EXPLANATION OF LABEL SYMBOLS AND STATEMENTS

ATTENTION Consult accompanying documents

CE 0120

Medical Devices Directive 93/42/EEC

Electrical Protection Type B

Class II Equipment (Double Insulated)

This is a functional earth and not a protective earth

Do not dispose of with the normal household waste

WARNING This is a statement that alerts the user to the possibility of serious injury or other adverse reactions with the use or misuse of the device

CAUTION This is a statement that alerts the user to the possibility of a problem with the system associated with its use or misuse

CLASSIFIED C UL US 1BD1

This product is CLASSIFIED by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with UL60601-1 and CAN/CSA-C22.2 No. 601.1

U.S. PATENT PENDING

USER MANUAL PART NUMBER 50-02-05-100/6

TALLEY MEDICAL

Multipulse™ 500 Compression Therapy System

User Manual

TALLEY GROUP

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02/2012

BHTA British Healthcare Trades Association

CE 0120

Notes

Guidance and Manufacturer's Declaration on Electromagnetic Immunity and Emissions

Class A industrial 55001

Manufacturers declaration - Electromagnetic Emissions		
Model Type 9b is intended for use in the electromagnetic environment specified below The customer or user of the Type 9b systems should assure that it is used in such an environment		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Class A	The Type 9b systems are suitable for use in all other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonics emissions 61000-3-2	N/A	
Voltage Fluctuations/ Flicker emissions 61000-3-3	N/A	

Manufacturers declaration - Electromagnetic Immunity			
The Tye 9b systems are intended for use in the electromagnetic environment specified below. The customer or user of the Type 9b system should assure that it is used in such an environment			
Immunity test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8Kv air	± 6kV contact ± 8Kv air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 Kv For power supply lines ± 1kV For input/output lines	± 2 Kv For power supply lines ± 1kV For input/output lines	Mains power quality should be that of a typical commercial hospital environment
Surge IEC61000-4-5	± 1kV line(s) to line	± 1kV line(s) to line	Mains power quality should be that of a typical commercial hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 %Ur (>95 %Ur) for 0.5 cycle 40 %Ur (60% dip in Ur) for 5 cycles 70 %Ur (30% dip in Ur) for 25 cycles >5 %Ur (>95 % dip in Ur) for 5 seconds	<5 %Ur (>95 %Ur) for 0.5 cycle 40 %Ur (60% dip in Ur) for 5 cycles 70 %Ur (30% dip in Ur) for 25 cycles >5 %Ur (>95 % dip in Ur) for 5 seconds	Mains power quality should be that of a typical commercial hospital environment. If the user of the Type 9b system requires continued operation during power mains interruptions', it is recommended that the Type 9b be powered from an uninterruptible power supply or a battery
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Contents

Introduction

Thank you for choosing to use the MULTIPULSE™ 500 compression therapy system. The MULTIPULSE™ 500 system comprises five chamber pneumatic leg or arm garments for the non-invasive treatment of lymphoedema, venous insufficiency, and some chronic non-healing wounds and ulcers. The garment chambers inflate sequentially from the foot / hand to give gradient compression to the limb.

The MULTIPULSE™ 500 represents the pinnacle of technology in external pneumatic compression therapy. Features include:-

- Adjustable pressure ranges (30 - 120mmHg)
- Adjustable cycle times (6 to 80 seconds per chamber)
- 3 distinct programmable therapy periods (10 - 120 mins) per session
- Fixed or adjustable gradiency
- Saves up to 9 individual treatment sessions

The MULTIPULSE™ 500 compression therapy system will benefit from careful installation and use, providing a long and effective service life. Please read this user manual in order to achieve the best possible results.

Talley Medical products are manufactured to comply with BSI, IEC, UL and other European safety standards.

Talley Medical design and manufacture products to conform to the requirements of ISO9001, ISO13485 and Directive (93/42/EEC).

Talley Medical reserves the right to modify the specification of any product without prior notice in line with a policy of continual product development. Our standard terms and conditions apply.

Specification

Pump Unit

Model Reference:	MULTIPULSE™ 500 (TM300/4)
Width:	325mm (12.8”)
Height:	233mm (9.2”)
Depth:	165mm (6.5”)
Weight:	3.4kg (7.5lbs)
Construction:	ABS Plastic
Power Cord:	5 metres (16’)
Cycle Time:	30 to 400 seconds
Cell Inflation Time:	12 to 160 seconds* (2/5 of cycle time)
Cell Deflation Time:	18 to 240 seconds* (3/5 of cycle time)
Power Supply:	Europe: 230V +/- 10% 50Hz
	USA: 110V +/- 10% 60Hz
Power Consumption:	8W
Fuse Rating:	500 mA
Electronics Control:	Type 9
Pressure Range:	30-120mmHg (leg)

*with automatic extension of up to 10 seconds per cell if required pressure is not reached in nominal inflation time.

Garments

Material:	PU coated Nylon
Closure Method:	Zipper (velcro on garments with expander panel)
Type:	Five chamber garments

List of Components

Your MULTIPULSE™ 500 compression therapy system consists of these items - please ensure you have all necessary components before application.

- MULTIPULSE™ 500 power unit with display
- Compression garment(s):-

Full leg	-	s, m*, l*, xl*
Calf	-	one size
Arm	-	s, m, l
Forearm	-	one size

* medium, large and extra large full leg garments are available with an attached expander panel for use when a larger garment is required.

Cautions and Warnings

Only use this device on the recommendation of a licensed physician.

Before using this product ensure that:

- the electricity supply is of the type indicated on the power unit.
- the mains lead is free from damage and is positioned so as not to cause an obstruction.
- the system is not used in the presence of flammable anaesthetics.

For 110V units only - means to isolate the power unit from the electricity supply shall be carried out via disconnecting the plug attached to the non-detachable mains cord from the wall socket.

Do not place garments or power unit on or near a heat source. Do not use with hot water bottles or electric blankets.

Although the materials used in the manufacture of all components of the MULTIPULSE™ 500 compression therapy system comply to the latest fire safety regulations, Talley Medical advises against smoking while the system is in use, to prevent the accidental secondary ignition of associated items which may be flammable.

The equipment conforms to IEC 60601-1-2 for electromagnetic interference, however should the equipment be subjected to electromagnetic interference outside this standard then the unit should be reset.

Contraindications

The use of external compression may not be recommended in the following conditions:

1) Known or suspected deep vein thrombosis
2) Congestive heart failure, pulmonary oedema
3) Active infections
4) Local conditions (e.g. dermatitis, skin graft).

The MULTIPULSE™ 500 power unit will also notify you of the following problems if they occur:-

● Service due	Contact Talley Medical to arrange service
● Kinked tube	Check tubing for kinks or obstruction
● No garment	Connect required garment(s)
● Invalid garment	Select correct garments for use with the MULTIPULSE™ 500 power unit
● Uncalibrated	Contact Talley Medical for recalibration

Fault Finding

The MULTIPULSE™ 500 power unit has several alarm systems to warn of possible malfunction. All alarms can be silenced and reset by pressing the MUTE button. The MULTIPULSE™ 500 power unit has a Fault Log that records the last 5 faults via the Date Information display mode (see page 14).

AC Fail – indicates a mains power failure. A continuous alarm will sound if power is interrupted, e.g. pump switched off, power cut, disconnection of mains lead. Press MUTE or re-connect to power supply.

Rotor System – indicates automatic sequential cycle has stopped or there is a fault in the system. Switch power off, press MUTE button, then switch power on again. If fault re-occurs, contact Talley Medical.

Low Pressure – will alert if pressure falls below minimum allowable levels. Press MUTE button to clear alarm. Check hose connections and inspect garment for leaks. (To ensure garment hose plug is properly connected to the pump, it is essential that 2 clicks are heard, confirming both sides of the connector are in place - refer to initial MENU to check display indicates correct garment connection). Check that rapid deflation device on leg garment is fully closed. Note that alarm will reoccur if fault persists. If problem reoccurs, contact Talley Medical.
NB. Also confirm that 'Please Wait' is displayed during initialisation, and not 'Uncalibrated' or 'Service Due'. If either of these statements are displayed, contact Talley Medical.

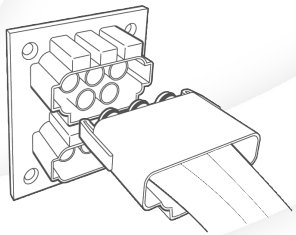
EMI – indicates that the unit detects the pressure sensor amplifier is adversely affected by external RF fields. This will clear when interference ceases.

OTHER ALARMS
There is a PUMP OR TRIAC fault that indicates a triac failure or an open pump coil fault. Should this, or any other fault display occur, contact Talley Medical.

Garment Application and System Set-Up

1. Remove garments from packaging. Check that the garments are not damaged.
2. Check that the mains lead on the power unit is not damaged.
3. Adjust the hanging brackets, following instructions shown on back of power unit to enable the power unit to be hung from the footboard of a bed. The power unit may also be placed on the floor or table top.
4. Plug mains lead into power outlet. Ensure that the mains lead is positioned so as not to cause an obstruction.
5. Fit garment(s) to patient, according to the following instructions.
   a) Unfold and unzip garment and place under limb. (If using garment with attached expander panel, unfasten zipper fully to release panel.) Be sure that the side with the air tubing attached is on the outside and tubing is not trapped between the garment and the skin.
   b) Fasten garment zip (or secure with velcro if using garment with expander panel) ensuring tubing is not trapped.

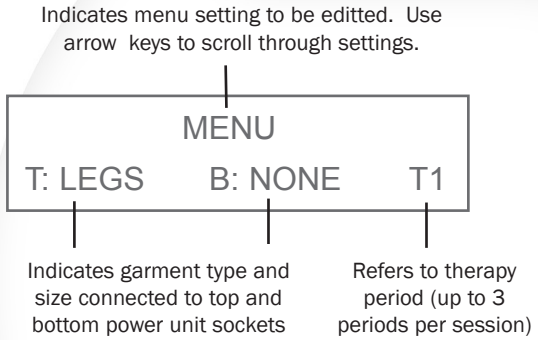
   NB. Garment will be loose fitting at this stage, to allow for inflation when in operation.
6. Connect garment hose(s) to outlet(s) on side of pump.



   a) Push garment hose plug into either socket until it clicks into place with 2 clicks. TO ENSURE PLUG IS PROPERLY CONNECTED IT IS ESSENTIAL THAT 2 CLICKS ARE HEARD, CONFIRMING BOTH SIDES OF THE CONNECTOR ARE IN PLACE.
   b) Repeat for second garment, if using.

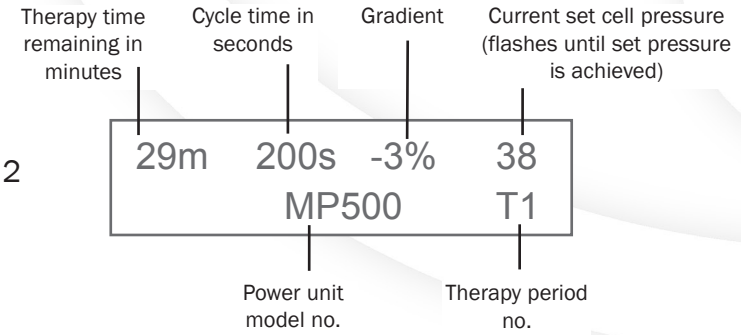
7. Switch power on at the left-hand side of the power unit. The unit will initialise with 'Please Wait' on the display. When initialised, the power unit will display the initial MENU screen (Fig. 1).

Fig. 1



8. Therapy settings can now be loaded or new settings programmed (please see Therapy Settings section). Press START/STOP to activate operation of the power unit. (Last used treatment session will operate if no other session is recalled). When in operation the screen displays selected settings and current operation status (Fig. 2).

Fig. 2



Care and Maintenance

Garments

Always keep the garments as clean as is practicable. The garments will withstand the thermal disinfection washing procedures described in the Department of Health Circular HSG(95)18. For day to day cleaning purposes it is suggested that garments are cleaned using hot water and soap or neutral detergent, or chlorine releasing agents at a concentration of 1000 ppm.

Do not use bleach, chlorine releasing agents in concentrations over 1000 ppm, solvents or alcohol-based cleansers, e.g. Phenicol, Hibiscrub, Clearsol, Stericol, Hycoline as these will destroy the material. Do not Autoclave. Do not immerse the garments in water, unless air tubes and rapid deflation device are sealed, as fluid may enter the air chambers and tubing.

Power Unit

Always disconnect the power unit from the electrical supply before cleaning. The power unit can be wiped down with a damp cloth or alcohol wipe. Do not use solvents.

The unit contains no user serviceable parts, and should only be serviced by a competent electrical technician, or returned to Talley Medical or your local authorised dealer.

All Talley Medical products should be serviced regularly by Talley Medical or authorised dealer in order to comply with warranty conditions. NB: Before returning equipment to Talley Medical for service, be sure that it has been properly cleaned and disinfected in accordance with local health service guidelines.

Talley Medical recommend the use of TECare™ sanitising products for the cleaning and decontamination of patient care equipment and the surrounding environment to provide prolonged microbial protection for up to 4 weeks after application.

time by pressing START/STOP after reconnection. However, if connecting a different garment type than previous, return to initial MENU screen (press 'down' then 'up' arrow buttons) and press START/STOP to commence therapy period with current therapy settings.

Data Information

To enter this mode, scroll down from initial MENU screen using arrow button. When 'Data Information' is displayed, press DATA button to select. Using arrow buttons scroll to view the following information:-

- Fault Log Entries 1-5
- Software ID
- Boot Loader
- Hours Run
- Hours to Service
- Hire Time
- Product Code
- Serial No.
- Last Service Date
- Owner
- Contact Name
- Telephone
- Hospital
- Ward
- Patient
- Ref.

A range of test and service modes are available for access by trained personnel. Information is available from Talley Medical on request.

9. If a timed treatment session has been selected an alarm will sound and DISCONNECT GARMENT will be displayed on screen when treatment session is complete (press MUTE to silence alarm). To disconnect garment hoses squeeze both sides of garment plug and remove from socket.

10. Place user manual in a safe place for future use.

IMPORTANT

Switching The Unit Off

On switching the unit power off, the mains fail alarm will operate automatically indicated by 'AC FAIL' on the display. Simply press the MUTE button to silence the alarm.

Therapy Settings

The MULTIPULSE™ 500 power unit allows the setting up of up to 9 treatment sessions, each comprising up to 3 therapy periods. Each therapy period (T1, T2 and T3) has its own variable duration, pressure, cycle time and gradient settings. Setting ranges are as follows (these may be limited by garment type connected):-

Therapy: 10 to 120 minutes or continuous (in 10 minute increments). Continuous period will continue indefinately until START/STOP is pressed or power removed.

Pressure: 30mmHg to 120mmHg (in 5mmHg increments)

Cycle Time: 30 to 400 seconds (in 10 second increments). Automatic extension of up to 10 seconds per cell if required pressure is not reached in nominal inflation time.

Gradient: -1.5% (displayed as 1%), -3% or -6% or individually set pressures (ISP) may be selected. The set pressure is reduced by the selected gradient level for each successive chamber after the first (foot section). In ISP mode each chamber may be set to any value to maintain a negative gradient.

Selecting Therapy Settings

Before selecting any settings, initial MENU screen (Fig. 1) must be displayed. If unit is already in operation, press STOP/START.

If more than one therapy period is required within a treatment session, settings must be selected in parallel across each required therapy period, e.g. therapy time for T2 / T3 must be selected before moving on to pressure settings. Toggle between therapy periods using the THERAPY/SKIP button. If T2 is set to 0 minutes cycle time, only T1 will operate. If T3 is set to 0 minutes then only T1 and T2 (if set) will operate.

User Guidelines

Only use this device on the recommendation of a licensed physician.

Contraindications

The use of external compression may not be recommended in the following conditions:

a) Known or suspected deep vein thrombosis
b) Congestive heart failure, pulmonary oedema
c) Active infections
d) Local conditions (e.g. dermatitis, skin graft)

The digital display on the front of the power unit will display all errors, faults, warnings and relevant unit information.

All air tubing must be free of kinks, twists, and be properly connected (ensure garment type is displayed on initial MENU screen to confirm correct connection).

Compression should be terminated and garments removed if patient experiences pain, tingling, or numbness.

If power unit should cease operation during treatment and air becomes trapped in the leg garment, air can be quickly released by disconnecting garment plug from power unit.

If the power unit is stopped prior to the end of the therapy period, the power unit will continue with the remaining therapy time when restarted. However, the remaining time may be cleared by pressing MUTE at the initial MENU screen or by editing the therapy time for a new value.

If a garment is connected or disconnected whilst the power unit is operating, the power unit will stop and display GARMENT PLUG ERROR. If disconnection was accidental, current therapy may be resumed with remaining therapy

If a particular setting is seen to blink, this is because the cycle time is too low for the pressure selection or garment type in use.

Loading Therapy Settings

If therapy settings have previously been selected and saved, these can be loaded as follows:-

Switch power unit on, wait for initial MENU screen display

Press ↓ to scroll to SAVE/LOAD

Press DATA to select

Press ↓ to scroll down to 'Load Settings' and select required treatment session setting number

Press DATA to load setting and return to menu

Press ↑ to return to initial MENU screen

Press START STOP to start treatment session

Therapy settings are selected as follows:-

THERAPY	Press ↓	to scroll to THERAPY
	Press DATA	to select
	Press ↓ & ↑	to select therapy time
If required	Press THERAPY SKIP	to select T2/T3 and set as above
	Press DATA	to save and return to menu
PRESSURE	Press ↓	to scroll to PRESSURE
	Press DATA	to select
	Press ↓ & ↑	to select pressure setting
If required	Press THERAPY SKIP	to select T2/T3 and set as above
	Press DATA	to save and return to menu
CYCLE TIME	Press ↓	to scroll to CYCLE TIME
	Press DATA	to select
	Press ↓ & ↑	to select cycle time
If required	Press THERAPY SKIP	to select T2/T3 and set as above
	Press DATA	to save and return to menu

GRADIENT

Press ↓ to scroll to GRADIENT

Press DATA to select

Press ↓ & ↑ to select gradient setting

If required *Press THERAPY/SKIP to select T2/T3 and set as above*

Press DATA to save and return to menu

If ISP gradient is selected the individual cell pressures can be set as follows. These settings are global for all therapy periods within a treatment session. If -1.5%, -3% or -6% gradient is selected the individual cell pressure settings are overridden.

CELL 1 to CELL 5 settings can also be used to allow the individual chamber to be skipped during the compression cycle to avoid compression over painful areas. If a cell is set to 'skip' it will be given a value of 0mmHg and will therefore not inflate. The settings for skipped cells are global for all therapy periods within a treatment session.

CELL 1

Press ↓ to scroll to CELL 1

If 'skip' required

Press THERAPY/SKIP to set cell to 'skip'

or to set cell pressure

Press DATA to select CELL 1

Press ↓ & ↑ to select cell pressure

Press DATA to save and return to menu

CELL 2 - 5

As above, pressing ↓ to scroll to each cell

SAVE/LOAD

Press ↓ to scroll to SAVE/LOAD

Press DATA to select

Press ↓ & ↑ to select 'Save Settings'

and select setting number against which to

save treatment session (1 - 9)

Press DATA to save and return to menu

To load treatment session at this point, press

DATA again to re-select SAVE/LOAD menu.

Press ↓ to scroll down to 'Load Settings'

and select required treatment session

Press DATA to load session and return to menu

Press ↑ to return to initial MENU screen

Press START/STOP to start treatment session

IMPORTANT: It is necessary to scroll back to initial MENU screen using

↑ before pressing START/STOP to start the treatment session.

NB. The selection process may be ended at any time by pressing the MUTE button to return to the menu level without updating the setting.