

KENDALL

AV impulse
system®

B Y N O V A M E D I X

MODEL 6060

**OPERATOR'S
INSTRUCTION MANUAL**

**FOR CONTROLLER AND
ACCESSORIES**

CONTENTS

	<i>Page</i>
INTRODUCTION	3
THE KENDALL A-V IMPULSE SYSTEM®	3
INDICATIONS FOR USE	4
CONTRAINDICATIONS	4
CONTROLLER – MODEL 6060	5
INSTALLATION	6
OPERATION OF THE A-V IMPULSE SYSTEM ACCESSORIES AND CONTROLLER	
(A) Directions for ImPad® rigid sole foot cover	6
(B) Directions for ImPad® under cast inflation pad	7
(C) Directions for Controller Set Up	8
Preset Operating Parameters	8
Customizing Parameters	10
Operating the System	11
ALARM INDICATION AND CORRECTION	12
Fault Codes	12
GENERAL USE NOTES	13
PATIENT AND SKIN CARE	13
MAINTENANCE	
Cleaning	13
Fault Conditions	14
Repair	14
SAFETY NOTES	14
SPECIFICATIONS	14
ORDERING INFORMATION	16

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 calf 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. This important physiological process led to the design of the A-V Impulse System Controller and Accessories.

The Kendall A-V Impulse System® foot pump 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.

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 indications where medical judgment assesses the need for improved blood circulation.

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

THE KENDALL A-V IMPULSE SYSTEM

The A-V Impulse System Model 6060 uses state-of-the-art microprocessor controls and displays for optimum performance, simplicity of set up and troubleshooting. The system consists of a controller connected by air supply hoses to specially designed inflation pads – ImPad.

The ImPad inflation pad is rapidly inflated by a controlled impulse of air from the controller. After each impulse the controller automatically allows the inflation pad to deflate. To deliver the impulse pressure effectively to the extremity, the ImPad inflation pad must be retained in the correct position. The inflation pad is available as an ImPad rigid sole foot cover and as an under cast inflation pad which can be fitted inside an immobilization cast.

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

INDICATIONS FOR USE

The A-V Impulse System foot pump is safe and effective for the following indications. The proper duration for use for each indication is subject to the clinical judgment of the prescribing physician.

Recommended Guidelines are as follows:

INDICATION

RECOMMENDED GUIDELINES

Circulation Enhancement

For temporary impairments 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.

Deep Vein Thrombosis Prophylaxis

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

Edema – Acute

Continuous use until edema is reduced.

Edema – Chronic

As required, but at least 4 hours per day.

Extremity Pain Incident to Trauma or Surgery

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

Leg Ulcers

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

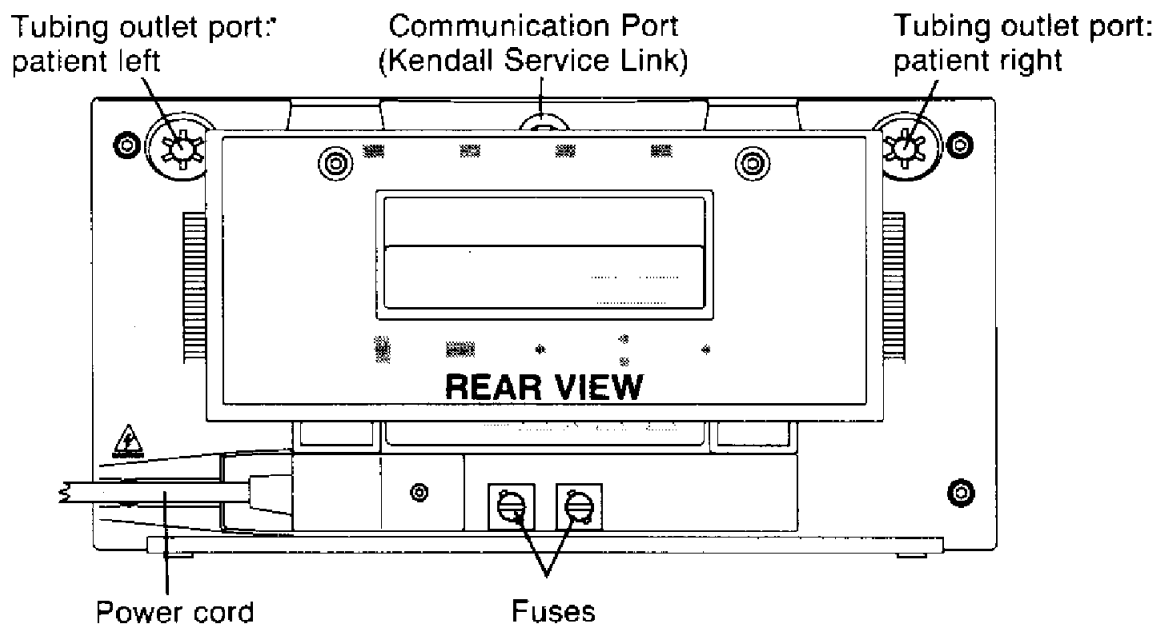
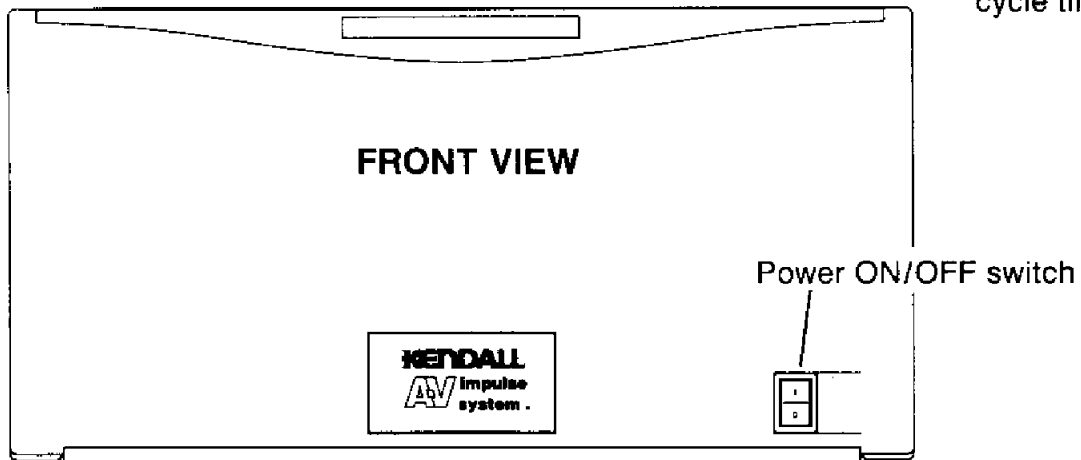
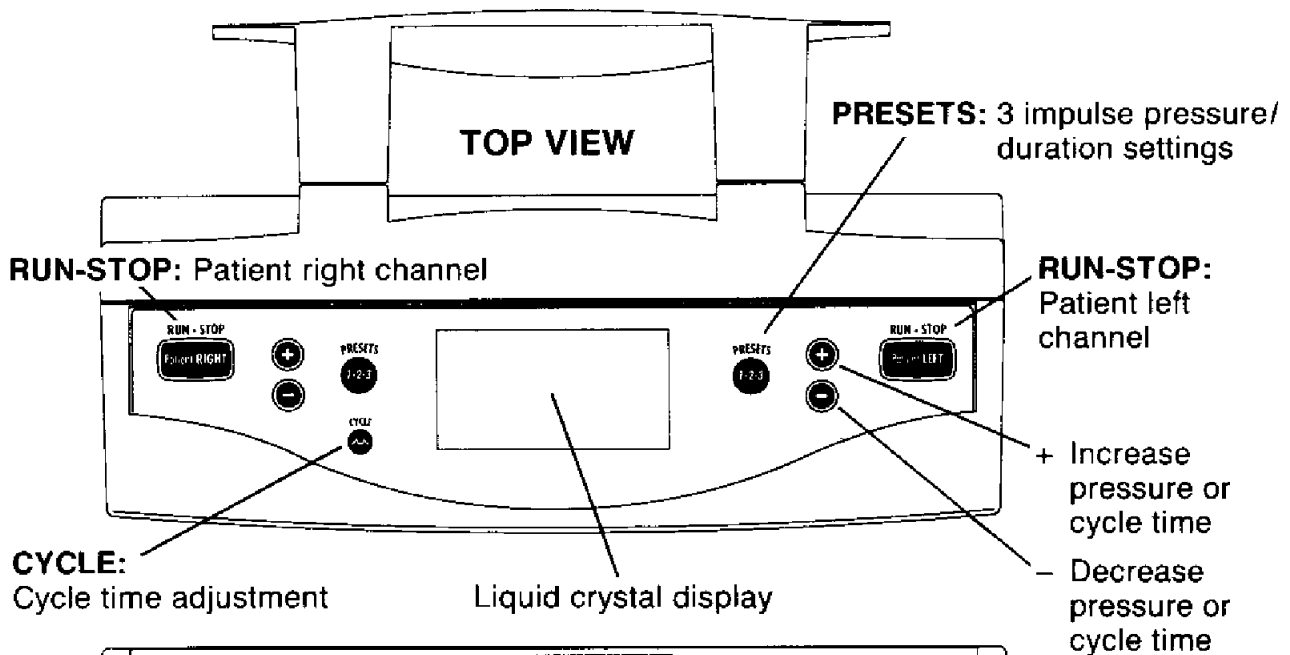
Venous Stasis/ Venous Insufficiency

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.

CONTRAINDICATIONS

The A-V Impulse System is contraindicated for patients with conditions where an increase of fluid to 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.

CONTROLLER – Model 6060



INSTALLATION

Controller

Check electrical rating on label on rear of unit.

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

Connect the fitted plug to a **GROUND**ED ELECTRICAL SUPPLY.

WARNING: Controller **MUST** be properly grounded at all times.

The Model 6060 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 supplied allowing the controller to be positioned conveniently either on the floor, on a table or on the bed foot board using the built in bed hook. When used on the foot board, ensure that the controller is securely attached, preferably in the center 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 FREE AIR CIRCULATION AND THAT THERE IS REASONABLE FREEDOM FROM DUST. DO NOT USE ON WET SURFACES.

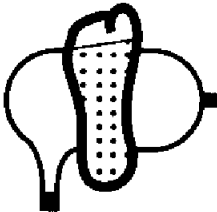
OPERATION

Operation of the A-V Impulse System foot pump Accessories and Controller


A. Directions for applying the ImPad® rigid sole foot cover

Step 1  Apply T.E.D.® Anti-embolism stockings or stockinette over the foot and ankle as required.

Avoid wrinkles.

Step 2  Place the foot centrally on the ImPad foot cover as shown by the graphics on the inflation pad.

CAUTION: ENSURE THAT THE INFLATION PAD IS PLACED DIRECTLY UNDER THE ARCH OF THE FOOT.

Step 3  Wrap the inside of the ImPad foot cover over the top of the foot and then overlap the outside of the ImPad foot cover, pulling to 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 ImPad foot cover is fitted securely and the patient is comfortable.

For Controller Directions see Section C.

CAUTION: THE PATIENT MUST NOT WEIGHT BEAR WHILE THE SYSTEM IS OPERATING AS THIS MAY REDUCE IMPAD FOOT COVER LIFE.

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

B. Directions for ImPad® under cast inflation pad

Step 1



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

Step 2



Select a cast pad.

Red graphics – *Left*. Blue graphics – *Right*.

Wrap WEBRIL® 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 WEBRIL 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 CAST PAD UNTIL THE CAST IS FULLY HARDENED.

Use 1 second inflation duration for the cast limb.

For Controller Directions see Section C.

C. Directions for Controller Set Up

First fit the ImPad foot cover or under cast inflation pad to the patient. See Sections A and B.

CAUTION: INFLATING THE IMPAD FOOT COVER WHEN NOT FITTED TO THE PATIENT PROPERLY, WILL REDUCE PRODUCT LIFE.

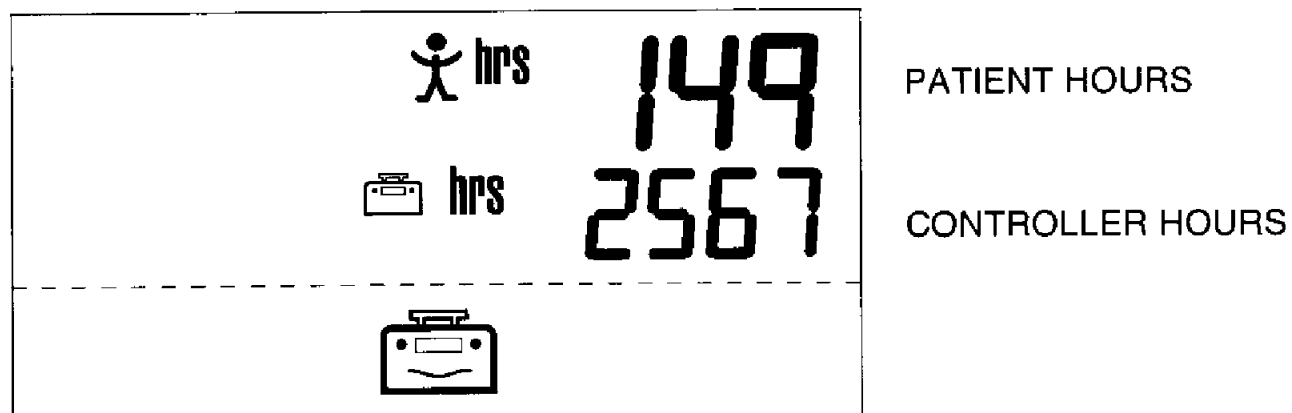
Hose Connection

The air supply hoses connect to output sockets on the rear of the controller, they click into place. To disconnect the hose, pull the connector from the socket.

Power – ON

Press 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 brief self-test program.

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 the controller has been used are displayed.



When displayed, the treatment hours can be zeroed by pressing either of the PRESET buttons.

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

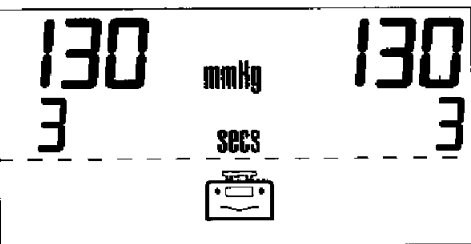
PRESET OPERATING PARAMETERS

Once the five second countdown is complete, the LCD shows the default setting. The top section of the display shows the impulse settings (mmHg pressure and seconds duration) and the bottom section graphically shows the status of the controller. Graphics in the lower section 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 cycle time defaults to 20 seconds for all PRESET settings.


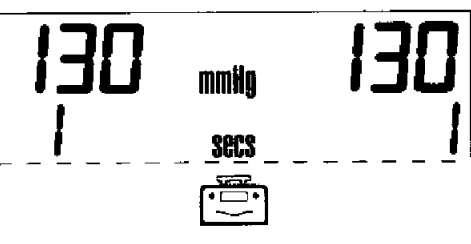
Automatic Default

130 mmHg Impulse Pressure
3 seconds Impulse Duration

USE FOR:	BUTTON TO PRESS	SCREEN DISPLAY
<ul style="list-style-type: none"> ● optimal venous return ● edema reduction ● deep vein thrombosis prophylaxis ● arterial enhancement 	<p>NONE</p> <p>Default setting when controller switched ON</p>	


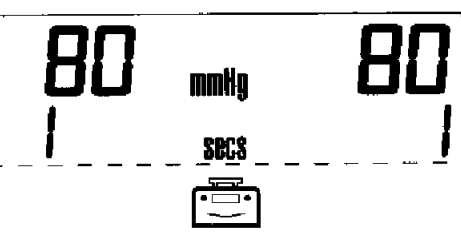
PRESET 2

130 mmHg Impulse Pressure
1 second Impulse Duration

USE FOR:	BUTTON TO PRESS	SCREEN DISPLAY
<ul style="list-style-type: none"> ● casted limb ● patients with sensitive limb to maximize comfort 	<p>Press</p> <p>PRESETS</p> 	

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 	<p>Press</p> <p>PRESETS</p> 	

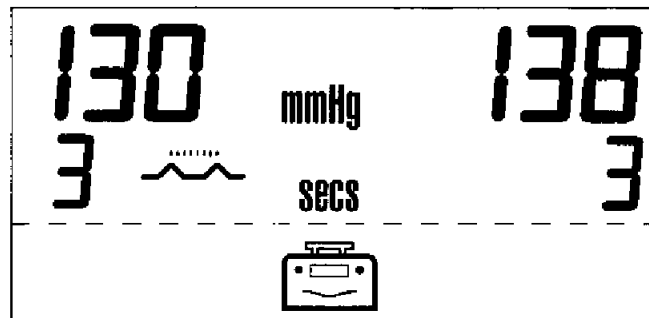
CUSTOMIZING PARAMETERS

Note: The impulse pressure, duration and cycle time should be specified by the prescribing physician, according to clinical judgment.

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

PARAMETERS	STEPS TO CUSTOMIZE
Impulse Pressure: mmHg of pressure delivered by controller	Impulse Pressure: Press  to increase in increments of 10 mmHg Decrease Pressure: Press  to decrease in increments of 10 mmHg
Impulse Duration: Time pressure is applied for Two options: 1 or 3 second	3 seconds: is the default setting 1 second: Press  to choose either (130 mmHg, 1 second) or (80 mmHg, 1 second)
Time Cycle:* Time between impulses	Default: 20 seconds CYCLE Press  Increase cycle time: Press  to increase in increments of 5 seconds Decrease cycle time: Press  to decrease in increments of 5 seconds

*The CYCLE icon is left displayed if the default setting of 20 seconds is not used.



OPERATING THE SYSTEM

The System is ready for operation once the following steps have taken place:

1. ImPad foot cover(s) is/are fitted 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 and that this mimics the normal action of walking.

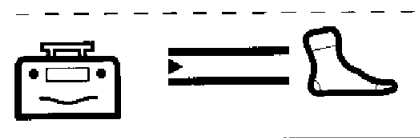
To start impulsing:

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

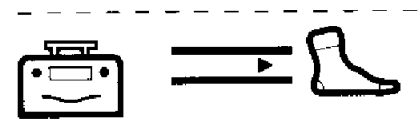
To stop impulsing:

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

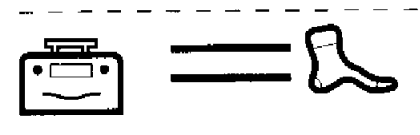
When a channel is turned on, the bottom section of the screen graphicly displays the controller, the air hose and the ImPad foot cover. A few seconds before an impulse is due to be delivered, an arrow head flashes on the controller end of the hose icon.



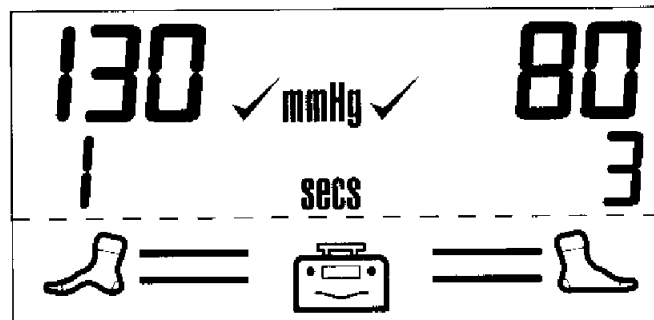
The arrow head moves down the air hose flashing one second before the impulse is delivered.



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



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 check mark (✓) appears next to the pressure display. The smiling controller icon shows that the system is operating correctly.



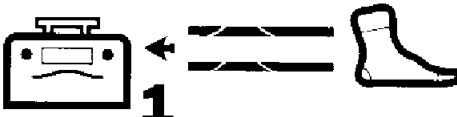
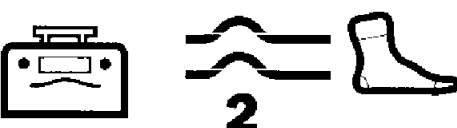


The controller makes automatic adjustments for patient positioning and tightness of the foot cover. If the check mark does not appear, check the fit of the ImPad foot cover.

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.

CODE 1 AIR HOSE NOT CONNECTED	
Arrow points at controller icon 	<i>CHECK:</i> connection of air hose to rear outlet socket on controller foot cover for fit and leaks
CODE 2 AIR HOSE KINKED	
Air hose icon appears kinked 	<i>CHECK:</i> for air hose kink or occlusion
CODE 3 LOW PRESSURE ALARM	
Arrow points downward from foot icon 	<i>CHECK:</i> that foot cover is not too loose on patient foot cover for leaks
CODE 4 HIGH PRESSURE ALARM	
Arrow points upward from foot icon 	<i>CHECK:</i> foot cover is not too tight that air hose is not occluded
★ Excess pressure is immediately vented ★	
★ Controller operation is suspended ★	

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

GENERAL USE NOTES

For optimum results, good priming of the veins is required. This is assisted by a slight degree (15 degrees) of leg dependency. Avoid leg elevation unless using a T.E.D.[®] anti-embolism stocking, and letting the limb get cool.

For optimum DVT prophylaxis venous flow, it is recommended the A-V Impulse System be used with T.E.D. anti-embolism 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 8 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.
- ✓ ImPad foot cover fits snugly and comfortably.
- ✓ Skin integrity. (Remove stocking/stockinette.)
- ✓ Skin (color) redness.

WARNING: Special attention, additional padding and checking three times a day should be given to patients with poor circulation, fragile skin, insensitive extremities, 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 reddening and any early signs which may lead to tissue viability problems. Use additional padding, or discontinue treatment, according to clinical judgement.

MAINTENANCE

CLEANING

ImPad Foot Cover and Under Cast Pad

ImPad inflation pads are supplied in individually sealed packages. They are for single patient use only and are not reusable or reprocessible.

Controller

WARNING: Before beginning cleaning procedures, the equipment *MUST* be switched off and unplugged 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.

The A-V Impulse System controller cannot be effectively sterilized by liquid immersion, autoclaving or ETO sterilization 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.

Repair

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 readjustments, modifications or repairs are carried out by the Kendall Service Department, and the equipment is used in accordance with the Instruction Manual.

SAFETY NOTES

WARNING: Disassembly of the controller must only be carried out by ESD trained and qualified personnel. Beware of electrical shocks, switch off the unit and disconnect from power supply before cleaning, maintenance and 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 further information contact:

Kendall Customer Service: 1-800-421-8268.

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 unit and disconnect from power supply before cleaning, maintenance and repair.

SPECIFICATIONS

All values stated are nominal.

A-V System Controller

Height: 6.4in (16.2cm) overall

Depth less handle: 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 (Antisurge)

The Controller is built and tested to UL544.

Performance

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

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

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

ORDERING INFORMATION

CODE No.	DESCRIPTION	SHIPPING UNIT
6060	A-V IMPULSE SYSTEM Controller	1 each
	IMPAD Foot Cover	
5065	Regular Size, fits Left and Right	4 pairs/case
5067	Large Size, fits Left and Right	4 pairs/case
	IMPAD Under Cast Inflation pad	
5087	Right Foot	12 eaches/case
5089	Left Foot	12 eaches/case

IMPAD RIGID SOLE FOOT COVER SIZING CHART

	REGULAR	LARGE
Women's shoe size	5½-9	9½-11½
Men's shoe size	4½-8	8½-12½

Note: For ImPad Under Cast Inflation Pads, one size fits all.

Distributed by:

Kendall Healthcare Products Company,
a Division of The Kendall Company,
A **tyco** INTERNATIONAL LTD. COMPANY
Mansfield MA 02048.
Kendall Customer Service 1-800-421-8268

Novamedix, A-V Impulse System and ImPad are Trademarks of Novamedix Ltd. U.K.

Kendall and T.E.D. are Trademarks of The Kendall Company. Webril is a Trademark of Veratec, Inc.

Made in England under one or more of the following Patents: U.S. Patent Numbers:
Re.32,939 Re.32,940 4,696,289 4,721,101. © Novamedix Ltd. 1994. All rights reserved.

In line with its policy of continuing product improvement, the Company maintains the right to change specifications without notice.

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

98887
ISS 1 1995