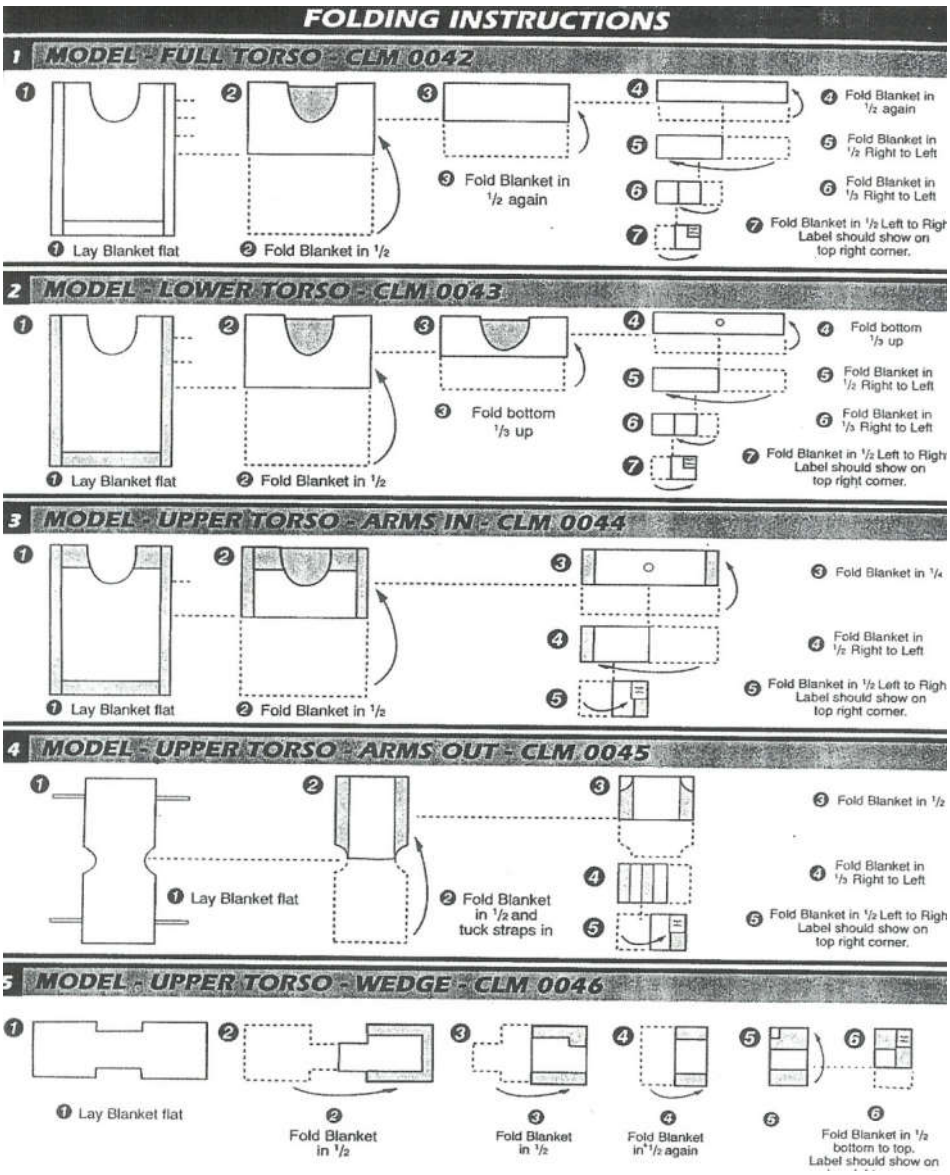
Tumble Drying

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.



Sterilisation

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