UŽDAROJI AKCINĖ BENDROVĖ „MEDICINOS PROJEKTAI“

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DĖL PASIŪLYMO PAAIŠKINIMO

Atsakydami į Jūsų 2015 metų balandžio 3 dienos raštą Nr. S-(1.27)-5357 dėl 2014-10-30 Centrinėje viešųjų pirkimų informacinėje sistemoje (toliau CVP IS) skelbtam atviram konkursui **„Ligonių šildymo sistema“** (pirkimo numeris: 157082) pateikto pasiūlymo, pateikiame reikalaujamų parametrų reikšmių pagrindimo patikslinimą:

1. Specialiųjų reikalavimų punktas 1.1: „Šildomas elektra (su integruotu šildymo elementu) – originali vartotojo instrukcija, 5 psl. (atžymos su vertimu į lietuvių kalbą);
2. Specialiųjų reikalavimų punktas 11: „Perspėjimo signalas ir automatinis šildytuvo išjungimas, viršijus maksimalią leistiną temperatūrą“ - originali vartotojo instrukcija, 10 psl. (atžymos su vertimu į lietuvių kalbą);
3. Specialiųjų reikalavimų punktas 12: „Neribojama nepertraukiamo darbo trukmė“ - originali vartotojo instrukcija, 1 psl. (atžymos su vertimu į lietuvių kalbą);

Pardavimų padalinio vadovas Saulius Lapinskas

LIETUVOS RESPUBLIKA
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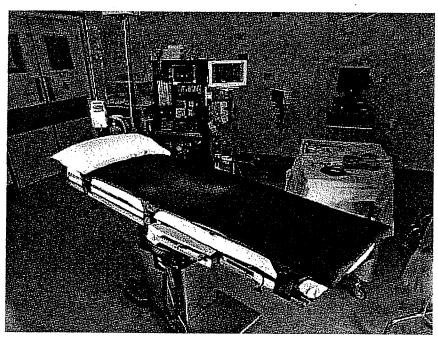
Nr.1
VILNIUS

INDITHERM
Medical



Patient Warming Systems

Operating Instructions

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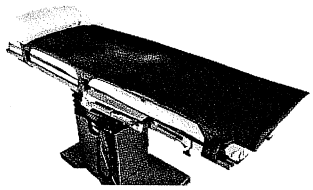
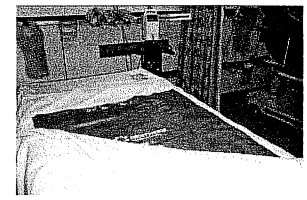
Introduction:





The Inditherm Patient Warming Systems are designed for use in the operating room, recovery room, anaesthetic room, intensive care and emergency department. They provide safe and controlled warming to assist patients to maintain normal body temperature. The warming medium is available as:

- A mattress for use under a patient
- A recovery blanket or operating room blanket to be placed over a patient.

In addition to warming, the mattresses also include a pressure-relieving pad. This is achieved using an integral pressure relieving foam pad under the flexible heating surface, ensuring no degradation of heating performance.

Different sizes and models of mattress and blanket are available for various procedures and situations. They are sealed to prevent ingress of fluids and allow cleaning. Integral straps are provided to ensure mattresses can be securely fastened to the operating table or trolley.

The system is powered and controlled by an electronic control unit. The mattresses and blankets are powered at low voltage, ensuring safety for patients and operators. The temperature is controlled automatically to user-selected level. An over-temperature safety cut-out is integrated into each mattress and blanket.

The control unit can be placed on a flat surface or mounted on an IV pole, anaesthetic machine, etc. It has a standard mains supply input and a working voltage of 24Vac to the mattress or blanket. The system has 4 pre-set operating temperatures of 37, 38, 39 and 40°C and is designed to be operated continuously, maintaining a uniform heat under or over the patient.

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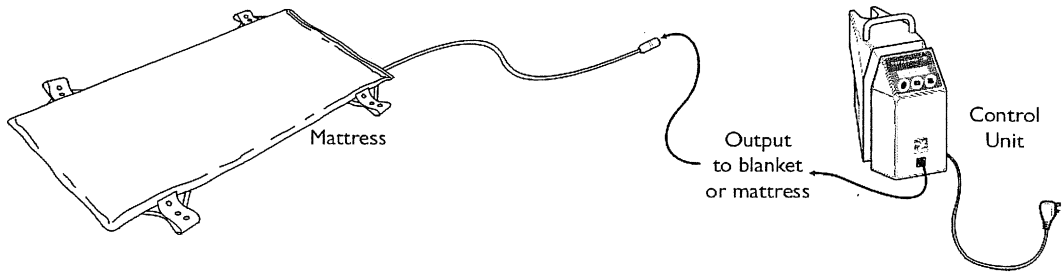
Sistema yra skirta būti eksploatuojama nepertraukiamai (nenutojama darbo dienos)

Description of Parts and Range of Products

Note: Any mattress / blanket can be used with any control unit.



Model	Size	Description
OTM1	1900 x 585 x 40 mm	Operating Room Mattress, Full Length
OTM1 N	1900 x 535 x 40 mm	
OTM2	1200 x 585 x 40 mm	Operating Room Mattress, ¾ Length
OTM2 N	1200 x 535 x 40 mm	
GTM1	1070 x 585 x 40 mm	Operating Room Mattress, ½ length
GTM1 N	1070 x 535 x 40 mm	
PTM1	560 x 500 x 40 mm	Operating Room Neonatal Mattress
OTB1	500 x 1070 x 40 mm	Operating Room Blanket, Long
OTB2	870 x 500 x 40 mm	Operating Room Blanket, Short
RB1	1660 x 800 x 40 mm	Recovery Room Blanket, Full length
RB2	1660 x 1200 x 40 mm	Recovery Room Blanket, Wide
MECU1	160 x 240 x 230 mm	Electronic Control Unit

Valdymo blokas naudojamas su elektrišku šildomais čiužiniais ir antklodėmis.

System Description

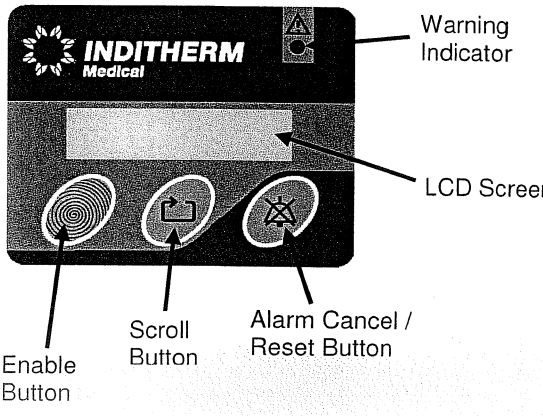
Control Unit

p.1.1 The control unit is a precision temperature control unit to be used in conjunction with the electrically heated blanket or mattress.

Mains voltage is supplied to the control unit via a captive mains lead. A recess is provided to allow the mains cable to be safely coiled around the unit when not in use. There is a power switch on the right side of the unit that illuminates when the power is on.

At the top is a carrying handle and to the rear is a clamp to allow the unit to be mounted on a pole or anaesthetic trolley.

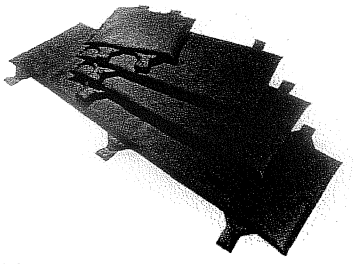
On the front of the unit is a display and control panel from which all the functions can be accessed, there are three control buttons, and an LCD display. The cable for the mattress or blanket is at the front.



The control unit input is protected by a 1600mA fuse, which is accessible from the base of the unit.

The control unit provides a 24Vac supply to the mattress or blanket and receives temperature information back. The temperature setting is indicated on the display. The unit automatically adjusts to the type of mattress or blanket connected.

Mattress



The mattress is available in various sizes and is only designed to operate under the patient. The mattress provides an even temperature over the whole surface and is extremely flexible.

The basic construction of the mattresses remains the same throughout the range.

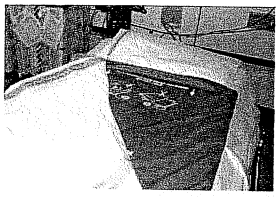
The mattresses are water and solvent resistant and have been tested for bio-compatibility to allow skin contact during use. All seams are fully sealed by RF Welding and are latex free.

p.1.1 The internal patented Inditherm carbon polymer material provides the heat source, and an internal temperature sensor provides the output to the control unit for temperature control. The mattress has a thermal protector that will not allow the mattress to overheat.

A pressure relief pad is integrated into the mattress, underneath the flexible warming surface. This helps reduce the incidence of pressure sores without any attenuation of the warming performance.

Integral straps are used to retain the mattress in-situ.

Blanket



The blanket is designed to operate over the patient. There are two types of blanket available, both are constructed in the same manner as the mattresses, but without the pressure relief pad, which is replaced by a soft insulating material.

Šilumos šaltinis - integruotas anglies polimeras

General Performance

On initial start up, if the ambient temperature is low, the mattress / blanket will take longer to achieve the desired temperature. If the selected temperature is not achieved within 40 minutes a *Low Temperature* warning will be displayed for one minute and an alert tone will sound for 20 seconds.

The system will continue to warm the mattress / blanket. The alert tone may be silenced if desired by pressing the **Alarm Cancel** button. The system will automatically re-check every 20 minutes thereafter to confirm that the selected temperature is achieved. The alert will repeat if appropriate. If the alert persists then consult a qualified engineer.

The mattress will not cause any environmental heating and contains a special conductive heating material. The heat given off by this material will only be felt by the user / patient when applying pressure / weight to the mattress. It is normal that the mattress or blanket do not feel particularly warm to the touch when left uncovered.

The control unit will monitor temperature performance, and when the mattress/blanket reaches the desired temperature the control unit will stop heating the mattress/blanket. If the maximum allowed temperature is exceeded the over temperature alarm will sound. An internal safety cut-out temperature management system will operate if any fault condition causes the mattress/blanket to exceed a temperature of 43°C.

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For best performance it is recommended that the system is switched on and left to run at set temperature in advance of placing the patient.

Viršijus leistiną maksimalią temperatūrą pasigirsta garsinis perspėjimo signalas. Vidinė apsauginė sistema atjungia šildymą..

Guidance and manufacturer's declaration – electromagnetic emissions The systems are intended for use in the electromagnetic environment specified below. User should assure use is in such environment		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Systems use RF energy only for internal function. RF emissions are very low and unlikely to cause interference in nearby electronic equipment
RF emissions CISPR 11	Class B	Systems are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies them.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity The systems are intended for use in the electromagnetic environment specified below. User should assure use is in such environment			
Immunity test	IEC 60601 test level		Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	Pass	Floors should be wood, concrete or ceramic tile. If floors are synthetic material, relative humidity should be at least 30%
Electrostatic fast transient / burst IEC 61000-4-4	±2kV power supply lines ±1kV input/output lines	Pass	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1kV line to line ±2kV line to earth	Pass	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power input lines IEC 61000-4-11	<5% U_T for 0.5 cycle 40% U_T for 5 cycles 70% U_T for 25 cycles <5% U_T for 5 sec	Pass	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during mains power interruptions the battery option should be fitted or a UPS used.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	Pass	If interference is suspected it may be necessary to move the system further from sources of power frequency magnetic fields or install magnetic shielding.
Note: U_T is the ac mains voltage prior to application of the test level			