

Ordering Information

Code No	Description	Shipping Unit
5050	A-V Impulse System® Controller	1 each

Impad® Foot Cover

5055	Regular Size, Fits Left and Right	4 pairs/case
5075	Large Size, Fits Left and Right	4 pairs/case

Impad Sterile Foot Cover

5066	Regular Size, Fits Right	4 eaches/case
6057	Regular Size, Fits Left	4 eaches/case

Impad Under-Cast Inflation Pad

5087	Right Foot	12 eaches/case
5099	Left Foot	12 eaches/case

Impad Hand Cover

5082	Right Hand	4 eaches/case
6083	Left Hand	4 eaches/case

Air Supply Hose

5047	Hose Assembly	1 each
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Impad Rigid Sole Foot Cover Sizing Chart

	REGULAR	LARGE
Women's shoe size	5 1/2 - 9	9 1/2 - 11 1/2
Men's shoe size	6 1/2 - 9	8 1/2 - 12 1/2

Note: For Impad Under-Cast Inflation Pads, use size fits all.

Distributed by: **KENDALL**

Healthcare

Mansfield MA 01948

Kendall Customer Service 1-800-421-8168

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FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

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NOVA-METRIC
A-V Impulse Systems®
MODEL 6060

OPERATOR'S INSTRUCTION MANUAL
FOR CONTROLLER AND ACCESSORIES

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Safety Notes

WARNING: Disassembly of the controller must only be carried out by EMD trained and qualified personnel. Remove all electrical sparks, wires, or the controller and disconnect from the power supply before cleaning, re-assembly or repair. The 6 pin communication port on the rear of the controller is for use by Kendall authorized service personnel ONLY and MUST only be connected to a fibre optic serial data converter. For more information contact Kendall Customer Service 1-800-431-8265.

DANGER: This system is not explosion proof and must not be used in the presence of flammable anesthetics or other gases.

DANGER: This system should not be used on wet surfaces, nor while the patient is bathing or otherwise in contact with water.

DANGER: Switch off the controller, and disconnect from power supply before cleaning, re-assembly or repair.

Specifications

All values stated are nominal.

A-V Impulse System Controller

Height	6.4in (16.2cm) overall	Depth	10.2in (26.0cm) overall
Width	9.2in (23.4cm)	Weight	7.5lb (3.4kg)
Electrical Supply	120V 0.6A 60Hz		
Fuses	T1A x 20mm (Airtight)		

The Controller is built and tested to IEC 60601-1.

Performance

Output Impulse Pressure: 60 to 200 mmHg adjustable through + and – buttons.

Impulse Duration: 1 or 3 seconds adjustable through PRESSURE buttons.

Cycle Time: Impulse delivered every 20 seconds in default, adjustable from 12 to 50 seconds through CYCLE buttons.

Maintenance

CLEANING

InPad foot cover (non-sterile or sterile), Hand Cover and Under-Cast Pad
InPad inflation pads are supplied in individually sealed packages. They are for single patient use only and are not reusable or reprocessible.

Controller

WARNINGS: Before beginning cleaning procedures, the equipment MUST be switched off and disconnected from the power supply.

Cleaning can be carried out using a mild soap solution, antiseptic or disinfectant wipes. Care must be taken to avoid excessive moisture on the controller case.
NO solvent based cleaning materials should be used. Liquids must NOT be sprayed through the air vents.

The A-V Impulse System controller cannot be effectively sterilised by liquid immersion, autoclaving or ETO sterilisation methods as irreparable damage will occur.

FAULT CONDITIONS

If the unit does not operate when power is switched on, check that there is electrical supply to the unit. Check the fuses on the rear panel and replace if necessary with fuses of the correct value and type.

REPAIRS

In the event of any problem occurring with this equipment, contact your local representative for the proper return procedure and prompt replacement or call Kendall Customer Service at 1-800-421-8268.

The Company accepts responsibility for the effects of safety, reliability and performance only if repairs, modifications or repairs are carried out by an authorised Kendall Service Department, and the equipment is used in accordance with the Instruction Manual.

Introduction

The veins in the sole of the foot act as a very powerful natural blood pump during weight bearing and walking. Upon weight bearing, the veins in the foot are forcibly emptied into the deep veins of the leg. The blood flow generated is highly pulsatile and is so powerful that it can overcome a cuff inflated to 100 mmHg. This action alone is sufficient to return blood from the foot to the right atrium of the heart in the upright position. A similar pumping mechanism exists in the palm and back of the hand. These important physiological processes led to the design of the A-V Impulse System Controller and Accessories.

The A-V Impulse System has been developed to mimic the natural effects of walking on the circulation of blood in the legs. For the patient who is immobile or partially mobile as a result of trauma, surgery or pathology, the system has been shown to increase substantially the circulation of blood in the legs. The A-V Impulse System can also enhance circulation in the arms by applying impulse compression to the hand. Venous stasis is accepted as being a major factor in the development of deep vein thrombosis. The A-V Impulse System has been shown to be highly effective in increasing the circulation of blood in patients with restricted mobility. It provides great benefits by reducing pain and swelling after injury and surgery, by preventing venous stasis and its associated complications and can assist in many situations where medical judgement assesses the need for improved blood circulation.

The maintenance of blood circulation in the extremities is essential in the traumatic patient. The A-V Impulse System achieves this simply, safely and effectively.

The A-V Impulse System

The A-V Impulse System Model 8060 uses state-of-the-art microprocessor controls and a liquid crystal display for optimum performance, simplicity of set up and trouble shooting. The system consists of a controller connected by air supply hoses to specially designed inflation pads - InPads.

The InPad inflation pad is rapidly inflated by a controlled impulse of air from the controller. As each impulse the controller automatically allows the inflation pad to deflate. To deliver the impulse pressure effectively to the extremity, the InPad inflation pad must be retained in the correct position. The inflation pad is available as an InFoot rigid cast foot cover, a non-sterile and sterile form, as an undercast inflation pad which can be fitted inside an immobilisation cast, and as a hand cover.

The system has built-in alarms and display to alert attention to adjustment requirements and to assist with rapid troubleshooting.

Indications for Use

The A-V Impulse System is safe and effective for the indications shown below. The proper duration for use for each indication is subject to the clinical judgment of the prescribing physician. Note that the indications and recommended guidelines vary depending on whether the pump is used with the In-Pad foot cover or hand cover. Recommended Guidelines are as follows:

Indication

Recommended guidelines

A. Foot Cover

Chronic Venous Insufficiency

Relieve circulatory disorders secondary to diminished blood flow, such as ischaemia secondary to peripheral vascular disease.

For temporary impairment, such as temporary trauma or disease conditions, continuous use until the condition is resolved. For chronic impairments, daily use depending on the severity of the patient's condition and activity level.

Deep Vein Thrombosis Prophylaxis and Post-operative Thrombosis Prophylaxis

Assists in treating patients at risk for deep vein thrombosis (DVT) and pulmonary embolism (PE), including providing pre, intra and post-operative prophylaxis for DVT and PE.

Continuous use until the patient is fully ambulatory and weight bearing (not just modified).

Acute Edema

Reduces acute edema, such as elevated compartment pressures, edema secondary to trauma and/or surgical procedures, post-bypass graft edema, post-operative edema secondary to venous ligation or venous stripping and edema secondary to sprains, strains and sports related injuries of the lower extremity.

Chronic Edema

Reduces chronic edema

As required, but at least 4 hours per day

General Use Notes

The optimum results, good fitting of the vein is required. This is assisted by a slight degree (15 degrees) of leg dependency (foot rise) or positioning of the hand below the heart (hand use). Avoid leg elevation unless using an anti-embolism stocking, and do not let the hand get cool.

For optimum DVI prophylaxis, it is recommended the A-V Impulse System be used with TEDs and/or elastic stockings on moderate and high risk patients.

PATIENT AND SKIN CARE

As with any treatment technique it is important to check regularly and at least every 2 hours, for patient comfort and compliance and to pay particular attention to skin care and hygiene.

CHECK REGULARLY

Impulse is felt directly under the arch of the foot or in the palm of the hand.

In Pad foot or hand cover fits snugly and comfortably.

Skin integrity (remove stocking/stockinette).

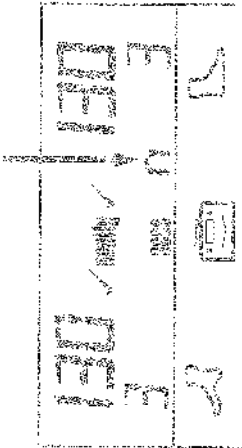
Skin (color) redness.

WARNING: Special attention, additional padding and checks three times a day should be given to patients with poor circulation, fragile skin, insulative coverings, diabetes and those who may be predisposed to tissue viability problems, including those receiving anti-coagulation therapy. To minimize pressure effects, reduce the impulse pressure and set the impulse duration to 1 second. Check for skin redness and any early signs which may lead to tissue viability problems. Use additional padding or discontinue treatment, according to clinical judgement.

Alarm Night Mode

This feature minimizes patient disturbance at night while still giving clear indication of a fault code. In Night Mode the audible alarm sounds less frequently and the LCD flashes to draw attention in dimly lit conditions. To select Night Mode double press the interval button, and 'N' is shown on the LCD.

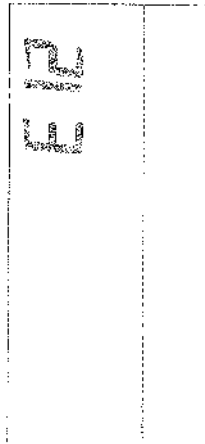
'N' shown on the LCD



To cancel Night Mode double press the interval button.

Error Codes

The activation of an error code suspends unit operation. If code E12 is displayed this shows that the over temperature protection has operated. Check that the air vents on the rear of the unit are unobstructed, that there is nothing preventing free air circulation around the unit and that the environment is not excessively hot. Allow the unit to cool and it will automatically reset. If the problem re-occurs see EUPAIR page 16.



Indication

Leg Pain Incident to Trauma or Surgery

Relieves pain, increases range of motion and limb mobility and expedites return of function following trauma or surgery.

Leg Ulcers

Aids in healing of cutaneous ulcers.

Continuous use until ulcer severity is reduced or physician recommends alternative therapy.

Venous Stasis/Venous Insufficiency

Treats venous stasis, venous insufficiency and varicose veins.

For temporary impairments such as temporary trauma or disease conditions, continuous use until condition is resolved. For chronic impairments, daily use depending on the severity of the patient's condition and activity level.

Lymphoedema

Reduces lymphoedema, including lymphoedema secondary to trauma and/or surgery and reduces or controls chronic lymphoedema, including post-paralytic lymphoedema due to stroke or spinal cord injury.

R. Hand Use

Acute Edema

Reduces acute edema, such as elevated compartment pressures, edema secondary to trauma and/or surgical procedures, and edema secondary to sprains, strains and other sports related injuries of the upper extremity.

Continuous use until edema is reduced.

Indication

Recommended guideline

Chronic Edema

Reduces chronic edema.

As required but at least 4 hours per day.

Chronic Pain Management

Reduces chronic pain management secondary to limb edema, such as ischemia secondary to peripheral vascular disease.

For temporary impairment, use as temporary means of disease condition; continuous use will be condition is resolved.

Evening Pain Reducing to Therapy or Surgery

Relieves pain, increases range of motion and limb mobility and expedites return of function following trauma or surgery.

Continuous use a sufficient quantity of pain is reduced or physician recommends alternative therapy.

Lymphedema

Treats lymphedema, including lymphedema secondary to trauma, infection, surgery, post-surgical lymphedema, and trauma or congenital chronic lymphedema including post-traumatic lymphedema due to stroke or spinal cord injury.

As required, but at least 4 hours per day.

Contraindications

The A-V Impulse System is contraindicated for patients with conditions where an increase of fluid in the heart may be detrimental, including some patients with congestive heart failure, and those with pre-existing deep vein thrombosis, thrombophlebitis or pulmonary embolism. The device should be used with caution on the infected or insensitive extremity.

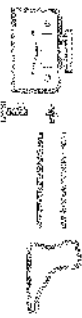

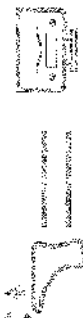
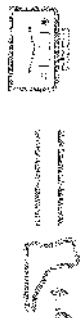
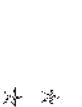
Alarm Indication and Correction

The A-V Impulse System controller is capable of automatic adjustment to correct many situations which may lead to an alarm indication. If the controller is unable to make the necessary adjustment, then an audible alarm will sound and the controller graphic will show where an adjustment is needed.

FAULT CODES

The fault codes and corrective actions are shown below.

NOTE: The FOD shows a fault icon during either foot or hand cover inhaled use.

FAULT CODE 1	AIR HOSE NOT CONNECTED
	<p>CHECK: connection of air hose to seat air on pin socket on controller foot or hand cover for hand/berka</p>
FAULT CODE 2	AIR HOSE KINKED
	<p>CHECK: for air hose kink or occlusion</p>
FAULT CODE 3	LOW PRESSURE ALARM
	<p>CHECK: that foot or hand cover is not too loose on patient foot or hand cover for cable foot or hand has not been removed from time</p>
FAULT CODE 4	HIGH PRESSURE ALARM
	<p>CHECK: foot or hand cover is not too tight that air hose is not occluded</p>
<p>Arrow points upward from Inhaled Icon</p>	<p>CHECK: foot or hand cover is not too tight</p>
	<p>that air hose is not occluded</p>
<p>★ Excess pressure is immediately vented</p>	<p>★</p>
<p>★ Controller operation is suspended</p>	<p>★</p>

Alarms will automatically self-cancel if the controller can make the necessary adjustment or the problem resolves, such as a kinked hose becoming unlinked. The alarm will automatically cancel when the problem has been corrected. While making the necessary adjustments, the alarm and impeding can be stopped by pressing the STOP-STOP button. After completion, press the KUM-STOP button again to cancel the fault code and restart the system.

Operating the System

The System is ready for operation once the following steps have been placed:

1. InPac(s) is/are filled to the patient and connected to the controller;
2. The controller power is switched on; and
3. Appropriate impulse parameters are set.

Before impulsing, reassure the patient that they will feel a bump on the sole of the foot, or pain of the hand, and that this mimics the normal action of walking or flexing of the hand.

To start impulsing:

Press RUN STOP Patient Right and/or Patient Left button(s).

To stop impulsing:

Press RUN STOP Patient Right and/or Patient Left button(s).

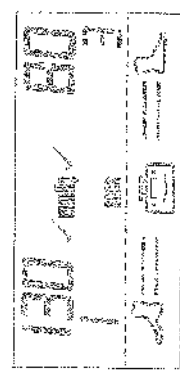
When a channel is turned on, the bottom section of the screen graphically displays the controller, the air hose and the InPac. A few seconds before an impulse is due to be delivered, an arrow head flashes on the controller end of the hose icon.

The arrow head moves down the air hose flashing one second before the impulse is delivered.

The impulse is shown on the InPac icon at the precise moment the impulse is delivered.

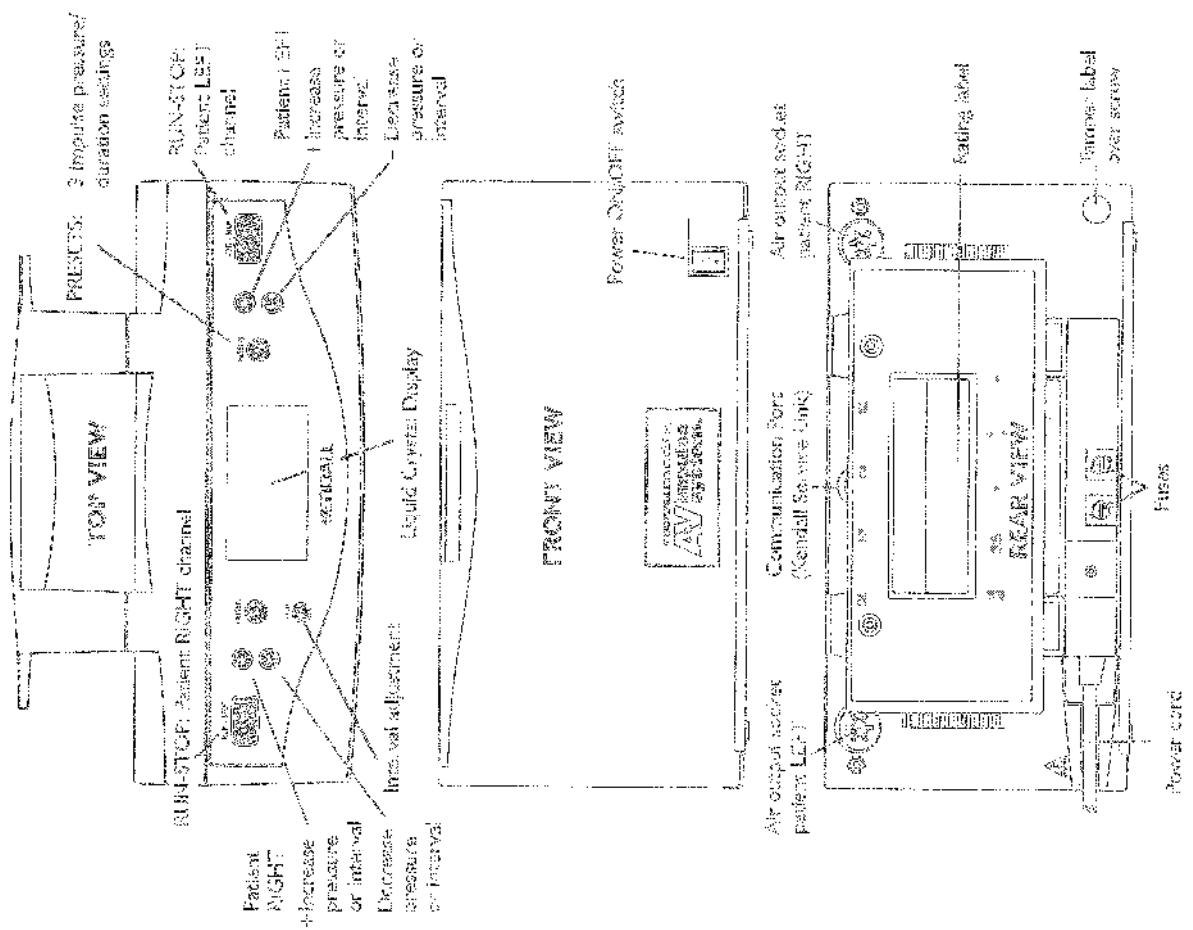
NOTE: The LCD shows a foot icon during either foot or hand over InPac use.

The impulse pressure progressively increases over a few cycles to obtain the set pressure. This allows the patient to become accustomed to the sensation. Once the set pressure has been achieved a checkmark (✓) appears next to the pressure display. The smiling controller icon shows that the system is operating correctly.



The controller makes automatic adjustments for patient positioning and rightness of the InPac. If the checkmark does not appear, check the fit of the InPac.

Controller - Model 6060



Installation

Controller

Check electrical rating on label on rear of controller.

WARNING! DO NOT connect to the power supply if the electrical rating is incorrect.

Connect the rated plug to an ELECTRICAL SUPPLY.

WARNING! Controller MUST be properly grounded at all times.

The Model 6050 can treat two limbs and is fitted with independent channel controls for each limb for optimum set-up. The air output sockets are on the rear of the controller.

Long air supply hoses are applied allowing the controller to be positioned conveniently either on the floor on a table or on the bed foot board using the built in foot hook. When used on the foot board, ensure that the controller is securely attached, preferably to the surface of the foot board, so that it cannot be easily dislodged.

WARNING! IT IS IMPORTANT THAT ADEQUATE CLEARANCE IS PROVIDED AROUND THE CONTROLLER TO ALLOW FOR REPAIR CIRCULATION AND THAT THERE IS REASONABLE FREEDOM FROM DUST. DO NOT USE ON WET SURFACES. DO NOT COVER CONTROLLER.

Operation

Operation of the A-V Impulse System

A. Directions for applying the InPad rigid sole foot cover

Step 1

Apply THE D.V. Antistatic/Inion sealings or sachets over the foot and ankle as required.

Avoid wrinkles.

Step 2

Select an InPad.

Red graphics - Left. Blue graphics - Right.

Place the foot centrally on the InPad foot cover as shown by the graphics on the InPad pad.





CAUTION! ENSURE THAT THE IMITATION PADS IS PLACED DIRECTLY UNDER THE ARCH OF THE FOOT.



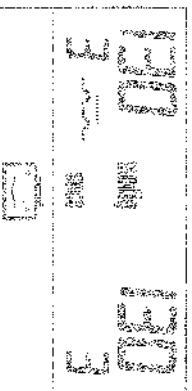
Customising Parameters

Note: The impulse pressure, duration and interval should be specified by the prescribing physician, according to clinical judgement. As various reprinting is more rapid in the hand than foot, the interval can be customized when using the InPad hand cover in the range from 12-20 seconds, according to clinical judgement.

There are three parameters that can be adjusted for individual patient requirements. These parameters are the impulse pressure, cycle time and impulse duration. Customising can be carried out while the controller is impinging.

PARAMETER	STEPS TO CUSTOMISE
Impulse Pressure range of impulse delivered by controller Range: 60-230 mmHg	Increase Pressure  Press to increase in increments of 10 mmHg
Impulse Duration: Time pressure is applied for Cycles: 1 or 3 seconds	3 seconds is the default setting 1 second  Press to decrease in increments of 10 mmHg
Impulse Cycle Time between impulses Range: 12-50 seconds	Increase in 20 seconds 100% Press  Press to increase in increments of 5 seconds between 25-50 (foot) and increments of 2 seconds between 12-20 (hand)
20-50 seconds for InPad foot cover 12-20 seconds for InPad hand cover	Decrease interval  Press to decrease in increments of 5 seconds between 30-50 (foot) and increments of 2 seconds between 12-20 (hand)

On the screen it can be left displayed if the default setting of 20 seconds is required.



Press: Operating Parameters

Once the five record controller is complete, the LCD shows the controller settings. The top section of the display shows five impulse settings (initial pressure and seconds duration) and the bottom section graphically shows the status of the controller (charging which channel is running). Graphs in the lower section also provide a clear representation of any fault code or required adjustments.

The controller has three commonly used impulse pressure/duration settings programmed for user convenience. These settings are available through use of the PRESET buttons. The interval time defaults to 30 seconds for all preset settings.

PRESET 1

130 mmHg Impulse Pressure - 3 second Impulse Duration

USE FOR:	BUTTON TO PRESS	SCREEN DISPLAY
<ul style="list-style-type: none"> • optional venous return • edema reduction • deep vein thrombosis prophylaxis • arterial enhancement 	NONE	

PRESET 2

130 mmHg Impulse Pressure - 1 second Impulse Duration

USE FOR:	BUTTON TO PRESS	SCREEN DISPLAY
<ul style="list-style-type: none"> • avoid limb • patients with sensitive limbs to moderate compression 	Press PRESS	

PRESET 3

80 mmHg Impulse Pressure - 1 second Impulse Duration

USE FOR:	BUTTON TO PRESS	SCREEN DISPLAY
<ul style="list-style-type: none"> • patients with very sensitive extremities • to allow patient to become accustomed to treatment before selecting higher pressure 	Press PRESS	

Step 2

Wrap the inside of the InPad foot cover over the top of the foot and then overlap the outside of the InPad foot cover, pulling it fit snugly and secure with the fastener strap.



Next wrap the rear strap around the back of the heel and secure in place with the fastener strap.

Check that the InPad foot cover is fitted securely and the patient is comfortable.

For Controller Directions see Section E.

CAUTION: FOR FULL IMPACT, DO NOT WALK OR WEIGHT BEAR ON THE INPAD AND ONLY INFLATE WHEN FITTED TO THE FOOT.

WARNING: CHECK FOR SKIN IRRITATION AND USE ADDITIONAL PADDING ACCORDING TO CLINICAL JUDGEMENT.

B. Directions for InPad under cast inflation pad

Step 1



Apply stockinette over foot, ankle and leg as required. Avoid wrinkles.

Step 2



Select a cast pad.

Read graphics - *Left* Plus graphics - *Right*.

Wrap WHEEL® Undercast Padding around the foot. Place the foot centrally on the printed side of the inflation pad as shown by the graphics on the pad.

CAUTION: THE CAST INFLATION PAD MUST BE PLACED DIRECTLY UNDER THE ARCH OF THE FOOT.

Step 3



With the pad central under the arch, wrap the strap over the top of the foot and secure with the adhesive tab. The pad inlet tube should be on the inside of the foot pointing to the rear.

Step 4



Completely cover and secure the cast pad in place with WHEEL® Undercast Padding. Ensure that extra padding is placed over ankle bones and on top of the foot to eliminate possible irritation. Cast normally and take extra care that the inside of the cast is smoothly finished. Ensure the inlet tubing does not kink or become obstructed.

CAUTION: DO NOT INFLATE THE CAST PAD UNTIL THE CAST IS FULLY HARDENED.

Use 1 second impulse duration for the cast limb.

For Controller Directions see Section E.

12. Directions for applying the sterile InPad foot cover

Step 1 Drape the patient area prepared the operative limb.

Step 2 Apply impervious stockinette. The stockinette is stretched over the foot and up to the knee.
If using the stockinette, use a collective bandage.

Step 3 In the sterile field, peel open the sterile InPad foot cover pouch and remove the foot wrap and tubing from the CSR wrap.

Step 4 Apply the sterile foot cover to the foot of the operative limb. When applying the foot wrap, be certain that the tubing remains in the sterile field.

Place foot centrally on top of the InPad inflation pad as shown by the graphics on the inflation pad.

Wrap the inside of the sterile InPad foot cover over the top of the foot and then overlap the outside of the inflated foot cover pulling it snugly and secure with Velcro tab. Next wrap the rear strap around the back of the heel and secure in place with the fastener tab.

Check that the sterile InPad foot cover fits securely.

Step 5 Lift patient leg to eliminate the tubing length required to perform the intracranial limb manipulation.

Step 6 Secure the tubing by twisting the sterile drape around the tubing and clips. This will prevent the position of tubing required for the limb manipulation from dropping below the operating table.

Step 7 Insert sterile InPad foot cover tubing directly into the A-V bipole system connector.

Step 8 Apply non-sterile foot wrap to non-operative limb per section A (optional).

For Connector Directions see Section E.

13. Directions for InPad hand cover

Step 1 Apply stockinette over the hand.

Avoid wrinkles.

Step 2 Select an InPad.

Red graphics - Left Blue graphics - Right

Place the hand on top of the inflation pad as shown by the graphics on the InPad, with the thumb located into the cutout provided.

Wrap the ends of the cover across the back of the hand, fitting snugly and secure with the fastener tab.

Next wrap the wrist strap around the base of the thumb and secure with the fastener tab.

Check that the hand cover is fitted snugly and the patient is comfortable.

CANNULA FOR FULL INTRALIMB ONLY (PELATI) WITH STERILIZED TUBING

E. Directions for Connector Set Up

Insert the InPad foot cover (non-sterile or sterile), hand cover or under cast inflation pad to the patient. See Sections A, B, C and D.

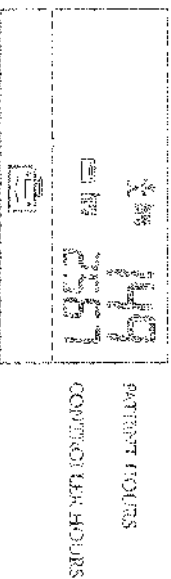
These Connections

The air supply hoses connect to air output sockets on the rear of the controller. They plug into place. Do not connect the hose, pull the connector from the socket.

Power - ON

When the power switch located on the front lower right of the controller. When the power is turned on, the liquid crystal display (LCD) will illuminate. The controller then goes through a self-test program and displays certain technical model, variant and service data.

After the self-test, a 5 second countdown is shown on the upper left corner of the display during which the number of patient treatment hours and the number of hours that the controller has been used are displayed.



When displayed, the patient treatment hours can be zeroed by pressing either of the **RESETS** buttons.

If the **SUN-STOP** buttons are not activated within 2 minutes, the compressor turns itself off to save energy and the controller goes into standby.