Alpha
Patient Warming Systems
for all clinical situations
Innovative technology for better patient care
There is widespread clinical evidence of the benefits of patient warming for the prevention of hypothermia. These studies are wide-ranging, covering surgery, anaesthesia, recovery room, the pre-operative period, emergency department, patient transport, and more.\textsuperscript{1, 3, 7, 8, 9}

The clinical benefits are clearly demonstrable, such as improved morbidity and mortality, lower infection rates, less time in recovery, reduced incidence of pressure sores, shorter hospital stays and large cost savings.

Clinical considerations

The thermoregulatory system is affected from the onset of anaesthesia, with the fastest fall in temperature during the initial period. This makes hypothermia a real possibility, even for short surgical procedures. Similarly, trauma and other emergency situations often lead to rapid depression of core temperature.

There is little dispute that prevention of hypothermia leads to better outcomes for the patient and savings for the hospital. It has also been well established that maintenance of normothermia is much better than re-warming. The continuing number of publications advocating greater use of warming will inevitably increase the need to change routine clinical practice in all areas where the risk of hypothermia exists.

Warming technology

A range of technologies have been used for patient warming over the years. Traditional methods all have their shortcomings in terms of performance, convenience or cost. Inditherm have revolutionised the technology for warming and produced a system that out-performs the traditional methods in all respects.

Inditherm’s patented flexible carbon polymer technology has been used as an innovative solution for preventing hypothermia. The Inditherm \textit{Alpha} systems combine more effective thermal transfer with simplicity of use that makes them superior to other methods currently available. The technology provides significant financial benefits, making routine warming of all patients affordable and convenient.
Features and Benefits

Inditherm Medical have used their carbon polymer technology to produce a patient warming system that is practical, convenient and very effective. Key features and benefits include:

**Best warming performance**
- Uses latest patented technology
- High thermal transfer characteristics
- Clinically proven
- Better performance than forced air warming and other traditional methods

**Prevents pressure sores**
- Pressure relief built-in, under the heating surface
- Proven to out-perform gel pads and standard operating table mattresses

**Ultimate convenience**
- Compact control unit fits on anaesthetic trolley or drip stand
- Lightweight and silent
- X-ray translucent
- Simple to use

**Significant cost savings**
- No disposables, no leaks, very low maintenance
- Warm all patients at no extra cost
- Better overall outcomes and shorter post-operative stays

**Safe & robust**
- Low voltage operation
- Fully sealed with RF welded seams
- Durable, latex-free cover
- Fully approved to medical device standards

**Unhindered access to patient**
- Fits under patient, yet warms better than forced air systems
- No warming of surrounding environment or surgical team

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[Image of a patient being warmed by a portable warming device]

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**Warming Performance**

Inditherm’s warming products are based on their patented flexible polymer technology. Heat is produced by a uniform sheet of soft conductive material which gives even warming across the whole surface. The design ensures that the mattresses mould to the shape of each patient, giving large contact area and high thermal transfer characteristics. Clinical trials have shown that the Inditherm Alpha system outperforms air warming, giving best efficacy available. 4, 6, 10

**Pressure Relief**

Using flexible polymer technology enables the integration of a pressure relief pad into the mattress, under the heating surface. This ensures that there is no attenuation of the warming performance in addition to helping to prevent pressure sores. A clinical study has shown that the Inditherm Alpha system provides better pressure relief than gel pads or standard operating table mattresses. 9

Warming is known to improve perfusion and therefore applying this under the patient can further contribute to reducing the risk of pressure sores.
Cost Savings

The Inditherm mattresses are completely re-usable and can be cleaned in exactly the same way as the existing operating table surface. Experience has shown that the saving on cost of disposable air warming blankets typically pays for an Inditherm system in less than six months – and the system can be used on all patients with no extra cost or inconvenience. There are none of the maintenance, reliability or running costs associated with water mattresses.

The benefits of preventing hypothermia are well documented1, 11, 12 and have shown that post-operative costs can be significantly reduced by warming patients. The wider use of warming facilitated by the Inditherm Alpha system should yield additional savings that are an order of magnitude higher than the reduction in consumable costs.

Convenience and Simplicity

There is nothing obstructing the surgical field, nor is there any warming of the surrounding area or surgical team, when using Inditherm Alpha products. No time is wasted setting up or adjusting the system and no additional items such as gel pads are required. Mattresses are lightweight for ease of handling and fully sealed, making them simple to clean using existing infection control procedures. The control unit is compact and easily accommodated, with simple temperature control and clear display. The mattress runs at low voltage, ensuring safety for the patient and staff, and is X-Ray translucent.
Product Range

The Inditherm Alpha range comprises mattresses and blankets of different sizes, to suit different clinical needs and situations. Products can be customised to meet individual requirements in terms of sizes, shape, fixings, heat output and other design aspects, on request.

Mattresses are particularly suited to use in the operating room and the pre-operative period. These give the most efficient heat transfer and are completely unobtrusive, being under the patient. Blankets are typically used in the recovery room (PACU) and other situations where it is not practical to place a mattress under the patient.

The standard Control Unit can be used with any mattress or blanket in the range, giving complete flexibility.

The advanced AlphaPlus unit offers a range of additional features to cater for different clinical situations. The unit is mains powered, with options to add integrated battery and DC power input. The battery will power the largest mattress for at least an hour, and is automatically re-charged when the unit is connected to mains power. The DC power input can be run from any supply between 12Vdc and 28Vdc, such as from a vehicle supply.

The AlphaPlus unit can be specified with an optional Patient Temperature Monitor function.

Applications

Mattresses and blankets are available to suit the full range of surgical procedures. The system has been proven to meet the demands of burns, gynaecology, urology, vascular, cardiothoracic, orthopaedic, plastic, paediatric, maxillo-facial, general surgery – and more.

The Inditherm Alpha patient warming range is well suited for use in the recovery area, intensive care unit and during the pre-operative period. TraumaTherm and CosyTherm systems are also available, specifically for the emergency department, ambulance, internal transport and neonatal areas.

The AlphaPlus system is specifically designed for use in transport and other patient transfer situations. The compact, lightweight design, combined with battery operation and DC power input make it a perfect solution for these applications.

Inditherm patient warming systems are also in widespread use by international armed forces, including active service in conflict zones.
## Mattress Construction:

- Inditherm® flexible polymer heating sheet, with pressure relief pad under and 305g.m⁻² expanded polyester comfort lining over.
- Encapsulated in latex-free, nylon fabric cover, with non-microporous polyurethane coating, fully sealed with RF welded seams.
- In-built temperature sensor and over-temperature thermal cut-out.
- Connection cable, 200 mm long, with strain relief, fully sealed entry grommet and IP61 rated waterproof connector.
- Sensors and cables let into pressure relief pad for patient comfort.

## Temperature Output Range:

- 37°C to 40°C (99°F to 104°F) in steps of 1°C (2ºF)
- Over-temperature safety cut-out at 43°C (109°F)

## Power:

<table>
<thead>
<tr>
<th>Component</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alpha Control Unit</strong></td>
<td>100 Vac or 110 Vac or 230 Vac (±6%), 50Hz/60Hz, 75 W</td>
</tr>
<tr>
<td><strong>Alpha™ Control Unit</strong></td>
<td>100 Vac to 240 Vac (±6%), 50Hz/60Hz (auto-ranging), 100W</td>
</tr>
<tr>
<td>Battery Input (Optional)</td>
<td>1 hour for standard full length mattress [OTM1] from full charge</td>
</tr>
<tr>
<td>Capacity</td>
<td>Automatic charging when mains power applied</td>
</tr>
<tr>
<td>Charging</td>
<td>18 hour charge time from complete discharge to fully charged</td>
</tr>
<tr>
<td>D.C. Input (Optional)</td>
<td>12Vdc to 28Vdc (±10%)</td>
</tr>
<tr>
<td>Patient Temperature Monitor function (Optional):</td>
<td>Requires approved patient temperature probe</td>
</tr>
</tbody>
</table>

## Mattresses and Blankets:

- 24 V (nom.)
- 25 W to 65 W, depending on size

<table>
<thead>
<tr>
<th>Type</th>
<th>Size</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha Control Unit:</td>
<td>MECU1 160 x 240 x 230 mm 4.1 kg</td>
<td></td>
</tr>
<tr>
<td><strong>Alpha™ Control Unit</strong></td>
<td>MCU200 280 x 155 x 140 mm 2.0 kg</td>
<td></td>
</tr>
<tr>
<td><strong>Mains Power</strong></td>
<td>MCU204 280 x 155 x 140 mm 3.2 kg</td>
<td></td>
</tr>
<tr>
<td><strong>Mains and Battery</strong></td>
<td>MCU205 280 x 155 x 140 mm 4.0 kg</td>
<td></td>
</tr>
<tr>
<td><strong>Mains, Battery and D.C. Input</strong></td>
<td>MCU202 280 x 155 x 140 mm 4.0 kg</td>
<td></td>
</tr>
<tr>
<td><strong>Mains Power with patient temperature monitor</strong></td>
<td>MCU203 280 x 155 x 140 mm 2.0 kg</td>
<td></td>
</tr>
<tr>
<td><strong>Mains and Battery with patient temperature monitor</strong></td>
<td>MCU204 280 x 155 x 140 mm 3.2 kg</td>
<td></td>
</tr>
<tr>
<td><strong>Mains, Battery and D.C. Input with patient temperature monitor</strong></td>
<td>MCU205 280 x 155 x 140 mm 4.0 kg</td>
<td></td>
</tr>
</tbody>
</table>

## Connecting Cable:

- 4 m

## Compliance:

- EN60601-1, Class IIb, Type BF
- EN60601-1-2
- EN60601-2-3S
- UL 60601
- 93/42/EEC, EEC Medical Devices Directive

## Environmental:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient Temperature (Operating):</td>
<td>10°C to 40°C (50°F to 104°F)</td>
</tr>
<tr>
<td>Ambient Temperature (Storage):</td>
<td>-10°C to 55°C (14°F to 131°F)</td>
</tr>
<tr>
<td>Relative Humidity:</td>
<td>30% to 75%</td>
</tr>
</tbody>
</table>

Due to continuous product development the company reserves the right to change these details without notice.

Caution: United States Federal law restricts this device to sale by or on the order of a physician.
1. Maintaining perioperative normothermia.
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7. The role of systemic warming of “at risk” surgical patients during the initial hospital phase.
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   Kumar, S., Wong, P.F., Bohra, A.K., Leaper, D.
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   Dept. of Anaesthesia, University Hospital, Queen Medical Centre, Nottingham, UK.

    Baker, E.A., and Leaper, D.J.
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11. Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalisation.
    Kurz, A., Sessler, D.I., Lenhardt, R.

12. Mild intraoperative hypothermia prolongs postanaesthetic recovery.
    Lenhardt, R., Marker, E., Goll, V., Tschernich, H.,
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