



User-Service Manual

Joerns® ClimateCare®

Microclimate management overlay

To avoid injury, read user's manual before using.



Important Precautions

Important Notice: The equipment must be installed and operated in the manner for which it was intended. Facility staff/user is responsible for reading and understanding the product user manual and contacting Joerns Healthcare, if anything in this manual is unclear. Joerns will not be held responsible for any injuries resulting from failure to comply with the instructions and precautions in this manual.

Warning: Joerns' specialty support surface covers are designed as mattress cover systems. The risk of entrapment may occur when the equipment is placed on bed frames that leave gaps of even a few inches between the mattress and the headboard, footboard, and bed or side rails. The equipment is NOT to be used when such gaps are present.

Facility staff/user is responsible for ensuring that all mattresses properly fit the bed frames. Joerns is not responsible for the placement of its equipment on bed frames that leave gaps between the mattress and the headboard, footboard or bed or side rails which present a risk of harm to patients.

Warning: An optimal bed system assessment should be conducted on each patient by a qualified clinician or medical provider to ensure maximum safety of the patient. The assessment should be conducted within the context of and in compliance with the state and federal guidelines related to the use of restraints and bed system entrapment guidance, including the Clinical Guidance for the Assessment and Implementation of Side Rails published by the Hospital Bed Safety Workgroup of the U.S. Food and Drug Administration. Further information can be obtained at the following web address: <http://www.fda.gov/cdrh/beds/>.

When using the cover on a mattress system, always ensure that the patient is positioned properly within the confines of the bed. Do not let any extremities protrude over the side or between the bed rails when the mattress is being used.

Danger: Explosion Hazard: Do not use in the presence of flammable anesthetics. Do not use in the presence of smoking materials or open flame. Air flowing through the air mattress will support combustion.

Danger: To reduce the risk of shock, adhere to the following instructions. Failure to do so could result in personal injury or equipment damage. Immediately after using the ClimateCare, unplug it from its power source.

- Do not place or store the product where it can fall or be pulled into a tub or sink.
- Do not place or drop the product into water or other liquid.
- Do not disassemble the back of the control unit. Refer servicing to Joerns.

Warning: To reduce the risk of burns, shock, fire, or personal injury, adhere to the following instructions. Failure to do so could result in personal injury or equipment damage.

1. Use this product only for its intended purpose as described in this manual. Only use attachments and/or accessories that are recommended by the manufacturer.
2. If this product has a damaged power cord or plug, is not working properly, has been dropped or damaged, or has been dropped into water, do not operate it. For examination and repair, return the product to Joerns.
3. Keep the control unit and power cord away from heated surfaces, e.g. space heaters.
4. Keep the air openings free of lint and hair.
5. Never drop or insert any object into any opening.
6. Do not spill food or liquids onto the control unit. If a spill occurs, turn off the unit, disconnect it from its power supply and allow at least 24 hours for drying.
7. Do not use the product outdoors, or where aerosol-spray products are used.
8. Plug this product only into a properly grounded outlet. Refer to "Power Cord".
9. Ensure nothing is placed on the power cord and ensure it is not located where it can be stepped on or tripped over.
10. Do not attempt to service the control unit. Please call Joerns for any service requests.
11. The therapy pad (top cover) of this product is not air permeable and may present a suffocation risk. It is the responsibility of the caregiver to ensure that the patient can use this product safely.

Save These Instructions for Future Reference

Bed System Entrapment Information

Although essential in the practice of long-term care, bedside rails, in recent years, have also been a subject of regulatory review and evolution in design and use.

That focus includes not only the challenge of achieving an appropriate balance between resident security and unnecessary restraint, but also the additional safety issue of entrapment.

The U.S. Food and Drug Administration (FDA), working with our company and other industry representatives has addressed the potential danger of entrapment with new safety guidelines for medical beds. These guidelines recommend dimensional limits for critical gaps and spaces between bed system components.

Entrapment zones involve the relationship of components often directly assembled by the healthcare facility rather than the manufacturer. Therefore, compliance is the responsibility of the facility.

As the leading manufacturer of long-term care beds and a frontrunner in addressing this critical issue, Joerns Healthcare can offer you the expertise, assistance and products to bring your facility into compliance.

Joerns Compliance Solutions

Matching the right bed components in order to meet regulatory guidelines can be complex.

That is why Joerns offers a wide array of compliance options. We assist customers in selecting compliant accessories recommended for their specific bed model.

Creating a Safer Care Environment

While the guidelines apply to all healthcare settings (hospitals and nursing homes), long-term care facilities have particular exposure since serious entrapment events typically involve frail, elderly or dementia patients.

For More Information

To learn more about compliance options with Joerns products, visit our website at www.joerns.com, or contact our Customer Care reps at 800-826-0270 and ask for free informational publications.

To learn more about entrapment zones, assessment methods and guidelines concerning entrapment, contact Joerns Healthcare at 800-826-0270 or consult the FDA website: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/default.htm>.

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Introduction

The ClimateCare, provided by Joerns Healthcare, is a unique therapy system that provides microclimate management. When used in conjunction with a pressure redistribution mattress, ClimateCare is designed to address the root causes of tissue breakdown through the management of temperature and moisture (microclimate) at the interface between the patient and the surface.

⚠ Warning: The risk of entrapment can arise when equipment is placed on bed frames that leave gaps of even a few inches between the mattress and the headboard, footboard, and bed or side rails. The equipment is NOT to be used when such gaps are present. See "Important Precautions" section of this manual.

The ClimateCare microclimate management system is suitable for both the treatment of existing pressure ulcers as well as those who have been assessed at risk from the complications of immobility. The ClimateCare is quiet, comfortable and simple enough for single caregiver installation.

Additionally, low friction and low shear materials, together with a high rate of moisture vapor transfer, means that the ClimateCare meets the comfort and clinical requirements of your patients up to 1000 lbs.

We have ensured that the ClimateCare addresses the key areas in the treatment of compromised skin: microclimate management, and reduction in both friction and shearing forces.

Shear and Friction Reduction

Shearing occurs when the skin is stationary in relation to the support surface, while the underlying tissues and vessels are stretched and damaged. When a patient's skin rubs against another surface, the result is friction. The top surface of the ClimateCare overlay is constructed from a very smooth nylon fabric with low friction and shear properties to protect the patient's skin from these damaging forces.

Indications for Use

Note: The selection of a mattress overlay needs to be based on each individual patient's clinical condition, diagnosis and/or co-morbidities. The choice and use of a mattress overlay is one factor in a holistic program of wound care and treatment.

The ClimateCare microclimate management system is indicated for use in conjunction with a pressure redistribution surface in order to aid in the prevention and treatment of skin breakdown and pressure ulcers for patients who require microclimate management of the skin.

Spinal Cord Injury

The ClimateCare is not recommended for use by patients with unstable spinal fractures. Advice should be obtained from the appropriate physician before using the ClimateCare system for these patients.

Note: Refer to and follow any contraindications in the product labeling for the pressure redistribution surface and/or bed frame being used with the ClimateCare.

Features

The ClimateCare is comprised of three components:

- Therapy control unit
- Mattress overlay
- Power supply and cord

Therapy Control Unit Features

- Compact lightweight and portable control unit is quiet, robust and powerful.
- Specially designed enclosure for low noise and durability.
- Reusable control unit that can be cleaned between patients.

Mattress Overlay Features

- Disposable, single patient use overlay.
- Constructed from a very smooth nylon fabric with low friction and shear properties to protect the patient's skin from damage.
- Coverlet incorporates mattress attachment loops for stability.
- Maximum weight capacity of 1000 lbs.*
- Coverlet is constructed with latex free materials.
- Breathable, moisture vapor permeable fabric allows air to circulate within the overlay and wicks away excess moisture. This keeps your patient dry and helps to prevent skin maceration.
- Designed for optimal comfort, moisture vapor transfer, and ease of use.

Power Cord

Only use a grounded power outlet and the power cord supplied with the ClimateCare power supply.

⚠ Warning: Use a properly grounded outlet for this product. Failure to use a grounded outlet could result in personal injury or damage to equipment or house wiring, including risk of fire. A qualified electrician should be contacted to correct the wiring and ensure a properly grounded outlet.

Position the power cord to avoid a tripping hazard and/or damage to the cord. Should the power cord become worn or damaged, immediately discontinue use of the ClimateCare and contact Joerns Healthcare to order a replacement.

General Protocol

Avoid contact of the ClimateCare overlay with sharp objects and instruments. Cuts, tears, or punctures in the coverlet will prevent proper operation. Prior to each use, ensure the surface is free from rips or tears.

* *Mattress weight capacity only; total weight must not exceed bed frame manufacturers' specified load capacity.*

Setup

⚠ Warning: For important precautions, see page two.

⚠ Caution: Position the power cord to keep personnel from tripping over it.

1. Remove the overlay and control unit from packaging.
2. Remove sheets and covers from the existing pressure redistribution surface.
3. Attach the control unit to the overlay
 - a. Unzip the foot end of the overlay.
 - b. Align the pegs on the control unit through the holes in the overlay (Figure 1).

⚠ Caution: Ensure the square and round holes in the coverlet are aligned with the corresponding shapes on the controller.

- c. Slide the control unit cover into place (Figure 2).
4. Place the assembled overlay on the existing surface with the foot end of the overlay at the foot end of the mattress.

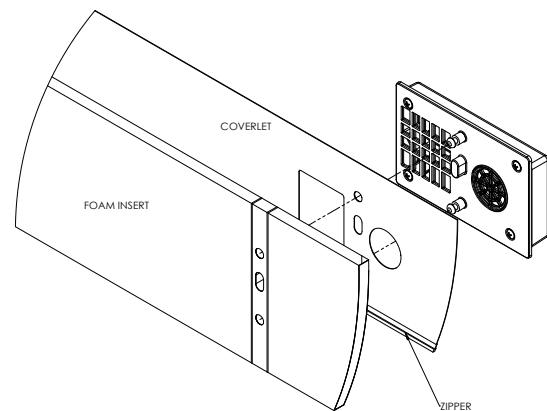


Figure 1

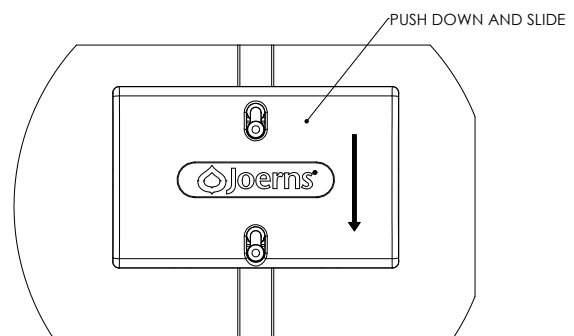


Figure 2

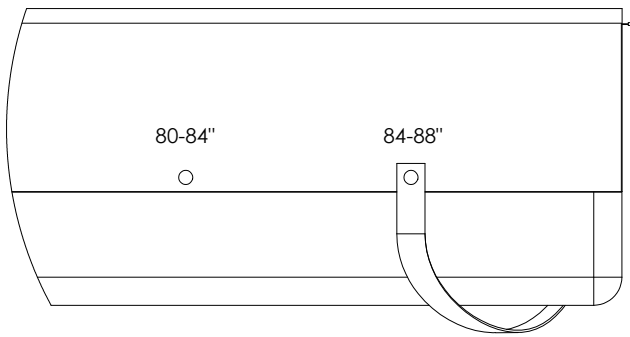


Figure 3

5. Secure the straps at the head end by connecting using the appropriate set of snaps depending on the length of the mattress (Figure 3)
6. Secure the straps at each corner of the foot end ensuring not to trap the power cord or mattress hosing (if applicable) under the strap.
7. Smooth any wrinkles on the coverlet.
8. Note the therapy start date on the Care and Cleaning tag attached to the foot end of the coverlet. Failure to track duration of use may void warranty.
9. Connect the power supply to the cord coming from the control unit.
10. Connect the power cord to the power supply brick.
11. Plug the power cord into a grounded electrical wall outlet.
12. Position the power cord assembly under the bed to reduce the possibility of injury.

Warning: Verify cables are routed safely and free of moving parts by checking all bed functions and movement.

13. Verify the control unit is working by listening for a low hum and feeling a slight vibration when placing a hand over the control unit.

Cleaning

Warning: Unplug the control unit from its power source. Failure to do so could result in personal injury or equipment damage.

Warning: Do not expose the unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.

Caution: Do not use harsh cleansers/detergents, such as scouring pads and heavy-duty grease removers, or solvents, such as acetone. Equipment damage could occur.

Control Unit

Wipe off dust. If necessary, clean the housing exterior with a disinfectant solution or a mild detergent and a damp cloth. Then wipe dry.

Coverlet

During patient use, we recommend that you clean the ClimateCare coverlet with a mild detergent and warm water. Do not machine wash the coverlet. Replace the coverlet every 60 days and/or between patients.

Nursing Procedures

Recommended Linen:

Special linens are not necessary for the ClimateCare. There is no need for a bottom sheet.

Based upon the patient's specific needs, the following linens may be utilized:

- Draw or slide sheet to aid in positioning and to further minimize friction and shearing
- Incontinence barrier pad for patients incontinent of urine and/or stool, and patients with heavily draining wounds
- Add top sheet, blanket and/or bedspread as needed for patient comfort
- Keep the amount of padding between the patient and bed to a minimum for optimum performance

Note: The use of layers between the patient and the coverlet may reduce the moisture vapor transmission rate of the ClimateCare overlay.

Changing the Coverlet

The coverlet is a 60-day single patient use product. The control unit, power supply, and power cord are reusable.

1. Unplug power cord from wall outlet.
2. Unplug power supply from control unit.

⚠ Caution: The cord features a locking connector. Disconnect the cord by pulling on the locking connector. Failure to do so may result in damage to the cord.

3. Remove control unit from coverlet.
4. Dispose of the coverlet per approved facility procedures.
5. Clean the control unit as described in the Cleaning section.
6. Reassemble the control unit with a new coverlet as described in the Setup section.

Patient Positioning and Comfort

General Repositioning

Patients should be turned and repositioned per individual turning schedule or per facility policy. Unless contraindicated, it is desirable to keep the head of the bed in the low position to provide optimal pressure relief and minimize the risk of shearing injuries.

Incontinence

Moisture against the skin surface leads to maceration, or softening of the tissues. In the event of incontinence or excess drainage on the therapy pad, you should wipe off the excess fluid from the bed surface to prevent maceration.

Safety Information

Patient Migration

Specialty bed products are designed to provide pressure redistribution and relief from the shearing and friction forces on the patient's skin. The risk of gradual movement and/or sinking into hazardous positions of entrapment and/or inadvertent bed exit may be increased due to the nature of these products.

Traction

With any traction or unstable fractures, maintain physician- directed angle of articulation and guard against risks of patient migration or inadvertent deflation of patient surface.

Skin Care

Monitor skin conditions regularly, particularly in areas where incontinence and drainage occur or collect, and consider adjunct or alternative therapies for high acuity patients. Early intervention may be essential to preventing serious skin breakdown.

Bed Height

To minimize the risks of falls or injury the patient surface should always be in the lowest practical position when the patient is unattended. Make sure areas under and around the frame are clear of objects, persons and parts of body before adjusting height.

Storage and Care

When the product is not in use, properly store the power cord and power supply. Failure to do so could result in personal injury.

Note: Clean the ClimateCare control unit as described in the Cleaning section prior to storage.

Control Unit

The power cord and power supply may be wrapped around the unit for convenience. Wrap the unit in a plastic bag for dust resistance then store the unit in an area appropriate for an electronic medical device.

Coverlet

Unused coverlets may be stored in the original packaging.

Note: The coverlet is a single patient use product. Dispose of used coverlet per approved facility procedures. Only unused coverlets should be placed in storage.

Electromagnetic Immunity

Electromagnetic Immunity is always relative and standards are based on anticipated environments of usage. If the user notes unusual device behavior, this could be an indication of electromagnetic interference. If such behavior is observed it may be associated with the nearby usage of radio or tv transmitters, cell phones, electro-surgical equipment, etc. and the user should try moving the interfering equipment further from this device.

System Specifications

Weight

Control Unit.....0.7 lbs (.32 kg)
Coverlet.....2.4 lbs (1.1 kg)
Maximum Weight Capacity*.....1000 lbs (454 kg)

* Overlay weight capacity only; total weight must not exceed mattress or bed frame manufacturers' specified load capacity.

Electrical

Voltage.....100 - 240 VAC
Frequency.....50 – 60 Hz
Ampere rating.....2.5 A
Power Cord Length.....11.5 ft (3.5 m)

Environmental Conditions

Operating Conditions:

Ambient temperature: +0°C to +40°C
Relative humidity: non-condensing
Altitude: up to 3000 m

Storage / Shipping Conditions:

Ambient temperature: -20°C to +60°C
Relative humidity: 10% to 100%

Call for Assistance

If you have any questions or require service on a Joerns product, please call Joerns Healthcare at 800.826.0270.

I.D. Label Symbol Definition



Attention, Consult accompanying documents



Class II Device



Type B Applied Part



Indoor Use



Conforms with the Medical Device Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive

Appendix A: Electromagnetic Compatibility (EMC) Information

ClimateCare Microclimate Management Overlay

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment.


The use of Accessories, transducers, and cables other than those specified by the manufacturer, may result in increased Emissions or decreased Immunity of the ClimateCare.

Guidance and Manufacturer's Declaration –Electromagnetic Emissions		
Mains operated ClimateCare device is intended for use in the environment specified below. Customer and end user should assure that it is in said environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1 and 2	ClimateCare is suitable for use in all establishments, and those connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity:

Model ClimateCare is intended for use in the environment specified below. Customer and end user should assure that it is in said environment

Immunity Test	IEC60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 2, 4, 8 kV contact ± 2, 4, 8 kV air	± 2, 4, 8 kV contact ± 2, 4, 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV Input AC/DC ports ± 1 kV Signal ports	± 2 kV Input AC/DC ports ± 1 kV Signal ports	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	0.5 and 1.0 Kv line to line 0.5, 1.0 and 2.0 kV line to earth	0.5 and 1.0 Kv line to line 0.5, 1.0 and 2.0 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 70% U_T (30% dip in U_T) for 25 cycles 40% U_T (60% dip in U_T) for 5 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 70% U_T (30% dip in U_T) for 25 cycles 40% U_T (60% dip in U_T) for 5 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during very long power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A / m	3 A / m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Model ClimateCare is intended for use in the environment specified below. Customer and end user should assure that it is in said environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communication equipment should be used no closer to any part of the ClimateCare device including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d=1.2\sqrt{P}$ $d=1.2\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d=2.3\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^ashould be less than the compliance level in each frequency range. ^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Auto Vector Fluid Immersion Simulator is used exceeds the applicable RF compliance level above, the Auto Vector Fluid Immersion Simulator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Auto Vector Fluid Immersion Simulator.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distance between portable and mobile RF communications equipment and the ClimateCare			
ClimateCare is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the users of the ClimateCare can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ClimateCare as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.34	0.34	0.74
1	1.7	1.7	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			



Joerns Healthcare Warranty Program for Joerns® ClimateCare overlay system

Joerns Healthcare warrants the ClimateCare overlay mattress to be sold free from defects in workmanship and materials, under normal and proper use, for a period of thirty (30) days on the coverlet, and ninety (90) days on the control unit and electromechanical components (blower, power supply, and cords). Damages arising from improper use will not be covered by this warranty.

Improper use is defined as, but not limited to, those caused by:

- Burns
- Use of improper chemical agents
- Needle punctures, cuts, or abrasions
- Excessive loads
- Staining
- Negligent or excessive usage
- Improper maintenance, handling and/or cleaning
- Failure to use in the manner indicated in the ClimateCare user manual

Any modification, repair or alteration done to the ClimateCare that was not authorized in writing by Joerns will void this warranty.

Damage caused by use in unsuitable environmental conditions, abuse or failure to maintain the product in accordance with user and service instructions is not covered.

This warranty is extended to the original purchaser of the equipment and is not transferable.

Parts

Joerns' ClimateCare contains various parts that wear from normal use. Joerns' obligation under this warranty is limited to supplying replacement parts, repairing or replacing, at its option, any product which is found by Joerns to be defective. When requested by Joerns, parts must be returned for inspection at the customer's expense. Credit will be issued only after inspection.

Service

Most service requests can be handled by the facility Maintenance Department with assistance from the Joerns Product Service Department.

Warranty parts are shipped ground, and expedited delivery may be available at customer's expense.

Manufactured by:

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