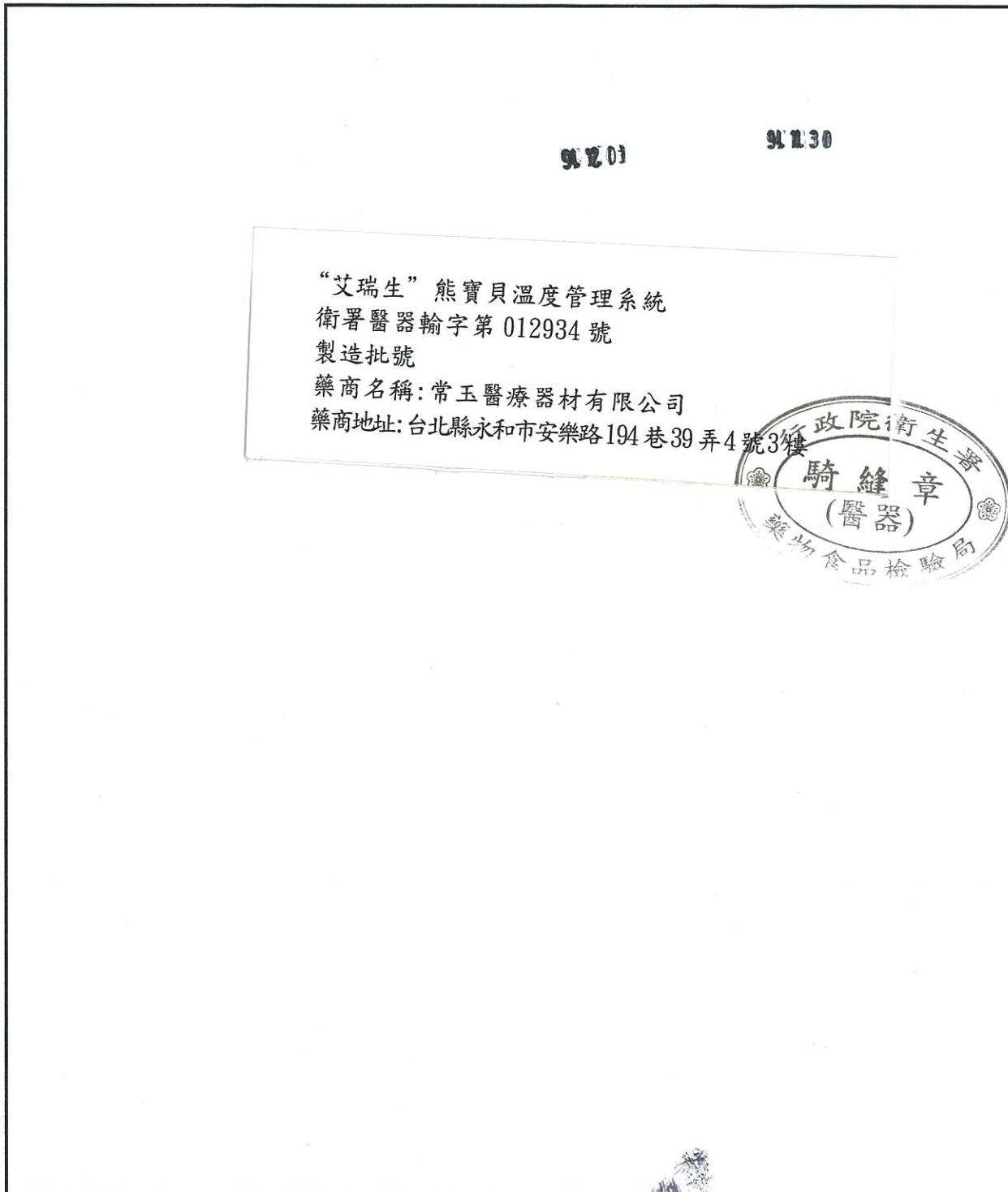


仿單標籤粘貼表

產品中文名稱	”艾瑞生”熊寶貝溫度管理系統	申請廠商	常玉醫療器材有限公司
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※ 貼產品之標籤仿單或包裝及實物正背面照片

※ 中文仿單（如背面所列項目）

“艾瑞生”熊寶貝溫度管理系統

“Arizant” Bair Hugger Patient Warming System

衛署醫器輸字第 012934 號

使用前請務必詳閱原廠之使用說明書遵照指示使用。

本案產品使用方法、禁忌症、警告及注意事項等請參照原廠資料

型號 :~~505 及 750~~

產品敘述及應用

熊寶貝全體加溫管理系統是由麻醉醫師為防止和處理常見但重要的低體溫症的問題而發展。 熊寶貝全體加溫管理系統的目前應用於麻醉照料單位(PACU)，恢復室，手術室，緊急部門，產科和加護區。此加溫系統透過過濾器引用周遭空氣並加溫空氣至特定的溫度。此時它透過一個軟管把這個暖空氣透過管子送到放置於病人身上的熊寶貝溫毯。當恰當地使用時，熊寶貝溫毯會分散暖氣到病人的身體四周，創造一個溫暖環境。

熊寶貝全體加溫管理系統包括**熊寶貝拋棄式耗材及熱空氣式加溫器組**。

熊寶貝溫毯是由長條管型航道來輸送管控的暖氣。溫毯設計成可圍裹病患。溫毯設計成各種形狀供特定用途。

適應症

- . 體溫低於 36°C
- . 病人發抖
- . 病人喊冷不適

此系統適用在低溫處於寒冷或發抖狀態之病患，給予溫暖。另外，此系統可以應用在任何導致病患低溫之狀況。

規格

型號：~~505~~

物理特性

體積	13" H * 10" D * 11" W (33cm H * 25cm D * 28cm W)
重量	11.5 磅 (5.2 公斤)
托架固定方式	可固定在點滴架上，置於硬的平面上或固定於活動架上
相關噪音程度	53 分貝
出風管	可分離，彈性的，可清洗，可與熊寶貝 241 輸血/輸液套相容
濾網系統	0.2 μm 空氣濾網
建議更換濾網時間	每六個月或 500 小時 視情況所需

溫度特性

溫度控制	電源控制
生產熱能	1800BTUs/Hr (平均)
到達 100°F (37°C) 之時間	17 秒
執行溫度	至病人身上溫度約低於設定溫度 2 °C
出風管口平均溫度	高：43°±3°C (109.4°±5.4°F) 中：38°±3°C (100.4°±5.4°F) 低：32°±3°C (89.6° ±5.4°F)

安全系統

自動調溫器	獨立電路迴路
過載保護	雙軌輸入保險絲
警示系統	溫度過高：紅色警示燈閃爍，警鳴，加熱及出風口自動停止

電力特性

操作速度	約 3150 rpm
風速	28-30 cfm
耗電量	高峰: 1000 W 平均: 450W
漏電	< 100 μ m
加熱元件	850 W 阻力
電源線	15呎, SJT, 3 cond., 10 A 4.6 公尺, HAR, 3 cond., 10 A
器材額定功率	110-120VAC, 60 Hz, 9.5A, 或 220-240VAC, 50 Hz, 4.5A, 或 100 VAC, 50/60 Hz, 10 A
保險絲	10A, 200mA and 500mA (110-120 VAC) 6.3A, 100mA and 500mA (220-240VAC) 10A, 160mA and 400mA (100 VAC)

型號:~~750~~

規格

型號: 750

物理特性

體積	12"高 * 13.5"長 * 10"寬 30cm 高 * 34cm 長 * 25cm 寬
重量	15.5 磅 (7 公斤)
相關噪音程度	53 dBA
出風管	彈性的, 可與熊寶貝 241 輸血/輸液套相容
濾網系統	0.2 μ m 空氣濾網
建議更換濾網時間	每六個月或視情況所需
固定方式	可固定在點滴架上, 置於硬的平面上, 或固定於活動架上

溫度特性

建議使用環境	15°~25°C
溫度控制	電源控制
生產熱能	1644 BTU/hr (平均), 482W(平均)
執行溫度	出風管口平均溫度 高 : $43^{\circ} \pm 1.5^{\circ}\text{C}$ $109.4^{\circ} \pm 2.7^{\circ}\text{F}$ 中 : $38^{\circ} \pm 1.5^{\circ}\text{C}$ $100.4^{\circ} \pm 2.7^{\circ}\text{F}$ 低 : $32^{\circ} \pm 1.5^{\circ}\text{C}$ $89.6^{\circ} \pm 2.7^{\circ}\text{F}$

安全系統

自動調溫器	獨立電路迴路；出風管口溫度高於 $53^{\circ}\text{C} \pm 3^{\circ}\text{C}$ 會自動關機，溫度過高儲備偵測位於出風管入口。
警示系統	溫度過高($53^{\circ}\text{C} \pm 3^{\circ}\text{C}$)：紅色警示燈閃爍，警鳴，加熱及出風口自動停止，操作指示燈不亮，控制面板無反應。
過載保護	雙軌輸入保險絲

電力特性

加熱元件	1400 W 阻力
鼓風馬達	操作速度:約 4,000rpm 風速:上至 48 cfm 或 23 L/s
耗電量	尖峰:1550W 平均: 800W
電源線	15 英呎., SJT, 3 cond., 13A 15 英呎., SJT, 3 cond., 15A 4.6 公尺, HAR,3 cond., 10 A
器材額定功率	110-120VAC, 50/60 Hz, 11.7 A, 或 220-240VAC, 50/60 Hz, 7.2 A, 或 100 VAC, 50/60 Hz, 14.5 A
保險絲	12 A (110-120 VAC) 8 A (220-240VAC) 15 A (100 VAC)

耗材：溫度管理系統之溫毯

Model	Part No.	品名 (中文/英文)	規 格
315	31500	多切式全身式溫毯 / Multi-Access Blanket	83" x 37" (211 x 94cm)
522	52200	上半身式溫毯 / Upper Body Blanket	74" x 24" (188 x 61cm)
525	52500	下半身式溫毯 / Lower Body Blanket	60" x 36" (152 x 91cm)

零配件 (可選購)：

Part No.	品 名 (中文 / 英文)
90009	濾網 / Filter for Model 505
90047	濾網 / Filter for Model 750
90003	液體加溫管 / Model 505 Fluid Warming Hose, 2m
90046	管+感應器配件 / Hose w/Sensor Assy
90050	推車 / Rolling cart (for 505)
90061	推車 / Rolling cart (for 750)
90048	置物籃 / Blanket Basket (for 505)
90018	IV 支架 / IV Pole
90068	IV 支架 / IV Pole, offset, pressure Inf., Top
90069	IV 支架 / IV Pole, offset, pressure Inf., Bottom
22110	溫度測試工具 / Temperature Test Kit
90026	軟管帽 / Fluid Warming Hose Cap
90063	毯子夾 / Sheet Clip
90017	管 夾 / Hose Clip
90067	扶手托架支桿 / Equipment Rail Mounting Rod
90033	電力組 / Power Pack – 120V/60Hz

製造廠名稱：Arizant Healthcare Inc.

製造廠地址：10393 West 70th Street, Eden Prairie, MN 55344 U.S.A.

藥商名稱：常玉醫療器材有限公司

藥商地址：台北縣永和市安樂路 194 巷 39 弄 4 號 3 樓

Model 505

The Bair Hugger® Total Temperature Management® System was developed by an anesthesiologist to

治疗技术1.

prevent and/or treat the common but significant problem of hypothermia. Examples of current

applications for Bair Hugger Total Temperature Management Systems are post anesthesia care units

Bair Hugger® Total Temperature Management System

(PACU), recovery rooms, operating rooms, emergency departments, obstetrical suites, and intensive

care areas. The warming unit draws ambient air through a filter and warms the air to the specified

temperature. It then delivers the warmed air through a hose to the Bair Hugger blanket which is

placed over the patient. When used properly, the Bair Hugger blanket distributes the warm air around

the patient's body, creating a warm environment. This manual includes instructions for operating

and maintaining Bair Hugger warming units, instructions for operating 241® fluid warming sets, and

specifications for both products. For information on how to use the unit with a specific blanket

model or the 241 fluid warming set refer to the instructions included with Bair Hugger blankets and

241 fluid warming sets.

音
義
叙述

Bair Hugger® Total Temperature Management® System

The Bair Hugger Total Temperature Management System consists of a disposable blanket and a warming unit. Bair Hugger warming therapy can also include 241° fluid warming therapy, described under *Warming Fluids Using the 241 Fluid Warming Set*.

Bair Hugger® Blankets

Bair Hugger blankets are made up of long, tubular channels which deliver controlled warmth. The blanket is designed to "hug" the patient. Blankets are designed in various configurations for specific applications. Follow the instructions provided with Bair Hugger blankets for specific information concerning their recommended use.

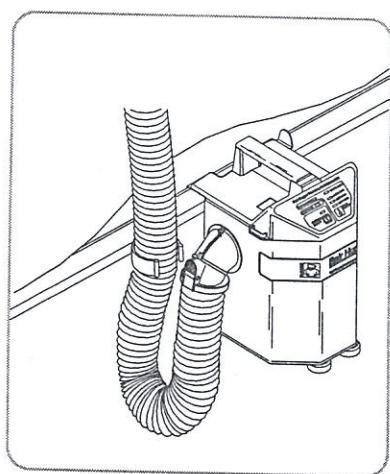


Figure D. Model 505 warming unit

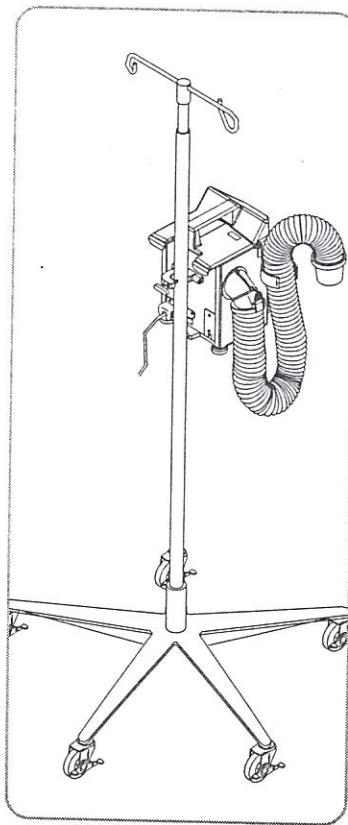


Figure E. Model 505 warming unit attached to an I.V. pole

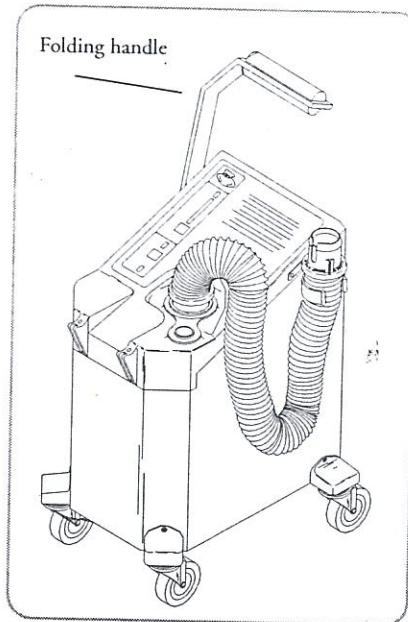


Figure F. Model 500/OR and Model 500/OR,E warming unit

Warming Units

The warming unit uses a high-efficiency motor, a heating element, and a solid-state temperature control to create a continuous flow of warm air to the blanket. Models 500/OR, 500/OR,E and 505 are designed for safe use in all areas, including the operating room.

The folding handle on the Model 500/OR, 500/OR,E warming units can be placed in two positions. The handle is moved forward and down for the folded position; it is pushed up and back for the upright position. In the folded position the warming unit can be rolled out of the way (for example, under the operating table) during warming therapy, and it can be stored more conveniently when warming therapy is completed. The upright position allows the warming unit to be easily transported between clinical areas.

The Model 505 warming unit can be attached to an I.V. pole or to the railing on a bed.

低溫症

Hypothermia: A Common Problem in Patient Care

Description

Hypothermia occurs when a patient's body temperature drops below 36°C (96.8°F). Sixty to eighty percent of all patients undergoing operative procedures become hypothermic.

Contributing Factors

Factors contributing to hypothermia include:

- Cold operating room environment
- Anesthetic drug effect
- Administration of cold intravenous fluids
- The opening of the body cavity
- Cold exposure
- Drowning
- Spinal trauma
- Geriatric thermoregulatory processes

Adverse Consequences

Adverse consequences of hypothermia include:

- Coagulopathy
- Hemodynamic instability
- Immunodepression
- Shivering and patient discomfort
- Altered drug effect
- Postoperative nitrogen wasting
- Cardiac dysfunction

適應症

Indications for Bair Hugger® Warming Therapy

Examples of indications for the Bair Hugger® Total Temperature Management® system include:

- Body temperature drops below 36°C (96.8°F)
- Patient exhibits shivering
- Patient complains of being uncomfortably cold

Also, to prevent hypothermia, the Bair Hugger Total Temperature Management system should be used whenever conditions exist that could cause patients to become cold.

禁忌症

Precautionary Information

Contraindications

Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury may occur if heat is applied to ischemic limbs.

警告

Warnings

- Do not use Bair Hugger® warming units with any forced-air blanket or cover other than Bair Hugger blankets. Thermal injury may result.
- Do not warm patients with the warming unit hose alone. Thermal injury may result. Always attach the hose to a Bair Hugger blanket before providing skin surface warming therapy.

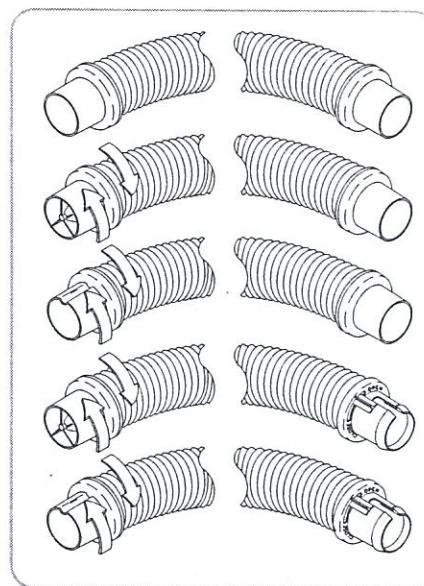


Figure Q. Hose assemblies

HOSE ASSEMBLIES

Warming unit hose assemblies are available in five options. The keyway on the extended length hose matches a keyway on warming units specifically calibrated for the extended length hose option, to ensure the delivery of proper temperature to the patient.

Model 505 units are only available with a snap-fit, extended length 241® fluid warming hose assembly, described in *Attaching and Storing the Model 505 warming unit hose*.

General Maintenance

Cabinet Cleaning

- 1) Disconnect the warming unit from the power source before cleaning.
- 2) Use a damp soft cloth and a mild detergent to clean the warming unit cabinet. Dry with a separate soft cloth.

CAUTION

- Do not use a dripping wet cloth to clean the cabinet. Moisture may seep into the electrical contacts, damaging the components.
- Do not use alcohol or other solvents to clean the cabinet. Solvents may damage the labels and other plastic parts.



Specifications

500/OR

Physical Characteristics

DIMENSIONS

24 in. high x 16 in. deep x 14 in. wide
61 cm high x 41 cm deep x 36 cm wide

WEIGHT

43 lb; 19.5 kg

505

Physical Characteristics

DIMENSIONS

13 in. high x 10 in. deep x 11 in. wide
33 cm high x 25 cm deep x 28 cm wide

WEIGHT

11.5 lb; 5.2 kg

500/OR**MOUNTING**

Supplied with swivel casters; floor use only

RELATIVE NOISE LEVEL
52 decibels**HOSE**Detachable, flexible, washable; compatible with
Bair Hugger 241® fluid warming system**FILTRATION SYSTEM**
0.2 μ M level**RECOMMENDED FILTER CHANGE**
Every 6 months or 500 hours of use**Temperature Characteristics****TEMPERATURE CONTROL**

Electronically controlled using a thermocouple sensor

HEAT GENERATED

1800 BTUs (average)

SYSTEM TIME TO 100°F (37.7°C)
~35 secs**OPERATING TEMPERATURES***Air temperatures reaching the patient are approximately 2°C lower than the listed temperatures.*Average temperatures at the end of the hose,
assuming the back pressure of an Augustine
Medical, Inc. warming blanket, or an Augustine
Medical, Inc. temperature test unit:

HIGH: 43° ± 3°C	109.4° ± 5.4°F
MED: 38° ± 3°C	100.4° ± 5.4°F
LOW: 32° ± 3°C	89.6° ± 5.4°F

Safety System**THERMOSTAT**

Independent bulb and capillary

OVERCURRENT PROTECTION

Dual fused input lines

ALARM SYSTEMOver-heat: flashing red light with audible alarm;
heater shuts down**CERTIFICATIONS**UL 544, CSA C22.2 No. 125, IEC 601-1, IEC
601-1-2, EN55014, AS 3200.1990**CLASSIFICATION**Classified under IEC 601-1 Guidelines as Class I,
Type BF, Ordinary equipment, Continuous operation**Electrical Characteristics****BLOWER MOTOR**Operating speed: 2650 rpm
Airflow: 28-30 cfm**POWER CONSUMPTION**Peak: 1000W
Average: 500W**505****MOUNTING**IV pole clamp, bed rail hook with safety strap;
can be placed on hard surface**RELATIVE NOISE LEVEL**
53 decibels**HOSE**Detachable, flexible, washable; compatible with
Bair Hugger 241® fluid warming system**FILTRATION SYSTEM**
0.2 μ M level**RECOMMENDED FILTER CHANGE**
Every 6 months or 500 hours of use**Temperature Characteristics****TEMPÉRATURE CONTRÔLE**

Electronically controlled using a thermocouple sensor

HEAT GENERATED

1800 BTUs (average)

SYSTEM TIME TO 100°F (37.7°C)
~17 secs**OPERATING TEMPERATURES***Air temperatures reaching the patient are approximately 2°C lower than the listed temperatures.*Average temperatures at the end of the hose,
assuming the back pressure of an Augustine
Medical, Inc. warming blanket, or an Augustine
Medical, Inc. temperature test unit:

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601-1-2, EN55014, AS 3200.1990**CLASSIFICATION**Classified under IEC 601-1 Guidelines as Class I,
Type BF, Ordinary equipment, Continuous operation**Electrical Characteristics****BLOWER MOTOR**Operating speed: 3150 rpm
Airflow: 28-30 cfm**POWER CONSUMPTION**Peak: 1000W
Average: 450W

500/OR

LEAKAGE CURRENT
 $<100\mu\text{A}$

HEATING ELEMENT
 850W Resistive

POWER CORD
 15-foot, SJT, 3 cond., 10A
 4.6 meter, HAR, 3 cond., 10A

DEVICE RATINGS
 110-120VAC, 60Hz, 9.5 Amperes, or
 220-240VAC, 50Hz, 4.5 Amperes, or
 100VAC, 50/60 Hz, 10 Amperes

FUSES
 10A, 200mA and 500mA (110 - 120 VAC Units)
 6.3A, 100mA and 500mA (220 - 240 VAC Units)
 10A, 160mA and 400mA (100VAC Units)

DIAGNOSTICS
 Over-heat test can be performed by the biomedical group.

✓

505

LEAKAGE CURRENT
 $<100\mu\text{A}$

HEATING ELEMENT
 850W Resistive

POWER CORD
 15-foot, SJT, 3 cond., 10A
 4.6 meter, HAR, 3 cond., 10A

DEVICE RATINGS
 110-120VAC, 60Hz, 9.5 Amperes, or
 220-240VAC, 50Hz, 4.5 Amperes, or
 100VAC, 50/60 Hz, 10 Amperes

FUSES
 10A, 200mA and 500mA (110 - 120 VAC Units)
 6.3A, 100mA and 500mA (220 - 240 VAC Units)
 10A, 160mA and 400mA (100VAC Units)

DIAGNOSTICS
 Over-heat test can be performed by the biomedical group.

Definition of Symbols



ON/STANDBY



ON (used on isolation switch)



OFF (used on isolation switch)



ON/OFF push button switch



Temperature Control



Equipotentiality plug (Ground)



Fuse



Warning/Caution (see appropriate documents)



Non Explosion-Proof



Dangerous Voltage



Type BF Equipment (patient applied)



Voltage, Alternating Current (AC)

Introduction *1-1*

Description of the Total Temperature Management System

The Bair Hugger brand Total Temperature Management system consists of a Model 750 forced-air temperature management unit (with available rolling stand and sheet clip) and Bair Hugger disposable components, including forced-air blankets and the 241* blood/fluid warming set. You can use the Model 750 temperature management unit in all clinical settings including the operating room to provide patient temperature management.

This manual includes operating instructions and unit specifications for the Model 750 temperature management unit. For information about using Bair Hugger blankets or the 241 blood/fluid warming set with the Model 750 temperature management unit, refer to the "Instructions for Use" included with each of these disposable components.

Indications for Use *適應症*

The Bair Hugger Model 750 Total Temperature Management system is intended to prevent and treat hypothermia and to provide warmth to cold or shivering patients. In addition, this system should be used whenever conditions exist that could cause patients to become cold.

Contraindication *禁忌症*

Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury may occur if heat is applied to ischemic limbs.

Warnings *警告*

- Do not warm patients with the temperature management unit's hose alone. Thermal injury may result. Always connect the hose to a Bair Hugger blanket before providing skin-surface warming therapy.
- Use only Bair Hugger disposable components with the Model 750 temperature management unit. This temperature management unit has been designed to operate safely with Bair Hugger disposable components. Use with non-Bair Hugger products may cause thermal injury. To the full extent permitted by law, the manufacturer and/or importer declines all responsibility for thermal injury resulting from the unit being used in conjunction with non-Bair Hugger products.

Specifications

規格

Physical Characteristics

物理特性

DIMENSIONS

12" high x 13.5" deep x 10" wide
30 cm high x 34 cm deep x 25 cm wide

WEIGHT

15.5 lb (7kg)

RELATIVE NOISE LEVEL

53 dBA

HOSE

Flexible, compatible with the Bair Hugger brand 241 blood/fluid warming system.

FILTRATION SYSTEM

0.2 μm air filter

RECOMMENDED FILTER CHANGE

Every 6 months or as needed.

MOUNTING

Can be clamped to an IV pole, placed on a hard surface, or mounted to the rolling stand accessory.

Temperature Characteristics

溫度特性

RECOMMENDED OPERATING ENVIRONMENT

15°C-25°C

TEMPERATURE CONTROL

Electronically controlled.

HEAT GENERATED

1644 BTU/hr (average), 482 W (average)

OPERATING TEMPERATURES

Average temperatures at the end of the hose:
 HIGH: $43^\circ \pm 1.5^\circ\text{C}$ $109.4^\circ \pm 2.7^\circ\text{F}$
 MED: $38^\circ \pm 1.5^\circ\text{C}$ $100.4^\circ \pm 2.7^\circ\text{F}$
 LOW: $32^\circ \pm 1.5^\circ\text{C}$ $89.6^\circ \pm 2.7^\circ\text{F}$

Safety System

安全系統

THERMOSTAT

Independent electronic circuit; thermal cutoff shuts the heater OFF at preset high temperature of $53^\circ \pm 3^\circ\text{C}$ at the end of the hose, back-up over-temperature detection at hose inlet.

ALARM SYSTEM

Over-temperature ($53^\circ \pm 3^\circ\text{C}$): red *Over-temp* indicator light flashes, alarm sounds, heater and blower shut down, operating indicator lights turn OFF, control panel becomes unresponsive.

Fault: amber *Fault* indicator light flashes, alarm sounds, up to three fault codes stored in nonvolatile RAM.

OVERCURRENT PROTECTION

Dual input fused lines.

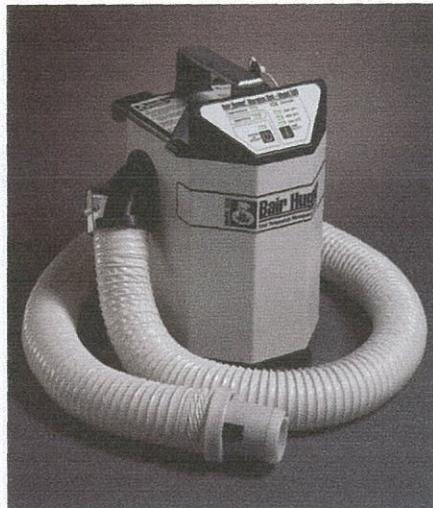
Specifications – Continued

Electrical Characteristics

HEATING ELEMENT	1400 W Resistive
LEAKAGE CURRENT	Meets UL 2601 and EN 60601-1 requirements.
BLOWER MOTOR	Operating speed: approximately 4,000 rpm Airflow: up to 48 cfm or 2,3 l/s
POWER CONSUMPTION	Peak: 1550 W Average: 800 W
POWER CORD	15 ft., SJT, 3 cond., 13 A 15 ft., SJT, 3 cond., 15 A 4.6 m, HAR, 3 cond., 10 A
DEVICE RATINGS	110-120 VAC, 50/60 Hz, 11.7 A, or 220-240 VAC, 50/60 Hz, 7.2 A, or 100 VAC, 50/60 Hz, 14.5 A
FUSES	12 A (110 - 120 VAC) 8 A (220 - 240 VAC) 15 A (100 VAC)
CERTIFICATIONS	EN 60601-1; EN 60601-1-2; UL 2601-1; CAN/CSA-C22.2, No. 601.1, EN 55011
CLASSIFICATION	Classified under EN 60601-1 Guidelines (and other national versions of the Guidelines) as Class I, Type BF, Ordinary equipment. Continuous operation. Not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide. Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 2601-1 and in accordance with Canadian/CSA C22.2, No. 601.1. Classified under the Medical Device (93/42/EEC) as a Class IIb device.
DIAGNOSTICS	A qualified service technician can perform over-temperature detection system testing, temperature output testing, operating temperature calibration, and fault code troubleshooting.

Warming units

Bair Hugger® warming units are the foundation of our forced air warming therapy. Each warming unit is individually tested to ensure years of safe, reliable and effective operation.



Model 505

The standard of excellence in forced air warming units, the Bair Hugger model 505 provides safe, quiet and effective warming to patients around the world.

- Small size gives you more useable work space
- Light weight makes transport and setup a breeze
- Freestanding, or easily attached to IV pole, bedrail or optional rolling stand
- Built-in hour meter makes it easy to monitor usage for preventative maintenance
- Unique snap-fit hose swivels at three points for easy blanket attachment and positioning
- Compatible with 241® blood/fluid warming set — provides two warming therapies with one machine

Specifications

Dimensions:

13" h x 10" w x 11" d (33 x 25 x 28 cm)

Weight:

11.5 lb (5.2 kg)

Operating Temperatures:

High:	43° ± 3°C	109.4° ± 5.4°F
Med:	38° ± 3°C	100.4° ± 5.4°F
Low:	32° ± 3°C	89.6° ± 5.4°F

Leakage Current:

Meets hospital and regulatory standards for leakage current.

Filter:

High-efficiency 0.2 µm filter

Device Ratings:

110-120 VAC, 60 Hz, 9.5 Amperes;
100 VAC, 50/60 Hz, 9.5 Amperes;
220-240 VAC, 50 Hz, 4.5 Amperes

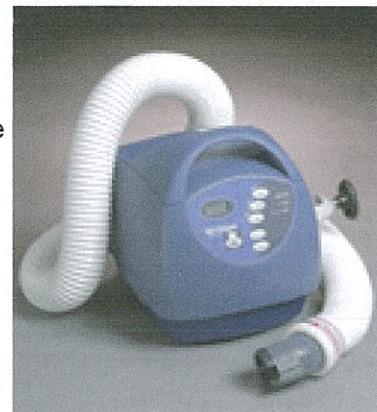


Bair Hugger® Temperature Management

Model 750 - Temperature Management Unit

What do you do when you have the standard to which all other forced-air warming units are compared? Make a better one. Bair Hugger introduces the next generation temperature management unit — the Model 750.

- Hose end temperature sensing and microprocessor control for accurate air temperature delivery
- Increased airflow for quicker response
- 3 temperature sensors for increased accuracy and safety
- Built-in hour meter makes it easy to monitor usage for preventative maintenance
- Temperature settings track and report forced-air warming therapy duration
- Over-temperature, calibration and fault code servicing right on the front panel, no need to open the unit
- Compact and lightweight like its predecessor



Bair Hugger temperature management units are the **ONLY** forced-air warming systems that can be used with an integrated, cost-effective method of fluid warming - The [Bair Hugger 241® fluid warming set](#).

Specifications

Dimensions:

12" h x 10" w x 13.5" d (30 x 25 x 34 cm)

Leakage Current:

Meets regulatory standards for leakage current

Weight:

15.5 lb (7 kg)

Filter:

High-efficiency 0.2 µm filter

Certifications

EN 60601-1, UL 2601-1, CSA C22.2 No. 601.1, EN 60601-1-2

Operating Temperature:

High: $43^\circ \pm 1.5^\circ\text{C}$ ($109.4^\circ \pm 2.7^\circ\text{F}$)
Med: $38^\circ \pm 1.5^\circ\text{C}$ ($100.4^\circ \pm 2.7^\circ\text{F}$)
Low: $32^\circ \pm 1.5^\circ\text{C}$ ($89.6^\circ \pm 2.7^\circ\text{F}$)

Device Rating:

110-120 VAC, 50/60 Hz, 11.7 Amperes
220-240 VAC, 50/60 Hz, 7.2 Amperes

Model 315

Multi-Access Blanket

The multi-access blanket offers you access to any part of the patient's body while providing full patient coverage.

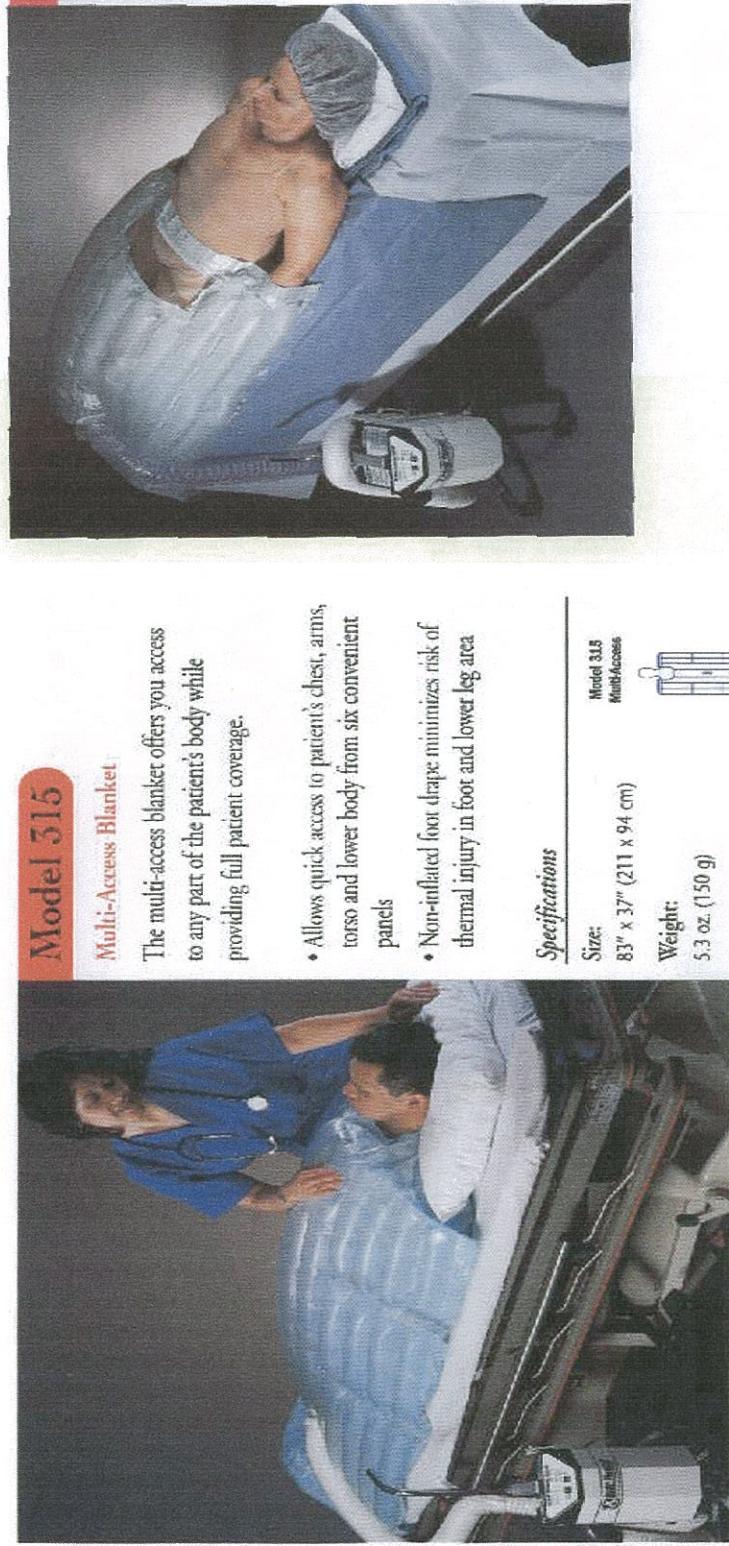
- Allows quick access to patient's chest, arms, torso and lower body from six convenient panels
- Non-inflated foot drape minimizes risk of thermal injury in foot and lower leg area

Specifications

Size:
83" x 37" (211 x 94 cm)

Weight:
5.3 oz. (150 g)

Model 315
Multi-Access



Model 630

Sterile Cardiac Blanket

The cardiac blanket is pre-positioned at the waist during prep, unrolled upon closure of the saphenous vein graft incision, and inflated post-bypass.

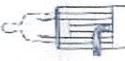
- Warms the lower body to reduce core-to-peripheral heat loss to help you prevent post-bypass after-drop
- Positions easily in the sterile field
- Groin window allows for access to the femoral artery
- Non-inflated foot drape minimizes risk of thermal injury in foot and lower leg area

Specifications:

Size:
60" x 36" (152 x 91 cm)

Weight:
8.0 oz. (227 g)

Model 630
Sterile Cardiac



Model 522

Upper Body Blanket

Designed for use during surgical procedures on the lower half of the body, the upper body blanket covers the upper torso, arms, neck and head of the patient.



- Commonly used in the supine position
- Can also be used with the patient in the prone and lithotomy position
- Two hose inlet ports provide flexibility in positioning the warming unit on either side of the patient
- Attached clear head drape to keep warm air around the intubated patient's head, and provide for visualization by the clinician (where applicable)

Specifications

Size:

24" x 24" (188 x 61 cm)

Weight:

3.5 oz. (99 g) with drape

Head Drape:

18" x 18" (45 x 45 cm)



Tie strips on each side are provided to keep the blanket in place.

Model 525

Lower Body Blanket

The lower body blanket is designed for use primarily during surgery on the upper half of the body.



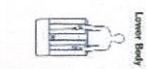
Specifications

Size:

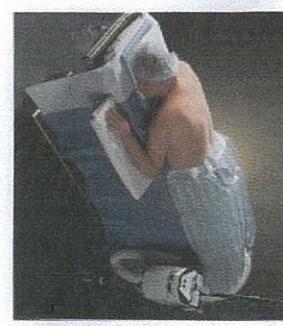
60" x 36" (152 x 91 cm)

Weight:

4.0 oz. (113 g) with drape



Lower body blanket being used with patient in lateral position



Lower body blanket being used with patient in lateral position

製造廠名稱: Arizant Healthcare Inc.
製造廠地址: 10393 West 70th Street, Eden Prairie, MN55344 USA

仿單標籤粘貼表

產品中文名稱	”艾瑞生”熊寶貝溫度管理系統	申請廠商	常玉醫療器材有限公司
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96.11.30



“艾瑞生”熊寶貝溫度管理系統
許可字號：衛署醫器輸字第 012934 號
製造批號：
藥商名稱：常玉醫療器材有限公司
藥商地址：台北縣永和市安樂路 194 巷 39 弄 4 號 3 樓

※ 貼產品之標籤仿單或包裝及實物正背面照片

※ 中文仿單（如背面所列項目）



“艾瑞生”熊寶貝溫度管理系統

“Arizant” Bair Hugger Patient Warming System

耗材 - 溫毯

衛署醫器輸字第 012934 號

使用前請務必詳閱原廠之使用說明書遵照指示使用。

本案產品使用方法、禁忌症、警告及注意事項等請參照原廠資料

■ 產品敘述及用途

Bair Hugger®溫毯是屬於熊寶貝全體加溫管理系統中的耗材配件。此系統產品皆為用來防止非預期之低體溫症的問題。此系統主要是經由加溫器製造暖氣。加溫器的暖氣是經由彈性風管輸送出去。此送風管連接溫毯入口處，視溫毯入口位置在病患上方或下方使其因灌入的暖氣而膨脹。暖氣經由毯子有氣孔的一面與病患直接接觸使病人溫暖。此溫毯系列為一質輕、單次使用無乳膠成份之產品。所有溫毯符合美國 16 CFR 1610 class 1 耐燃測試等級。

目前，溫毯依使用區分五大類：1.常規手術前等待及門診手術病人 2.手術中 3.手術後 4.小兒科 5.特殊用途

● 手術前等待及門診等待期間

此類溫毯通常用門診手術前等候中及常規手術前的等待病人，保溫及增加舒適。這類溫毯可用在病人坐著、半坐臥及仰臥的姿勢。寬大的摺邊可覆蓋住病人的肩膀、軀幹、及腿並且可隨著病人進入恢復室。此產品型號：

1. Model 110 門診手術用溫毯含保暖襪
2. Model 111 門診手術用溫毯

● 手術中

手術中的溫毯用在手術室幫病人加溫用。此類溫毯可提供均勻的暖氣輸送且視不同手術選擇適合款搭配。這系列溫毯有些包含足罩(使用與否，看狀況而定)以防止熱傷害，以及附有透明頭蓋(使用與否，看狀況而定)以保持插管病人頭部周圍充滿暖氣。這類產品型號如下：

1. Model 522 上半身式溫毯
2. Model 525 下半身溫毯
3. Model 540 上半身包覆式溫毯
4. Model 542 雙通口上半身包覆式溫毯
5. Model 610 全身手術用溫毯
6. Model 570 腹部手術用溫毯(中心開口式溫毯)

96. 11. 30

● 手術後

手術後的溫毯可用在術後恢復室中幫病人加溫。此類溫毯能提供均勻暖氣到每個角落及各類術後處置。此溫毯的特點是有足罩覆蓋可降低腳及下肢處的熱傷害。這類產品型號如下：

1. Model 300 全身式溫毯
2. Model 305 胸部式溫毯
3. Model 310 小孩全身式溫毯
4. Model 315 多切式全身式溫毯

● 小兒科

小兒科用毯用在小孩手術中全身加溫。此溫毯可提供新生兒、嬰幼兒或孩童在不同手術、不同姿勢作有效的溫度管理。這類產品型號如下：

1. Model 530 長型小兒全身式溫毯
2. Model 537 小型下半身式溫毯
3. Model 550 大型兒童全身式溫毯墊
4. Model 555 小兒全身式溫毯

● 專業型

專業型溫毯基本上用在心導管室，提供多樣的使用。這系列溫毯包括滅菌及未滅菌型。這類產品型號如下：

1. Model 545 成人用溫毯墊
2. Model 560 U型心導管用溫毯
3. Model 630 無菌開心手術用溫毯
4. Model 635 全通路式溫毯墊
5. Model 645 無菌U型開心手術用溫毯

* 如果主要包裝事先已被打開或損壞的話，請勿使用

■ 適應症

作為病患溫度管理用途。

■ 禁忌症

- 1.如果病患正在執行主動脈阻斷(開心手術)的情形下，下肢血液循環會呈現缺血狀況，不可予以加溫，此舉可能引起熱傷害。
- 2.在延長加溫治療期間不可在無監控系統下離開血流狀態不佳的病患。此舉可能會引起熱傷害。

■ 警告

1. 在延長加溫治療期間不可在無監視下離開血流循環不佳的病患。此舉可能引起熱傷害。

2. 當患者有下列狀態時，請勿在 200 系列加溫器(已停產)上使用 HIGH 溫度設定。

(200 系列加溫器適用 Model 110, 111, 305, 315, 530 之溫毯)

- 1 明顯的周邊血管疾病(阻塞或糖尿病)
- 2 低心輸出量
- 3 活動完全受限
- 4 皮膚呈現不良血液循環(發紫)

至少每 10 到 20 分鐘要監看病患體溫。對於此類病患，需格外注意熱傷害的風險。

3. 請勿將熊寶貝溫毯用於熊寶貝®以外的加溫器使用。此舉可能會引起熱傷害。
4. 勿單獨使用加溫器的送風管來加溫病患。此舉可能會引起熱傷害。提供治療前隨時要附上送風管與溫毯一起使用。
5. 隨時將有孔的一面蓋在病患身上，若將沒有氣孔的一面蓋在病患身上，可能引起熱傷害。
6. 假使警告指示燈亮起來並且警告聲響起時請勿繼續使用。因可能會引起熱傷害。關掉熊寶貝加溫器並且聯絡合格的技術人員。
7. 不適用局部出血的四肢作加溫治療，此舉可能會引起熱傷害。
8. 請避免接觸送風管及病患皮膚中間地帶，此舉可能會引起熱傷害。
9. 請勿在貼有膏藥的地方加熱；此舉恐會增強藥性的傳送，患者傷害或死亡機會。
10. 請勿使用型號 550, 555, 545, 635 的溫毯移動病患，可能會使患者受傷。
11. 超過病患頂端長度的溫毯請勿捲起來，此舉可能會引起熱傷害。
12. 當主動脈氣球幫浦在使用時請勿提供加溫治療；如果熱氣到四肢恐會引起熱傷害。

■ 預防措施

1. 加溫期間不可離開孩童病患使其無人照料。
2. 此溫毯未滅菌且為單一病患使用。在病患和溫毯中間置放一張床單並不能預防產品污染。
滅菌之溫毯僅為 Model 630, 645
3. 至少每隔 10 至 20 分鐘監控病患溫度，並且按時地監看病患的生命徵兆。當加溫的目標達成或發生生命徵兆不穩時，調整氣體溫度或停止加溫治療。生命徵兆不穩定時請立刻通知醫師。
4. 所有產品符合美國 16 CFR 1610 class 1 耐燃測試等級。然而使用高強度熱源時仍請遵照標準安全規範使用。

耗材：溫度管理系統之溫毯

Model	Part No.	品名 (中文/英文)	規 格
315	31500	多切式全身式溫毯 / Multi-Access Blanket	84" x 36" (213 x 91cm)
522	52200	上半身式溫毯 / Upper Body Blanket	74" x 24" (188 x 61cm)
525	52500	下半身式溫毯 / Lower Body Blanket	60" x 36" (152 x 91cm)
110	11000	門診手術用溫毯含保暖襪 / Outpatient blanket w/booties	84" x 36" (213 x 91cm)
111	11101	門診手術用溫毯 / Outpatient Blanket	84" x 36" (213 x 91cm)
300	30000	全身式溫毯 / Full Body Blanket	84" x 36" (213 x 91cm)
305	30500	胸部式溫毯 / Chest Access Blanket	72" x 36" (183 x 91cm)
310	31000	小孩全身式溫毯 / Pediatric Blanket	60" x 36" (152 x 91cm)
530	53000	長型小兒全身式溫毯/Pediatric Blanket Long	74" x 8.5" (188 x 22cm)
537	53700	小型下半身式溫毯/Small Lower Body Blanket	35" x 24" (89 x 21cm)

15
15

40	54000	上半身包覆式溫毯 / Torso Blanket	42" x 36" (107 x 91cm)
542	54200	雙通道上半身包覆式溫毯	42" x 36" (107 x 91cm)
545	54500	成人用溫毯墊 / Adult Underbody Blanket	74" x 36" (188 x 91cm)
550	55000	大型兒童全身式溫毯墊 / Large Pediatric Underbody Blanket	Un-inflated: 60x32 in (152 x 81cm) Inflated: 51x24 in (130x61 cm)
555	55501	小兒全身式溫毯/Pediatric Full Access Blanket	36" x 33" (91 x 84cm) Inflated: 31x29 in (79x74 cm)
560	56000	U型心導管用溫毯/Cath Lab Blanket	9" x 132" (23 x 335cm)
570	57000	腹部手術用溫毯(中心開口式溫毯) / Surgical Access Blanket	84 x 36 in (213 x 91cm)
610	61000	全身手術用溫毯/ Full Body Blanket	72 x 36 in (183 x 91 cm)
630	63000	無菌開心手術用溫毯/ Sterile Cardiac Blanket	60" x 36" (152 x 91cm)
635	63500	全通路式溫毯墊 / Full Access Underbody Blanket	Un-inflated: 84x36 in (221 x 91cm) Inflated: 79x24 in (201x61 cm)
645	64500	無菌 U型開心手術用溫毯/Sterile Cardiac Access Blanket	9" x 108" (23 x 274cm)

製造廠名稱：Arizant Healthcare Inc.

製造廠地址：10393 West 70th Street, Eden Prairie, MN 55344 U.S.A.

藥商名稱：常玉醫療器材有限公司

藥商地址：台北縣永和市安樂路 194 巷 39 弄 4 號 3 樓

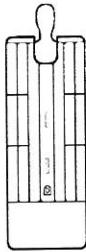


REF 31500
LOT M*****
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(01) 3 0608223 31500 3 (10) M*****



Multi - Access

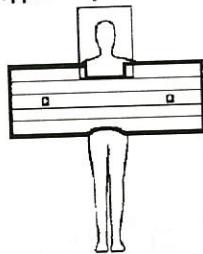


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(01) 3 0608223 31500 3 (10) M*****

CE 0470
200241-D

Upper Body



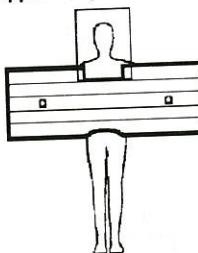
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(01) 3 0608223 52200 5 (10) U*****



CE 0470

Upper Body



REF 52200
LOT U*****
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(01) 3 0608223 52200 5 (10) U*****

CE 0470
200250-D

Lower Body



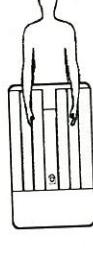
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(01) 3 0608223 52500 6 (10) L*****



CE 0470

Lower Body

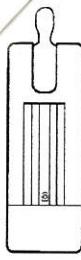


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CE 0470
200251-D

行医

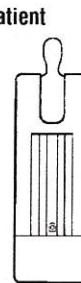


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CE 0470



REF 11101
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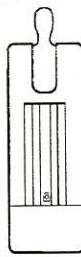
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CE 0470

200451-B
03/02

Outpatient



REF 11000
LOT O****
10

(01) 3 0608223 11000 4 (10) O****



CE 0470

Outpatient



REF 11000
LOT O****
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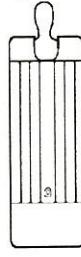
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CE 0470

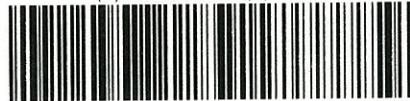
200245-D

Full Body



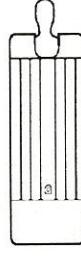
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LOT F****
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(01) 3 0608223 30000 9 (10) F****



CE 0470

Full Body



REF 30000
LOT F****
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(01) 3 0608223 30000 9 (10) F****



CE 0470

200244-D

Chest Access



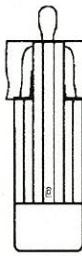
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CE 0470

Chest Access



REF 30500
LOT C****
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(01) 3 0608223 30500 4 (10) C****



CE 0470

200243-D

CE
200243-D
藥

Pediatric

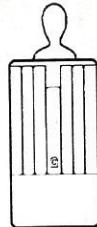


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(01) 3 0608223 31000 8 (10) P****



Pediatric



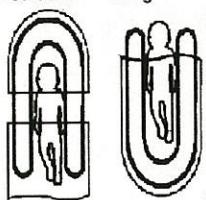
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(01) 3 0608223 31000 8 (10) P****



CE 0470
200242-D

Pediatric - Long



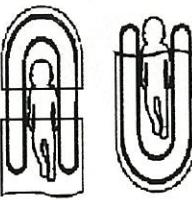
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LOT CL*****
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(01) 3 0608223 53000 0 (10) CL****



CE 0470

Pediatric - Long



REF 53000
LOT CL*****
10

(01) 3 0608223 53000 0 (10) CL****



CE 0470
200246-D

Small Lower Body



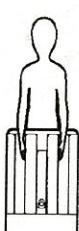
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(01) 3 0608223 53700 9 (10) SL****



CE 0470

Small Lower Body



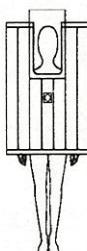
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CE 0470
200249-D

Torso



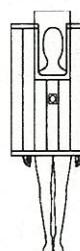
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CE 0470

Torso

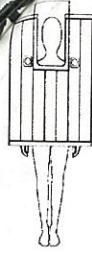


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(01) 3 0608223 54000 9 (10) T****



CE 0470
200252-D



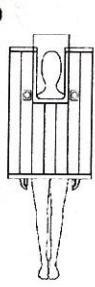
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LATEX



CE 0470

(01) 3 0608223 54200 3 (10) D****



REF 54200
LOT D****
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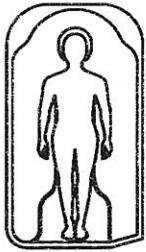
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CE 0470

201543-A
05/04

Adult Underbody



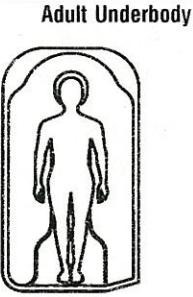
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LATEX



CE 0470

(01) 3 0608223 54500 4 (10) FA****



REF 54500
LOT FA****
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LATEX



CE 0470

200926-D
05/04

Lg Pediatric Underbody



REF 55000
LOT UA****
10

LATEX



CE 0470

(01) 3 0608223 55000 8 (10) UA****

Lg Pediatric Underbody



REF 55000
LOT UA****
10

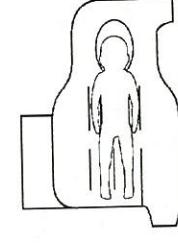
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CE 0470

200902-B
4/04

Pediatric Underbody



REF 55501
LOT PB****
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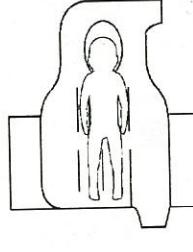
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CE 0470

(01) 3 0608223 55501 0 (10) PB****

Pediatric Underbody



REF 55501
LOT PB****
10

LATEX



CE 0470

200240-E

Cath Lab



REF

56000
CT****

LOT

10

LATEX



(01) 3 0608223 56000 7 (10) CT****

CE 0470



Cath Lab



REF
LOT

56000
CT****

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LATEX

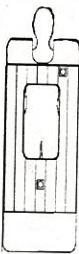


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CE 0470

560012-D

Surgical Access



REF

57000
SA****

LOT

10

LATEX



(01) 3 0608223 57000 6 (10) SA****

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Surgical Access



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LOT

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SA****

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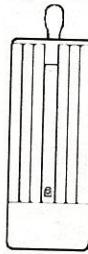


(01) 3 0608223 57000 6 (10) SA****

CE 0470

200286-C
02/06

Full Body Surgical



REF

61000
FC****

LOT

10

LATEX



(01) 3 0608223 61000 9 (10) FC****

CE 0470



Full Body Surgical



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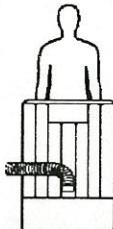


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200248-D

Cardiac



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63000
CB****

LOT

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STERILE EO

LATEX

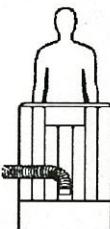


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CE 0470



Cardiac



REF
LOT

63000
CB****

5

YYYY-MM

STERILE EO

LATEX



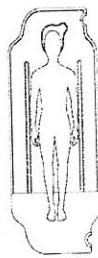
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CE 0470

630019-F

15
政

Full Access Underbody



REF **63500**

LOT **R******

5

NOT STERILE

LATEX

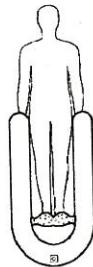


(01) 3 0608223 63500 2 (10) R****



CE 0470

Cardiac Access



REF **64500**

LOT **CC******

5

YYYY-MM

STERILE EO

LATEX

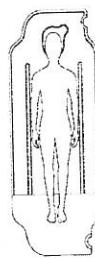


(01) 1 0608223 64500 7 (10) CC****



CE 0470

Full Access Underbody



REF **63500**

LOT **R******

5

NOT STERILE

LATEX



(01) 3 0608223 63500 2 (10) R****



CE 0470

201116-D
07/07

Cardiac Access



REF **64500**

LOT **CC******

5

YYYY-MM

STERILE EO

LATEX



(01) 1 0608223 64500 7 (10) CC****



CE 0470

645012-E

中文
稿來源

BAIR HUGGER BLANKETS

PRODUCT DESCRIPTION and INTENDED USE

The Bair Hugger® Blankets are part of the Bair Hugger brand Total Temperature Management System®. The Bair Hugger brand Total Temperature Management System is a group of products that are designed to prevent unintended hypothermia. A warming unit forms the base of the system by generating warmed air. The warmed air is transferred from the warming unit through a flexible hose. The hose is connected to an inflatable blanket positioned over, under or around the patient. The warm air is then passed through perforations on the underside of the blanket (that is, the side facing the patient's skin), warming the patient. The blankets are a lightweight, single use and latex free product. All blankets are classified as Class I Normal Flammability as defined by 16 CFR 1610.

Currently, there are 5 categories of blankets:

1. Pre-Op and Outpatient
2. Intraoperative
3. Postoperative
4. Pediatric
5. Specialty

Pre-Op and Outpatient Blankets

The pre-op and outpatient blankets are typically used for prewarming and to enhance patient comfort during outpatient procedures or before surgery. The blankets conform to the patient in the seated, semi-reclined or supine position. There is ample draping that tucks around the shoulders, torso, and legs for easy positioning and the blanket can follow the patient into recovery for additional thermal comfort. Models in this line are:

1. Model 110 Outpatient with Booties
2. Model 111 Outpatient

Intraoperative

The intraoperative blankets are typically used for warming patients in the operating room. The blankets are designed to provide even heat distribution in a variety of positions and during various surgical procedures. Some of the features of this line include non-inflated foot drapes (where applicable) to guard against thermal injury and attached clear head drapes (where applicable) to keep warm air around the intubated patient's head. Models in this line are:

1. Model 522 Upper Body
2. Model 523 XL Upper Body
3. Model 525 Lower Body
4. Model 540 Torso
5. Model 542 Dual Port Torso
6. Model 610 Full Body Surgical
7. Model 570 Surgical Access

Postoperative

The postoperative blankets are typically used for warming patients in the Post Anesthesia Care Unit. The blankets are designed to provide even heat distribution in a variety of positions and during various post surgical procedures. All the blankets in this line feature non-inflated foot drapes to guard against thermal injury to the foot and lower leg area. Models in this line are:

1. Model 300 Full Body
2. Model 305 Chest Access
3. Model 310 Pediatric
4. Model 315 Multi-Access

Pediatric

The pediatric blankets are used for warming pediatric patients throughout the perioperative setting. Pediatric blankets provide effective temperature management for the neonate, infant or child and are designed for use in a variety of positions and during various perioperative procedures. Models in this line are:

1. Model 530 Pediatric Long
2. Model 537 Small Lower Body
3. Model 550 Large Pediatric Underbody
4. Model 555 Pediatric Underbody

Specialty

The specialty blankets are typically used in a variety of cardiac procedures and allow easy access for multiple positions. This line of blankets includes sterile blanket models and non-sterile models. Models in this line are:

1. Model 545 Adult Underbody
2. Model 560 Cath Lab
3. Model 630 Sterile Cardiac
4. Model 635 Full Access Underbody
5. Model 645 Sterile Cardiac Access

Pre-Op and Outpatient Care

Warming patients for 30 minutes prior to surgery has been shown to add enough heat to maintain normothermia during short (less than two hours) surgical procedures.⁴



Model 110

Outpatient Blanket with booties

The Bair Hugger outpatient blanket makes it easy to give your patients the benefit of prewarming and enhance patient comfort during outpatient procedures.

- Conforms to the patient in seated, semi-reclined, or supine position
- Bair Hugger booties to cover the patient's feet are included with each blanket
- Ample draping tucks around shoulders, torso, and legs for easy positioning
- Blanket can follow patient into recovery for additional thermal comfort
- Natural latex-free, lightweight, and disposable

Specifications

Size

84 x 36 in [213 x 91 cm]

Weight [with booties]

5.6 oz [157 g]



Model 111

Outpatient Blanket

The Bair Hugger outpatient blanket makes it easy to give your patients the benefit of prewarming and enhance patient comfort during outpatient procedures.

- Conforms to the patient in seated, semi-reclined, or supine position
- Ample draping tucks around shoulders, torso, and legs for easy positioning
- Blanket can follow patient into recovery for additional thermal comfort
- Natural latex-free, lightweight, and disposable
- Non-inflated foot drape minimizes risk of thermal injury to feet and lower leg area

Specifications

Size

84 x 36 in [213 x 91 cm]

Weight

4.8 oz [134 g]



⁴ Seiler LH, Schreider M, Merrifield B, Matsukawa T, Cheng C. Optimal Duration and Temperature of Prewarming. *Anesthesia & Analgesia*. Nov 1995; 81(5):1251-1255.



Model 522

Upper Body Blanket

Designed for use during surgical procedures on the lower half of the body. The upper body blanket covers the upper torso, arms, neck, and head of the patient.

- Commonly used in the supine position
- Can also be used with the patient in the prone and lithotomy position
- Two hose inlet ports provide flexibility in positioning the temperature management unit on either side of the patient
- Patented attached clear head drape keeps warm air around the intubated patient's head and provides for visualization by the clinician

Specifications

Size
74 x 24 in [188 x 61 cm]

Weight
3.5 oz [99 g]

Head Drape
24 x 24 in [61 x 61 cm]



This blanket may be rolled and tucked to accommodate various patient positions

Tie strips on each side are provided to keep the blanket in place

Model 540

Torsa Blanket

The torso blanket is designed to affix to the lower abdominal area and to cover the upper half of the body.

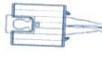
- Effectively used for patients in the supine, lateral, or prone position
- Attached clear head drape keeps warm air around the intubated patient's head and provides visualization by the clinician

Specifications

Size
42 x 36 in [107 x 91 cm]

Weight
3.2 oz [90 g]

Head Drape
24 x 24 in [61 x 61 cm]



Model 542

Dual Port Torsa Blanket

The torso blanket is also available in a two-hose port configuration.

Specifications

Size
42 x 36 in [107 x 91 cm]

Weight
3.2 oz [90 g]

Head Drape
24 x 16 in [61 x 41 cm]



Model 525

Lower Body Blanket

The lower body blanket is designed for use during surgery on the upper half of the body.

- Effectively used on patients in the supine, lateral, or prone position
- Foot drape minimizes risk of thermal injury in foot and lower leg area

Specifications

Size

60 x 36 in [152 x 91 cm]

Weight

4.0 oz [113 g]



Lower body blanket being used on patient in lateral position

Model 610

Full Body Surgical Blanket

The full body surgical blanket is designed for procedures on the head and neck. This lightweight blanket tapes across the patient's chest, providing a barrier to surgical sites involving the head or neck.

- Foot drape minimizes risk of thermal injury to feet and lower leg area
- Six convenient access panels allow for quick access to patient's chest, arms, and lower body

Specifications

Size

72 x 36 in [183 x 91 cm]

Weight

4.8 oz [134 g]



- Six convenient access panels allow for quick access to patient's chest, arms, and lower body

Model 570

Surgical Access Blanket

This unique blanket is designed to be used for many surgical procedures, including but not limited to: laminectomies, spinal procedures, abdominal procedures, and transplants.

- Two hose inlet ports provide flexibility in positioning the temperature management unit on either side of the patient
- Attached clear head drape keeps warm air around the intubated patient's head and provides for visualization by the clinician
- Large surgical access window (13.5 x 22 in) (34 x 56 cm)
- Adhesive strips on patient side designed to minimize airflow into sterile field
- Non-inflated foot drape designed to protect feet from thermal injury

Specifications

Size

84 x 36 in [213 x 91 cm]

Weight

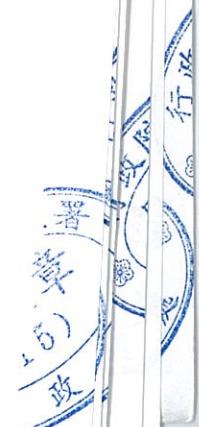
6.4 oz [181 g]

Head Drape

24 x 16 in [61 x 41 cm]



Lower body blanket being used on patient in prone position



Model 315

Multi-Access Blanket

The multi-access blanket offers access to any part of the patient's body while providing full patient coverage.

- Allows quick access to patient's chest, arms, torso, and lower body from six convenient panels
- Non-inflated foot drape minimizes risk of thermal injury to feet and lower leg area

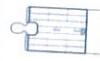
Specifications

Size

84 x 36 in (213 x 91 cm)

Weight

5.3 oz (150 g)



Model 305

Chest Access Blanket

The chest access blanket is designed specifically for the thoracic surgery patient.

- Chest drapes provide clear, easy viewing of the chest area
- Non-inflated foot drape minimizes risk of thermal injury to feet and lower leg area

Specifications

Size

72 x 36 in (183 x 91 cm)

Weight

4.7 oz (133 g)

Drape [2]

24 x 24 in (61 x 61 cm)



Specifications

Size

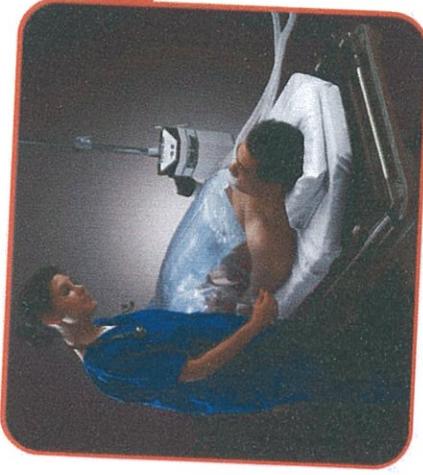
72 x 36 in (183 x 91 cm)

Weight

4.7 oz (133 g)

Drape [2]

24 x 24 in (61 x 61 cm)



Model 300

Full Body Blanket

The full body blanket covers the entire patient.

- Facilitates maximum thermal transfer with a blanket that "hugs" the patient
- Non-inflated foot drape minimizes risk of thermal injury to feet and lower leg area
- Soft and comfortable next to the patient's skin

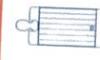
Specifications

Size

84 x 36 in (213 x 91 cm)

Weight

5.1 oz (145 g)



Model 310

Pediatric Blanket

The pediatric blanket is a smaller version of the full body blanket, providing warmth to smaller patients during recovery.

- Non-inflated foot drape minimizes risk of thermal injury to feet and lower leg area

Specifications

Size

60 x 36 in (152 x 91 cm)

Weight

4.8 oz (134 g)



Model 530

Long Pediatric Blanket

This blanket gently surrounds the child with temperature-controlled air. Use of one or two of the enclosed clear plastic drapes keeps warmed air near the skin.

Specifications

Size	24 x 8.5 in [68.8 x 22 cm]
Weight	1.0 oz [28 g]
Drape [2]	



Model 536

Short Pediatric Blanket

Similar to model 530, but just 36 inches long and with only one drape.

Specifications

Size	37 x 8.5 in [94 x 22 cm]
Weight	0.5 oz [14 g]
Drape	



Model 555

Pediatric Underbody Blanket

The design of the pediatric underbody blanket warms even the tiniest of patients while allowing full access for surgeons and staff.

- Fluid outlets minimize pooling of fluids on the blanket's surface
- Two drapes (included) form a "tent" of warm air that surrounds the intubated patient
- Hose ports at either end of blanket provide options for hose placement
- Tape and tuck flaps provide stability by securing the blanket to the OR/procedure table

Specifications

Size	24 x 38 in [61 x 46 cm]
Weight	3.0 oz [85 g]
Drape [2]	

Specifications

Size	Un-inflated: 35 x 33 in [91 x 84 cm] Inflated: 31 x 29 in [79 x 74 cm]
Weight	3.0 oz [85 g]
Drape [2]	

Model 537

Small Lower Body Blanket

A smaller version of the model 525 lower body blanket; this blanket is ideal for warming the large child or small adult during upper body surgery. It can be used in the supine, lateral, or prone position.

- Can also be used as a full body blanket on smaller patient
- Non-inflated foot drape minimizes risk of thermal injury to feet and lower leg area

Specifications

Size	24 x 24 in [61 x 61 cm]
Weight	1.5 oz [43 g]
Drape [2]	

Model 550

Large Pediatric Underbody Blanket

The under-patient design of the large pediatric underbody blanket conveniently warms the large child or small adult patient while allowing full access for surgeons and staff.

- Fluid outlets minimize pooling of fluids on the blanket's surface
- Two drapes (included) help retain the warm air that surrounds the patient
- Hose ports at either end of blanket provide options for hose placement
- Tape and tuck flaps provide stability by securing the blanket to the OR/procedure table

Specifications

Size	Un-inflated: 60 x 32 in [152 x 81 cm] Inflated: 51 x 24 in [130 x 61 cm]
Weight	4.8 oz [136 g]
Drape [2]	

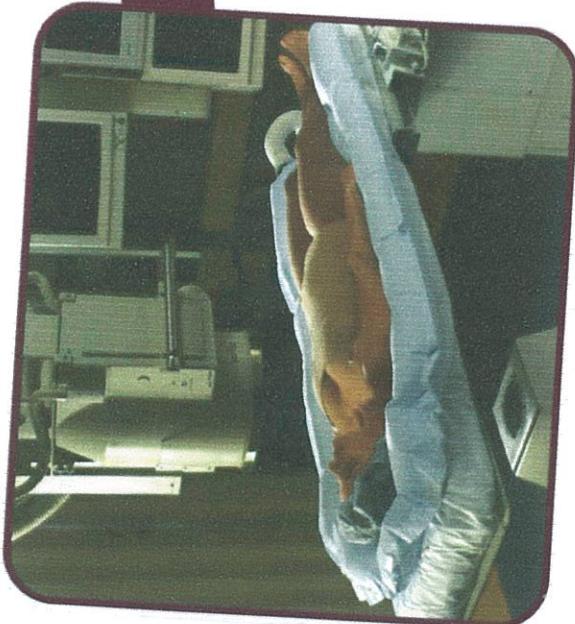


Model 545

Adult Underbody Blanket

The adult underbody blanket is conveniently positioned on the table before the patient arrives in the cath lab procedure suite. It's ready when you are.

- Fluid outlets minimize pooling of fluids on the blankets surface
- Underbody design warms the patient while allowing full access to the patient
- Unrestricted access to the femoral artery
- Radiolucent materials accommodate imaging requirements
- Non-inflated area at the foot of the blanket protects the feet from thermal injury



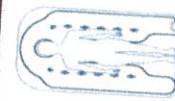
Specifications

Size

Un-inflated: 74 x 36 in [188 x 91 cm]
Inflated: 67 x 28 in [170 x 71 cm]

Weight

5oz [142 g]



Model 560

Cath Lab Blanket

The cath lab blanket, designed for use in the Cardiac Cath Lab, surrounds the patient with warm air and allows unrestricted access to the femoral artery.

- Radiolucent materials
- Tie strips keep blanket positioned securely around patient
- Foot pad protects feet from thermal injury

Specifications

Size	Weight
9 x 132 in [23 x 335 cm]	3.0 oz [85 g]



Model 646

Sterile Cardiac Access Blanket with Hose

The cardiac access blanket helps prevent unintended hypothermia and allows unrestricted access to the patient.

- Warms the lower body to reduce core-to-peripheral heat loss
- Provides localized warming to the legs throughout the procedure
- Allows full access to both legs



Model 645

Sterile Cardiac Access Blanket

The cardiac access blanket helps prevent unintended hypothermia and allows unrestricted access to the patient.

- Warms the lower body to reduce core-to-peripheral heat loss
- Provides localized warming to the legs throughout the procedure
- Allows full access to both legs
- Insulated pouch protects feet from thermal injury



Specifications

Size	Weight
9 x 108 in [23 x 274 cm]	8.0 oz [227 g]



Specifications

Size	Weight
9 x 108 in [23 x 274 cm]	4.0 oz [113 g]



Specialty Blankets - Cardiac Blankets

Help protect your patients from the adverse affects of unintended hypothermia.



Model 630 ✓

Sterile Cardiac Blanket

The cardiac blanket is pre-positioned at the waist during prep, unrolled upon closure of the saphenous vein graft incision, and inflated post-bypass.

- Warms the lower body to reduce core-to-peripheral heat loss
- Positions easily in the sterile field
- Groin window allows for access to the femoral artery
- Non-inflated foot drape minimizes risk of thermal injury to feet and lower leg area
- 36 inch sterile hose allows placement of temperature management unit further from sterile field



Specifications

Size

60 x 36 in [152 x 91 cm]

Weight

8.0 oz [227 g]

Hose

36 in [91 cm]



Model 635 ✓

Full Access Underbody Blanket

The full access underbody blanket is positioned on the procedure table before the patient arrives in the room. This revolutionary design delivers the clinical flexibility needed for cardiothoracic and other complex surgical procedures. This advanced blanket design can be used for patients in the supine, lateral or prone positions.

- Pass-through slit design allows for flexible patient positioning and accommodates the use of a drawsheet*
- Fluid outlets minimize pooling of fluids on the surface of the blanket
- Outer edges of blanket draw up next to the patient to surround them in warmth
- Perforated area at head of blanket can be removed to accommodate a full prone position
- Tape and tuck flaps provide stability by securing the blanket to the OR table
- Hose ports at either end of the blanket provide options for hose placement
- Foot pad protects feet from thermal injury

Specifications

Size

Un-inflated: 79 x 24 in [201 x 61 cm]
Inflated: 79 x 24 in [201 x 61 cm]

Weight

7 oz [198 g]

Drape

24 x 24 in [61 x 61 cm]



* Drawsheet not included

Bair Hugger® Blanket

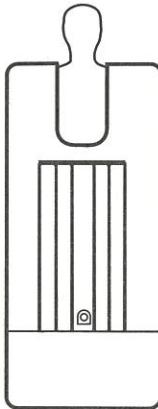


Preoperative
for patient temperature management

(01)00608223110003



Arizant
Healthcare
bright ideas that work



**REF 11000
with booties**

REF 11101

NOT STERILE

Model 110/111 Outpatient

Use only with a Bair Hugger temperature management unit.

Caution: Federal Law (USA) restricts this device to sale by or on order of a licensed healthcare professional.

Do not use if primary packaging has been previously opened or is damaged.

Bair Hugger Decke zur Regelung der Körpertemperatur bei Patienten
Präoperativ • Modell 110 Ambulanz • NICHT STERIL • Nicht verwenden,
wenn die innere Verpackung vorher geöffnet oder beschädigt worden ist.

Couverture Bair Hugger pour le traitement thermique des patients
Préopératoire • Modèle 110 Chirurgie ambulatoire • NON STÉRILE
Ne pas utiliser si l'emballage primaire est ouvert ou endommagé.

Coperta Bair Hugger per la gestione della temperatura corporea del
paciente • Preoperatoria • Coperta per uso ambulatoriale Modello 110
NON STERILE • Non utilizzare il prodotto se la confezione interna è stata
aperta o se è danneggiata.

Manta Bair Hugger para el control de la temperatura corporal del paciente
Preoperatoria • Modelo 110 para pacientes ambulatorios • NO ESTERILIZADA • No usar si el embalaje primario viene abierto o está dañado.

Manta Bair Hugger para controlar a temperatura do paciente
Pré-operatória • Modelo 110 para paciente em ambulatório • NÃO ESTÉRIL • Não utilize se o acondicionamento primário se encontrar
aberto ou danificado.

Bair Hugger deken voor temperatuurregeling bij patiënten
Pre-operatief • Model 110 Polikliniek • NIET STERIEL • Niet gebruiken
als de verpakking eerder geopend of beschadigd is.

Bair Hugger tæppe til varmometerapi
Præoperativ • Model 110 til ambulant behandling • IKKE STERILT • Må
ikke anvendes hvis emballagen er brudt eller beskadiget.

Bair Hugger täcke för temperaturkontroll av patient
Preoperativ • Modell 110 till poliklinisk bruk • EJ STERILT • Öppet
eller skadat paket får ej användas.

Bair Hugger-teppe til temperaturbehandling av pasienter
Preoperativ • Modell 110 til poliklinisk bruk • IKKE STERILT • Produktet
skal ikke brukes hvis emballasjen er skadet eller har vært åpen.

Bair Hugger -peite potilaan kehon lämpötilan säätelyyn
Käytetään ennen leikkausta • Malli 110, esilämmityspeite • EPÄSTERIILI
Älä käytä, jos pakkauks on avattu tai vaurioitunut.

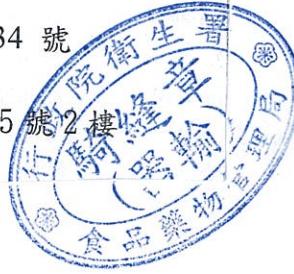
Bair Hugger ウォーミングカバー 患者体温管理用
外科手術前・モデル110・外来患者用ウォーミングカバー・
非滅菌・主要パッケージが既に開封または破損している
場合は、使用しないで下さい。

CE 0470

醫療器材仿單標籤粘貼表

產品中文名稱	“艾瑞生” 熊寶貝溫度管理系統 "Arizant" Bair Hugger Patient Warming System	申請廠商	常玉醫療器材有限公司
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“艾瑞生” 熊寶貝溫度管理系統
"Arizant" Bair Hugger Patient Warming System
型號：775
製造廠名：Arizant Healthcare Inc.
製造廠址：10393 West 70th Street Eden Prairie, MN
55344 U.S.A
製造日期：
製造批號：
許可證字號：衛器醫輸 字第 012934 號
藥商名稱：常玉醫療器材有限公司
藥商地址：台北縣中和市建八路 165 號 2 樓



- ※ 裝訂原廠之仿單、使用說明書及其中文仿單稿、最小包裝、標籤
- ※ 中文仿單稿包括適應症、禁忌症、型號（規格）、產品說明及注意事項等敘述，最後段須加刊
 製造廠名稱、地址及藥商名稱、地址，如有附件、配件請一併列明
- ※ 仿單標籤等實物過大或印於玻璃金屬容器等不便於黏貼時可將照相影本代替黏貼報核

“艾瑞生”熊寶貝溫度管理系統
“Arizant” Bair Hugger Patient Warming System

衛署醫器輸字第 012934 號

使用前請務必詳閱原廠之使用說明書遵照指示使用。
本案產品使用方法、禁忌症、警告及注意事項等請參照原廠資料。

型號 775

產品敘述及應用

熊寶貝全體加溫管理系統是由麻醉醫師為防止和處理常見且重要的低體溫症的問題而發展出此系列產品。熊寶貝全體加溫管理系統目前應用在麻醉照護單位(PACU)，恢復室(POR)，手術室(OR)，急診(ER)，產房(DR)及加護單位(ICU)等醫療照護單位。此加溫系統透過空氣過濾器引用周圍的空氣並予以加溫至選擇的特定溫度。經由加溫器配置的軟管將加溫的暖空氣輸送至使用在病人身上的熊寶貝溫毯。適當地使用此系統時，熊寶貝溫毯會均勻地將暖空氣包覆在病人周圍形成一個溫暖的空間。

熊寶貝全體加溫管理系統包括熊寶貝拋棄式耗材及熱空氣式加溫器組。

熊寶貝溫毯是由長條管行通道輸送管控的暖氣。溫毯設計可圍裹病人。溫毯有各種不同的設計供特定用途使用。

適應症

- 體溫低於 36°C
- 病人發抖
- 病人喊冷不適

此系統適用在低溫處於寒冷或發抖狀態之病人給予溫暖。另外，此系統可以應用在任何導致病患低溫之狀況。

規格

物理特性

尺寸	13英寸高 x 13英寸長 x 14英寸寬 33公分高 x 33公分長 x 36公分寬
重量	16 磅 (7.3公斤)
相對噪音水準	53分貝 (高速運轉風扇模式) 48分貝 (低速運轉風扇模式)
充氣管	有彈性並與Bair Hugger 牌241血液 (液體) 加溫器相容。
過濾系統	0.2μm空氣濾網
建議空氣濾網更換週期	每使用6個月或500小時更換一次。
安裝	可以夾在輸液架上、放置在硬質表面或固定推車上。

溫度特性

推薦的操作環境	15 °C - 25 °C
溫度控制	電子控制。
產生的熱量	高速運轉風扇模式： 1600 BTU/小時 (平均產生的熱量值) ， 470 W (平均值) 低速運轉風扇模式： 1330 BTU/小時 (平均值) ，390 W (平均值)
操作溫度	充氣管端的平均溫度： 高：43 °C ± 1.5 °C 109.4 °F ± 2.7 °F 中：38 °C ± 1.5 °C 100.4 °F ± 2.7 低：32 °C ± 1.5 °C 89.6 °F ± 2.7 °F

安全系統

恒溫器	獨立的電子電路；溫度保險絲關閉加熱器，以確保充氣管端的空氣保持在低於56 °C (53 °C± 3 °C，常態)；在充氣管入口有備用超溫檢測。
警報系統	溫度過高 (≤56 °C, 53 °C ± 3 °C，常態設置)：紅色 超溫指示燈閃爍，警示器發出聲音，加熱器和吹風器關閉，操作指示燈關閉，控制面板進入無應答狀態。
	故障：黃色故障指示燈閃爍，警示器發出聲音。

過電保護

雙輸入保險絲的電路。

電氣特性

加熱元件 1400 瓦電阻

洩漏電流 符合UL 60601-1和IEC 60601-1的要求。

風機電機 運行速度： 4700 rmp (高速運轉風扇模式) ,
4100 rmp (低速運轉風扇模式)
氣流： 可達48 cfm 或 23 L/s

功率消耗 峰值： 1500W
平均值： 800W

電源線 15 英尺、SJT、3芯、13 A ,
15 英尺、SJT、3芯、15 A ,
4.6 m、HAR、3 芯、10 A

設備等級 110-120 VAC、50/60 Hz、11.7 A或220-240 VAC、50/60
Hz、7.2 A或100 VAC、 50/60 Hz、15 A

保險絲 12 A (110 - 120 VAC)
8 A (220 - 240 VAC)
15 A (100 VAC)

製造廠名稱：Arizant Healthcare Inc.

製造廠地址：10393 West 70th Street Eden Prairie, MN 55344 U.S.A.

藥商名稱：常玉醫療器材有限公司

藥商地址：台中縣中和市建八路 165 號 2 樓





Bair Hugger® Therapy Temperature Management Unit

Model 775

15



Quiet. Adjustable. Safe. Effective.
It's everything you want from your forced-air warming unit...and more.



Quiet, adjustable warming options for all Bair Hugger® blanket styles



Arizant Healthcare introduced forced-air warming to the world in 1987 with the launch of Bair Hugger therapy. Since that time, our Bair Hugger warming units and blankets have safely and effectively warmed more than 110 million patients.

Our latest advancement in forced-air warming – **the Bair Hugger Model 775 temperature management unit** – is the future gold standard in patient warming. It offers adjustable airflow, precise temperature delivery and ease of use from a single, quiet warming unit.

Two airflow settings and hose-end temperature sensing ensure precise temperature delivery and compatibility with all Bair Hugger blanket styles – pediatric to adult.

Three temperature sensors and adjustable airflow provide safe, quick temperature response and greater heat transfer.

The Model 775 can track and report forced-air warming therapy duration, over-temperature information, calibration, built-in hour meter and fault codes all via the front panel – no need to open the unit.

Accessories for the Model 775 warming unit allow the unit to be mounted on a hard surface, an IV pole, bed rail or rolling cart.

Specifications

Dimensions

13'h x 14'w x 13'd (33h x 35w x 33d cm)

Weight

16 lb (7.3 kg)

Operating Temperatures

High: $43^\circ \pm 1.5^\circ\text{C}$ ($109.4^\circ \pm 2.7^\circ\text{F}$)
Med: $38^\circ \pm 1.5^\circ\text{C}$ ($100.4^\circ \pm 2.7^\circ\text{F}$)
Low: $32^\circ \pm 1.5^\circ\text{C}$ ($89.6^\circ \pm 2.7^\circ\text{F}$)

Fan Speeds and Relative Noise

High Fan Setting: 37 CFM (53 dBA)
Low Fan Setting: 32 CFM (48 dBA)

Ordering Information

Bair Hugger Model 775 Temperature Management Unit

Leakage Current

Meets UL 60601-1 and IEC 60601-1 requirements.
EN 60601-1-2; CAN/CSA-C22.2,
No. 601.1, EN 55011; ASTM F2196-02

Safety Systems:

Audible and visual alarms;
Over-temperature $\leq 56^\circ\text{C}$, $53^\circ\text{C} \pm 3^\circ\text{C}$ typical

Filter

High-efficiency 0.2 μm filter

Device Ratings

110-120 VAC, 50/60 Hz, 11.7 Amperes
220-240 VAC, 50/60 Hz, 7.2 Amperes
100 VAC, 50/60 Hz, 14.5 Amperes

Arizant
Healthcare

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**To order, please contact your Arizant Healthcare Inc. representative or
call 1-800-733-7775.**