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*A massage device*

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**Related Art**

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Title: A MASSAGE DEVICE

Abstract: A hand held massage device comprising a handle and an applicator head. The handle includes a press button for operation and a display. The applicator head has a medial narrowing and is adapted to free wheel in a rolling action relative to the handle. The end is rounded so that a user may deliver endwise vibration to a site to be treated in addition to the other therapeutic mode of operation involving rolling with the medial narrowing portion in contact with the surface being treated.
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL,
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A MASSAGE DEVICE

THIS INVENTION relates to a method of self administered massage and to a massage device for that purpose. In particular the invention relates to improvements in, or in relation to, hand held massagers and more particularly but not limited to a massage device for self administered vibratory therapy for treatment of lymphoedema.

Hand held massagers are known in for example in US patents 5,152,281; 4,669,452; 6,663,580; 5,575,760; 5,123,406; 6,352,518; 5,925,002; 5,711,758; 6,758,826; 5,716,130; 5,356,369 and 4,691,693. These massagers include various roller and vibrator arrangements including pistol like vibratory massagers.

Vibration has been used to treat lymphoedema. In WO02/065973 to Vibrant Medical Ltd and WO03/088889 to Niagara Therapy Mfg Australia Ltd so-called cycloid vibration is administered using a pad to treat lymphoedema by self administration.

The above prior art is incorporated herein by reference but its inclusion should not be taken as an admission that any of the listed prior art is common general knowledge in the art.

The present invention relates to this field but has general application to any useful application of a massage device of the type described including treatment of other forms of oedema. Other applications may include conditions where changes to the skin and superficial tissues may benefit from the application of a rolled-over vibration. Conditions where undesirable build up of fluids and scar tissue and the build up of fibrous tissue might be involved may also benefit from this treatment. Other instances may include post trauma treatment for burns and surgery. Other applications may include treatment of hypertension as an aid to improve peripheral blood flow, stimulation of tissues in bed sore management and so on.

In one broad method aspect there is provided a method of self administration of therapeutic massage using a hand held massager of the type having a handle and a roller head delivering vibration through the head to a treatment site, the method comprising the steps of applying the head in a roller action along the treatment site in a predetermined treatment direction.
Preferably, the roller head is applied under predetermined manual pressure superimposed upon a predetermined mechanical vibration having low frequency and low amplitude. The applied manual pressure may be monitored electronically using a transducer, typically an accelerometer, with audible or visual feedback to the user leading the user to reduce the applied manual pressure. The applied manual pressure may be monitored using an over-pressure sensor and indicator.

In one application of the method set out above the invention resides in a method of self administration of therapeutic massage for relief from lymphoedema using a hand held massager of the type having a handle and a roller head delivering vibration through the head to a treatment site, the method comprising the steps of applying the head in a roller action along the treatment site in a predetermined treatment direction. Preferably, the roller head is applied under light manual pressure superimposed upon a predetermined mechanical vibration having low frequency and low amplitude.

In the case of lymphoedema, the frequency of vibration should be selected to mimic lymphatic drainage therapy. In a device according to the invention where a motor with a rotating shaft is used, frequency, determined by rotation of the motor shaft may be quite low from a few Hz up to 100 Hz. However, somewhere around the middle of this range is preferred for treating lymphoedema with 30-50 Hz being considered optimum with a treatment time of about 10 minutes in the case of an arm. The amplitude of vibration, in the case of a motor with a rotating shaft and eccentric weight is determined by the mass of the eccentric weight, its eccentricity and dimensions, and should result in an amplitude at the treatment site of a few millimetres. Typically, the amplitude as applied to the tissue is in the range of 0.5-2.0mm and more preferably in the range of 1.0-1.5mm may be used for optimum results.

In the case of lymphoedema the applied manual pressure would not normally exceed the equivalent of about 250 gms applied. Pressure may be set for other applications that might require greater pressure say for deeper treatment as might be the case for sporting injuries.
In the case of lymphoedema it is preferable to first clear lymphatic regions adjacent the main site before treating the main site. For example, in the case of an arm, the regions of the neck and shoulder are first cleared.

However, it will be appreciated that useful outcomes may be achieved with a wide range of pressures, frequencies and amplitudes within practical limits of engineering and comfort to the patient. The present invention should not be considered as being limited to any particular pressure, frequency or amplitude or the condition or symptoms being treated.

In one broad apparatus aspect therefore the present invention resides in a massage device comprising a handle, an applicator head projecting from the handle and a vibratory source adapted to deliver vibration to the applicator head, the applicator head being coupled to the assembly and being adapted to roll over a surface being treated.

The applicator head is preferably coupled to the handle via a vibration dampening coupling and the source of vibration is preferably located in the applicator head.

The applicator head preferably comprises a hollow body housing a motor, the motor having an eccentrically mounted weight for the purpose of generating vibration within the applicator head. The motor housing typically has means enabling an outer portion of the head to roll on the motor housing. Preferably, the motor housing includes ribs on which the outer portion of the applicator head travels. The ribs preferably are circular ribs located on the motor housing which housing is a generally cylindrical motor housing.

Preferably, a generally cylindrical sheath locates across and over the motor housing, the sheath being able to rotate and slide on the ribs to give rotation of the sheath relative to the housing. The sheath preferably locates on the motor housing with a hand insertable clip action.

Preferably, the applicator head includes a removable outer portion in the form of a contact pad which fits over the sheath and is removable for cleaning purposes. The hand insertable clip action of the sheath to the motor housing ensures that the sheath remains in place as the contact pad is removed. Preferably, the contact pad is contoured or otherwise shaped to generally follow
the shape of the area being treated. Preferably, the contact pad is medially narrowed or narrowed at least to enable application of the applicator head to curved surfaces including regions of the arms and legs. Typically, treatment is applied by rolling the contact pad across the region being treated.

Preferably the applicator head includes an enlarged end. The enlarged end is typically generally rounded and more preferably is hemispherical. The end is also used for delivery of vibration as an alternative or adjunct to the roller treatment. In this case the enlarged end is applied as a point source of vibration.

Thus in a preferred form of the invention the assembly is generally pistol shaped, the applicator head having a bulbous or enlarged end enabling application of vibration in point form using the end of the applicator head in a non-rolling configuration to provide a second form of treatment. Normally, in addition to this point treatment, the applicator head is rolled across the surface being treated with the surface being treated in contact with the contoured portion of the applicator head in a manual rolling backward and forth fashion. Alternatively, treatment may be in a repetitive stroking form in a single direction from a starting point rather than back and forth.

Preferably, the applicator head and handle are made from separate parts assembled and connected together via the vibration dampening coupling. The vibration dampening coupling preferably includes cushion means located between the applicator head and the handle.

Preferably, the vibration dampening coupling includes a ball and socket arrangement where a ball and a socket either on the head or on the handle are located together to provide limited pivoting movement of the applicator head relative to the handle.

Preferably, the socket is located in the handle and the ball is located at one end of the applicator head. The ball is fitted into the socket and a fastener is passed through a portion of the handle to retain the ball and socket in operative position.

Preferably, the vibration dampening cushioning means is provided by an annular soft resilient surround which extends around the coupling between the head and the handle and extending about the ball and socket joint.
Preferably, the cushioning means comprises a lip extending across the joint and over a marginal edge portion of the motor housing and having an annular rib extending around the ball joint of the head and bridging between the handle and the head to assist with vibration dampening and to bias the head in resilient manner to a central position.

The handle preferably includes a display and PCB assembly, the display including a liquid crystal screen and there being a control button in order to operate a timing function. The timing function preferably comprises a numerical display of minutes of treatment, with a visual display of cumulative treatment time, typically in ten second intervals. Each ten second interval is usually displayed as a segment in a circular display divided into 12 segments which segments are lit as time progresses up to 12 of the segments for one minute. As minutes are reached numerals are displayed of the transpired minute count and the segments are cleared and begin to light progressively again up till the next minute, the minute display is incremented, the segments are then cleared and begin to light again and the process repeats. Thus, a user may easily and visually note the length of time a treatment has taken in accordance with their prescription from their physician. On, off, pause, reset functions and so on may be utilised with separate press buttons or a single press button may be utilised depending on whether there is a short switching or a time delay during switching to reset, start or switch off the unit as a whole.

The vibration may be constant across the surface of the applicator head or may vary. Preferably the vibration varies marginally with a vibration having an amplitude of about 1mm along the medial region and 1.5mm at the end of the head.

In order that the present invention may be more readily understood and be put into practical effect, reference will now be made to the accompanying drawings which illustrate a preferred embodiment of the invention and wherein:

Figure 1 is a perspective drawing of a vibration applicator according to the present invention;

Figure 2 is a perspective view from the opposite side;

Figure 3 is a side view;
Figure 4 is a partial exploded view;
Figure 5 is a partial exploded view of part of the assembly;
Figure 6 is a vertical section through the midline of the applicator;
Figure 7 is a horizontal section through the midline of the applicator head and part of the handle;
Figures 8 and 9 illustrate in more detail the vibration dampening coupling;
Figures 10 to 13 illustrate the assembly of the display and PCB board as a module;
Figure 14 illustrates a partial exploded view illustrating the insertion of the display and PCB board into the handle;
Figure 15 is a partial exploded view illustrating the motor and motor housing;
Figure 16 is an exploded view of the applicator and its associated cradle;
Figure 17 is a block diagram of a first embodiment of a circuit applicable to the present invention;
Figure 18 is a block diagram of a second embodiment of a circuit applicable to an applicator according to the present invention;
Figure 19 is a block diagram of a further embodiment illustrating more details of the massager operation and control in terms of the overall structure and motor frequency control;
Figure 20 is a flow diagram illustrating operation of the motor driver firmware (coarse control loop);
Figure 21 is a flow diagram illustrating the operation of the motor driver firmware (fine control loop);
Figures 22A and 22B are flow diagrams illustrating measurement of motor frequency;
Figure 23 is a flow diagram showing a typical process for providing an over-pressure indicator;
Figure 24 is a graph showing the participant agent in a clinical study;
Figure 25 is a graph showing the period of time from surgery to remove lymph nodes and the study; and
Figure 26 is a graph showing the period of time in months upon which participants in the study experienced clinically manifest lymphoedema.

Referring to the diagrams and initially to Figures 1-3 there is illustrated a hand held massage device 10 comprising a handle 11 and an applicator head 12. The handle includes a press button 13 for operation and a display 14. The applicator head 12 has a medial narrowing 15 and is adapted to free wheel in a rolling action relative to the handle 11. The end 16 is rounded so that a user may deliver endwise vibration to a site to be treated in addition to the other therapeutic mode of operation involving rolling with the medial narrowing portion 15 in contact with the surface being treated. Thus it will be appreciated that in the preferred embodiment two forms of treatment may be adopted.

Referring to Figure 4, there is shown an exploded view whereby the handle 11 is made up of two parts 17 and 18. Connected to the handle 11 is a motor housing 19 which has spaced ribs 20, 21, 22, 23 and 24. A roller sheath 25 clips onto the motor housing and travels on these ribs which in turn has a removal applicator 26 which passes over and is resiliently held on the sheath. The applicator 26 may be longer for leg treatment and in other shapes as may be desirable for different treatments.

The applicator 26 is of a flexible rubber like material and may be easily removed for cleaning.

Referring to Figure 5, the motor housing 19 and its connection to the handle section 17 is illustrated in exploded view where a ball section 27 co-operates with a clip 28 which passes through an opening in the handle section 17 and clips into the interior 29 of the ball section 27 to retain the ball in the handle. This will be illustrated in greater detail below.

Figures 6 and 7 illustrate sections through the device in its fully assembled form. A battery 30 is located inside the handle and a motor 31 with an output shaft 32 and an eccentric weight 33 is located in the head. The eccentric weight 33 creates a vibration which passes through to the applicator 26 via the sheath 25. The sheath 25 and applicator 26 roll on the ribs 20 through 24 while the handle is substantially isolated from the vibration by dampening means.
Figures 8 and 9 illustrate the connection of the motor housing to the handle where the ball section 27 of the motor housing fits into a corresponding socket section 34. The clip 28 (which is not present in Figure 8) is inserted into the position shown in Figure 9 and locks the joint together as shown. Vibration from the motor housing is dampened by a flexible spacer-come-washer arrangement illustrated at 32 which has two parts, an outer sealing part 33 and a bridging annular cushion part 34. The effect of this arrangement is that the motor housing via its ball joint arrangement, shown generally at 35, is effectively able to rock and joggle in any direction against the cushion afforded by the projection 34 and the seal 33. When the applicator head is applied to the surface being treated there is some give by reason of the ball joint connection and the vibration dampening arrangement, at the same time vibration is absorbed isolating the handle 11.

The display 14 is housed in a display module 36 illustrated in Figures 10 to 13 where the electronics in the PCB board and the display itself is held by a plate 37 which inserts into the housing 38 enabling the whole module to be screwed or otherwise secured in the handle as shown in Figure 14.

Figure 15 illustrates an exploded view of the motor housing 19 which is made from two parts screwed together and retaining the motor and its eccentric weight.

Figure 16 illustrates in exploded view a suitable cradle with the device able to be mounted for recharge and storage. This is how the final device would appear to the end user.

Figure 17 illustrates a simple block diagram of a typical circuit.

Figure 18 illustrates another version where an accelerometer at 39 is used to provide feedback to the user as to applied treatment pressure by way of a visual or audible signal when the applied pressure exceeds a predetermined limit. This is not essential to the invention but enables applied pressure by the user to the applicator head to be controlled other than by learned tactile control as in the case of Figure 17. This ensures that there is not over pressure as compared to the medical prescription for the treatment. This is particularly the
case in relation to lymphoedema where it is desirable to apply a relatively small load to the area being treated.

Applicant has found in relation to lymphoedema it is desirable to apply a relatively small load to the area being treated.

As described above, the massager unit has a user interface which consists of a single push button and an LCD. A single treatment involves 30 minutes of massage, the typical treatment procedure is set out later in this specification.

To initiate a treatment cycle the push button is pressed. The massage motor starts and the LCD backlight lights. The time display reads "30". Every 3 minutes an additional dial segment illuminates. After 30 minutes all 10 dial segments are illuminated indicating a complete cycle.

When the 30 minute cycle is complete the backlight will dim, and the motor will ramp down and turn off. The unit will remain in this stage for a period of 5 minutes. After 5 minutes has elapsed the system will shut down and enter a low power state. If the button is pressed before the 5 minute period has elapsed the unit will immediately shut down.

If the button is pressed during a session before the 30 minute cycle is complete, the unit pauses. In this state the motor and time stops, and the LCD backlight dims. The session can be continued with an additional press of the button. If the massager is left in pause for 5 minutes it will shut down, saving the session time in memory. Next time the button is pressed the unit will resume.

If the button is held down for 3 seconds (or longer) the unit will reset the timer, and power down.

If the unit is running, and placed on the charging dock, it will power down immediately, and store the timer value ready to resume on the next keypress.

When the unit is in the charging dock it does not respond to the button. (Assuming the charger is plugged in).

When the unit is charging, the battery icon is illuminated. The battery level segments on the LCD will step from left to right. When charging is complete icon turns off.
As the battery becomes exhausted the battery level segments will gradually reduce. When the battery is completely exhausted the outline will flash.

The massager charge port is a 2 wire interface. It is used for the dual purpose of battery charging and for data communication.

If the DC charge level is above a nominal threshold voltage the charger starts. If the level is pulsed below this threshold it can be used for communications.

The massager communications interface is configured as a slave. It will never attempt to send data unless it is requested to do so by the device connected to the interface.

This subsystem is based around a dedicated stand alone battery charger IC. It provides optimal charging conditions and protects the battery pack. The status of this device is monitored, but not controlled by the massager firmware.

The battery pack is a two cell rechargeable Ni-MH pack protected by an encapsulated polyswitch.

This subsystem is based around a dedicated power management IC. This steps the battery voltage up to a regulated 3.3V. This powers the entire circuit. This is protected against over voltage, over current, short circuit and has thermal cutout.

This subsystem inputs a PWM drive from the processor, and drives the motor. It also measures the motor voltage and motor current. These are monitored by the firmware, and are used along with the accelerometer data to control and regulate the motor speed by adjusting the PWM drive.

The motor driver uses the measured motor voltage, motor current and accelerometer frequency to accurately set and regulate the motor RPM.

The motor driver uses two separate control loops, one for course control as set out in Figure 20 and the second for fine control as set out in Figure 21.

On boot up the massager loads a target motor voltage out of the ERAM and into the memory. The main motor control loop starts the motor, measures the motor voltage and compares it to the target voltage. The control loop will continually adjust the PWM mark-space ratio to achieve this target voltage. This
is updated very quickly to accommodate and compensate for varying loads on
the motor - ie adjustments in application pressure, or during movement across
different densities of tissue or bone.

The unit frequency and motor firmware control is set out in Figures 22A
and 22B.

The motor frequency is obtained directly from the accelerometers. The
frequency is measured whenever the motor is turning, and is put into a running
average. This is high precision measurement with the absolute accuracy limited
by the CPU crystal. The motor frequency is compared to the target frequency
(42Hz). If the measured frequency differs from the target frequency the target
voltage is incremented or decremented and fed back into the coarse control
loop. On shut down the new target motor voltage is saved to ERAM.

This subsystem is used purely for motor frequency measurement.

This circuit is based around a 2 axis accelerometer, and associated
passive filtering components. The accelerometer is hard mounted on a remote
PCB at the tip of the contact head. This mechanically couples the accelerometer
to the motor/weight assembly which is also in the head (see Figure 15). The X
and Y axes are taken in a plane perpendicular to the motor axis (see Figure 5).
The signal amplitude is proportional to the tip acceleration, and the signal
frequency directly corresponds with the motor frequency. The measured
frequency is used by the firmware to set the motor speed.

The X and Y axis signal from the accelerometer are linked directly into the
processors high speed comparator input. An interrupt is caused at the signal X-
Y crossover point. A 1000ms gate is left open, and the crossover points are
counted. This directly corresponds to the motor frequency in hertz.

The measured frequency is discarded if it falls outside the band of 27-
60Hz. The sample period is 1000ms. A delay of 16ms is used to debounce the
measurement.

Referring to Figure 23, the over-pressure indication will now be described.

The unit contact head contains a two axis accelerometer. This is an electronic
measuring device used to measure and convert acceleration into an electrical
potential. In this application an accelerometer is used to measure the magnitude
and frequency of vibration of the contact head. This information is then used to extrapolate the applied pressure between the contact head, and the massage recipient.

As a result of the vibration generated by the unit motor/weight assembly the resultant waveform approximates two sine-waves, corresponding to the acceleration in the X and Y planes. The amplitude of each waveform is directly proportional to the acceleration.

Using classical physics formulae it is possible to use the above data to approximate the tip displacement in both X and Y planes.

When the contact head is held in free space the tip displacement is at a maximum. When the contact head is placed onto a medium some of the energy produced by the contact head is transferred into the medium. Assuming the medium does not resonate, this results in a proportional reduction of tip amplitude. As the contact pressure is increased, the tip amplitude will proportionally decrease.

The motor current, and voltage are monitored during run time. Assuming constant motor frequency, it is possible to use the motor current and voltage to measure variations in motor loading (Power applied to the motor). The motor loading value is used in conjunction with the accelerometer data to produce a numeric value. This numeric value is not calibrated, and therefore will be unit specific.

When the applied pressure exceeds a preset threshold value the "overpressure" icon will illuminate. When the applied pressure drops below the preset threshold the icon will turn off. The numeric value acquired is compared to a threshold value to illuminate the icon. The threshold value can be set and adjusted for each unit.

The processor is directly connected to the LCD. The processor contains all the hardware required to control the LCD.

The LCD backlight uses a PWM drive from the processor to set the LED junction current, controlling the backlight intensity. The intensity is modal, and is gently ramped.
The push button is directly connected to the processor, and polled by the firmware.

The massager may include other features including but not limited to the following:

During each session the firmware logs runtime data. These data logs can be accessed by connecting a custom interface box to the massager charging terminals.

 Principally for the purpose of preventative maintenance, the following data is logged:

- System odometer: Total accumulated run time in seconds (non resetable),
- System odometer: Total accumulated battery charge time in seconds (non resetable).
- System odometer: Total number of battery charges (non resetable).
- System odometer: Total number of key presses (non resetable).
- System odometer: Total number of sessions, where a session is defined as any run period over 50 seconds (non resetable).

The firmware automatically logs key usage statistics. The principle use of this feature is to provide technical feedback for consultants, and to aid in patient therapy progress analysis.

With the aid of a utility run on a desktop PC an administrator will be able to review each individual session length in minutes for the last 850 sessions. A real-time log start date can also be entered. This can also be cleared by an administrator.

As set out above, the applicant has found that application of low frequency vibration using a roller has the advantage of limiting damage to the skin while treating lymphoedema. The following treatment example was undertaken. A device according to the present invention was caused to vibrate at 42Hz with a tip amplitude of 1.5-2.0mm and a centre amplitude of 0.5-1.0mm, the device was applied with a rolling action using light pressure for a short 3-5 minute time over specific lymph drainage areas in patients with lymphoedema.
The trials resulted in a reduction of 5% of the total oedema and had the advantage of being self administered at home. Subjective patient response was very positive with 25% reduction in pain and improved movement of 28% after the first week. At the end of the second week perceived heaviness had improved by 26%, pins and needles reduced by over 24% and perceived arm size by 20%.

Applicant has further devised a home based sequence and protocol involving first clearing the lymph in regions adjacent the treatment site (eg neck and shoulder) before treating the site itself (eg the arm).

The preferred treatment is as follows:

Clearing the adjacent areas
- Roll the unit along the side of the neck from the shoulder to the base of the skull and back. Spend 2 minutes on each side of the neck.
- Use the head of the massage unit to massage gently into the non-affected armpit for 1 minute.
- Using the side of the massage unit, sweep across the top of the breast from the midline to the non-affected armpit and back for 1 minute.
- Using the side of the massage unit, sweep above the breast or scar from the affected armpit to the midline and back for 1 minute.
- Rest the side of the massage unit in the groin crease on the SAME side as the affected arm for 1 minute.
- Using the side of the massage unit sweep from underneath the breast or scar to the groin crease on the SAME side as the affected arm for 1 minute.

Massaging the Affected Arm
1. Using the side of the massage unit, sweep from the back of the elbow and up over the shoulder for 2 minutes.
2. Lift arm up, then using the side of the massage unit, sweep the inner side of the upper arm from the elbow down the side of your body. Make sure you pass the massage unit behind the armpit and not directly into it for 2 minutes.
3. Using the side of the massage unit, sweep the outer side of the forearm from the hand to the elbow for 2 minutes.

4. Using the side of the massage unit, sweep the inner side of the forearm from the hand to the elbow for 2 minutes.

To Finish

1. Using the side of the massage use long strokes from the affected outer fingers, over the outer arm to over the shoulder for 1 minute.

2. Using the side of the massage unit, use long strokes from the wrist, over the inner arm and down the side of the body for 1 minute.

3. Using the side of the massage unit, use long strokes from the affected armpit to the non-affected armpit for 1 minute.

The above procedure was followed in clinical studies of 30 patients. The procedure and results set out above are repeated in the context of the study which details follow.

Patients were randomly allocated to either the control group (who received current best information about skin and limb care, but on other standard treatment or management) and an experimental group who received treatment according to the present invention.

Sample size for the study was 30 control limbs and lymphoedema limbs.

The duration of the study was 28 days per patient. Patient to self administer as per the protocol. Treatment application can be morning or evening but there was a preference for evening. Patients were instructed to consume a full glass of water prior to and after each session. Patients and their partners were given full instructions on the equipment use prior to unsupervised use. A telephone support system was offered if required.

Patients presenting either of the following were to be included in the sample:

1. Patients presenting or diagnosed with clinically manifest chronic secondary unilateral arm lymphoedema.

2. Duration of lymphoedema greater than 1 year or a lesser period if the arm is already significantly large. Fluid rich arms are preferred over the middle stage fatty and the latter stage fibrous arms, as the percent of them which is the
more easily moveable fluid is less. However, this is not to be taken that vibration
is not likely to have an impact on late stages of lymphoedema. Specific
frequencies of vibration may have to be determined to ensure the optimal
targeting of these types of limbs.

Patients presenting any of the following were to be excluded in the
sample:

1. Current uncontrolled cancer
2. Recent surgery, ie within 1 month of treatment, in any other part of the
   body
3. Uncontrolled hypertension
4. Underlying lipoedema or myxoedema
5. Underlying primary lymphoedema
6. Arthritic or other skeletal changes
7. Blood clotting problems within last month
8. Recent treatment for lymphoedema in last month

NB: The majority of patients entered into the trial however had prior
treatment, often the best currently available.

Suitable patients were to have the following standard tests performed
immediately prior to the application of the treatment and at weekly intervals until
the completion of the trial at 28 days. Patients were reassessed for longer term
benefits after one month.

Assessment included the standard assessment procedures currently used
in the Flinders Lymphoedema Assessment Clinic at Flinders University in South
Australia. These were:

25  •  Subjective indicators of problems such as heaviness, tension,
bursting pains, pins and needles, and areas of paraesthesia
logged on 10 point Lichert scales.

25  •  Objective determination by tonometry of the levels of fibrotic
induration in each of the major limb and thoracic territories.

30  •  Objective determination of the amount of free extracellular and
intracellular fluids by bio-impedance.
Objective determination of limb volumes using perometery (circumference measurement in 200 positions on the limb and volume determination calculated from this).

All assessments were made by qualified persons (nurses and lymphoedema therapists) who were 'blinded' as far as possible with respect to the treatment the patients received.

The basic patient protocol included detailed instruction about how the patient should first clear the thoracic and attempt to clear the pelvic area. The development of the clearance program was undertaken by a Manual Lymphatic Drainage therapist, since clearance of the trunk is crucial to optimise the outcomes.

The full protocol and times are indicated below although from patient feedback it would seem that the majority undertook a slightly abbreviated version of this which more suited them. In the first part of the trial participants undertook self massage on the truncal regions and axilla but in later participants the hand held unit was used for this. There was no significant difference statistically between these two usage patterns and it is possible that the shorter participant based hand massage could be used to save time and make it easier for those with arm mobility issues and from those whose lymphoedema was on the dominant limb.

Clearing the Adjacent Areas.
1. Roll the unit along the side of the neck from the shoulder to the base of the skull and back. Spend 2 minutes on each side of the neck.
2. Use the head of the massage unit to massage gently into the non-affected arm pit for 1 minute.
3. Using the side of the massage unit, sweep across the top of the breast from the mid line to the non-affected arm pit and back for 1 minute.
4. Using the side of the massage unit, sweep above the breast or scar from the affected arm pit to the midline and back for 1 minute.
5. Rest the side of the massage unit in the groin crease on the SAME side as the affected arm for 1 minute.
6. Using the side of the massage unit sweep from underneath the breast or scar to the groin crease on the SAME side as the affected arm for 1 minute.

Massaging the Affected Arm.

1. Using the side of the massage unit, sweep from the back of the elbow and up over the shoulder for 2 minutes.

2. Lift arm up, then using the side of the massage unit, sweep the inner side of the upper arm from the elbow down the side of your body. Make sure you pass the massage unit behind the armpit and not directly into it for 2 minutes.

3. Using the side of the massage unit, sweep the outer side of the forearm from the hand to the elbow for 2 minutes.

4. Using the side of the massage unit, sweep the inner side of the forearm from the hand to the elbow for 2 minutes.

To Finish

1. Using the side of the massage unit use long strokes from the affected outer fingers, over the outer arm to over the shoulder for 1 minute.

2. Using the side of the massage unit, use long strokes from the wrist, over the inner arm and down the side of the body for 1 minute.

3. Using the side of the massage unit, use long strokes from the affected armpit to the non-affected armpit for 1 minute.

After the first demonstration of technique, patients were checked carefully prior to sending them home. The patient's partner, where possible, was also instructed on technique and given a full explanation of the process to support the participant. Instructions were given however, that the participant only should conduct the massage.

The participant's style and accuracy was checked in a subgroup of the participants. In this subgroup of 5 patients, they were asked to present to the clinic and the full range of measurements of perometry and bio-impedance made immediately prior to and immediately after their use of the hand held massage unit. Not only did this allow us to check technique and confirm that patterns and pressures were within our normal range, but also it allowed us to check the
specific effects of the use of the hand held massage unit over a short period of time with no confounding variables interfering.

Ideally the arm should be supported gently during the massage. This can range from resting in on a pillow or a wedge through to having a partner gently supporting it. To gain the best results it is best if the muscle elements of the upper and fore arms are as relaxed as possible.

The following analysis represents primarily a descriptive analysis only, that is one describing the trial outcomes only as they relate to the study group. The analysis of the trial data set is however, a full stand alone analysis describing the details of the trial.

Thirty valid patients are included in the results analysis. On occasions data may be missing from patients in this valid data set due to the patient being unable to present at the required time, machine measurement error (and thus the result was excluded on data checking) and on two occasions the measurement was unable to be made due to staff illness.

The mean age of the patients (depicted graphically in Figure 24) was 60.07 years with a standard deviation of 10.4. This is slightly older than the average diagnosis time of breast cancer but is in concert with the fact that lymphoedema takes an average of 3 years to become clinically manifest. Of the 30 participants, 25 were right handed and 5 left handed. Twelve had a partial mastectomy and axillary clearance while 15 had a total mastectomy and axillary clearance and 3 had a lumpectomy only.

**Surgical: number of nodes removed**

<table>
<thead>
<tr>
<th>Number of nodes removed</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>11-20</td>
<td>13</td>
<td>43.3</td>
</tr>
<tr>
<td>21-30</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>All visible</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Not known</td>
<td>8</td>
<td>26.7</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>
The average period of time from the indicated surgery was 10 years. The average date of the surgical intervention was 1996 and the most common date 1997. This is depicted graphically in Figure 25.

Eleven of the 30 patients had no positive lymph nodes, while 5 had 1-5 positive nodes, 2 had 6-10 positive nodes and the remainder more than 10. The nodal status was unknown in 8.

Twenty eight of the participants had radiotherapy while 17 had chemotherapy.

One person had un-medicated hypertension while another reported hypertension when unwell. Twenty three reported their blood pressure in normal range while 5 were under medication for their hypertension. A review of the two hypertensives showed that these had outcomes similar to those of the non hypertensives.

Three of the group had thyroid issues but all of these were medicated and this factor had no influence on outcomes.

Nine of the group reported some form of arthritis and on two possible occasions, when this involved the shoulder this resulted in some minor difficulties in undertaking the self massage.

Twenty five of the participants were post menopausal. Two were currently on HRT while two were previously on it. This factor had no impact on outcomes.

The average period of time after surgery that patients were first aware of what could be described as clinically manifested lymphoedema was 30 months. This is depicted graphically in Figure 26. This is in concert with prior studies about the onset of lymphoedemas.

The causes of the lymphoedema were wide ranging with 12 participants not being really sure of the precipitating factor. There was no relationship between precipitating factors and the outcome measures.
### LO: cause of LO

<table>
<thead>
<tr>
<th>Cause</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scratch</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Not Known (uncertain)</td>
<td>12</td>
<td>40.00</td>
</tr>
<tr>
<td>Hot weather</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Overuse of affected arm</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>Insect bite</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Cellulitus</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Shingles</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Long aircraft flight</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>Reconstructive surgery</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Renovating house</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

### LO: worse in evening

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>19</td>
</tr>
<tr>
<td>No</td>
<td>11</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30</strong></td>
</tr>
</tbody>
</table>

### LO: worse in hot weather

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>24</td>
</tr>
<tr>
<td>No</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30</strong></td>
</tr>
</tbody>
</table>

These reported scenarios of worsening however, had no impact on outcomes measured in this trial.

It is rare that a patient presents who has not had some prior treatment.

Further, some of them may have had the best currently available treatments.
However, it's important that any participant has not had active treatment within the last month as this could possibly mask the effect of the hand held result.

The distribution of last treatment periods are indicated in the table below.

<table>
<thead>
<tr>
<th>LO: last treatment</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 1 month ago</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>2-6 months ago</td>
<td>11</td>
<td>36.7</td>
</tr>
<tr>
<td>&gt; 6 months</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>&gt; 1 year</td>
<td>9</td>
<td>30.0</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>

In terms of the last active treatment, this ranged from complex physical therapy (1), Manual Lymphatic Drainage (22), compression bandaging (13), Laser (11) and Tai Chi (2). There was no relationship between the trial outcome measures and either the time of prior treatment or the type of prior treatment.

All results of arm measurements of bio-impedance, perometry and tonometry take into account the initial differences between the affected and unaffected (normal) arm and consider the impact of the variation in the normal arm values as the trial progresses.

Bio-impedance measures the amount of total segmental fluids in the limb up to the apex of the shoulder. The segmental fluids include the extracellular compartment volumes (consisting of fluids within the lymphatics, fluids within the blood vessels and mainly the fluids within the extracellular spaces) and the intracellular compartment (consisting of fluids within the cells – which normally are constant).
Mean fluid volume changes (mls) (Complete data set)

<table>
<thead>
<tr>
<th>Value</th>
<th>LO- Normal limb vol diff</th>
<th>mls reduction over period</th>
<th>% reduction in excess fluids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>642</td>
<td>-----</td>
<td>---------------------------</td>
</tr>
<tr>
<td>One week</td>
<td>612</td>
<td>35</td>
<td>5.7</td>
</tr>
<tr>
<td>Two weeks</td>
<td>575</td>
<td>26</td>
<td>4.5</td>
</tr>
<tr>
<td>Three weeks</td>
<td>587</td>
<td>36</td>
<td>6.1</td>
</tr>
<tr>
<td>Four weeks</td>
<td>607</td>
<td>39</td>
<td>6.4</td>
</tr>
<tr>
<td>One month after end treat</td>
<td>637</td>
<td>-2.0</td>
<td>0</td>
</tr>
</tbody>
</table>

None of these differences were statistically significant due to the small reductions (which was expected) and the relatively small sample size. These reductions were however practically and biologically significant as is shown in subsequent sections of this report.

Of greatest interest was that the highest reductions were achieved in those persons with the largest initial volume differences (one case is presented below). This outcome needs to be further explored in a more detailed analysis of inter-relationships.

<table>
<thead>
<tr>
<th>Value</th>
<th>LO- Normal Vol difference</th>
<th>mls reduction over period</th>
<th>% reduction in excess fluids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>1050</td>
<td>-----</td>
<td>---------------------------</td>
</tr>
<tr>
<td>One week</td>
<td>480</td>
<td>450</td>
<td>45.7</td>
</tr>
<tr>
<td>Two weeks</td>
<td>450</td>
<td>42.8</td>
<td></td>
</tr>
<tr>
<td>Three weeks</td>
<td>310</td>
<td>29.5</td>
<td></td>
</tr>
<tr>
<td>Four weeks</td>
<td>340</td>
<td>32.4</td>
<td></td>
</tr>
<tr>
<td>One month after end treat</td>
<td>90</td>
<td>8.6</td>
<td></td>
</tr>
</tbody>
</table>

Interestingly this does show what is possible in a large and relatively fluid rich arm. The reasons for the excellent result at one week and then a declining result are not clear.

Perometry measures the total limb volume, but is only able to measure it into the middle upper-arm and does not account for changes in limb size in the axillary area. Bio-impedance does take into account fluid changes in this area. For this reason there can be a discrepancy between these values. However, in
general terms, some of the larger differences in perometry and bio-impedance can be accounted for in terms of the effect of treatment either on the fluid alone or on the tissue composition, for instance changes in fat or perhaps even muscle volumes.

<table>
<thead>
<tr>
<th>Value</th>
<th>LO- Normal limb vol diff</th>
<th>mls reduction over period</th>
<th>% reduction in excess tissues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>1026</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>One week</td>
<td>1017</td>
<td>2</td>
<td>0.2</td>
</tr>
<tr>
<td>Two weeks</td>
<td>1017</td>
<td>5</td>
<td>0.5</td>
</tr>
<tr>
<td>Three weeks</td>
<td>1010</td>
<td>33</td>
<td>3.3</td>
</tr>
<tr>
<td>Four weeks</td>
<td>977</td>
<td>25</td>
<td>2.5</td>
</tr>
<tr>
<td>One month after end</td>
<td>1047</td>
<td>+59</td>
<td>5.7</td>
</tr>
</tbody>
</table>

This measurement of the whole limb indicates that most fluid reductions must be occurring in the most proximal part of the upper arm — that is its root, which encompasses the axillary area. The outcomes indicate that in order to maintain control that treatment must be continued. This need is in concert with all other professionally administered treatments for lymphoedema.

<table>
<thead>
<tr>
<th>Value</th>
<th>LO- Normal limb vol diff</th>
<th>mls reduction over period</th>
<th>% reduction in excess tissues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>633</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>One week</td>
<td>638</td>
<td>24</td>
<td>3.8</td>
</tr>
<tr>
<td>Two weeks</td>
<td>621</td>
<td>30</td>
<td>4.8</td>
</tr>
<tr>
<td>Three weeks</td>
<td>631</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Four weeks</td>
<td>637</td>
<td>27</td>
<td>4.2</td>
</tr>
<tr>
<td>One month after end</td>
<td>624</td>
<td>+67</td>
<td>10.5</td>
</tr>
</tbody>
</table>

Some of the improvement however, clearly occurs in the forearm and this tends to occur fairly quickly, that is within the first week of treatment.

Tonometry is a surrogate measure of the amount of fibre in the tissues. Its value also may change when a limb becomes smaller and this artifactual hardening must be taken into account when examining tonometry data. Given the gentle nature of the hand held massage and its relatively short duration per day great changes in tonometry are not expected.
Mean Group Tonometry values

<table>
<thead>
<tr>
<th>Detail</th>
<th>Baseline</th>
<th>Week 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphoedema Forearm</td>
<td>4.71</td>
<td>4.86</td>
</tr>
<tr>
<td>Lymphoedema Upper arm</td>
<td>5.25</td>
<td>5.23</td>
</tr>
<tr>
<td>Affected anterior thoracic</td>
<td>8.81</td>
<td>8.87</td>
</tr>
<tr>
<td>Affected posterior thoracic</td>
<td>3.34</td>
<td>3.83</td>
</tr>
<tr>
<td>Normal Forearm</td>
<td>4.63</td>
<td>4.73</td>
</tr>
<tr>
<td>Normal Upper arm</td>
<td>5.77</td>
<td>5.70</td>
</tr>
<tr>
<td>Normal anterior thoracic</td>
<td>9.56</td>
<td>9.19</td>
</tr>
<tr>
<td>Normal posterior thoracic</td>
<td>3.51</td>
<td>3.2</td>
</tr>
</tbody>
</table>

While none of these values are statistically significant they do show that there has been no progression of the induration over the treatment period and in fact the trend shows a tendency to soften in the affected arm as well as the posterior thorax on the affected side.

There is strong evidence in the literature that as far as the patient is concerned they are mostly concerned about how their limb feels rather than its size. Accordingly, increasing weight is being placed on the impact of treatments on subjective issues.

Subjective data will be presented in two formats firstly looking at the % change of the various parameters and then looking at the statistical significances.

Subjective parameters where statistically significant improvements are observed. While this statistically significant improvement is crucial and important to satisfy the scientific and medical community what is important from the patient perspective is how the limb feels and looks.

Statistically significant differences are indicated in bold and greatest raw and percent difference indicated in bold italics. When the difference is statistically significant and the largest reduction this is indicated in italics.
Mean subjective indicators (based on 1-10 point boxed scale)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Baseline</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>One month FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>1.83</td>
<td><strong>1.37</strong></td>
<td>1.44</td>
<td>1.65</td>
<td>1.49</td>
<td>1.52</td>
</tr>
<tr>
<td>Heaviness</td>
<td>4.23</td>
<td>3.89</td>
<td>3.11</td>
<td><strong>3.46</strong></td>
<td>3.36</td>
<td>4.10</td>
</tr>
<tr>
<td>Tightness</td>
<td>3.33</td>
<td><strong>2.63</strong></td>
<td>2.67</td>
<td>3.00</td>
<td>3.40</td>
<td>3.62</td>
</tr>
<tr>
<td>Hardness</td>
<td>3.67</td>
<td>3.52</td>
<td><strong>3.17</strong></td>
<td>3.46</td>
<td>3.80</td>
<td>3.81</td>
</tr>
<tr>
<td>Temperature</td>
<td>2.23</td>
<td>1.81</td>
<td>2.07</td>
<td>1.77</td>
<td>1.80</td>
<td>2.29</td>
</tr>
<tr>
<td>Cramps</td>
<td>1.00</td>
<td><strong>1.00</strong></td>
<td>1.11</td>
<td>1.08</td>
<td>1.04</td>
<td>1.00</td>
</tr>
<tr>
<td>Pins/needles</td>
<td>1.53</td>
<td>1.22</td>
<td><strong>1.15</strong></td>
<td>1.38</td>
<td>1.40</td>
<td>1.24</td>
</tr>
<tr>
<td>Arm size</td>
<td>7.08</td>
<td><strong>6.29</strong></td>
<td>5.80</td>
<td><strong>5.58</strong></td>
<td>5.24</td>
<td><strong>5.81</strong></td>
</tr>
<tr>
<td>Range of Movement</td>
<td>3.67</td>
<td><strong>2.63</strong></td>
<td>2.59</td>
<td>2.96</td>
<td>2.44</td>
<td><strong>2.71</strong></td>
</tr>
</tbody>
</table>

Percentage (%) reductions in the indicated parameters from baseline

<table>
<thead>
<tr>
<th>Condition</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>One month FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td><strong>25.1</strong></td>
<td>21.3</td>
<td>9.8</td>
<td>18.5</td>
<td>16.9</td>
</tr>
<tr>
<td>Heaviness</td>
<td>9.9</td>
<td>26.5</td>
<td><strong>18.8</strong></td>
<td>20.6</td>
<td>3.1</td>
</tr>
<tr>
<td>Tightness</td>
<td><strong>21.0</strong></td>
<td>19.8</td>
<td>9.9</td>
<td>+2.1</td>
<td>+8.7</td>
</tr>
<tr>
<td>Hardness</td>
<td>4.0</td>
<td><strong>13.6</strong></td>
<td>5.7</td>
<td>+3.5</td>
<td>+3.8</td>
</tr>
<tr>
<td>Temperature</td>
<td>18.8</td>
<td>7.1</td>
<td><strong>20.6</strong></td>
<td>19.2</td>
<td>+2.6</td>
</tr>
<tr>
<td>Cramps</td>
<td><strong>0.0</strong></td>
<td>+11.0</td>
<td>+8.0</td>
<td>+4.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Pins/needles</td>
<td>20.2</td>
<td><strong>24.8</strong></td>
<td>10.0</td>
<td>8.5</td>
<td>18.9</td>
</tr>
<tr>
<td>Arm size</td>
<td><strong>11.1</strong></td>
<td><strong>20.4</strong></td>
<td>23.5</td>
<td>26.0</td>
<td><strong>17.9</strong></td>
</tr>
<tr>
<td>Range of Movement</td>
<td><strong>28.3</strong></td>
<td><strong>29.4</strong></td>
<td>19.3</td>
<td>33.5</td>
<td><strong>26.1</strong></td>
</tr>
</tbody>
</table>

While the outcomes of this home based treatment regimen do not seem great, they are very significant in the picture of attempts to control lymphoedemas.

For instance in the following intensive treatment programs the following percentage reductions were obtained. There are many other such studies and many of them do not have as good an outcome as these.

- Swedborg et al ('93) - MLD 2 wk 10%
- Johansson et al ('98) - MLD 4 wk 15%
- Carati and Piller et al ('03) Laser 8 wk 18%
(These studies have been used since they are scientifically strong and have used formulae similar to those used in this study).

The remainder of the discussion must be read in this context.

Self management of chronic arm lymphoedema in the home certainly can lead to an excellent outcome for the patient both from the point of view of the actual size and fluid volume in the limb, but also (and perhaps most importantly) from the point of view of how the limb feels - that is the subjective indicators. As mentioned previously, how the limb feels can often be more important to the patient than the size of the limb.

The key finding of this report must be couched in the knowledge that this group of patients had received in the main some of the best treatment that was available at a health professional level and were generally well aware of what their strategies were to apply optimal care for the limb. The findings of this trial must be viewed with this knowledge clearly on ones mind.

It should also be remembered that neither, for at least the month prior to or during this trial, did any of the patients receive any professional treatment. Given that the aim of this hand held unit was to help maintain treatment reductions in between treatments from health professionals, it exceeded expectations in that it alone was able to facilitate a range of subjective and objective reductions.

Whilst many of the objective reductions were not statistically significant, they no doubt were of strong practical and biological significance as can be gained from the statistically significant reductions in a range of subjective parameters including perceived limb hardness and range of movement.

Using the hand held unit for a week was able to result in an average 5.7% reduction in the excess oedema fluid volume. This improved to 6.4% at four weeks but within a month of ceasing treatment the limb had returned to its normal size again - emphasizing the need for ongoing management.
Larger more fluid rich arms responded better than smaller fluid rich arms and these better than those which were slightly fatty or fibrousy. One patient with an arm fluid volume difference of over one litre obtained an initial 45% reduction in this excess volume, although this outcome could not be maintained over the duration of the trial.

Generally speaking perometry showed slightly lesser reductions (as this measures whole limb volume - which includes fluid, fat, fibre and muscle). However, small % reductions were recorded which reversed at the cessation of treatment.

Generally speaking tonometry showed little change over the treatment period although there was always a tendency for the limbs and the anterior and posterior thoracic area to soften. This indicates a reduced level of fibrous tissue. It is interesting that this occurred since the patients were selected in their relatively early stage of lymphoedema when fibrotic induration was not significantly outside of normal range.

Specifically speaking the subjective changes far outweighed the objective ones and as mentioned previously this is often what is most important for the patient.

Many subjective parameters showed rapid and early improvement with pain reducing by over 25% and range of movement improving by 28% by the end of the first week.

Heaviness improved by over 26%, pins and needles by over 24% and perceived arm size by over 20% by the end of the second week.

If a patient can achieve these outcomes alone (albeit under our instruction), it is a strong sign that even better results may be obtained when the patient receives treatment from a health professional.

The ability to self manage lymphoedema will reduce the overall cost for lymphoedema treatment for the patient since there may be a reduced need for visits to the health professional.

The outcomes from this study may be able to be extrapolated to other conditions of fluid accumulation in the body such as lymphoedema of the legs or truncal regions. There may also be an opportunity to suggest and
extrapolation to venous oedemas although this perhaps would need a small additional investigation of this specific group.

Whilst the above has been given by way of illustrative example of the present invention many variations and modifications thereto will be apparent to those skilled in the art without departing from the broad ambit and scope of the invention as herein set forth. In addition, the use of "comprising" should not be taken as exhaustive and additional features may be added to the combination specified in any case.
1. A massage device comprising a handle, an applicator head projecting from the handle, a vibratory source adapted to deliver vibration to the applicator head, and an over-pressure sensor and indicator, wherein the applicator head is coupled to the handle and adapted to roll over a surface being treated.

2. A massage device according to claim 1, wherein the applicator head is coupled to the handle via a vibration dampening coupling and the vibratory source is located in the applicator head.

3. A massage device according to any one of claims 1 or 2, wherein the applicator head comprises a hollow motor housing and a motor, the motor having an eccentrically mounted weight for the purpose of generating vibration within the applicator head.

4. A massage device according to claim 3, wherein the motor housing comprises ribs for enabling a sheath on the applicator head to rotate on the motor housing.

5. A massage device according to any one of the preceding claims, wherein the applicator head includes a removable outer portion in the form of a contact pad which fits over the sheath and is removable for cleaning purposes.

6. A massage device according to any one of the preceding claims, wherein the device is generally pistol shaped, the applicator head having a roller with a side and a bulbous or enlarged end enabling application of vibration in point form using the end of the applicator head in a non-rolling configuration and the side of the roller in a rolling action.
7. A massage device according to any one of claims 2 to 6, wherein the vibration dampening coupling includes a ball and socket arrangement where a ball and socket either on the applicator head or on the handle are located together to provide limited pivoting movement of the applicator head relative to the handle.

8. A massage device according to any one of claims 2 to 7, wherein the vibration dampening coupling comprises a cushioning means.

9. A massage device according to claim 8, wherein the cushioning means is provided by an annular soft resilient surround which extends around the coupling between the applicator head and the handle and extending about the ball and socket arrangement.

10. A massage device according to any one of the preceding claims, wherein the handle includes a display and PCB assembly, the display including a liquid crystal screen and there being a control button in order to operate a timing function.

11. A massage device according to claim 10, wherein the timing function comprises a numerical display of minutes of treatment, with a visual display of cumulative treatment time.

12. A massage device according to any one of the preceding claims, further comprising a frequency controller wherein the vibration frequency is automatically adjusted during use.

13. A method of self administration of therapeutic massage using a hand held massager of the type having a handle and a roller head delivering vibration through the roller head to a treatment site, the method comprising the step of applying the roller head in a roller action along the treatment site in a predetermined treatment direction, and under a predetermined manual
pressure, wherein the manual pressure is monitored using an over-pressure sensor and indicator.

14. A method of self administration of therapeutic massage according to claim 13 wherein the roller head is applied under a predetermined mechanical vibration having low frequency and low amplitude in order to approximate lymphatic drainage massage.

15. A method of self administration of therapeutic massage according to any one of claims 13 or 14 wherein the manual pressure is monitored electronically using a transducer with feedback to the user leading the user to reduce the applied manual pressure in case of over-pressure.

16. A method of self administration of therapeutic massage according to any one of claims 13 to 15 for relief from lymphoedema, wherein the vibration frequency is up to 100 Hz.

17. A method of self administration of therapeutic massage according to any one of claims 13 to 16 for relief from lymphoedema, wherein the vibration frequency is in the range from 30-50 Hz.

18. A method of self administration of therapeutic massage according to any one of claims 13 to 17 for relief from lymphoedema, wherein the massager has vibration amplitude at the treatment site of a few millimetres as applied to the tissue in the range 0.5- 2.0mm.

19. A method of self administration of therapeutic massage according to any one of claims 13 to 18 for relief from lymphoedema, wherein the applied manual pressure does not exceed the equivalent of about 250 gms applied.
20. A method of self administration of therapeutic massage according to any one of claims 13 to 19 for relief from lymphoedema at a main site, the method involving first clearing lymphatic regions adjacent the main site before treating the main site.
FIG. 19
Other system tasks

Measure $V_{motor}$

$V_{motor} > Target_{motor\_voltage}$

- NO: increment $target_{motor\_pwm}$
- YES: decrement $target_{motor\_pwm}$

Motor $PWM > Target_{PWM}$

- NO: increment $motor\_pwm$
- YES: decrement $motor\_pwm$

update motor

FIG. 20
Other system tasks

Calculate Frequency_error

Frequency_error = 0?

NO

Frequency_error Positive?

YES

Target_motor_voltage + 0.001

NO

Target_motor_voltage - 0.001

FIG. 21
On 1000mS interrupt:

Accf_pulsecounts > 27 and < 60?

- No: Accf_pulsecounts = 0
- Yes:
  - Acc_frequency = Accf_pulsecounts
  - Append to running average of Accf_pulsecounts
  - Accf_pulsecount = 0

Return

FIG. 22A

On X - Y crossing (Comparator interrupt):

- Increment Accf_pulsecount
- Disable Comparator Interrupt
- Enable and start TCNT0 for debounce delay

...16.4mS later...

Return

On TCNT0:

- Stop and disable TCNT0
- Enable Comparator Interrupt

Return

FIG. 22B
START

Motor_Freq = Target_freq?

No

Measure X and Y accelerometer voltages, append to running average

Yes

Calculate Motor_loading based on motor current and voltage

Calculate Tip Amplitude value based on volatge

Calculate Tip_force_value

Tip_Force_value > threshold?

No

Yes

Illuminate "Overpressure" icon

Turn off "Overpressure" icon

Return

FIG. 23