COCOON™

Essential care before, during and after surgery.

Convective Warming Machine

CWS 5000

SERVICE MANUAL

CARE ESSENTIALS™

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INTRODUCTION

It is a pre-requisite for all persons skilled in servicing medical devices to understand the information contained in this Manual. Read and understand this Manual and the Operator Manual and all precautions prior to servicing the Cocoon Convective Warming System.

Intended Use

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.

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.

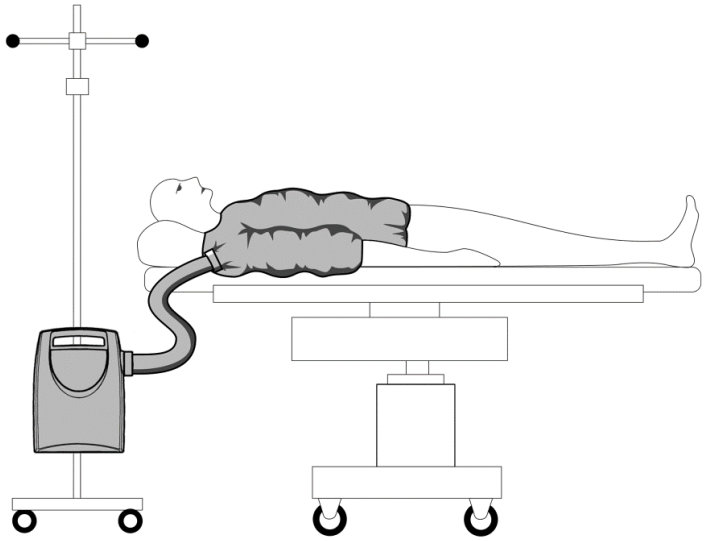


Figure 1 Convective Warming System

Care Essentials recommend that a program of regular routine maintenance, electrical safety and performance inspections be instituted for the CWS5000 as described in Section 3 below.

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. The temperature of the air delivered to the blanket can be set to one of five 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 rear of the CWS5000 and passes through a bacteriological HEPA filter. The CWS5000 includes a number of under- and 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 service information for the Care Essentials CWS5000 Cocoon Warming System. This information is provided as a service to engineering and technical personnel. This information is intended for the fair 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 welcome. Our contact details are located on the first page of this Manual.

1. OPERATION

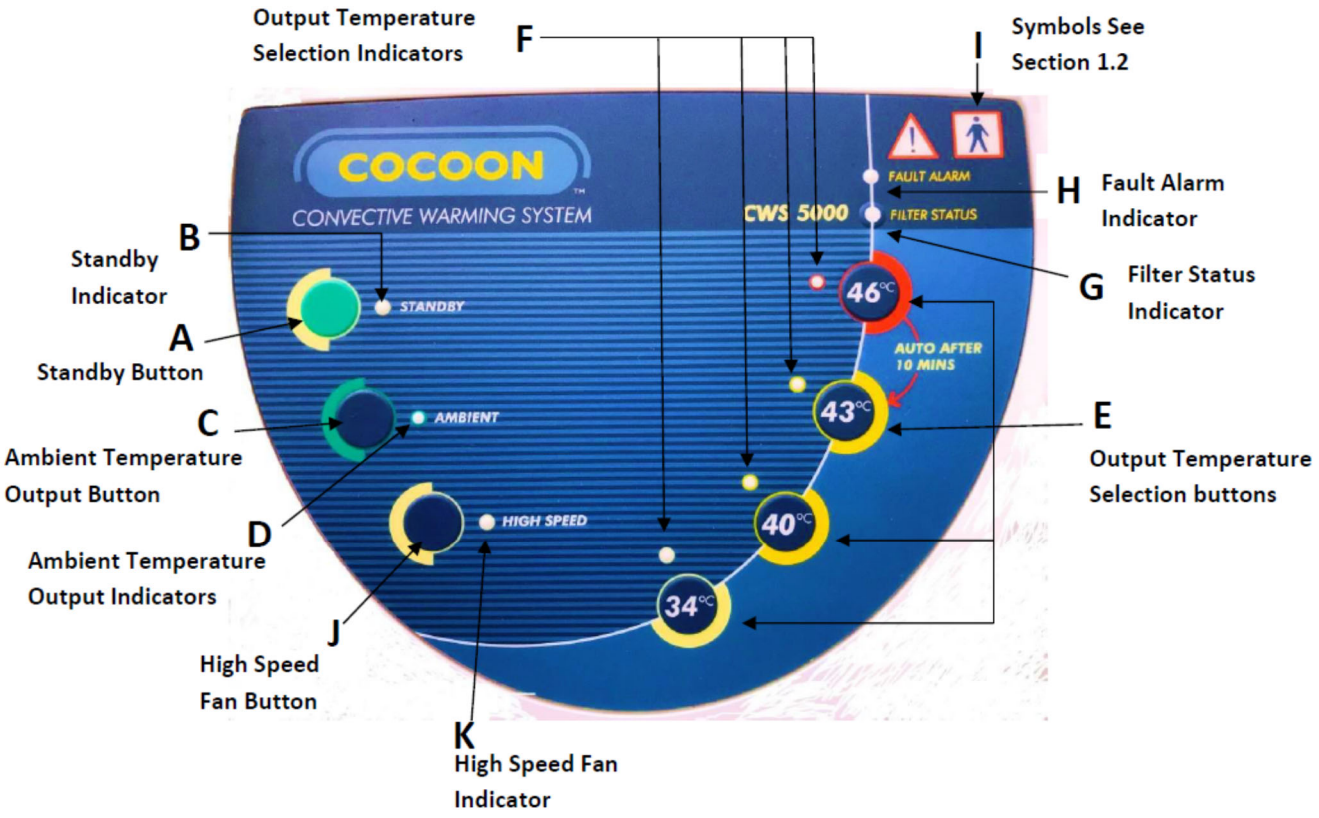


Figure 2 Operator control panel

1.1. Unit Operation Procedure

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.

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.

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

Select high speed fan button (J) to increase the fan speed, which allows release of more air to the blanket. The orange indicator (K) will illuminate when the high speed fan is on.

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)**.

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

1.2. Symbols

The following symbols are used on the CWS5000:

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

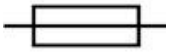
Keep Dry

Date of Manufacture

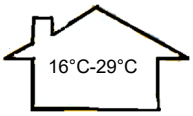
European Authorized Representative

European Conformity

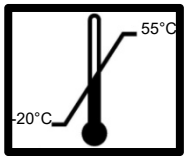
Protective earth ground



Fuse



Ambient operating temperature range, indoor use only



Storage Conditions

1.3. Accessories

Care Essentials manufactures both Cocoon Single use and Reusable (available Australia only) Patient Warming Blankets. It recommended that Cocoon warming machines should be used on cocoon warming blankets, failure to do so may result into thermal injury.

Cocoon Disposable Patient Warming Blankets

Features 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.
- Flam resistance
- Sterile disposable blankets are also available
- Full range of blankets:- refer www.careessentials.com.au for details

Cocoon Reusable Patient Warming Blankets

Features include:-

- Technically advance 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.
- Washing Instructions- Please refer **CWS 5000 Operator Manual Appendix 2 Cocoon Reusable Blanket**
- Specific instructions for use refer to **CWS 5000 Operator Manual Appendix 2 Cocoon Reusable Blanket**

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 the White side of the blanket is placed on 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.

1.3.1. Stand

An optional stand for the CWS5000 is available with or without basket.

1.3.2. User Training

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

2. SAFETY PRECAUTIONS

Review the following safety precautions prior to servicing the CWS5000.

2.1. Danger

- Explosive hazard. Do not use in the presence of flammable anaesthetic agents.
- Risk of electric shock. Disconnect mains power before servicing the CWS5000.

2.2. Contra-indications

- The 46°C 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

2.3. 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 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 CWS5000.
- 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 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 manual.
- In case the warming through CWS5000 is not found effective, senior clinicians should be informed for an alternative warming.
- In the event of excess fluid contact with the CWS5000 the unit should 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 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.
- To avoid the risk associated voltage and fire,
    - Do not use wet power cord.
    - Only the power cord supplied by Care Essentials i.e. Manufacturer should be used with this device and failure to do so may lead to fire risk.
    - CWS 5000 should only be connected to supply mains with protective earth & specified power source as per the rear warning label.
    - Keep power cord clear & the socket outlet should be easily accessible in case of emergency.
    - Fuse replacement should be done by qualified personnel such as certified biomedical electronics technicians or certified clinical engineers. See section 8.0 of this manual for fuse details.
    - Unnecessary manipulation of power cord connector, including unnecessary wiggling while unplugging or plugging, should be avoided to avoid the risk of damage to the pins
    - When connecting the power cord, ensure power cord connector is fully inserted into the male pins of the power entry module to allow for full mating.
- The decontamination procedure should be completed before returning for service.
- 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 flat, hard, dry 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
- Don't use any liquid cleaning spray either inside or outside the machine, while the machine is switched on.
- After cleaning with liquid spray give sufficient to dry up before switching on.
- 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.
- Do not undertake service of the device while in use.

2.4. Caution

- Operate the CWS5000 only in the specified supply voltage range as stated on 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 at least 2 wheels with breaking pedals and maximum height of 1m.

- 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.
- Make sure that power cord connector is properly fitted into power entry module before switching ON or before running the warming machine.
- While the fan/heating is ON, should not take off the plug from power entry module.

2.5. 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.

3. PREVENTATIVE MAINTENANCE

3.1. 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.
- After use of any liquid or spray give sufficient to dry up before switching the machine on.
- 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.

3.2. Electrical Safety 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 recommend that the CWS5000 receive at least an annual performance inspection. 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 responsible for the technical management of the CWS5000.

3.3. Performance Inspection

Care Essentials recommend that the CWS5000 receive at least an annual performance inspection to verify CWS5000 functions. The CWS5000 does not require adjustment or calibration.

Items Required:

- CWS5000 Operator & Service Manuals.
- Digital Thermometer.

STEP	PROCEDURE
1	If you have not already done so, read the CWS5000 Operator and Service Manuals.
2	• Place the CWS5000 on a firm, level surface. • Do not connect the delivery hose to a warming blanket. • Connect the CWS5000 to mains power.
3	Familiarise yourself with the operation of the CWS5000 by operating the CWS5000 with reference to the CWS5000 Operator and Service Manuals.
4	The temperature control system is verified as follows: • Ensure unit itself has not been brought in from a very cold/hot environment just prior to testing. If unit was not kept in test environments then the unit should be kept at ambient test conditions for a reasonable time or run unit at ambient mode at test conditions for at least 10 min prior to conducting this test • Ensure the delivery hose cover is undamaged and that it covers the entire hose. • Ensure the environmental conditions are 20ºC (68º F) to 22ºC (71.6º F), 30% to 70% relative humidity, non-condensing. • Place the digital thermometer sensor in the centre of the delivery hose outlet as shown in Figure 3. • Select required temperature settings (34, 40, 43 or 46) as well as fan settings (high or low) . • Check that the temperature of delivered air stabilises within five (5) minutes following a change in set temperature. • Check that the temperature of delivered air corresponds with the set temperature to within ±2ºC (3.6º F). • Note that some variation between the set temperature and temperature of delivered air is possible because of heat loss that occurs in the delivery hose. The magnitude of the heat loss will depend on the ambient temperature and the degree to which the hose is bent, longitudinally compressed or extended.

	• Preferable settings are 46 and high fan.

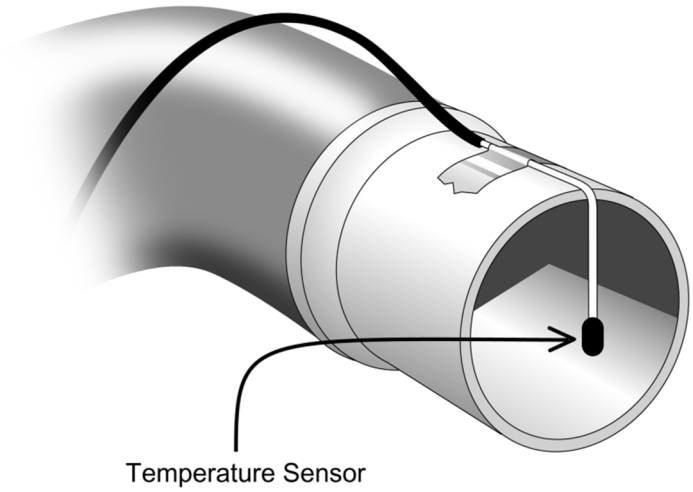


Figure 3 Delivery hose outlet showing temperature sensor position

3.4. Temperature Limit Thermostat Test Procedure

The CWS5000 temperature limit thermostat test is optional and may be performed at the discretion of those responsible for the technical management of the CWS5000. The CWS5000 temperature limit thermostat function does not require adjustment or calibration.

The maximum delivered air temperature is not only limited by the control system but by two series-connected bimetallic auto-resetting thermostats. These thermostats are located in the exhaust air stream and will interrupt power to the CWS5000 should the output air temperature exceed a predetermined limit. Either of these two independently operating thermostats will remove power from the CWS5000 if the delivered air exceeds a pre-set high limit temperature, automatically restoring power when the thermostat temperature fails to a safe level.

This test procedure may be briefly described as follows. The CWS5000 is set up with the various items required to perform the test. The CWS5000 is energised and operated at a set temperature of 46°C and low fan until it has "**warmed up"** at least for 10 min prior to test. The test is commenced through a special process that switches the heater on continuously, simulating a possible fault condition. The test time and delivery hose air temperature are monitored. The test is passed if the CWS5000 is de-energised in ten (10) minutes after the test start. ***Note that this test will only produce a valid result if it is performed at an ambient temperature of 21°C (69.8ºF), or greater***.

Items Required:

- CWS5000 Operator and Service Manuals.
- CWS5000 RS232/USB Communications Cable.
- Personal Computer (PC) with a free serial communications (Com) port and a suitable Terminal program, eg HyperTerminal™, which is part of Microsoft Windows™.
- Digital Thermometer with ±0.5ºC (0.9ºF) accuracy.

STEP	PROCEDURE
1	If you have not already done so, read the CWS5000 Instruction Manual and Service Manual. Read all of this procedure.
2	• Place the CWS5000 on a firm, level surface. • Do not connect the delivery hose to a warming blanket. • Disconnect the CWS5000 from mains power.
3	• Locate the small black cable socket on the rear of the CWS 5000. • Insert the cable plug into the socket. It should snap into place. • Insert the cable USB connector into a free USB port connector on the PC.
4	Place the digital thermometer sensor in the centre of the delivery hose outlet as shown in Figure 3 above.
5	• Connect the CWS5000 to mains power. • Select the 46ºC temperature setting and make sure unit is operating with low fan. • Operate the CWS5000 on the 46ºC temperature setting for at least 10 minutes prior to commencing the thermostat test.
6	While the CWS5000 is "warming up", start the Terminal program on the PC.

STEP	PROCEDURE
7	Follow the instructions shown on the Terminal window: • When a correct connection is established between the CWS5000 and the PC, a dot (.) is received every second. • Press the **spacebar** to display the root screen. • Press **"T"** to display the over-temperature thermostat test screen. • The 46ºC temperature setting and low fan must be selected in order for the test to proceed. • Wait for 5 min after above settings have been made. • To initiate the over-temperature thermostat test, **SLOWLY** type, **"YES"** then press the **Enter** key. To stop the test, press any key or change the CWS5000 temperature setting. • The CWS5000 is deemed to have passed the test if thermostat trips in ten (10) minutes. • Confirm that the thermostat resets after several minutes, restoring power to the CWS5000.
8	• Disconnect the CWS5000 from mains power. • Disconnect the cable from the CWS5000 and PC.
9	Confirm that the CWS5000 functions correctly by undertaking a performance inspection as detailed in Section 3.3 above.

3.5. Filter Replacement

The CWS5000 has a replaceable HEPA 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 will warn of the need for filter replacement.

Items Required:

- CWS5000 Operator & Service Manuals.
- Philips Number 1 and 2 Screwdrivers.
- 13 mm spanner.
- HEPA filter.

STEP	PROCEDURE
1	If you have not already done so, read the CWS5000 Operator and Service Manuals.
2	• Place the CWS5000 on a firm, level surface. • Do not connect the delivery hose to a warming blanket. • Disconnect the CWS5000 from mains power.
3	• Locate the rear enclosure with the warning label. • Remove the seven (7) Philips head screws located around the perimeter of the enclosure rear. • Slowly remove the rear enclosure being careful not to stress cable assemblies that run between the enclosure front and rear. • To disconnect the membrane keypad tail from the Control Board, hold the blue connector and pull. Do not pull the tail itself, as damage will almost certainly result.
4	• Connect the CWS5000 to mains power. Exercise care, as there will be dangerous voltages present on some internal parts of the CWS5000. • Read and note the run hour meter on the control board. Hour digits are sequentially displayed followed by an "h", "r", and a pause. • Mark the new HEPA filter with the hour meter reading and date of replacement. • Record these figures in the CWS5000 service record. • Reset the filter life 1000-hour counter by pressing and holding the switch next to the hour meter display. A steady green FILTER STATUS indicator and a long beep will indicate the successful

STEP	PROCEDURE
	reset of the 1000-hour counter. • Disconnect the CWS5000 from mains power.
5	• Disconnect the main board & sensor board connection cable (Red/Yellow/Black) from the main board. • Disconnect the green 4 pin fan wire from the main board. • To disconnect the membrane keypad tail from the Control Board, hold the blue connector and pull. Do not pull the tail itself, as damage will almost certainly result. • Lay CWS 5000 horizontally to give better access for filter changing. • Remove the nut and washer securing the HEPA filter. • Remove the old HEPA filter and discard. Check for the filter stud seal, it should be sitting on the main baffle screw where filter is fixed. • Install the new HEPA filter. Make sure to mark meter reading hours & date of installation on it. • Replace the nut and washer securing the HEPA filter.
6	• Keep CWS 5000 stand up for assembling • Connect power supply connection (6 pin green) to main board . • Connect Red/Yellow/Black wire to Main board. • Connect green 4 pin connector to main board. • Connect keypad to main board, ensure it is properly connected. • Replace the rear panel by reversing step 3. Make sure proper connection of membrane key pad, otherwise it may lead to malfunctioning of operating key on the keypad.
7	Confirm that the CWS5000 functions correctly by undertaking a performance inspection as detailed in Section 3.3 above.

3.6. Power Entry Module and Main Fuses

During annual preventive maintenance check power entry module (PEM).

- PEM and fuses should be inspected and if required change the fuse /or PEM.
- Clean the interior of PEM, the two ends of the fuses and receptors for the fuses on PEM with clean, dry cloth.
- Apply a very thin smear of surface contact grease (Electrolube EGC53A), only to the end surface of the fuse end cap for 100V and 110V-120V units.

4. TROUBLESHOOTING

4.1. Warming Blanket Will Not Inflate

- Make sure the CWS5000 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.
- In case of a multi-port blanket, it is possible that both the ports may be opened inadvertently. In that case, change the blanket.

- Request qualified service personnel to check for a clogged or dirty filter.
- Check for fault alarm.

4.2. Standby Indicator Will Not Light

- Extremely high storage temperatures (such as those found in motor cars on hot summer days) can cause the temperature limit thermostats in the CWS5000 to actuate. Should this occur, the STANDBY indicator 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 will light.
- Request qualified service personnel check for blown mains power fuses.

4.3. Fault Alarm and Fault Indicator is Activated

- The unit should be switched off and switched on within a few seconds.
- Check the power connecting plug at the back of the unit for tight/secure connection.
- After doing above, if the fault alarm and fault indicator is still illuminating, request qualified/trained service personnel to check.

4.4. Fault conditions

The CWS 5000 convective warning unit recognizes several nonhazardous fault conditions including:

- Sensor failure
- Heater failure
- Software failure
- Keypad failure
- Power supply failure
- Fan motor failure
- Over temperature test failure

When a fault condition exists, the following events can occur:

- Red fault indicator light flashes
- Audible alarm sounds
- Key pad does not respond to input
- Warning message on HyperTerminal program

When the audible alarm sounds, the unit must be unplugged.

When very high voltage applied, the unit goes into fault conditions and then follow above action.

For detailed fault conditions, please refer to annexure 02

4.5. 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.

5. 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 on extra cost.

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.

6. RETURN OF UNIT FOR REPAIR

6.1. 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.

6.2. 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

7. Spare Parts and Accessories

Spare Parts

PART NO			DESCRIPTION
CWS5000 220V-240V Warming unit	**CWS5000 110V-120V Warming unit**	**CWS5000 100V Warming unit**	
CWS5 110	CWS5 510	CWS5 510	Control Board
CWS 112	CWS 112	CWS 112	Sensor Board
CWS 121	CWS 121	CWS 121	Air Delivery Hose and Fittings
CWS5 142	CWS5 142	CWS5 142	Membrane Keypad
CWS5 146	CWS5 546	CWS5 846	Heater Element
CWS5 158	CWS5 158	CWS5 158	Fan Motor
CWS 160	CWS 160	CWS 160	HEPA Filter
CWS 164AU (for Australian Version) CWS 164UK (for UK Version) CWS 164EU (for European Version) CWS 164IN (for Indian Version)	CWS 564 (Canada and USA Version)	CWS 864 (Japan Version)	Power Cord – 5 metres
CWS 169	CWS 569	CWS 869	Fuse – Power Entry Module
CWS 190	CWS 190	CWS 190	Test Lead
CWS 196	CWS 196	CWS 196	Hose Cover

Accessories

PART NO	DESCRIPTION
CWS 107	Trolley – Stand
CWS 211	Hose Clip (Blue)
CWS 226	Hose Clip (White)
CWS 109	Trolley Stand with Basket
CWS 166	Pole Clamp Knob
CWS108	Basket
CWS109	Trolley stand with basket

Content in a box of cocoon warming unit

1. Cocoon warming machine
2. Test Report
3. Operator and Service Manuals on USB
4. Power cord
5. Hose Clip Blue
6. White clip (Optional)
7. Test Lead (Optional)

8. SPECIFICATIONS

ELECTRICAL	
Rated input	220-240 VAC, 50/60Hz 110-120 VAC, 50/60 Hz 100VAC, 50/60Hz
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 SJT 3 COND, 10A 125V (For 110V-120V) 5m, VCTF 3 COND, 12A 125V (For 100V) 5m, H05VV-F 3 COND, 10A 250V (For 220V- 240V)
Leakage Current	Meets UL 60601-1 3rd + A1 edition and IEC 60601-1 3rd + A1 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/AMD1:2016)**
Applied Parts	Warming Blanket
Applied Part classification	Type BF
Device classification	Class IIb/ Class II
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, 34º±2ºC (93.2º±3.6ºF), 40º±2ºC (104º±3.6ºF), 43º±2ºC (109.4º±3.6ºF), 46º±2ºC (114.8º±3.6ºF), 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 16ºC (60.8 ºF) to 29 ºC (84 ºF)
Temperature accuracy of delivered air, except for the ambient temperature setting	± 2ºC (±3.6ºF) with delivery hose cover. Not specified without delivery hose cover.
Environmental conditions required to achieve the specified temperature accuracy	16ºC (60.8 ºF) to 29 ºC (84 ºF), 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±2ºC to 37ºC	2 – 5 minutes depending on the blanket models
SAFETY SYSTEMS	
Dual temperature limit thermostats	Either of two independent 53ºC (127.4 ºF) self-resetting thermostats removes power from the CWS5000 if the delivered air exceeds a preset limit temperature.
Heater temperature limit devices	A 98ºC(208.4ºF) 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 Kilograms (approximate)
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

9. APPROVALS

The CWS5000 has achieved the following medical device approvals.

Certifying Body	Title	Standard
UL International 333 Pfingsten Rd, Northbrook IL, 60062	Medical Electrical Equipment Part 1: General requirements for basic safety and Essential performance Collateral Standard: Electromagnetic Compatibility	Particular Standard - IEC 60601-1-2:2014 (fourth edition)
UL International 333 Pfingsten Rd, Northbrook IL, 60062	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

Annexure 1: CWS5000 Preventive Maintenance Service Schedule

	Check	Frequency	Action
1	Cleaning	Annually / as required	• Disconnect the device from the power source before cleaning. • Clean accumulated dirt and lint from the air inlet slots using a vacuum cleaner. • Clean the CWS5000 control panel, enclosure exterior, and hose with a soft cloth lightly dampened with a non-staining hospital disinfectant or mild detergent. • Dry with separate soft cloth. • ***Do not immerse the device or hose while cleaning.*** • ***Do not use a dripping wet cloth to clean the device.*** • ***Do not use strong alcohol or other solvents to clean the labels of the device.***
2	Filter Replacement	Annually or 1000 hrs whichever occurs first or when filter status red	• Replace the filter • Reset the filter hour meter • Note down filter hour on the new filter • Install the new filter. • Follow the procedure as per service manual Para 3.5
3	Check power entry module (PEM) fuses and apply contact surface grease	Annually	• PEM and fuses should be inspected and if required change the fuse /or PEM. • Clean the interior of PEM, the two ends of the fuses and receptors for the fuses on PEM with clean, dry cloth. • Apply a very thin smear of surface contact grease (Electrolube EGC53A), only to the end surface of the fuse end cap for 100V and 110V-120V units.
4	Electrical Safety Inspection	Annually	• As per the relevant technical standards
5	Performance Inspection	Annually	• Ensure the delivery hose cover is undamaged and that it covers the entire hose. • Check that the temperature of delivered air corresponds with the set temperature to within ±2ºC (3.6º F) of selected settings. • Procedure as per service manual Para 3.3
6	Temperature Limit Thermostat Test Procedure	Optional- refer section 3.2 service manual	• Connect the unit to desire mains power. • Select the 46ºC temperature setting. • Operate the CWS5000 on the 46ºC temperature setting for at least 5 minutes prior to commencing the thermostat test. • Conduct the temperature limit thermostat

			test as per service manual para 3.4 • The unit is deemed to have passed the test if a thermostat trips in ten (10) minutes. • Confirm that the thermostat resets after several minutes, restoring power to the unit
7	Power Cord	Annually	• Check whether the correct power cord is being used. • Check whether the receptor of the power cord and the pins of PEM are in good condition (eg. they are not bent, not widened and not blackened). Change the power cord or PEM, if not found in good condition. • The power cord must be P-clipped as per the picture below for 100V/110-120V device.  • Check the condition of the P-clip. Replace if needed. • Unscrew the P-clip and check the condition of the power cord under the P-clip. If the power cord is in good condition re-screw the P-clip with the power cord, otherwise replace the power cord. • Check P-clip is properly screwed and power cord is fully secured through the P-clip.

Annexure 2: Fault Alarm System- CWS5000 Convective Warming System

The possible activation of CWS 5000 fault alarm system as follows:

Fault 1: Under temperature fault:

Fault Alarm: Red LED flashing and audio alarming after 10min of unit in operation.

Cause of Alarm: Delivered air temperature is 3 degree Celsius less than set temperate.

Remedies: Check the ambient temperature, check for delivery air temperature, check heater element.

Fault 2: Over temperature fault:

Fault Alarm: Red LED flashing and audio alarming after 10min of unit in operation

Cause of Alarm: Delivered air temperature is 3 degree Celsius more than set temperature.

Remedies: Check the ambient temperature, check for delivery air temperature, check heater element.

Fault 3: Software failure:

Fault Alarm: Red LED flashing and audio alarming.

Cause of Alarm: Software failure

Remedies: Check main PCB.

Fault 4: Sensor failure:

Fault Alarm: Red LED flashing and audio alarming after 10min of unit in operation

Cause of Alarm: Faulty sensor leads to increase the temperature, which cause to blow heater element thermal fuse.

Remedies: Check for delivery air temperature, check heater element.

Fault 5: PCB failure:

Fault Alarm: Red LED flashing and audio alarming.

Cause of Alarm: Faulty PCB

Remedies: Check main PCB

Fault 6: Sensor failure:

Fault Alarm: Red LED flashing and audio alarming after 10min of unit in operation

Cause of Alarm: Faulty heater leads to fluctuating the temperature.

Remedies: Check for delivery air temperature, check heater element.

Fault 7: Power Supply failure:

Fault Alarm: Red LED flashing and audio alarming.

Cause of Alarm: Loose connection between power inlet and plug.

Remedies: Check power inlet connection at the back of the unit.

Fault 8: Broken communication between sensor board and Main PCB:

Fault Alarm: Red LED flashing and audio alarming as soon as any button press on the Keypad

Cause of Alarm: Broken connection between sensor board and Main PCB.

Remedies: Check connection between sensor and PCB.