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

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

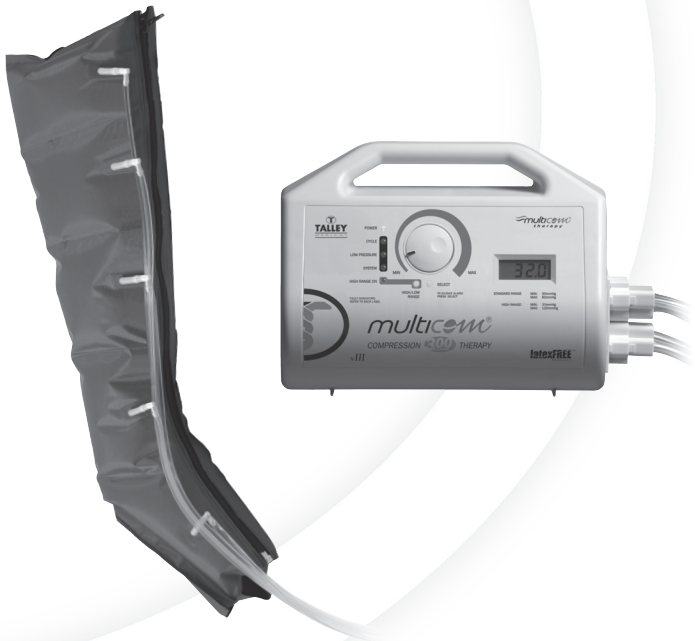
This product is CLASSIFIED by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with UL60601-1 and CAN/CSA-C22.2 No. 601.1

PATENT PENDING

USER MANUAL PART NUMBER 50-02-02-112/3

TALLEY MEDICAL

Multicom™ 300/5 *v.111* Compression Therapy System



User Manual

TALLEY GROUP

TALLEY MEDICAL USA
1070 E. Wieland Road
Lansing, MI 48906, USA
Web: www.talleymedical.com
USA re-order:- 888-259-9994

06/2008

BHTA

CE 0120

Notes

Manufacturer's Declaration of Conformity

PRODUCT IDENTIFICATION
PRODUCT:- MULTICOM 300/5 (TM300/5)
TYPE:- COMPRESSION HOSIERY

DECLARATION
The above Class 2b Medical Device conforms with Directive 93/42/EEC, Annex II (excluding Section 4). All supporting documentation is retained at the premises of the manufacturer.

CE 0120

Tested by:	EMC Projects Ltd. UL
Standards:	IEC 601-1 EN 60601-1-2:1993 UL 60601-1 2003
Test Report No:	EMC File: 5616/03 UL File: E 215705
Manufacturer:	Talley Group Limited, Premier Way, Abbey Park Industrial Estate, Romsey, Hampshire, SO51 9DQ, UK
Notified Body:	Is subject to the procedure set out in annex 2 of Directive 93/42/EEC under the supervision of Notified Body Number 0120 SGS United Kingdon Limited, Unit 202B, Worle Parkway, Somerset BS22 6WA

Contents

TALLEY MEDICAL

Introduction

Thank you for choosing to use the MULTICOM™ 300/5 compression therapy system. The MULTICOM™ 300/5 system comprises five chamber pneumatic leg or arm garments for the non-invasive treatment of lymphedema, 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 MULTICOM™ 300/5 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.

Specification

Pump Unit

Model Reference:	MULTICOM™ 300/5 *v.III* (TM300/5)
Dimensions:	13.2” x 9.2” x 6.5”
Weight:	7.5 lbs
Construction:	ABS Plastic
Power Cord:	11.5’
Cycle Time:	30-60mmHg (low) range - 3 minutes nominal variable to 5 minutes
	30-120mmHg (high) range - 3 minutes nominal variable to 7.5 minutes
Power Supply:	110V +/- 10% 60Hz
Power Consumption:	12W
Fuse Rating:	500 mA
Electronics Control:	Type 14
Pressure Range:	30-60mmHg (low range)
	30-120mmHg (high range)

Garments

Material:	PU coated Nylon
Closure Method:	Zipper
Type:	Five chamber garments

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 ISO9001:2000, ISO13485:2003 and Directive (93/42/EEC) Annex II (excluding Section 4).

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.

Fault Finding

The MULTICOM™ 300/5 power unit has several alarm systems to warn of possible malfunction. All alarms can be silenced and reset by pressing the SELECT button.
NB. Press and hold the SELECT button during normal operation to illuminate the most recent fault indicator.

AC Fail Alarm – 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 SELECT button and re-connect to power supply.
NB. The power unit features an illuminated on/off switch to indicate correct power supply. If switch fails to illuminate when connected to power source and switched on, check mains lead and fuses.

Cycle Alarm – will alert if a fault occurs with the cycle control. Press SELECT button to reset. If fault reoccurs contact Talley Medical.

Low Pressure Alarm – will alert if pressure falls below set level. Check air tubing connections between power unit and garment, ensuring that rapid deflation device on leg garment is fully closed. Press SELECT button to reset. If fault reoccurs contact Talley Medical.

System Alarm – will alert if a fault occurs with the cycle control valve. Press SELECT button to reset. If fault reoccurs contact Talley Medical.

NB. 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 you have any queries relating to this system please contact Talley Medical or your authorized local dealer.

List of Components

Your MULTICOM™ 300/5 compression therapy system consists of these items - please ensure you have all necessary components before application.

- MULTICOM™ 300/5 power unit
- Compression garment(s):-

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

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

Caution

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 anesthetics.

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 MULTICOM™ 300/5 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 edema
3) Active infections
4) Local conditions (e.g. dermatitis, skin graft).

Care and Maintenance

Garments
Always keep the garments as clean as is practicable. 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 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 authorized dealer.

All Talley Medical products should be serviced regularly by Talley Medical or authorized dealer in order to comply with warranty conditions.

NOTE: 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.

To change the operating pressures to the 30-120mmHg range, press and hold the HIGH/LOW RANGE button until alarm sounds and HIGH RANGE ON green indicator is illuminated. Operating pressure can be set by turning the pressure setting dial to required pressure. The set pressure will show on the digital display, as before. To return to the 30-60mmHg low range, press and hold the HIGH/LOW RANGE button again until alarm sounds and HIGH RANGE ON green indicator is no longer illuminated.

Switching The Unit Off

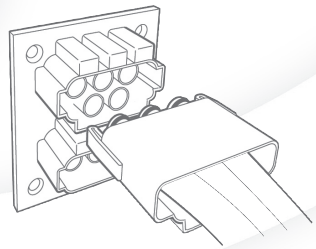
When switching the unit power off, or whenever the mains power is removed for any reason, the mains fail alarm will operate automatically indicated by 'AC Fail' on the display and an audible alarm. Press SELECT to cancel the 'AC Fail' indicator and audible alarm.

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.

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. The power unit may 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 left hand side of power unit.

8. Adjust pressure according to required therapy and physician's advice (please see User Guidelines section).

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

NB. The unit will stop functioning after 60 minutes displaying 'Stop', and the alarm will 'beep' for 3 seconds.

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 edema
c) Active infections
d) Local conditions (e.g. dermatitis, skin graft)

All air tubing must be free of kinks, twists, and be properly connected.

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

Selecting Operating Pressure
The MULTICOM™ 300/5 power unit operates over two pressure ranges: 30-60mmHg (low range) and 30-120mmHg (high range). On switching on the power unit, the default 30-60mmHg pressure range is in operation. Turning the pressure setting dial will increase or decrease pressure between these limits. The set pressure is shown on the digital display. Pressing the SELECT button during normal operation will change the display to show the actual pressure in the chamber at that instance. After ten seconds the system reverts back to displaying set pressure.

High Range Pressures
Certain therapies may require the use of higher compression pressures. The HIGH/LOW RANGE button will change the operating pressure range to 30-120mmHg.

WARNING - ONLY USE AT HIGH RANGE OPERATING PRESSURES IF DIRECTED BY YOUR PHYSICIAN.