Records processed under FOIA Request 2013-1897; Released 9/15/14

U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K053225 - 1108 pages
COMPANY:	LPG ONE, INC (LPGONE)
PRODUCT:	MASSAGER, THERAPEUTIC, ELECTRIC (ISA)
SUMMARY:	Product: CELLU M6 KEYMODULE I
DATE REQUESTED:	Jun 23, 2014
DATE PRINTED:	Jun 23, 2014
Note:	Printed

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

K053225

page 1 out 2

510(k) Summary
As Required by 21 section 807.92 (c)

NOV - 6 2006

1-Submitter Name: LPG One, Inc
2-Address: 801 Brickell Ave. Suite 850. Miami, FL 33131
3-Phone: (305) 379- 8800
4-Fax: (305) 375- 0903
5-Contact Person (Consultant): Jay Mansour of Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA
(678) 908-8180. Fax (678) 623-3765
6-Date summary prepared: September 16th, 2006
7-Device Trade or Proprietary Name: CELLU M6 KEYMODULE i
8-Device Common or usual name: Massager
9-Device Classification Name: Electrical Therapeutic Massager
10-Substantial Equivalency is claimed against the following devices:

1- LPG One (formerly LPG USA) ES1 Massager- 510k #K990445
2- Shepard Medical's Sport Pump- 510k #K912004
3- Progressive Medical's Multipulse Sequential Compression unit- 510k #K914774
4- Grad-Line's Atlant's- 510k #K974395
5- Model SC-3008 Sequential Circulator- 510k #K043423
6- Flexitouch (also known as Biotouch)- 510k #K013061

11-Description of the Device:

The Cellu M6 Keymodule i electrical therapeutic massager is comprised of a program console housing a vacuum pump and a regulation system. The main treatment head i50 consists of two parallel motorized rollers housed in a chamber which produces both negative pressure above the rollers and positive pressure below the rollers. This technology creates a skin fold between the two rollers in a suction chamber, thus mimicking the "rolled palpation" of manual massage techniques.

In addition to Head i50 which is meant primarily for the upper arm and for legs, auxiliary heads T615, T615-A, T630, T630-A, T644 and T644-A are also used, as they better suit smaller morphology (parts) of the body. Details are provided along the labeling provided.

This device has the capability to produce both constant and sequential aspiration. Constant aspiration provides a deeper massage, which also mobilizes the muscle fascia. With sequential aspiration, the suction power is cyclically interrupted to provide pulsation to the skin fold between the two rollers and a softer, gentler stroking action of the tissues.

The suction power ranges from 45 mm Hg to 180 mmHg, which is represented by a power level scale ranging from 1 to 4.

12-Intended use of the device: (refer to FDA form attached)

The intended uses of this device are:

PAGE 3.1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Reduction of secondary lymphedema of the Arm (SLA) Post Mastectomy
Improvement of secondary lymphedema
Improvement of lymphatic circulation in the treated area

13-Safety and Effectiveness of the device:

This device is safe and effective as the predicate devices cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate devices. Refer to the explanations/details within the main submission.

FDA file reference number	510k # K912004, K914774, K974395, K043423 and K013061	510k #K990445
TECHNOLOGICAL CHARACTERISTICS	**Comparison result of this device with the predicate devices**	
Indications for use	Identical	Different
Target population	Identical	Different
Design	Similar in terms of mode of action	Very similar
Materials		
Performance		
Sterility	Not applicable	
Biocompatibility	Similar	
Mechanical safety		
Chemical safety	Not applicable	
Anatomical sites	Similar	Similar
Human factors		Similar
Energy used and/or delivered		Very similar
Compatibility with environment and other devices		Identical
Where used		Similar
Standards met		Very similar
Electrical safety		Very similar
Thermal safety	NOT APPLICABLE	
Radiation safety		

Refer to the submission for more details.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LPG One, Inc.
C/o Jay Mansour, MSQA, BE, RAC
President, Mansur Consulting, LLC
845 Aronson Lake Court
Roswell, GA 30075

NOV - 6 2006

Re: K053225
Trade/Device Name: Cellu M6 Keymodule i
Regulation Number: 21 CFR 890.5665
Regulation Name: Therapeutic Massager
Regulatory Class: 21 CFR 890.9 - Limitations of exemptions from section 890.5660 - Class I
Product Code: ISA - IRO
Dated: June 23, 2006
Received: July 3, 2006

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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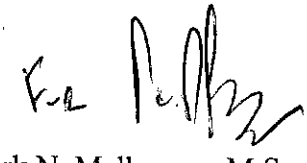
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- 410 DGRND
D.O.

f/t: DXV: 10- 31-06

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Indications for Use

510(k) Number (if known): K053225

Device Name: CelluM6 Keymodule i

Indications For Use:

Reduction of Secondary Lymphedema of the Arm (SLA) Post Mastectomy
Improvement of Secondary Lymphedema
Improvement of lymphatic circulation in the treated area

Prescription Use ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K053225

(Division Sign-Off)
Division of General, Restorative, Page 1 of 1
and Neurological Devices

510(k) Number K053225 PAGE 4.1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DXV

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administratio

Memorandum

Date: 11/7/06

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K053225/A2

To: Division Director: PM/DGRND

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checke below.

_____Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____Additional information requires a new 510(k); however, the information submitted is incomplete; (Noitify company to submit a new 510(k);[Prepare the K30 Letter on the LAN]

_X_No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____Information requires a CLIA CATEGORIZATION; the complexity may remain the sam as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

____Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)

_____No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: MN

Date: _____

Draft #2 : 9/8/99
Draft #3: 1/3/00
Draft #4: 3/7/03

DMC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MANSOUR CONSULTING

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER HFZ-401

9200 CORPORATE BLVD
ROCKVILLE, MD 20850

ATTENTION: DR DORA VEGA, M.D., Ph.D
TEL (NEW) 240 276 3609 FAX (NEW) 240 276 3602

K053225 / A2

SUBJECT: 510K #K053225

Dear Dr Vega,

In follow up to our recent phone discussions and emails and faxes, please find attached the following documents, sent in duplicates (1 original, 1 copy):

1- Revised summary (Tab 1)
2- Revised indications for use form (Tab 2)
3- Revised brochure (Tab 3)
4- Revised directions for use (Tab 4)

The above sections have been updated to reflect the **deletion** of the following indications for use:

(b)(4) [redacted]

I hope that this letter will satisfactorily answer any remaining concerns.

Thank you very much for the cooperation and assistance throughout this lengthy process.

Please don't hesitate in pointing out any minor adjustment that may still be required. We will make sure to rectify any issue immediately, as minor as it may be.

Best Regards,

Jay Mansour, MSQA, BE, RAC, LA
President
Mansour Consulting LLC for LPG One

K26
2

Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA

Phone: 1-678-908-8180
Fax: 1-678-623-3765

info@mansourconsulting.com
www.mansourconsulting.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary
As Required by 21 section 807.92 (c)

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3-Phone: (305) 379- 8800
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The intended uses of this device are:

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TECHNOLOGICAL CHARACTERISTICS	**Comparison result of this device with the predicate devices**	
Indications for use	Identical	Different
Target population	Identical	Different
Design	Similar in terms of mode of action	Very similar
Materials		
Performance		
Sterility	Not applicable	
Biocompatibility	Similar	
Mechanical safety		
Chemical safety	Not applicable	
Anatomical sites	Similar	Similar
Human factors		Similar
Energy used and/or delivered		Very similar
Compatibility with environment and other devices		Identical
Where used		Similar
Standards met		Very similar
Electrical safety		Very similar
Thermal safety	NOT APPLICABLE	
Radiation safety		

Refer to the submission for more details.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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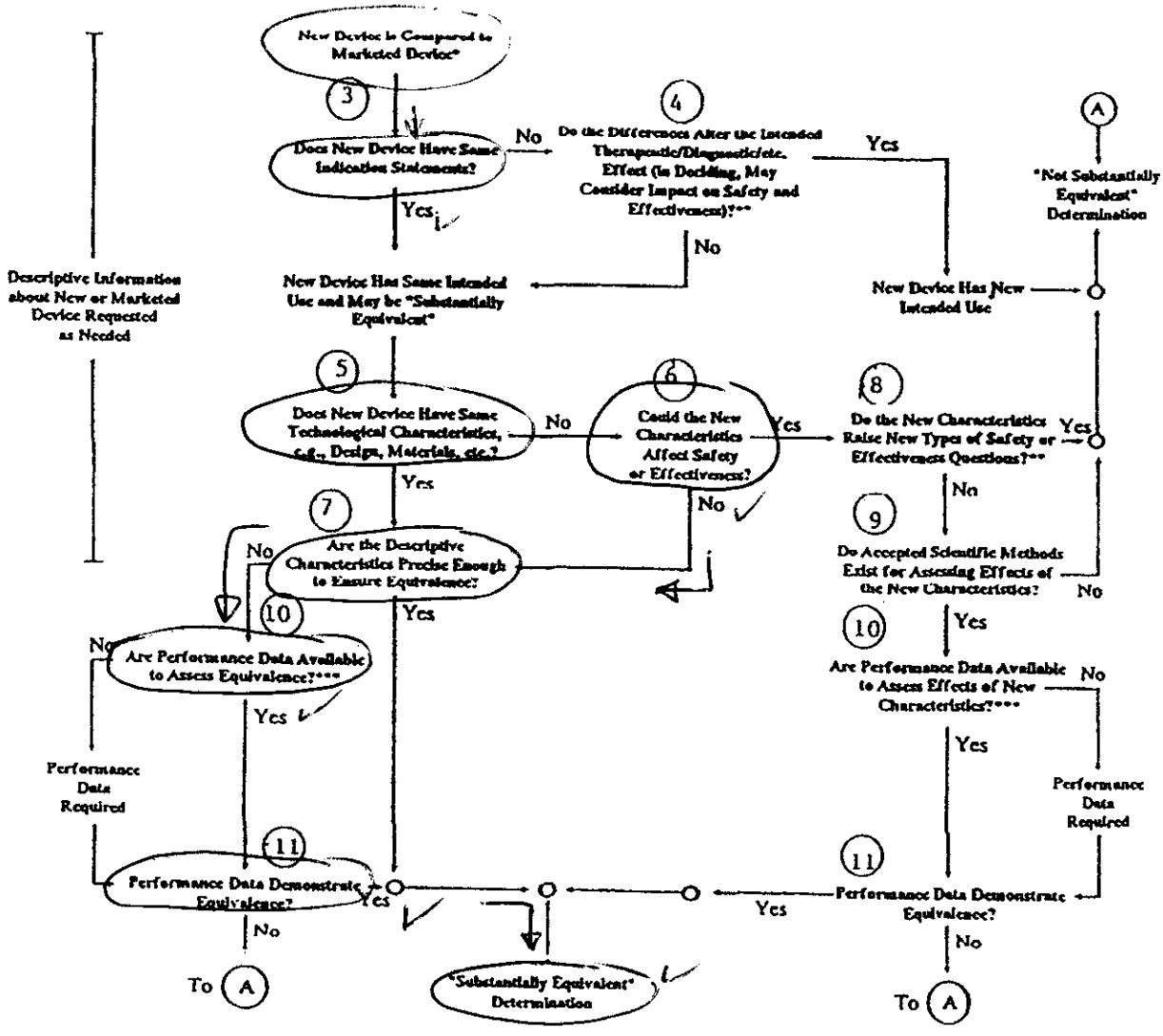
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Indications for Use

510(k) Number (if known): K053225

Device Name: CelluM6 Keymodule i

Indications For Use:

Reduction of Secondary Lymphedema of the Arm (SLA) Post Mastectomy
Improvement of Secondary Lymphedema
Improvement of lymphatic circulation in the treated area

Prescription Use ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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ATTACHMENT 17

CELLU M6® KEYMODULE *i*

LPG

CAUTION: Federal law restricts this device to sale by or on the order of a clinician licensed by the law of the state where he/she practices to use or order the use of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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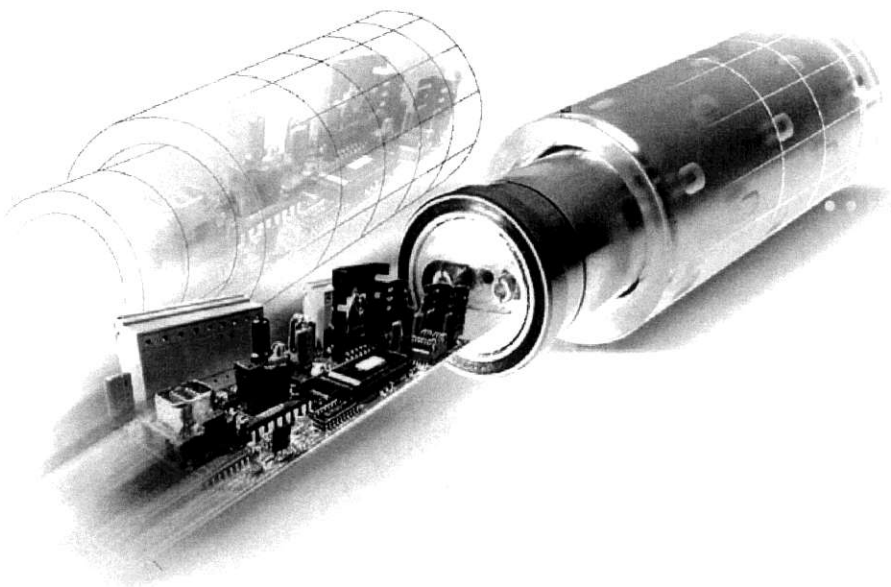
MOBILITY

TISSUE TREATMENT IN ALL ITS DIMENSIONS

Each roller incorporates a miniaturized high-technology motor, allowing for optimal mobilization of the tissues.



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SELECTIVITY

THERAPEUTIC BENEFITS □□□□

- Secondary lymphedema of the arm post-mastectomy
- Secondary lymphedema
- Lymphatic circulation

A NEW INTELLIGENT INTERFACE

The ***Cellu M6 Keymodule i*** is your gateway to the field of therapeutics. Fast and intuitive navigation will enable you to achieve your goal: targeted results that will satisfy your patients.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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584 - English - LPG Systems Siren 335 183 836 RC5 Romans - © Copyright LPG 2002 - LPG, Cellu M6, Keymodule, Roll in, Roll out and Roll up are registered trademarks. Any reproduction - even in part - is strictly prohibited. Non-binding photos.

CE 0088

LPG
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801 Brickell Avenue • Suite 850 • Miami, FL 33131
Tel: 800.222.3911 • Fax: 305.375.0903
www.endermologie1.com
www.lpgone.com

LPG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Use of the Keymodule device is contraindicated for:

The CelluM6 Keymodule i should not be used on certain areas or under certain conditions.

1. This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.

2. Do not treat wounds, infected areas, skin tumors, open sores, scars form recent surgery, the eyes, intra-cavity areas, mucous membranes, the genitals or directly over nipples.

3. Do not treat patients with infectious progressive illnesses.

4. Do not treat patients with active cancer or a growing tumor. (Consult with the doctor if the patient has had a case history of tumors or is in remission.)

5. This device is contraindicated for skin cancer, tumors and other cancerous lesions in the area to be treated.

6. Do not treat patients suffering from inexplicable and persistent pain without seeking medical advice or without training in the LPG technique in this particular area.

7. Do not treat patients following invasive medical treatment without seeking the medical advice of the doctor or surgeon who performed this operation, or without training in the LPG technique in this particular area.

8. Not recommended for anyone under medical care for circulatory conditions without first consulting a physician.

9. Not recommended for pregnant women.

10. Stop treatment immediately if patient experiences any pain and consult the physician.

11. Avoid possible bruising. Use caution when determining a patient's sensitivity level.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT 18

Directions for Use

Cellu M6 Keymodule i
(Refer to Operator's Manual)

Caution: Federal law restricts this device to sale by or on the order of a clinician licensed by the law of the state where he/she practices to use or order the use of the device.

This device is indicated for use for the following:

- Reduction of secondary lymphedema of the arm (SLA) post mastectomy
- Improvement of secondary lymphedema
- Improvement of lymphatic circulation in the treated areas

Directions for Use

The directions for use for this device are illustrated in this section over the following pages. For maximum efficiency, the treatment heads should be chosen according to the morphology of the treated area as illustrated below:

Motorized Heads:

i50	for the upper arm in the treatment of SLA; for abdomen and legs in the treatment of lymphedema

Auxiliary Heads (*Active* and *Inactive*):

T644-A/T644	(as needed for small morphology)
T630-A/T630	(as needed for smaller morphology)
T615-A/T615	(as needed for smallest morphology)

Active auxiliary heads are loaded with springs behind the rollers. The function of the springs in the *Active* auxiliary heads is to allow for optimal movement of the rollers on the tissues when using sequential aspiration (or pulsating) programs designed to create the pump or wave-like action when treating lymphedema-related conditions.

Inactive heads do not have springs behind the rollers, and are meant to be used with constant suction settings for more static and deeper actions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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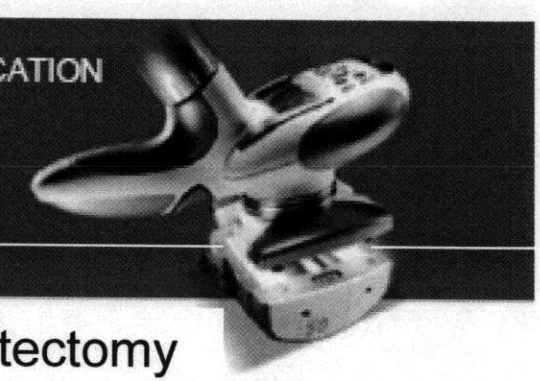


Secondary Lymphedema of the Arm Post Mastectomy

To prepare: 7 min.

EVALUATION ■ OEDEMA, POST RADIOTHERAPY FIBROSIS

OBJECTIVE ■ TO PREPARE THE ANASTOMOSIS

MANŒUVER ■ DIRECT LINE

To mobilize: 12 min.

EVALUATION ■ ŒDEMA, FIBROSIS

OBJECTIVE ■ TO MOBILIZE

MANŒUVERS ■ ARM, FOREARM, HAND TRANSVERSAL, LONGITUDINAL ASCENDING DIRECT LINE

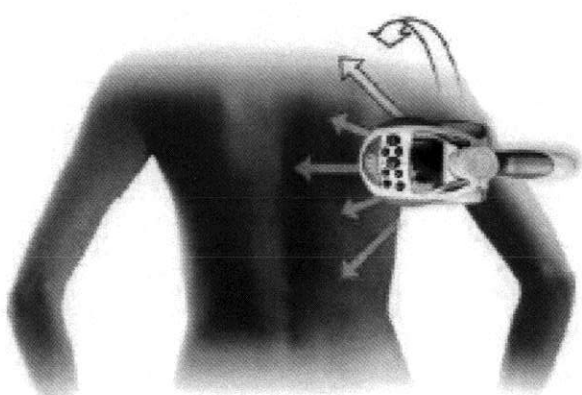
CYCLE: 30

FREQUENCY: 80

V1: 60

V2: 40

POWER: 1-3



> Over irradiated area towards the lymph nodes area. Front / back.

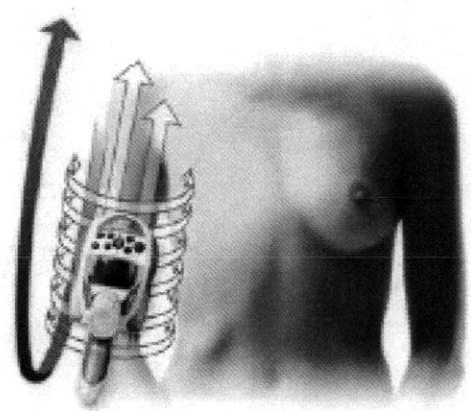
CYCLE: 100

FREQUENCY: 0

V1: 80

V2: 40

POWER: 1-3



The treatment head is chosen according to the morphology of the treated area (i50 ; auxiliary heads).

PAGE 27.2 13

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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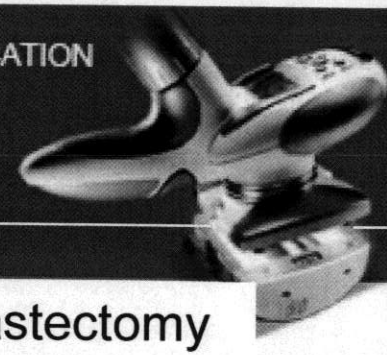
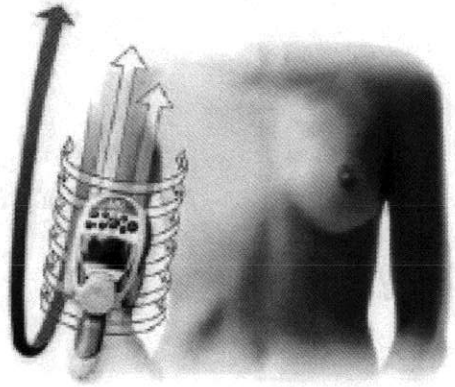


Secondary Lymphedema of the Arm Post Mastectomy

To drain - phase 1: 5 min.

EVALUATION ■ ŒDEMA
OBJECTIVE ■ TO DRAIN LYMPH
MANŒUVERS ■ TRANSVERSAL,
ARM, FOREARM, HAND
LONGITUDINAL ASCENDING
DIRECT LINE

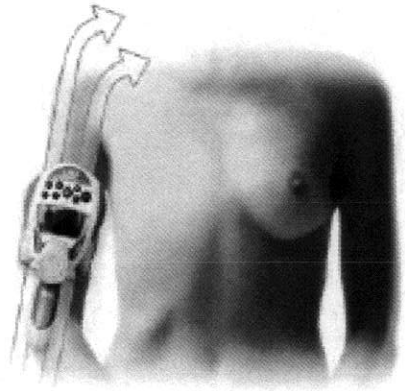
CYCLE: 40
FREQUENCY: 75
V1: 60
V2: 40
POWER: 2-4



To drain - phase 2: 6 min.

EVALUATION ■ ŒDEMA
OBJECTIVE ■ TO DRAIN LYMPH
MANŒUVERS ■ HAND, FOREARM, ARM
LONGITUDINAL ASCENDING
DIRECT LINE

CYCLE: 40
FREQUENCY: 75
V1: 60
V2: 40
POWER: 2-4

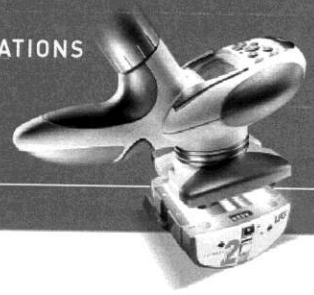


The treatment head is chosen according to the morphology of the treated area (i50 ; auxiliary heads).

PAGE 27.3 14

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

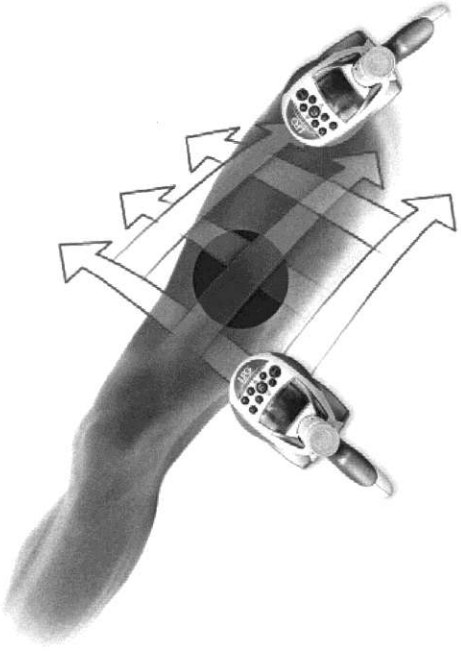
Records processed under FOIA Request 2013-1897; Released 9/15/14



Secondary Lymphedema

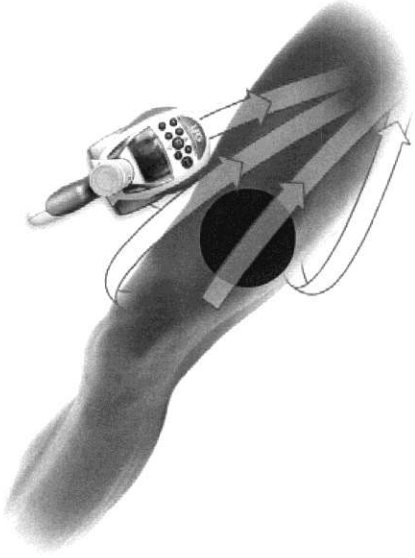
to collect

EVALUATION ■ EDEMA
OBJECTIVE ■ TO COLLECT
MANŒUVERS ■ **GRID**
DIRECT LINE
CYCLE: 40
FREQUENCY: 80
POWER: 3.0 +



to drain

EVALUATION ■ EDEMA
OBJECTIVE ■ TO DRAIN
MANŒUVERS ■ **LYMPHATIC PATHWAY**
DIRECT LINE
CYCLE: 40
FREQUENCY: 4
POWER: 2.0 +



- All indicated protocols are also recommended for the improvement of lymphatic circulation in the treated areas.
- The treatment head is chosen according to the morphology of the treated area (i50 ; auxiliary heads).

PAGE 27.4

Réf. : 100 58 65 PR. GB - KMI - 5.1 - A

575-3 - GB - LPG Systems - public company with share capital of 2.000.000 euros - Siren 335 183 836 RCS Romans - © Copyright LPG Systems 2006 - LPG, Cellu M6, Keymodule are registered trademarks.
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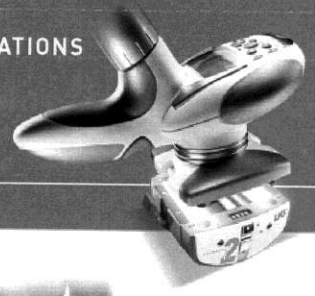
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14



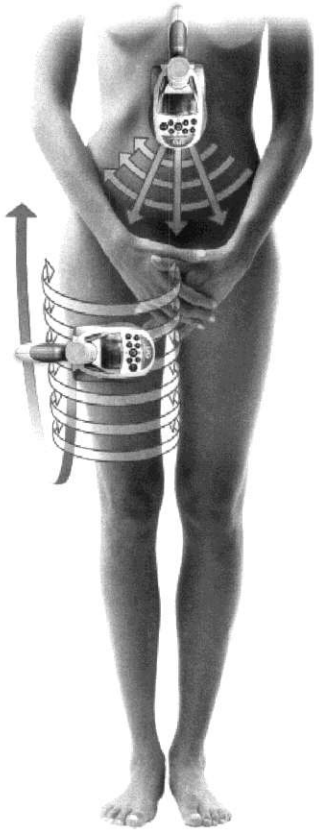
Lymphatic Circulation

to drain

EVALUATION	EDEMA, HEAVY LEGS	CYCLE: 40
OBJECTIVE	TO DRAIN	FREQUENCY: 75
MANŒUVERS	TRANSVERSAL	V1: 80
	DIRECT LINE	V2: 60
		POWER: 2.0 +

to mobilize

OBJECTIVE	TO MOBILIZE	
MANŒUVERS	TRANSVERSAL	CYCLE: 100
	DIRECT LINE	FREQUENCY: 0
	BOUNCING	V1: 80
		V2: 60
		POWER: 2.0 +



to drain

EVALUATION	EDEMA, HEAVY LEGS	CYCLE: 40
OBJECTIVE	TO DRAIN	FREQUENCY: 75
MANŒUVERS	TRANSVERSAL	V1: 80
	DIRECT LINE	V2: 60
		POWER: 2.0 +

to mobilize

OBJECTIVE	TO MOBILIZE	CYCLE: 100
MANŒUVERS	TRANSVERSAL	FREQUENCY: 0
	BOUNCING	V1: 80
	DIRECT LINE	V2: 60
		POWER: 2.0 +

➜ + Foot sole.

- The treatment head is chosen according to the morphology of the treated area (i50 ; auxiliary heads).

PAGE 27.5

16

PR. GB - KMI - 4.1 - A

Ref. : 100 58 65

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Use of the Keymodule device is contraindicated for:

The CelluM6 Keymodule i should not be used on certain areas or under certain conditions.

1. This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.

2. Do not treat wounds, infected areas, skin tumors, open sores, scars form recent surgery, the eyes, intra-cavity areas, mucous membranes, the genitals or directly over nipples.

3. Do not treat patients with infectious progressive illnesses.

4. Do not treat patients with active cancer or a growing tumor. (Consult with the doctor if the patient has had a case history of tumors or is in remission.)

5. This device is contraindicated for skin cancer, tumors and other cancerous lesions in the area to be treated.

6. Do not treat patients suffering from inexplicable and persistent pain without seeking medical advice or without training in the LPG technique in this particular area.

7. Do not treat patients following invasive medical treatment without seeking the medical advice of the doctor or surgeon who performed this operation, or without training in the LPG technique in this particular area.

8. Not recommended for anyone under medical care for circulatory conditions without first consulting a physician.

9. Not recommended for pregnant women.

10. Stop treatment immediately if patient experiences any pain and consult the physician.

11. Avoid possible bruising. Use caution when determining a patient's sensitivity level.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 30, 2006

LPG ONE, INC
C/O MANSOUR CONSULTING, LLC
1308 MORNINGSIDE PARK DRIVE
ALPHARETTA, GA 30022
ATTN: JAY MANSOUR

510(k) Number: K053225
Product: CELLU M6
KEYMODULE I

Extended Until: 16-MAY-2006

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

717

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

MANSOUR CONSULTING

January 26, 2006

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER HFZ-401
9200 CORPORATE BLVD
ROCKVILLE, MD 20850

SUBJECT: EXTENSION OF TIME FOR 510K #K053225 FOR CELLU M6 KEYMODULE I

Dear Madam/Sir,

In reference to your letter dated January 17, 2006, we kindly request a 3-month time extension, in order to allow us to respond fully to your questions, i.e., by April 17, 2006.

Furthermore, kindly update our address for this 510k from 1308 Morningside Park Drive, Alpharetta, GA 30022 to the new one, which is 845 Aronson Lake Court, Roswell, GA 30075

Appreciating your early response,

Jay Mansour
Mansour Consulting LLC for LPG ONE, INC

New address: 845 Aronson Lake Court. Roswell, GA 30075
Cell 678-908-8180. Office 770-777-4146. Fax 678-623-3765

K43

718

Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA
Phone: 1-770-777-4146
Fax: 1-678-623-3765
info@mansourconsulting.com
www.mansourconsulting.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 17, 2006

LPG ONE, INC
C/O MANSOUR CONSULTING, LLC
1308 MORNINGSIDE PARK DRIVE
ALPHARETTA, GA 30022
ATTN: JAY MANSOUR

510(k) Number: K053225
Product: CELLU M6
KEYMODULE I

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

November 17, 2005

LPG ONE, INC
C/O MANSOUR CONSULTING, LLC
1308 MORNINGSIDE PARK DRIVE
ALPHARETTA, GA 30022
ATTN: JAY MANSOUR

510(k) Number: K053225
Received: 17-NOV-2005
Product: CELLU M6 KEYMODULE I

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/oivd/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation

741

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LPG One, Inc.
C/o Jay Mansour, MSQA, BE, RAC
President, Mansur Consulting, LLC
845 Aronson Lake Court
Roswell, GA 30075

NOV - 6 2006

Re: K053225
Trade/Device Name: Cellu M6 Keymodule i
Regulation Number: 21 CFR 890.5665
Regulation Name: Therapeutic Massager
Regulatory Class: 21 CFR 890.9 - Limitations of exemptions from section 890.5660 - Class I
Product Code: ISA - IRO
Dated: June 23, 2006
Received: July 3, 2006

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- 410 DGRND
D.O.

f/t: DXV: 10- 31-06

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Indications for Use

510(k) Number (if known): K053225

Device Name: CelluM6 Keymodule i

Indications For Use:

Reduction of Secondary Lymphedema of the Arm (SLA) Post Mastectomy
Improvement of Secondary Lymphedema
Improvement of lymphatic circulation in the treated area

Prescription Use ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K053225

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K053225 PAGE 4.1

4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

LPG One, Inc.
C/o Jay Mansour, MSQA, BE, RAC
President, Mansur Consulting, LLC
845 Aronson Lake Court
Roswell, GA 30075

NOV - 6 2006

Re: K053225
Trade/Device Name: Cellu M6 Keymodule i
Regulation Number: 21 CFR 890.5665
Regulation Name: Therapeutic Massager
Regulatory Class: 21 CFR 890.9 - Limitations of exemptions from section 890.5660 - Class I
Product Code: ISA - IRO
Dated: June 23, 2006
Received: July 3, 2006

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson, M.S.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE COPY

OFFICE	SURNAME	DATE		OFFICE	SURNAME	DATE		OFFICE	SURNAME	DATE
HFZ-410	DYV	11.2.06								
410	Chen	11/2/06								

U.S. GPO 1986-169-089

6

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- 410 DGRND
D.O.

f/t: DXV: 10- 31-06

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 03, 2006

LPG ONE, INC
C/O MANSOUR CONSULTING, LLC
845 ARONSON LAKE COURT
ROSWELL, GA 30075
ATTN: JAY MANSOUR

510(k) Number: K053225
Device: CELLU M6
KEYMODULE I

Extended Until: 12-DEC-2006

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

MANSOUR CONSULTING

ORIGINAL

June 23, 2006

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER HFZ-401
9200 CORPORATE BLVD
ROCKVILLE, MD 20850

SUBJECT: EXTENSION OF TIME FOR 510K #K053225 FOR CELLU M6 KEYMODULE I

Dear Madam/Sir,

In reference to your letter dated June 15, 2006, we kindly request a 6-month time extension, in order to allow us to respond fully to your questions, i.e., by December 15, 2006.

Appreciating your early response,

Jay Mansour
Mansour Consulting LLC for LPG ONE, INC

New address: 845 Aronson Lake Court. Roswell, GA 30075
678-908-8180. Fax 678-623-3765

247

Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA

Phone: 1-770-777-4146
Fax: 1-678-623-3765

info@mansourconsulting.com
www.mansourconsulting.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

MANSOUR CONSULTING

PHOTOCOPY

June 23, 2006

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER HFZ-401
9200 CORPORATE BLVD
ROCKVILLE, MD 20850

SUBJECT: EXTENSION OF TIME FOR 510K #K053225 FOR CELLU M6 KEYMODULE I

Dear Madam/Sir,

In reference to your letter dated June 15, 2006, we kindly request a 6-month time extension, in order to allow us to respond fully to your questions, i.e., by December 15, 2006.

Appreciating your early response,

Jay Mansour
Mansour Consulting LLC for LPG ONE, INC

New address: 845 Aronson Lake Court. Roswell, GA 30075
678-908-8180. Fax 678-623-3765

248

Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA

Phone: 1-770-777-4146
Fax: 1-678-623-3765

info@mansourconsulting.com
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

MANSOUR CONSULTING LLC
845 ARONSON LAKE CT
ROSWELL, GA 30075

NORTH METRO GA 300
24 JUN 2006 PM 10 L

FOOD & DRUG ADMINISTRATION (FDA)
CENTER FOR DEVICES & RADIOLOGICAL HEALTH (CDRH)
DOCUMENT MAIL CENTER HFZ-401

9200 CORPORATE BLVD
ROCKVILLE, MD 20850

20850+3225 C122

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LPG One, Inc.
% Mr. Jay Mansur
Mansur Consulting, LLC
845 Aronson Lake Court
Roswell, GA 30075

JUN 15 2006

Re: K053225/S001
Trade Name: Cellu M6 Keymodule I
Dated: May 9, 2006
Received: May 16, 2006

Dear Mr. Mansur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require you provide the following information:

Regarding your response to deficiency #1, in our fax dated January 13, 2006:

1. You confirmed your acceptance to change the device's prescription statement to be: "Caution: Federal law restricts this device to sale by or on the order of a clinician licensed by the Law of the State where she/he practices to use or order the use of the device." You also state that all of your labeling documents have been updated accordingly. However, the above statement was not included in the first page of the device labeling. Please revise your labeling to include the prescription label in the first page of the device labeling.

Regarding your response to deficiency #2, in our fax dated January 13, 2006:

2. Your response dated May 9, 2006 states that the device labeling has been updated to reflect only the specific indications for use as mentioned on page R (Tab 7) of the submission, and that these changes are: (a) Reduction of secondary lymphedema; (b) Reduction of lymphedematous fibrotic induration; (c) Improvement of primary and secondary lymphedema; (d) Prevention of venous stasis and venous insufficiency; (e) Prevention of deep vein thrombosis (DTV); and (f) Improvement of lymphatic circulation in the treated area. The predicate devices you identified do not have the specific indication for use of (b)(4) [redacted] (b)(4) [redacted] nor are we aware of any device for this specific indication. In addition, in "Selectivity," Therapeutic benefits, Attachment 31, page A4 in your response indicates (b)(4) [redacted] (b)(4) [redacted] as a use for the device." Please provide medical/scientific rationale and supporting clinical performance data for the use of the device for these IFU and a discussion

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

supporting equivalence with the predicates, which contraindicate the use of the device in (b)(4) [redacted] (b)(4) [redacted] Otherwise, please remove these claims from your labeling.

Regarding your response to deficiency #5 in our fax dated January 13, 2006:

3. The response in your letter dated May 9, 2006 provides information that clarifies the technological specifications in the different types of the device heads (i.e., i1, i2, and i3.) However you mention that "there are three auxiliary heads intended for use for treatment of lymphedema in smaller areas of the body," (Attachment 3a and Attachment 31, page B1), which significantly differ (e.g., [redacted] from the physical dimensions reported for the heads i1, i2, and i3 reported above. In addition, the revised labeling of the device still has some apparent discrepancies in the device specifications (e.g., [redacted] (b)(4) [redacted] in the device, Attachment 3a.) Please provide information that adequately clarifies the physical dimensions in the device heads as well as a discussion about the substantial equivalent performance of the varied dimensions in the device heads, and the vacuum.

Regarding your response to deficiency #7, in our fax dated January 13, 2006:

4. You report that the software components tested used the Stand-alone Cellu M6 Keymodule I with *various* heads attachments. It is unclear which specific device heads were tested for the intended use for the device. Please provide information that clarifies the device heads tested and a discussion about their suitability for the intended use for the device.

Regarding your response to deficiency #9, in our fax dated January 13, 2006:

5. The Sequential Circulator, Model SC-3008 that you identify as a new predicate for your device in your letter dated May 9, 2006 is an inflatable pneumatic sleeve, which exerts up to 150 mm Hg positive pressure at the treatment site. Your Cellu M6 Keymodule I differs in the mode of action because it operates by suction reaching a maximum vacuum (negative) pressure up to (b)(4) [redacted] Despite the similar Indications for Use for the treatment of primary or adjunctive treatment of lymphedema, due to the device technological differences with the predicate Sequential Circulator, Model SC-3008 it is unclear how the clinical data submitted for the predicate can be used to support the safety and effectiveness of your device. Please provide valid scientific evidence supporting your claim for substantial clinical equivalence between your proposed Cellu M6 Keymodule I and the predicate Sequential Circulator, Model SC-3008.

6. Please revise the Operator's Manual to include instructions on what the user should do if the treatment head locks up on a patient's skin during treatment.

When using a standard to demonstrate equivalence, providing a declaration of conformity or a statement that the device will comply prior to marketing, may be provided in lieu of data. Please refer to our document, titled Use of Standards in Substantial Equivalence Determinations located at <http://www.fda.gov/cdrh/ode/guidance/1131.pdf> for additional guidance.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
)200 Corporate Boulevard
Rockville, Maryland 20850

252

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

If you have any questions concerning the contents of the letter, please contact Dora Vega, M.D., Ph.D., at (301) 594-3090 x 142. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

for Mark N. Melkerson, M.S.
Director Division of General, Restorative
and Neurological Devices
Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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LPG One, Inc.
% Mr. Jay Mansur
Mansur Consulting, LLC
845 Aronson Lake Court
Roswell, GA 30075

Re: K053225/S001
Trade Name: Cellu M6 Keymodule I
Dated: May 9, 2006
Received: May 16, 2006

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Records processed under FOIA Request 2013-1897; Released 9/15/14

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9200 Corporate Boulevard
Rockville, Maryland 20850

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Sincerely yours,

Mark N. Melkerson, M.S.
Director Division of General, Restorative
and Neurological Devices
Office of Device Evaluation

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410- DGRND - REDB
D.O.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ 410	Stevens	6/14/10						

257

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

LPG ONE, INC.

22942

REFERENCE NO	DESCRIPTION	INVOICE DATE	INVOICE AMOUNT	DISCOUNT TAKEN	AMOUNT PAID
MD6023242-	PI#MD6023242-956733	11/2/05	3,833.00		3,833.00

K053225
ORIGINAL SUBMISSION

CHECK DATE	CHECK NO.	PAYEE	DISCOUNTS TAKEN	CHECK AMOUNT
11/2/05	22942	US Food and Drug Administration		$3,833.00

22942

LPG ONE, INC.
(305) 379-6800
801 BRICKELL AVENUE
SUITE 850
MIAMI, FL 33131

BANK OF AMERICA
MIAMI, FL 33131
63-4/630

CHECK NO.	DATE	AMOUNT
22942	Nov 2, 2005	****$3,833.00

Three Thousand Eight Hundred Thirty-Three and 00/100 Dollars

PAY TO THE ORDER OF: US Food and Drug Administration

AUTHORIZED SIGNATURE

⑈022942⑈ ⑆063000047⑆ 0054854997 94⑈

LPG ONE, INC.

22942

REFERENCE NO	DESCRIPTION	INVOICE DATE	INVOICE AMOUNT	DISCOUNT TAKEN	AMOUNT PAID
MD6023242-	PI#MD6023242-956733	11/2/05	3,833.00		3,833.00

CHECK DATE	CHECK NO.	PAYEE	DISCOUNTS TAKEN	CHECK AMOUNT
11/2/05	22942	US Food and Drug Administration		$3,833.00

PAGE A

742 K-2 PMA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

–>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

LPG ONE INC
1308 Morningside Park Drive
Alpharetta GA 30022
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4) [redacted]

2. CONTACT NAME
Jay Mansour

2.1 E-MAIL ADDRESS
jay@mansourconsulting.com

2.2 TELEPHONE NUMBER (include Area code)
678-908-8180

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
678-623-3765

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
(b)(4) [redacted]
01-Nov-2005

Form FDA 8601 (08/2003)

Close Window

SIGNATURE FOR LPG ONE BY JAY MANSOUR:
DATE OF SIGNATURE: 11/01/05
(JAY MANSOUR OF MANSOUR CONSULTING LLC)

PAGE B 743

Print Cover sheet

PAGE C

744

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

510k NOTIFICATION SUBMISSION
LPG One, Inc

CELLU M6- KEYMODULE i

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: September 30, 2004.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
11/10/2005	MD6023242-956733	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (120 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☑ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
Amendment	Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
Supplement	Supplement			
	Report			
	Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☑ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: LPG ONE, INC	Establishment Registration Number *(if known)*: 3004887948
Division Name *(if applicable)*:	Phone Number *(including area code)*: (305) 379 8800
Street Address: 801 Brickell Avenue, Suite 850	FAX Number *(including area code)*: (305) 375 0903

City	State / Province	ZIP/Postal Code	Country
Miami	FL	33131	USA

Contact Name: Mr Michel Van Welden

Contact Title	Contact E-mail Address
Chief Operating Officer	MVanWelden@LPGONE.COM

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name: Mansour Consulting LLC

Division Name *(if applicable)*:	Phone Number *(including area code)*: (770) 777-4146
Street Address: 1308 MORNINGSIDE PARK DRIVE	FAX Number *(including area code)*: (678) 623-3765

City	State / Province	ZIP/Postal Code	Country
ALPHARETTA	GA	30022	USA

Contact Name: Jay Mansour

Contact Title	Contact E-mail Address
President	jay@mansourconsulting.com

FORM FDA 3514 (12/03)

PAGE F

PSC Media Arts (301) 443-1090 EF

747

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- [ ] Withdrawal
- [ ] Additional or Expanded Indications
- [ ] Request for Extension
- [ ] Post-approval Study Protocol
- [ ] Request for Applicant Hold
- [ ] Request for Removal of Applicant Hold
- [ ] Request to Remove or Add Manufacturing Site

- [ ] Process change:
  - Manufacturing
  - Sterilization
  - Packaging
  - Other *(specify below)*

- [ ] Response to FDA correspondence:

- [ ] Change in design, component, or specification:
  - Software / Hardware
  - Color Additive
  - Material
  - Specifications
  - Other *(specify below)*

- [ ] Labeling change:
  - Indications
  - Instructions
  - Performance
  - Shelf Life
  - Trade Name
  - Other *(specify below)*

- [ ] Location change:
  - Manufacturer
  - Sterilizer
  - Packager

- [ ] Report Submission:
  - Annual or Periodic
  - Post-approval Study
  - Adverse Reaction
  - Device Defect
  - Amendment

- [ ] Change in Ownership
- [ ] Change in Correspondent
- [ ] Change of Applicant Address

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- [ ] New Device
- [ ] New Indication
- [ ] Addition of Institution
- [ ] Expansion / Extension of Study
- [ ] IRB Certification
- [ ] Termination of Study
- [ ] Withdrawal of Application
- [ ] Unanticipated Adverse Effect
- [ ] Notification of Emergency Use
- [ ] Compassionate Use Request
- [ ] Treatment IDE
- [ ] Continued Access

- [ ] Change in:
  - Correspondent / Applicant
  - Design / Device
  - Informed Consent
  - Manufacturer
  - Manufacturing Process
  - Protocol - Feasibility
  - Protocol - Other
  - Sponsor

- [ ] Report submission:
  - Current Investigator
  - Annual Progress Report
  - Site Waiver Report
  - Final

- [ ] Repose to FDA Letter Concerning:
  - Conditional Approval
  - Deemed Approved
  - Deficient Final Report
  - Deficient Progress Report
  - Deficient Investigator Report
  - Disapproval
  - Request Extension of Time to Respond to FDA
  - Request Meeting
  - Request Hearing

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- [ ] New Device
- [x] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify)*:

DEVICE CLEARED EARLIER UNDER 510K #K990445 WITH PRODUCT CODE ISA, BUT CURRENT INDICATIONS FOR USE UNDER THIS SUBMISSION RELATE TO PREDICATES WITH PRODUCT CODE IRP.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	IRP	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K912004	1	SPORTMED PUMP	1	SHEPARD MEDICAL
2	K914774	2	MULTIPULSE SEQUENTIAL COMPRESSION UNIT	2	PROGRESSIVE MEDICAL
3	K974395	3	ATLANT'S	3	GRAD-LINE
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Powered inflatable tube massager

	Trade or Proprietary or Model Name for This Device		Model Number
1	CELLU M6 KEYMODULE i	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K990445	2 K954399	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [x] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
ISA	890.5660	[redacted] I

- [ ] Class II
- [ ] Class III
- [ ] Unclassified

Classification Panel

PHYSICAL MEDICINE

Indications *(from labeling)*

PLEASE REFER TO SUBMISSION DUE TO LACK OF SPACE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☑ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☑ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)* ( )
Street Address		FAX Number *(including area code)* ( )
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)* ( )
Street Address		FAX Number *(including area code)* ( )
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Mansour Consulting LLC
1308 Morningside Park Dr
Alpharetta, GA 30022 USA
(770) 777-4146

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

FDA/CDRH/OCE/DID
2005 NOV 11 A 9:36

November 10, 2005

Subject: **510(k) Notification**

Sir or Madam,

LPG ONE, INC seeks permission to distribute in interstate commerce a device intended for human use and hereby notifies the Food and Drug Administration as required by law. in accordance with section 510(k) of the Food, Drug and Cosmetic Act as amended.

Accordingly, please find enclosed two copies of 510(k) Abbreviated Notification (one original and one copy) for **CELLU M6 KEYMODULE i** for your review/approval.

This device is similar to other ones already manufactured/sold in interstate commerce.

All of the AVAILABLE documentation has been included to substantiate above.

510(k) Summary is included for your reference as well as a table of contents detailing the sections of the main submission.

We hope you will find the contents in order.

Yours,

Jay Mansour, MSQA, BE, LA, RAC
Mansour Consulting LLC (Consultant)
1308 Morningside Park Drive
Alpharetta, GA 30022 USA

On behalf of
LPG One, Inc (Submitter/owner)
801 brickell ave.
Suite 850
Miami, FL 33131 (Refer to Appendix 1 for Authorization)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

510(k) Summary
As Required by 21 section 807.92 (c)

1-Submitter Name: LPG One, Inc
2-Address: 801 Brickell Ave. Suite 850. Miami, FL 33131
3-Phone: (305) 379- 8800
4-Fax: (305) 375- 0903
5-Contact Person (Consultant): Jay Mansour of Mansour Consulting LLC
1308 Morningside Park Drive
Alpharetta, GA 30022 USA
(770) 777-4146. Fax (678) 623-3765
6-Date summary prepared: November 10, 2005
7-Device Trade or Proprietary Name: CELLU M6 KEYMODULE I
8-Device Common or usual name: Massager
9-Device Classification Name: Electrical Therapeutic Massager
10-Substantial Equivalency is claimed against the following devices:
"Shepard Medical's Sport Pump"- 510K# K912004
"Progressive Medical's Multipulse Sequential Compression unit"- 510K# K914774
"Grad-Line's Atlant's"- 510K# K974395

11-Description of the Device:

The Cellu M6 Keymodule i electrical therapeutic massager is comprised of a program console housing a vaccum pump and a regulation system. The main treatment head consists of two parallel motorized rollers housed in a chamber which produces both negative pressure above the rollers and positive pressure below the rollers. This technology creates a skin fold between the two rollers in the suction chamber, thus mimicking the "rolled palpation" of manual massage techniques.

This device has the capability to produce both constant and sequential aspiration. Constant aspiration provides a deeper massage, which also mobilizes the muscle fascia. With sequential aspiration, the suction power is cyclically interrupted to provide pulsation to the skin fold between the two rollers and a softer, gentler stroking action of the tissues.

The suction power ranges from 50 to 500 mmHg which is represented by a power level scale ranging from 1 to 10.

12-Intended use of the device: (refer to FDA form attached)

This device is intended for use for:
Reduction of secondary lymphedema of the arm (SLA) post mastectomy
Reduction of lymphedematous fibrotic induration
Improvement of primary and secondary lymphedema
Prevention of venous stasis and venous insufficiency
Prevention of deep vein thrombosis (DVT)
Improvement of lymphatic circulation in the treated area

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13-Safety and Effectiveness of the device:

This device is safe and effective as the predicate devices cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate device. Refer to the explanations/details within the main submission.

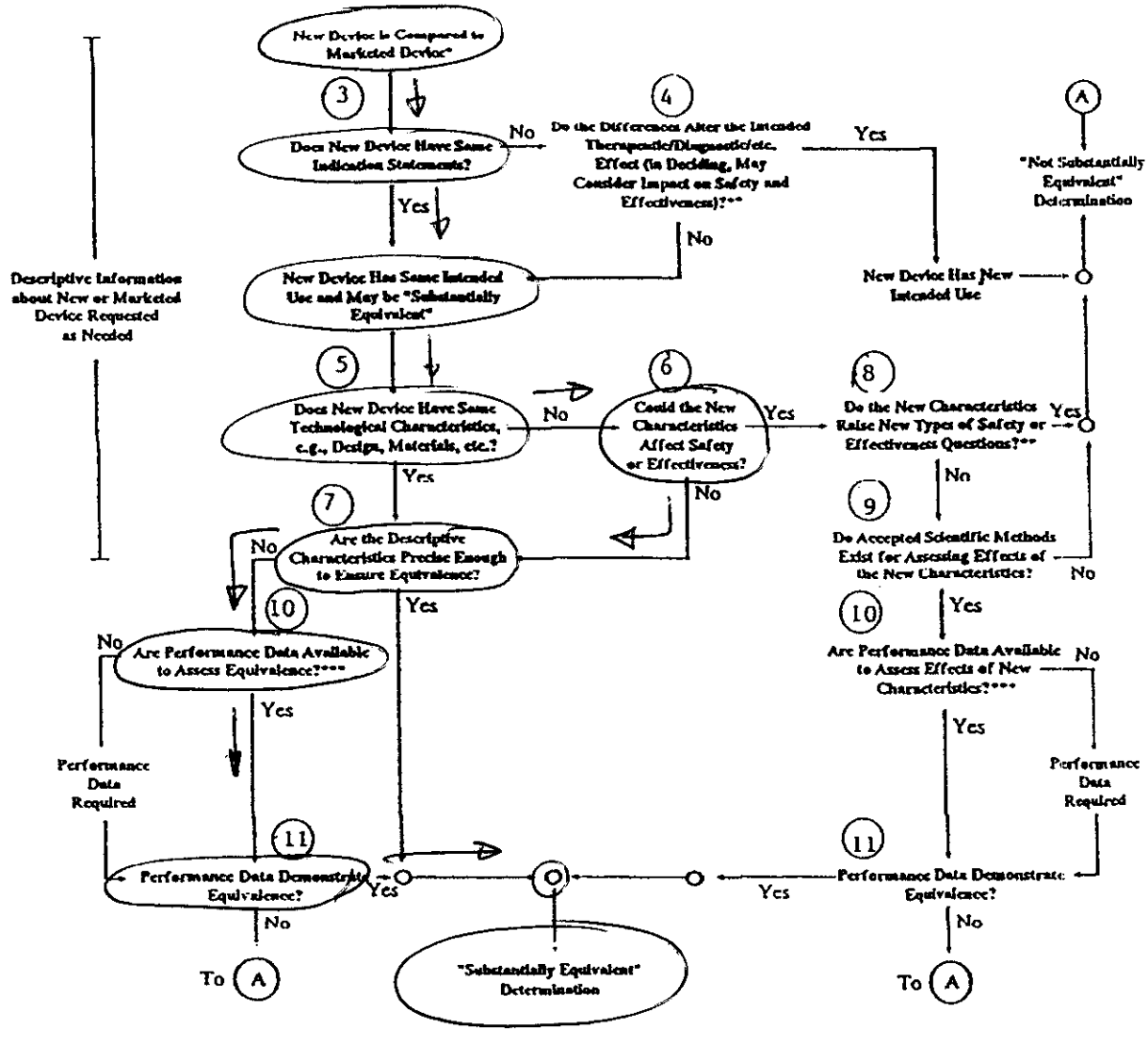
FDA file reference number	510k # K912004, K914774 and K974395
TECHNOLOGICAL CHARACTERISTICS	Comparison result
Indications for use	Identical
Target population	Similar
Design	Similar
Materials	
Performance	
Sterility	Not applicable
Biocompatibility	Similar
Mechanical safety	
Chemical safety	Not applicable
Anatomical sites	Similar
Human factors	
Energy used and/or delivered	
Compatibility with environment and other devices	
Where used	
Standards met	
Electrical safety	
Thermal safety	NOT APPLICABLE
Radiation safety	

Refer to the submission for more details.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

PAGE N 755

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as the Chief Operating Officer of LPG One, Inc, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and no material fact has been omitted.

(Signature)

Michel Van Welden

(Typed name)

11/01/2005

(Dated)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Mansour Consulting LLC
1308 Morningside Park Dr
Alpharetta, GA 30022
(770) 777- 4146

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

Re: 510(k) Notification

Sir or Madam,

In our opinion, the **CELLU M6 KEYMODULE i** is comparable and substantially equivalent to other medical devices in commercial distribution.
The following information concerning the device is submitted for your consideration:

1-Device Trade Name: CELLU M6 KEYMODULE i
2-Device common or usual name: Massager
3-Device Classification: ISA
4-Device class: 1
5-Panel: Physical Medicine
6-Regulation Number: 890.5660
7-Submitter's name and address:
LPG ONE, INC
801 Brickell Ave. Suite 850. Miami, FL 33131 USA
8-Establishment registration number: 3004887948
9-Contact person, telephone number and fax number:
Michel Van Welden, Chief Operating Officer
Tel 305-379-8800. Fax 305-375-0903
10-Manufacturing facility:
(b)(4) [redacted]

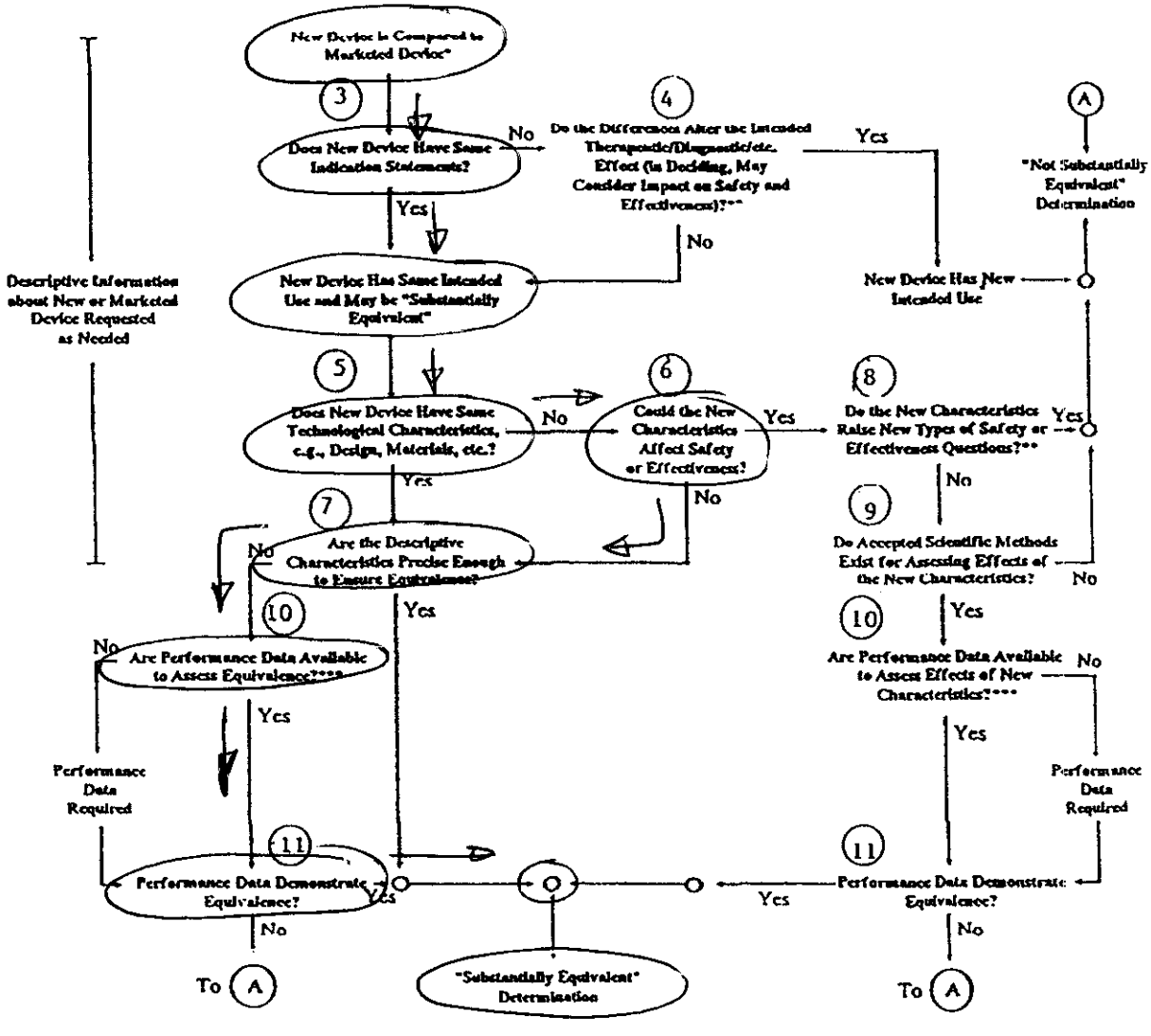
11- Foreign Exporter: Registration 3005180725
(b)(4) [redacted]

12- Sterilization facility:
NOT APPLICABLE
13- Submission correspondent: (refer to Appendix 1 for authorization letter)
Jay Mansour, President
Mansour Consulting LLC
1308 Morningside Park Dr. Alpharetta, GA 30022
770-777-4146 Fax 678-623-3765

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

510(k) Number (if known):

Device Name: CELLU M6 KEYMODULE i

Indications For Use:

This device is indicated for use for:

Reduction of secondary lymphedema of the arm (SLA) post mastectomy
Reduction of lymphedematous fibrotic induration
Improvement of primary and secondary lymphedema
Prevention of venous stasis and venous insufficiency
Prevention of deep vein thrombosis (DVT)
Improvement of lymphatic circulation in the treated area

Prescription Use ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Sterilization:

NOT APPLICABLE

Manufacturing:

The complete manufacturing process will be carried out according to current Good Manufacturing Practice requirements (cGMP/QSR). The manufacturer's quality system certifications are enclosed.

Biocompatibility and material specifications:

Product already cleared under 510k #K990445.

History, Contraindications, Side effects and complications:

Massagers have been marketed and used in US for many decades and proven to be safe and effective without side effects or complications generated from the use of the device itself.

Contraindications and warnings are as per the enclosed labeling.

For the indications for use subject of this submission, the following sentence applies:

Caution: Federal (US) law restricts this device to sale by or on the order of a licensed and trained massage therapist or physical therapist.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

CERTIFICAT D'APPROBATION

Nous certifions que le Système de Management de la Qualité de la société:

(b)(4)

[redacted]

a été approuvé par la société Lloyd's Register Quality Assurance selon les normes de Management de la Qualité suivantes:

NF EN ISO 13488:2001

Le Système de Management de la Qualité concerne:

Fabrication d'appareils dans le domaine médical incluant des équipments de thérapie électromedicale. Remise en état des systèmes électroniques composant ces appareils.

Manufacture of equipment to be used in the medical field including electromedical therapy equipment. Reconditioning of electronic systems used in these machines.

Ce certificat fait partie de l'approbation identifiée sous le certificat numéro LRQ 0963638

Certificat d'approbation No: LRQ 0963638/D

Première approbation: *18 Juillet 2000*

Certificat en cours: *15 Décembre 2003*

Expiration du certificat: *30 Juillet 2006*

RT Modcraft

Emis par: LRQA Coventry

UKAS QUALITY MANAGEMENT
001

Ce document est sous réserve de la provision sur l'inverse.

Cette approbation est soumise aux procédures d'audit, de certification et de surveillance de LRQA.

L'utilisation du logo d'accréditation UKAS désigne l'accréditation par rapport aux activités couvertes par le Certificat d'Accreditation Numéro 001

Macro Revision 10.1

PAGE T 761

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

CERTIFICAT D'APPROBATION

Nous certifions que le Système de Management de la Qualité de la Société:

(b)(4)

[redacted]

a été approuvé par la société Lloyd's Register Quality Assurance France SAS selon les normes de Management de la Qualité suivantes:

ISO 9001 : 2000

Le Système de Management de la Qualité concerne:

Fabrication d'appareils dans le domaine médical, sportif, esthétique et bien être.
Remise en état des systèmes électroniques composant ces appareils.

Manufacture of products to be used in the medical, sport, aesthetic and wellness fields.
Reconditioning of electronic systems used in these machines.

Certificat d'approbation No: 9917501

Première approbation: *le 4 juillet 2003*

Certificat en cours: *le 4 juillet 2003*

Expiration du certificat: *le 31 juillet 2006*

Emis par : LRQA France SAS

cofrac
CERTIFICATION D'ENTREPRISES & DE PERSONNELS
ACCREDITATION
N° 4003/96

Le présent document est soumis aux dispositions énoncées au verso
Cette approbation est soumise aux procédures d'audit, de certification et de surveillance de LRQA.
Macro rev 4.0

PAGE U 762

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Section 1

Intended use:

The intended use for the CelluM6 Keymodule i device is for the following claims:

Part 1
- Reduction of secondary lymphedema of the arm (SLA) post mastectomy
- Reduction of lymphedematous fibrotic induration

Part 2
- Improvement of primary and secondary lymphedema
- Prevention of venous stasis and venous insufficiency
- Prevention of deep vein thrombosis (DVT)
- Improvement of lymphatic circulation in the treated areas

This LPG technique performed with the Cellum6 Keymodule i is similar to the technique of (b)(4) [redacted] (b)(4) [redacted] It can also produce similar effects on lymphedema as compared to the Shepard Medical Products Sport Pump, the Talley Group Multipulse Compression Unit and the Atlant's powered inflatable tube massager for the eight lymphedema-related claims. This paper will demonstrate those similarities and the effective use of the CelluM6 Keymodule i for the claims listed above.

Description of the device:

The original version of the LPG machine, the ES1, was classified and distributed in the United States as a Class 1 medical device exempted from pre-market notification and as a therapeutic massager, 21 CFR Section 890.5660. The CelluM6 Keymodule i is the latest version of the LPG professional machines with an improved design and change in material tested and validated to safety, regulatory and LPG design rules and requirements. Changes to performance specifications does not affect indications for use, does not requires new clinical data, does not raise safety or degrades the performances. Therefore, based on the company's internal evaluation system, the CelluM6 Keympodule i is equivalent to the ES1.

The suction power ranges from (b)(4) [redacted] which is represented by a power level scale ranging from 1 to 10. The updated design of the CelluM6 Keymodule i has the capability to produce (b)(4) [redacted] (b)(4) [redacted] aspiration to provide a pulsation to the skin in order to massage the tissues in various ways.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The CelluM6 Keymodule i therapeutic massager is comprised of a program console housing a vacuum pump and a regulation system. The main treatment head, protected by United States patent numbers 4.729.368, 4.883.047, consists of two parallel motorized rollers housed in a chamber which produces both (b)(4) [redacted] This technology creates a skin fold between the two rollers in the suction chamber, thus mimicking the "rolled palpation" of manual massage techniques.

The LPG technique:

(b)(4) [redacted]

The CelluM6 Keymodule i version of the machine has the capability to utilize the rollers in a forward, backward, inward or outward direction. Multidirectional maneuvers can be performed with these different roller rotations, allowing them to reach specific tissue layers. (b)(4) [redacted] aspiration settings can be used to perform deeper massage and mobilize more blood flow to the skin's surface, while sequential aspiration settings, with a wide variety of duty cycles and frequencies, can be used to perform lighter, more superficial massage and create a (b)(4) [redacted] action on the tissues.

Current indications for use:

The CelluM6 Keymodule i is exempted from pre-market notification requirements as a low-risk device for the following indications:

- Temporarily improves the appearance of cellulite and circumferential body measurements of cellulite treated areas
- Temporary improvement in local blood circulation
- Relieves DOMS (Delayed Onset Muscle Soreness)
- Relieves minor muscle aches and pains
- Relieves muscle spasm
- Relieves minor muscle aches and pains, relieves muscle spasm, and improves local circulation during burn rehabilitation (prescriptive use only)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Contraindications:

The CelluM6 Keymodule i should not be used under the following conditions:

- Known sensitivity to the device
- Skin cancer in the treated area
- Do not treat over open wounds, infected areas, skin tumors, scars from recent surgery
- Do not treat patients with infectious progressive illnesses
- Not recommended for pregnant women
- Not recommended for anyone under medical care for circulatory conditions without first consulting a physician

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CELLU M6® KEYMODULE *i*

LPG

1.4

766

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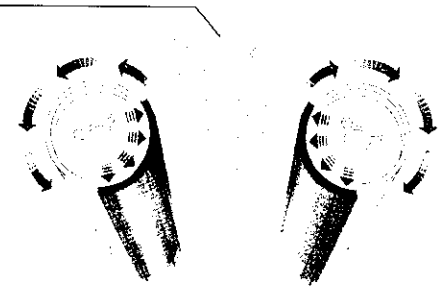
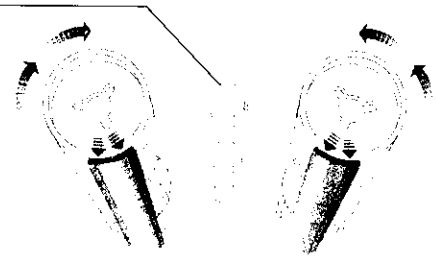
KEYMODULE *i*

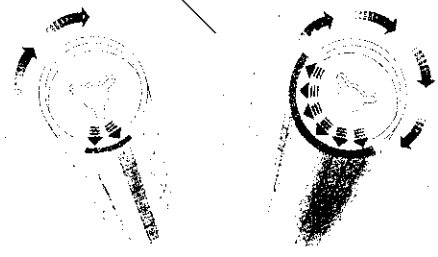
ROLL'IN™
the direction of rotation of the 2 rollers converges towards the inside of the treatment chamber.



ROLL'OUT™
the direction of rotation of the 2 rollers diverges towards the outside of the treatment chamber.



ROLL'UP™
Adjustment of the speed differential between the rollers allows the fold to be moulded accurately.



CUTANEOUS

INDEPENDENT DOUBLE MOTORISATION

In order to allow the operator to treat the encountered tissue precisely, LPG has invented a new technology that is opening up unexplored fields of research. A technology where each roller comprises a miniaturised motor that gives it unprecedented independence (speed and direction of rotation) inside an airtight, mobile treatment chamber. This specific technological feature enables the operator to obtain a large variety of skin folds in terms of their shape, depth and thickness.

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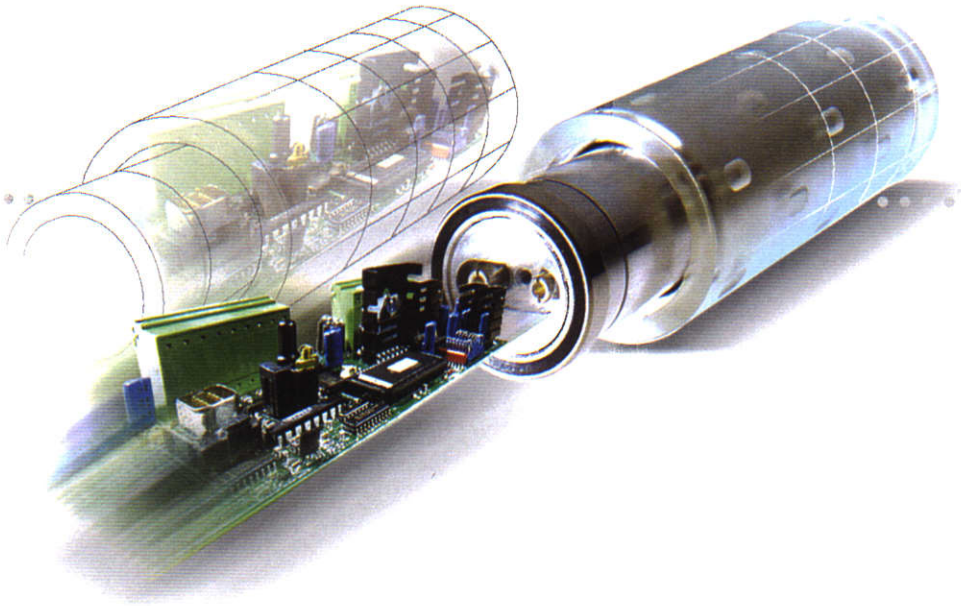
FLEXIBILITY

TISSUE TREATMENT IN ALL ITS DIMENSIONS

Each roller incorporates a miniaturised high-technology motor, thereby allowing it unprecedented autonomy (speed and direction of rotation).



1.6

768

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ADAPTABILITY

KEYMODULE™, INNOVATION AND MODULARITY

LPG has invented independently motorised Keymodule™, which can be detached and interchanged within a few seconds.

KEYMODULE /1
AESTHETICS

CHOOSE YOUR TOOL ACCORDING TO THE TREATMENT GOALS

As each application has specific characteristics, LPG has developed a focused software and interchangeable treatment Keymodule™. Designed for each specific area of application, they make it possible to treat each patient as a unique case. Software and Keymodule™ allow you to adapt your device to the treatment objectives sought.

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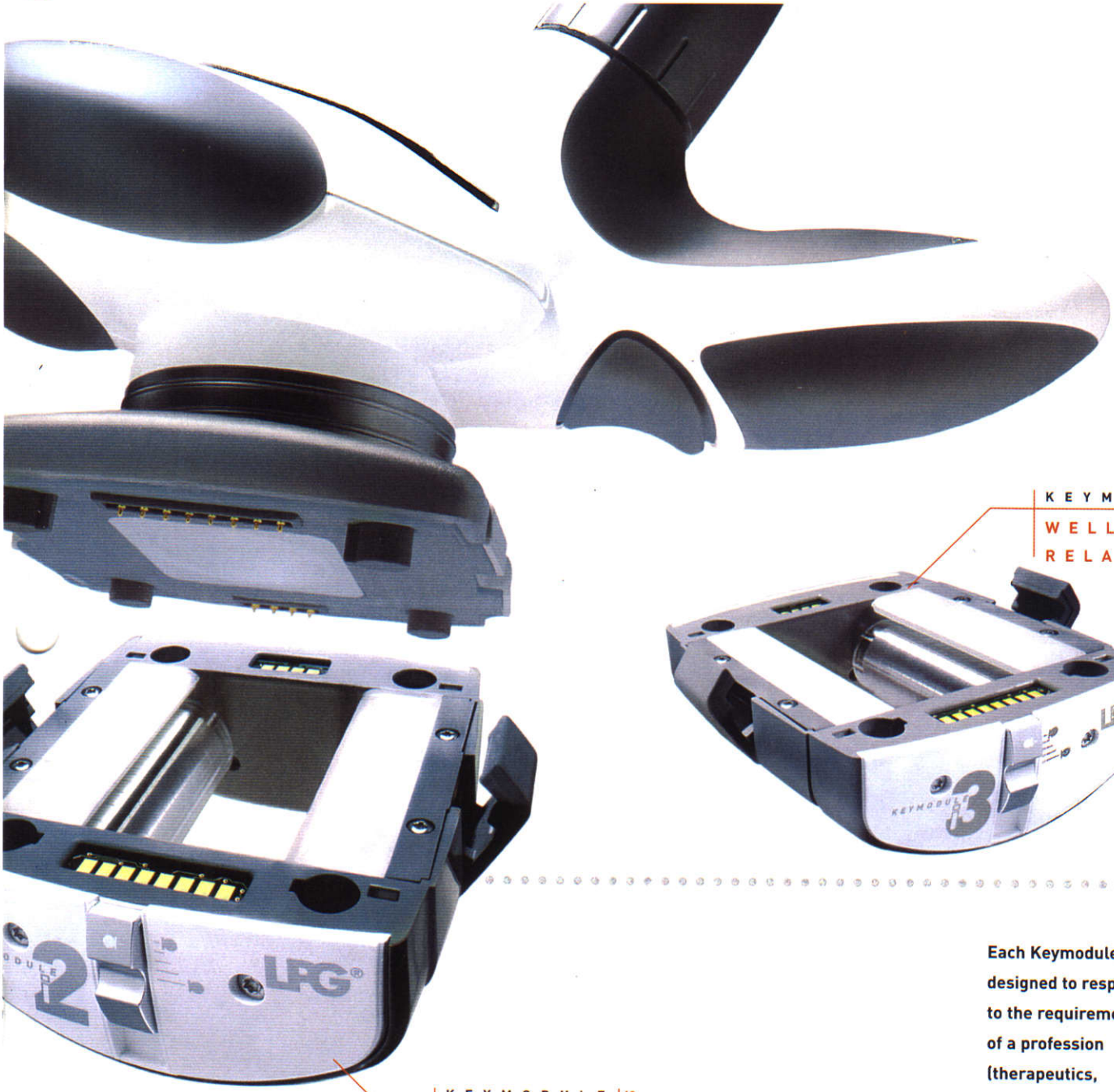

KEYMODULE | i3
WELL-BEING
RELAXATION

KEYMODULE | i2
THERAPEUTICS
SPORT

Each Keymodule is designed to respond to the requirements of a profession (therapeutics, sport, aesthetics, well-being).

1.8

770

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SELECTIVITY

THERAPEUTICS

- Edema
- Fibrosis
- Stiffness
- Venous stasis
- Venous insufficiency
- Deep vein thrombosis
- Blood circulation
- Lymphatic circulation

SPORT

- Delayed onset muscle soreness
- Muscle spasm
- Muscle aches and pains

ESTETHICS

- Appearance of cellulite and circumferential body measurements of cellulite treated areas
- Relaxation

A NEW INTELLIGENT INTERFACE

The **Cellu M6 Keymodule *i*** is your gateway to the fields of therapeutics, sport, aesthetics and well being. Fast and intuitive navigation will enable you to achieve your goal: targeted results that will completely satisfy your patients.

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CE 0088

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www.lpgsystems.com

LPG

1.11

773

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LPG Engineers Solutions

[redacted] (b)(4)

- User-friendly menu

LPG

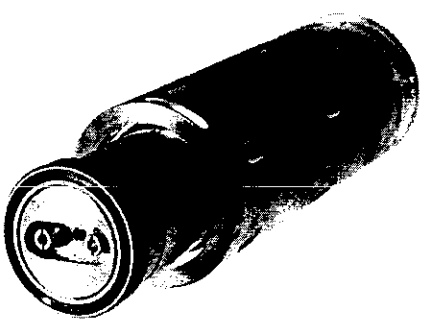
☞ All this information led to a new patented technology that revolutionizes the LPG technique.

LPG

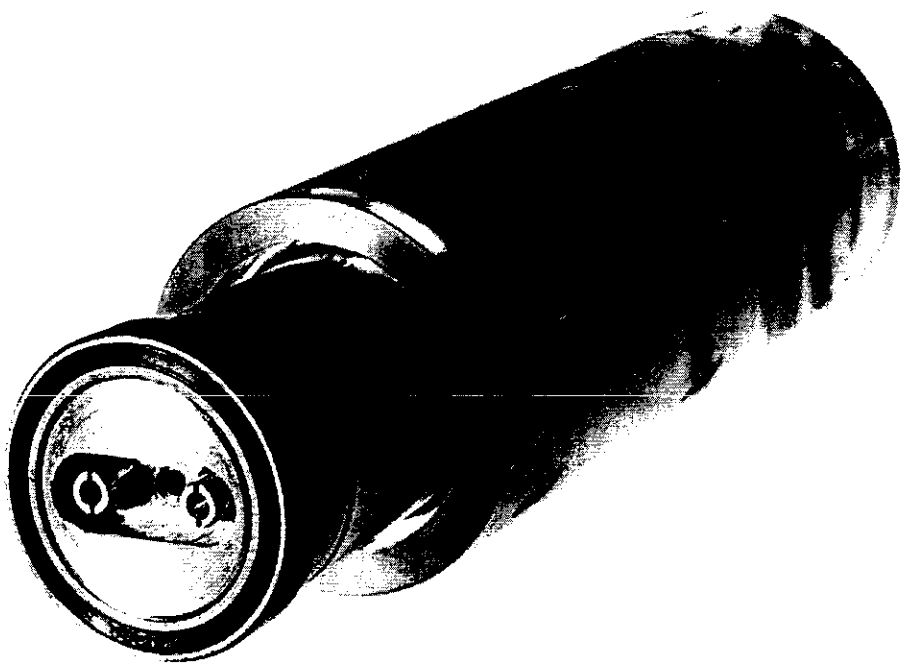
A Unique Technology

1.12

[redacted] (b)(4)



LPG



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The Keymodule® Heads

(b)(4) [redacted]

(b)(4) [redacted]

A new successful way of working the skin fold

(b)(4) [redacted]

An efficient software

(b)(4) [redacted]

1·13

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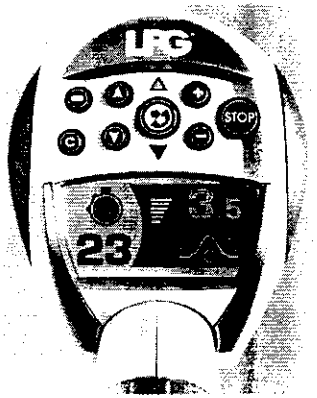
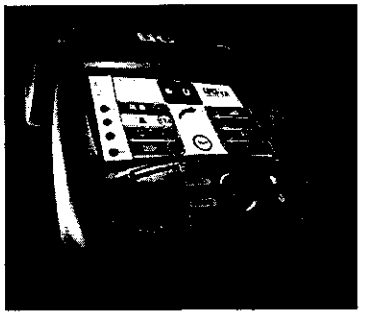
Revolutionary treatment head

- Patented independent [redacted] (b)(4)
- Redesigned ergonomics
- New intelligent software
- New control options



The User Interface and Software

- Simple, intuitive and fast access to the treatment programs
- New range of programs:
  - 55 programmes for Cellu M6 Keymodule® *i*



1.14

776

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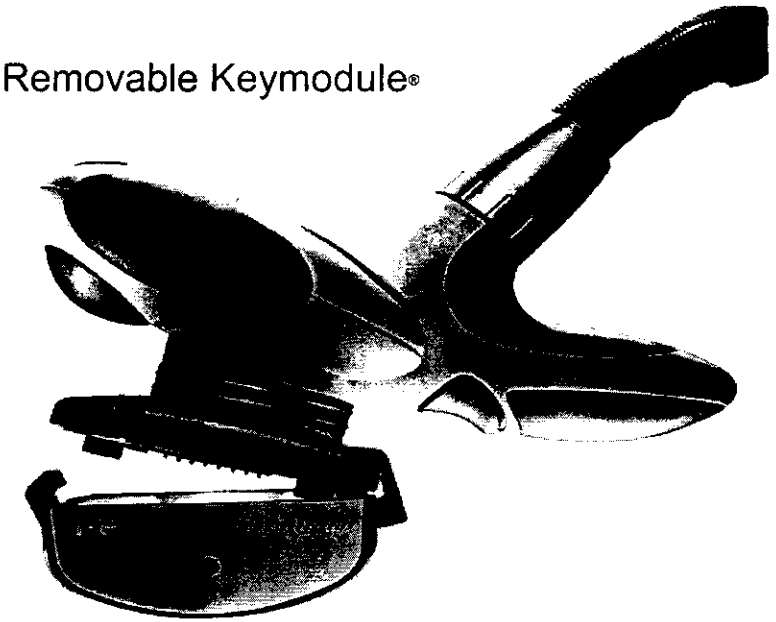
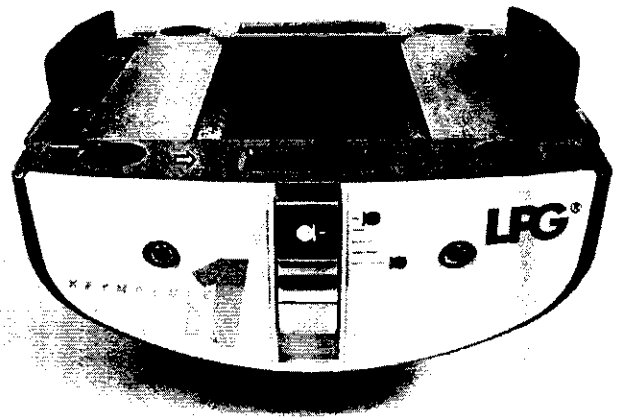
Removable Keymodule®



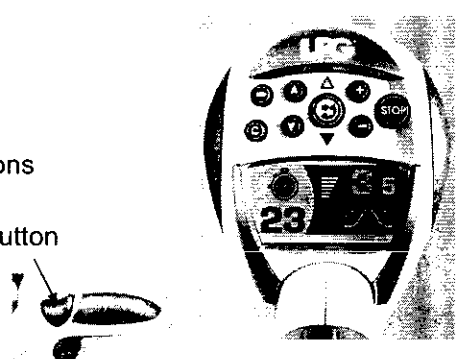
Cursor on Cellu M6 Keymodule® *i*



Allows an action in depth

The Ergonomic Main Head

- Lighter and handier
- Easy to access functions
- "One click" direction button



1.15

777

[redacted]

Ergonomic Auxiliary Head

[redacted] (b)(4)

[redacted]

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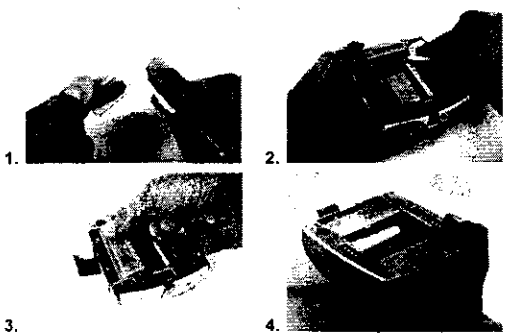
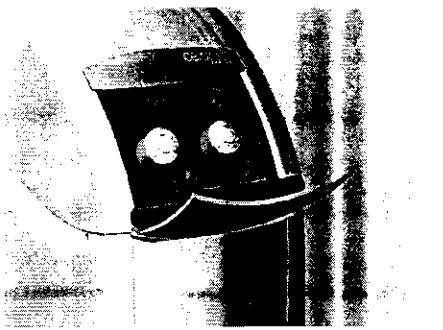
Removable Airtight Flaps

- Hygienic and safe
- Easy to remove
- Easy to clean



Filtering system

- With the new disposable filters, daily cleaning is no longer necessary.



Traditional Roll Up

(b)(4)

New Roll Up
Unlimited skin fold forms

(b)(4)

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Roll Out
Superficial action

- Outward rotation of the rollers induces a thin and delicate skin fold

(b)(4)

Roll In
Deep Action

- Inward rotation of the rollers induces a deep and thick skin fold

(b)(4)

1.17

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Inflammatory Tissue

Treatment: *Pain / Inflammation*

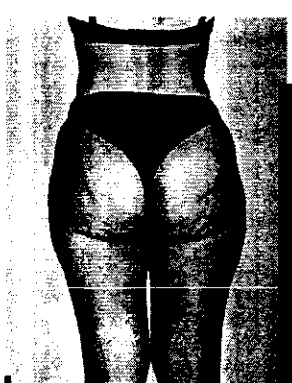
[redacted] (b)(4)

Worre

Edematous Tissue

[redacted] (b)(4)

Edematous Cellulite Tissue

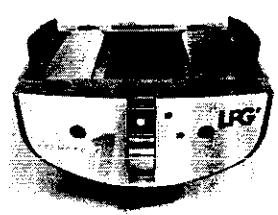


Treatment: *Edema*

[redacted] (b)(4)

Keymodule® *i*1

- Aesthetic Keymodule (Endermologie)
- Roller diameter [redacted] (b)(4)
- [redacted] (b)(4) increase of treatment area [redacted] (b)(4)
- Used for aesthetic programs



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Keymodule® *i3*

- Aesthetic and well-being Keymodule®
- Diameter (b)(4)
- (b)(4) ncrease of treatment area
- Superficial action (b)(4)

1.19

781

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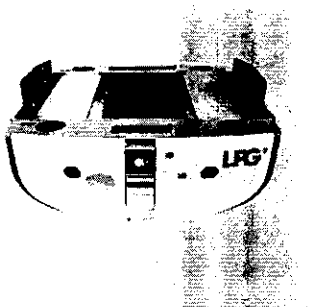
Keymodule® *i*2

- Therapeutic Keymodule®

(b)(4)



Pathology & Results

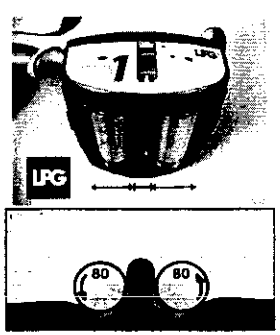
Therapeutic applications
- stiffness
- fibrosis
- traumatic scars
- burn scars
- micro-circulatory disorders
- lymphedema
- traumatic edema

Sport applications
- warm up
- recovery

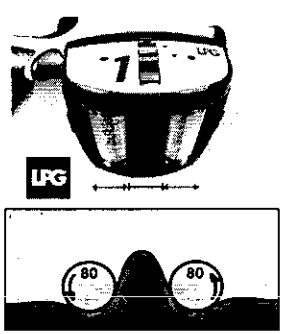
Lesions
- contracture
- muscular disorder
- tendinitis

The cursor

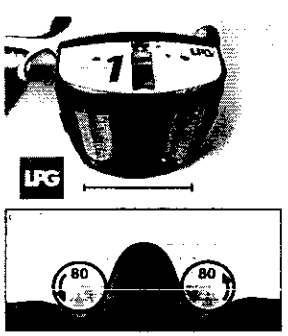
1.2



Small gap between rollers
Action limited to the surface



Intermediate gap between rollers
Subcutaneous action



Gap between rollers is constant and maximum. Deep action up to the muscle and on fibrosis

782

Simplified Maneuvers

(b)(4)

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Section 2 - Definitions

Edema and the lymphatic system

Edema is a swelling of the tissues and is a very common condition. This pathology appears after an injury or after local surgery (including breast mastectomy with axillary lymphatic node removal). The result is a circulatory imbalance with either an increasing of filtration, decreasing of resorption or both of these. The resorption pathway is venous and lymphatic. The venous system is in control of fluid elimination while the lymphatic system provides elimination of fluid with materials including plasma proteins, colloids and cells (>20).

Drainage of the protein-containing fluid from the interstitium is the primary function of the lymphatic system. Fluid may be reabsorbed by the capillaries to some extent, but there is no other route besides the lymphatic vessels through which free proteins can be removed from the interstitium. The flow of lymph is normally very slow, since there is no pumping force like that provided by the heart in the cardiovascular system. Any factor that tends to increase interstitial hydrostatic pressure increases the rate of lymph flow. The presence of one-way valves ensures that fluid moves in only one direction whenever a lymph vessel is compressed. Lymph flow is sustained primarily by the milking action of muscle contractions[1,2,3]. Active exercise increases lymph flow by as much as 5 to 15 times normal[4]. This lymph-flow mechanism provides the rationale for the widespread use of high-voltage galvanic muscle stimulation and intermittent pneumatic compression for mobilizing edema[5,6,7].

Lymphedema

Lymphedema is chronic unilateral or bilateral edema of the extremities due to accumulation of interstitial fluid as a result of the stasis of lymph. This is caused by the obstruction of lymph vessels, which drain fluid from tissues throughout the body and allow immune cells to travel where they are needed.

There are many causes of lymphatic obstruction, or lymphedema. These include certain infections (i.e., chronic cellulitis or parasitic infections such as filariasis), trauma, tumors, certain surgeries, and radiation therapy. In addition, there are rare forms of congenital (present from birth) lymphedema, which probably result from abnormalities in the development of the lymphatic vessels.

Recurrent cellulitis, or infection of the skin, can damage lymphatic vessels and lead to lymphedema of the affected area. This is more commonly seen in obese patients. Chronic swelling, usually of the arm or leg, is the clinical hallmark of lymphatic obstruction.

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Physical exam and history are most important for diagnosis. In some cases, lymphangiography may be performed. This involves injection of dye into lymphatic vessels followed by x-rays of the area. Lymphangiography requires surgical isolation of the lymph vessels to be injected and is therefore a difficult procedure.

Lymphoscintigraphy is an alternative technique in which a radioactive substance that concentrates in the lymphatic vessels is injected into the affected tissue and mapped using a gamma camera, which images the location of the radioactive tracer. Lymphoscintigraphy is less invasive and more easily performed and is often used as a substitute for lymphangiography. Currently, MRI (magnetic resonance imaging) is being explored as a means to image lymphatic vessels.

Because lymphedema is a chronic disease, it usually requires lifelong management. In some cases, lymphedema improves with time, but some degree of swelling usually persists for years after onset. In addition to swelling of the affected limb, skin breakdown and formation of chronic wounds and ulcers are the primary complications of chronic lymphedema in severe cases. Thus, patients must be vigilant about skin care and hygiene. There is also a small risk of developing a lymph tissue-related cancer. Therefore, the need for effective devices to assist in the control and management of this condition is significant.

Classifications of Lymphedema

Primary:
1. Caused by malformations of the lymphatic system (excessive proliferation, underdevelopment, abnormal development or sclerosis of lymph nodes)
2. Can be present at birth (congenital lymphedema) or develop around the age of puberty

Secondary:
1. Caused by lymph node dissections, i.e. axilla, groin, pelvis or neck, radiation of lymph nodes, trauma or infection of the lymphatic system
2. Affects extremities, genitalia, abdomen or the face, or lymphedema occurring after the age of 35

Secondary lymphedema of the arm (SLA)

(Refer to the section on SLA.)

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Edematous fibrotic induration

Fibrous hardening of the tissues caused by prolonged swelling. (Refer to the section of SLA.)

Venous stasis and venous insufficiency

Venous stasis is defined as congestion and slowing of circulation in veins due to blockage by either obstruction or high pressure in the venous system, usually best seen in the limbs. Venous insufficiency is defined as a condition in which the veins do not channel the flow of blood adequately. This condition is most often seen in the veins of the lower extremities. Symptoms include leg swelling, leg pain and muscle cramps. This condition can lead to venous thrombosis or blot clots.

Deep vein thrombosis (DVT)

Deep vein thrombosis is defined as blood clotting in the veins of the inner thigh or leg. A blood clot can break off as an embolism and make its way to the lung where it has the potential of causing respiratory distress and respiratory failure. Thrombosis frequently results from poor venous return and can be prevented by massage. Based on a study in 1994, massage given unilaterally decreased the incidence of DVT in the treated limb by 82% compared with that in the untreated leg[8].

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Section 3 –
Secondary Lymphedema of the Arm (SLA) Post Mastectomy

In Western societies, one of the most common causes of lymphedema is mastectomy with axillary dissection (removal of the breast and underarm lymph tissue for breast cancer). This can cause lymphedema of the arm because the lymphatic drainage of the arm passes through the axilla (armpit), and tissue in the axilla has been removed during mastectomy. It is referred to as secondary lymphedema because if follows the primary cause of lymph node removal.

The pathophysiology of SLA is related to the disruption of lymph flow following severance or ligation of lymph vessels, lymph node removal and/or structural changes related to radiation therapy. These changes cause transport impairment in the afferent lymphatics of the affected drainage area[1]. The body's inability to compensate for the mechanical obstruction of the lymph circulation results in excessive interstitial accumulation of protein rich fluid and subsequent swelling of the affected arm.

Chronic SLA is a frequent and distressing complication associated with breast cancer treatments[2-3] with estimated 20-30%[2,5-6] of women developing it. Secondary lymphedema of the arm usually develops after an average latent period of 3.5 years. Often the arm swells to 10-200% of normal limb volume, with the excess fluid largely restricted to the subcutaneous tissue. Untreated, the condition progressively worsens with patients experiencing the symptoms of

- arm heaviness and weakness
- restricted arm movement
- tightness /hardness of the arm
- burning pains and elevated skin temperatures
- obvious swollen limb disfigurement
- psychological morbidity

Manual Lymphatic Drainage (MLD) is a specific form of massage that is designed to move fluid out of the lymphedematous arm. It involves massaging the whole upper body (torso and neck) plus the lymphedema arm using light skin stroking. MLD has been proven to reduce lower limb volume[7-8], improve limb tissues[9-10], subjective complaints like pain[11] and emotional well-being[10]. Physiologically, it reduces micro-lymphatic hypertension[12] and decreases expression of the pro-inflammatory genes responsible for the fibro-sclerotic reacitivity[13].

(b)(4) [redacted] the CelluM6 Keymodule i can be used in the same way to mobilize the lymphatic system in the treatment of SLA. In addition to the main treatment head on the machine (b)(4) [redacted] are also available to address parts of the body with less surface area, such as the arm and axillary areas. These (b)(4) [redacted] are comprised of (b)(4) [redacted] When

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attached to the machine's hose and applied to the skin, a (b)(4) [redacted] is created in the same way as it is with the main treatment head, although the rollers are (b)(4) [redacted]. The (b)(4) [redacted] (b)(4) [redacted] can also be used with (b)(4) [redacted] aspiration to gently massage the tissues and stimulate (b)(4) [redacted]

The two moving rollers shift over the skin and exert small negative pressure to deliver a light massage to the area being treated. This massage is delivered to the upper body, upper-arm and then to the lower arm, and then from the lower arm to the upper arm and finally to the upper body. Pilot studies of this equipment have shown that (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted] Based upon these preliminary studies (b)(4) [redacted] (b)(4) [redacted]

Methods of measurement included:

(b)(4) [redacted]

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(b)(4)

[redacted]

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(b)(4)

[redacted]

Impact of the LPG technique on SLA

The authors of this study stated that it is clear that the group treated with the LPG machine had statistically significant reductions in pain directly after treatment and at the end of the 4-week treatment. The LPG group also experienced significantly more softening in the anterior thorax at the end of week one and the end of the whole trial. The LPG technique demonstrated less fibrotic induration in the fascia of the upper arm and posterior thorax. There was also a significant decease of edema and fluid volume.

The fact that there were fluid reductions, tissue softening and, therefore, less fibrotic induration, and the fact the arm felt better to the women all indicate that there was a response to the treatment regime, and that the lymphatic system in the affected arm was generally working more effectivel(b)(4)

(b)(4)

[redacted]

These findings substantiate a positive benefit of performing the LPG technique with the CelluM6 Keymodule i in the treatment of secondary lymphedema of the arm post mastectomy. The LPG technique is a complimentary, all-inclusive therapeutic treatment to the traditional treatment of the SLA pathology. The LPG machine allows a standardization of the therapeutic approach, making it less operator-dependant than the manual technique. Utilization of pre-set program

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parameters on the machine also allows for the possibility of protocol optimization.

Another strong argument for validating the effectiveness of the LPG technique with the Keymodule device in the treatment of SLA is that LPG has received premarket notification for the claim "temporarily improves circumferential body measurements of treated areas." Though this claim was given in reference to cellulite reduction, it involved movement of fluids.

(b)(4)

[redacted]

Because the therapeutic massage device by LPG has been shown to effectively reduce fluid volume, its affects on SLA are significant.

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Section 4 - Techniques currently used to treat lymphedema and the LPG technique

Because edema is a blend of venous and lymphatic factors, therapeutic treatment is not a unitary approach[25]. The review of all the treatments available today shows the diversity for the same goal: the reduction of edema and the comfort of the patient. Each treatment has its own specificity. The following techniques are currently used to promote lymphatic drainage in the treatment of edema.

1. Massage or therapeutic massager

Massage means the manipulation of the superficial tissues of the human body with the hand, foot, arm or elbow. Various indications of massage are not described here. However, we know that different indications need different protocols and types of massage. The lymphatic system, more than other systems, needs a specific methodology. The therapist's hand sliding during common massage increases blood flow (b)(4) [redacted] (b)(4) [redacted]

The same thing occurs with the therapeutic massagers; the increasing of blood flow (which is an exempt claim for the therapeutic massager) (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted], these two factors having an effect on the rheology (study of the deformation and flow of materials) of the connective tissue.

If this overload is made either by manual massage or mechanical massage, the increase of fluid into the tissue could be taken by the lymphatic system, providing it is functional. Different studies have proven that in certain circumstances, lymphatic flow increases in order to eliminate the excessive quantity of interstitial fluid.

Concerning the effect of temperature, Yasuda[29] et al. reported the following:

> "By means of an intracellular glass microelectrode, action potential changes were successfully recorded in situ from the endothelial cells of rat mesenteric lymphatics over the temperature range of 27-40 degrees C. The frequency of action potential and the lymphatic contraction rate correlated well with temperature."

Thibaut measured variations of lymphatic flow:

> "A non-invasive isotope method was used to achieve a functional exploration of lymphatic circulation. Fifteen subjects were used in the study: 10 healthy subjects and 5 patients with lower extremity

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lymphedema. A first subcutaneous injection of technetium 99m rhenium sulfate (99mRTc) was performed in the first interdigital space of both feet. The radioactivity was recorded in 2 places. With the 2 types of recording procedures, it was possible to obtain a curve that showed the amount of radioactivity in relation to time. In order to obtain a muscular activity 55 minutes after the injection, each subject or patient spent 10 minutes on an ergometric bike. The statistical results of the experiment without treatment showed that in the healthy subjects, the amount of radioactivity increased during muscular activity. However, the muscular activity performed by a patient was unable to increase the radioactivity[30]."

How massage and therapeutic massagers affect the lymphatic system:

As shown above, some circumstances increase the interstitial fluid but not the lymph flow. If a forceful massage (manual or mechanical) is applied on edema or lymphedema, the result is an increase of interstitial fluid. However, in this case, the edema will not be absorbed by the lymphatic system because of the large quantity of fluids (and maybe the injury or pathology of the lymphatic system itself which is sometimes the cause of the edema.)

Then only a specific technique for the lymphatic system needs to be applied to improve the lymphatic flow and help the edema to resolve. This specific technique is called (b)(4) [redacted]

(b)(4) [redacted]

Based on scientific literature, LPG designed specific protocols to improve lymphatic circulation, lymphatic drainage and the reduction of edema. The LPG methodology for the lymphatic system takes into consideration the various therapeutic ways to treat edema:

(b)(4) [redacted]

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(b)(4) [redacted]

In 1995, A. Leduc et al. conducted a study of 10 healthy subjects to show the effect of the LPG technique on the lymphatic system. The subjects averaged about 23 years old and had no circulatory deficiency of the lower limbs. None was under medication. All were volunteer subjects. Injections were applied to the lower limbs and the study was divided into two stages. An experimental protocol was developed for the lower right limb, as well as for the left. On the right side, the injection was applied subcutaneously in the first interdigital space to visualize the internal saphenous lymphatic peduncle. On the left side, the injection was applied on the anthero-external surface of the distal third of the thigh. In this case, the visualized lymphatic peduncle as the internal saphenous peduncle. All procedures were performed on the thigh following the path of the internal saphenous lymphatic vessels and ended at the lymphatic inguinal nodes.

The results showed that the application of the LPG technique to activate superficial circulation of the lower limbs is useless and inefficient when performed on collectors that are filled with tracers or are located close to the injection site. After drainage of the collectors located farther from the injection site, it is recommended to overload again the collectors that are closer to the injection site by applying the LPG technique to the experimentally induced edema[33].

More recently in [redacted] (b)(4) reproduced this study on healthy volunteers.

(b)(4) [redacted]

In (b)(4) [redacted] performed this study to evaluate the physiological effects of the LPG technique on lymphatic flow, skin perfusion and venous flow in both muscles and subcutaneous tissue. By using proven techniques to measure thee effects, the data obtained would better substantiate the clinical significance of the animal study on pigs that was performed at the same time at (b)(4) [redacted].

Five human volunteers with no lymphedema, surgical incisions or pervious liposuction were recruited to participate in this half of the study. Skin perfusion was measured on the ipsilateral thigh before and after LPG treatments using a (b)(4) [redacted] Venous return was measured by (b)(4) [redacted] of the greater saphenous vein, superficial femoral vein and deep femoral vein. Lymphatic flow was measured by (b)(4) [redacted] using a (b)(4) [redacted] from a first web space injection.

(b)(4) [redacted] showed a dramatic increase in perfusion after the completion of the LPG technique. Skin perfusion increased 4- to 5-fold over baseline measurements, with a peak perfusion occurring 6 to 10 minutes after the LPG treatment. Although this peak was transient, the perfusion remained elevated for more than 6 hours after the completion of the treatment session. This effect was reproducible in all of the treatment sessions performed on different patients and in subsequent treatment sessions of the same patient. Venous flow velocity in the lower extremity veins showed a 2- to 3-fold increase in flow in the veins with the fat. Flow velocities increased 2- to 3-fold over baseline, with peak flow occurring 8 to 10 minutes after completion of the LPG treatment.

In contrast, the venous flow in the deeper muscular veins (deep femoral, superficial femoral and common femoral vein proximal to the confluence of the saphenous vein) showed a decrease in flow velocity. This decrease peaked at 10 to 14 minutes after the LPG treatment was completed. These effects were also noted to be prolonged and did not return to baseline throughout the 6-hour period of observation. Lymphoscintigraphy measurements in treated and untreated lower extremities showed a dramatic increase in lymphatic flow. When compared with the opposite untreated extremity, there was a 3-fold increase in lymphatic flow. Although this effect was observed as early as 30 minutes after the LPG treatment session, the most dramatic change in lymphatic flow occurred more than 3 hours after LPG treatment. This effect was reproducible in all of the patients who were studied. With (b)(4) [redacted] (b)(4) [redacted] the study was unable to document any systemic effect of the LPG technique, however[34].

(b)(4) [redacted]

This (b)(4) [redacted] study explored the action of the LPG technique as a sort of standardized massage procedure using two moving rollers shifting over the skin. This method created a kind of traction on the tissue together with an aspiration effect that could be both continuous and intermittent. The mechanical action on the skin represented a stimulation on the most superficial layers allowing for the softening of fibrosis.

The authors of this study used the LPG technique to reduce fibrosis in lymphedemas at advanced stages after treating them by combining complex decongestive physical therapies and microsurgical operation. The outcome of this study concluded that the LPG technique was shown to be a valid method to reduce and soften fibrosis in chronic extremity lymphedemas after reducing edema volume by physical therapies associated to microsurgery.

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The LPG Technique and Massage or Therapeutic Massager

The LPG Technique can be used to provide therapeutic massage. The CelluM6 Keymodule i utilizes a mechanized massage treatment head that includes two moving rollers that shift over the skin and exert slight negative pressure, delivering a light massage to the area being treated. Pilot studies of a similar version of this equipment have shown that it improves superficial lymphatic drainage[21] and lymphatic transport capacity[22], decreases fibrotic induration[23], and decreases functional discomfort[24]. Based upon these preliminary studies, it was hypothesized that the mechanized massage would result in an increase in lymphatic drainage with an accompanying reduction in limb volume, fibrotic induration and subjective symptoms.

2. Manual Lymphatic Drainage (MLD)

Developed over 100 yeas ago, the conception of this technique is based on specific rules such as, very light stroking of the surface of the skin, soft pressure applied on the skin, proximal treatment priority, and proximal to distal direction and chronology of the maneuvers regarding the direction of the lymphatic flow. Many techniques have been developed over the years following the same protocol. However, the goal in all techniques is to facilitate the resorption and the mobilization of the fluids without increasing the filtration. In order to achieve the desired affect, common massage techniques are prohibited and the maneuvers have to respect these four parameters: slowness, no rubbing, no pressure, and cutaneous stretching.

(b)(4) [redacted] very important to get an efficient treatment. Several authors have showed that this component is the first one and the most adapted to the lymphatic bio-mechanism. (b)(4) [redacted] stated:

> "A fundamental question concerns the mechanism that causes expansion and compression of the initial lymphatic. I presented several realistic proposals based on information currently on hand relevant to the tissue surrounding the initial lymphatic. To achieve a continuous lymphatic output, periodic (time variant) tissue stresses need to be applied. They include:
>
> - Arterial pressure pulsations
> - Arteriolar vasomotion
> - Intestinal smooth muscle contractions and motilities
> - Skeletal muscle contraction
> - Skin tension
> - External compression (such as walking, running, massage)
> - Respiration
> - Periodic tension in tendon

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Contraction and relaxation of the diaphragm
Contraction of the heart

Passive motion of the tissue on the lymphatic system was described[36]:

> The aim of this study was to examine how passive movement contributes to lymph flow rates. Lymph fluid was collected via a cannula inserted into one of the popliteal lymphatics in the rabbit hind leg. Lymph flow rates were measured during periodic whole leg rotation and controlled oscillatory massage of the dorsal skin of the foot. Without whole leg rotation, lymph flow remained at low values (<0.01 ml/h). Introduction of whole leg passive caused a frequency-dependent increase in lymph flow rates, which were increased linearly with the log of frequency between 0.03 and 1.0 Hz. Local skin massage in the region of the initial lymphatics also led to a similar increase of lymph flow rates. Recently, the action of indent on frequency as well as amplitude of skin displacement was studied. Lymph flow rates during local skin massage reached a comparable order of magnitude regardless of whether the animal was alive or the heart had been arrested, suggesting that local flow rates can be adjusted by periodic tissue motion independently of capillary fluid filtration pressures. The results indicate that periodic expansion and compression of initial lymphatics provide a mechanism for lymph pumping.

How MLD affects the lymphatic system:

MLD appears to be a specific technique with a specific pressure applied on the skin, a specific way to perform the maneuvers and a specific chronology of their application. Recently, [redacted] (b)(4) pointed out the importance of this methodology:

> Downstream maneuvers without sliding on the specific area
> Resorption maneuvers without sliding directly applied on the edema
> Very light pressure not producing rubbing.

A very successful and well-respected form of manual lymphatic drainage was perfected in the 1930's by a physical therapist from Denmark named Vodder. The Vodder technique is often used synonymously with MLD in the treatment of lymphedema.

The LPG Technique and Manual Lymphatic Drainage (MLD)

Because of the gentle stretching of the skin without rubbing or hyperemia, the LPG Technique can be used with this specific methodology regarding the lymphatic physiology. The (b)(4) [redacted] showed that the LPG technique could increase lymphatic flow because of its similar application on the lymphatic system. (b)(4) [redacted] study on healthy volunteers and on patients with lymphedema also demonstrated its efficacy.

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3. Sequential Pneumatic Compression (SPC)

Sequential Pneumatic Compression (SPC) is commonly used in the treatment of edema. Its effects have been well known for a long time. The pressure applied on the skin increases the tissue pressure and decreases the vascular pressure. The variation of these two pressures acts to regulate the edema by decreasing the filtration and increasing the resorption. Specific research studies have tried to evaluate the results of these therapies[38].[1]

Recently, Johanson has shown the difference between MLD and Sequential Pneumatic Compression[39]. Regarding the edema, the differences are not significant:

> We compared manual lymphatic drainage (MLD) with sequential pneumatic compression (SPC) for treatment of unilateral arm lymphedema in 28 women previously treated for breast cancer. After 2 weeks of therapy with a standard compression sleeve (part I) with maintenance of a steady arm volume, each patient was randomly assigned to either one of two treatment regimens (part II). MLD was performed according to the Vodder technique for 45min/day, and SPC was performed with a pressure of 40-60 mmHg for 2 hours/day. Both treatments were carried out for 2 weeks. Arm volume was measured by water displacement. Arm mobility, strength and subjective assessments were also determined.
>
> Lymphedema was reduced by 49 ml (7% reduction) ($p=0.01$) in the total group during part I. During part II, the MLD group decreased by 75 ml (15% reduction) ($p<0.001$) and the SPC group by 28 ml (7% reduction) ($p=0.03$). The total group reported a decrease of tension ($p=0.004$) and heaviness ($p=0.008$).
>
> MLD and SPC each significantly decreased arm volume, but no significant difference was detected between the two methods.

How SPC affects the lymphatic system:

While it appears that MLD acts on the edema by facilitating the resorption of proteins[40], SPC, because of pressure and depressurization, acts on the fluids[41]. These two procedures are complementary in the treatment of lymphedema and act together in the elimination of both lymphatic and venous fluids[42].

The LPG Technique and Specific Pneumatic Compression (SPC)

Because of the cyclic pulsation and the maneuvers, the LPG Technique can be compared with SPC. Applied along the lower or upper limb with dynamic

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maneuvers, for instance from the bottom to the top of the limb, the LPG Technique provides (b)(4) [redacted]
(b)(4) [redacted]
Because of the various adjustments of the CelluM6 Keymodule i, this movement can be applied without rubbing or hyperemia. Moreover, regarding the methodology of the application, the LPG Technique can be applied on the abdomen or above the breasts which cannot be done with SPC. For all of these reasons, the LPG technique is substantially equivalent to SPC.

Summary

The function of the lymphatic system and the means by which protein molecules enter the vessel depend upon the competence of the surrounding tissues. Movement of these tissues by compression and stroking brought about by physical forces such as massage, muscle pump and pulsation manipulates the lymphatic system in such a way to open junctions[43].

The positive effects on the lymphatic system demonstrated with the techniques of massage or mechanical massager, manual lymphatic drainage and specific pneumatic compression are all substantially similar to the positive benefits on the lymphatic system provided by the LPG device CelluM6 Keymodule i.

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Section 5 - Comparison of the CelluM6 Keymodule i to Substantially Equivalent Devices

Two classifications of devices are here for comparison, sequential pneumatic compression and mechanical massage. (Refer to section 3 for descriptions.) The predicate devices use pneumatic compression while the CelluM6 Keymodule i device uses mechanical massage. However, both types of devices provide a mechanical stimulation in order to obtain the same performance with respect to action on the lymphatic system.

Shepard Sport Pump

Although the technology differs between the CelluM6 Keymodule i and the Shepard Sport Pump, there are similarities in their function and the ultimate effect on the circulatory system.

The Shepard Sport Pump is a Class II device classified as a powered inflatable tube massager. It has received 510(k) clearance under #K912004 for:

1. Acute care of arm and leg swelling
2. Treatment of chronic edema
3. Treatment of lymphedema, including post traumatic and rheumatic edema and chronic venous insufficiency and venous stasis ulcers.

Use of the Sport Pump device is contraindicated for:

1. Acute deep vein thrombosis, pulmonary embolism or thrombophlebitis
2. Congestive heart failure or other conditions where increased venous and lymphatic return are undesirable
3. Cases of severe peripheral arterial disease or arterial in sufficiency ulcers
4. Lymphatic obstruction
5. Active infection in a limb, including erysipelas, lymphangitis and cellulitis

The Sport Pump sleeve is a triple wall sheath designed to encase an arm or leg. It consists of an interior and exterior bladder, each of which can be filled with air or fluid. The interior bladder is divided into longitudinally segmented interior cells. The exterior bladder is manufactured in two styles, allowing it to accommodate either single cell intermittent compression pumps or sequential pumps. As the bladders are filled, a force of positive pressure is exerted onto the limb, which in turn forces the accumulated fluid in the outer tissues to be moved into the underlying lymphatic vessels. The rest-to-pump time can be adjusted with the pump time set at three to four times that of the rest time.

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Mulitpulse Sequential Compression Unit

A similar device called the Multipulse Sequential Compression Unit is a Class II device classified as a powered inflatable tube massager. It has received 510(k) clearance under #K914774 for:

1. Primary lymphedema
2. Post mastectomy edema
3. Leg ulcers
4. Edema following trauma and sports injuries
5. Post immobilization edema
6. Prophylaxis of deep vein thrombosis
7. Venous insufficiencies due to muscle inactivity

Use of the Multipulse is contraindicated for:

1. Pulmonary edema
2. Acute thrombophlebitis
3. Acute congestive cardiac failure
4. Acute infections

The Multipulse is a new advancement in sequential compression therapy systems. It employs a contact pump unit featuring a power indicator, on/off switch, adjustable pressure control, pressure readout gauge and multiport garment attachment.

The system operates on the sequential wave principle, which releases the pressure on the tissue behind the wave of compression moving up the limb. The device has 10 individual chambers. Only 3 of the 10 chambers are inflated at any one time, which creates a painless wave-like action. This allows the therapist to apply greater pressures over a smaller area to increase the rate of edema reduction.

The sequencing action ensures that there is always at least one chamber of the garment inflated to prevent back-flow of fluid. This provides precise application of compression to the limb. Additionally, the entire garment is never inflated all at once. In the Multipulse, as chamber number 3 inflates, the pressure is being vented from chamber 1, releasing the compression on that tissue. Then, when chamber number 4 inflates, chamber number 2 deflates. This provides a sequential wave of compression up the limb, a true "milking" action. This produces the directional fluid control as desired, but eliminates the unnecessary tissue compression behind the wave.

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ATLANT'S Inflatable Boot

The ATLANT's is a Class II device classified as a powered inflatable tube massager. It has received it's 510(k) clearance under #K974395 for:

1. Chronic venous insufficiency
2. Lymphedema
3. Edema of venous origin
4. Post amputation
5. Lymphatic obstruction
6. Wound healing
7. Contusion

Us of the ATLANT'S is contraindicated for:

1. Non-treatable malignant tumors
2. Chronic inflammation
3. Vein thrombosis
4. Congestive heart failure
5. Cancer (in the treated limb)
6. Acute pulmonary edema
7. Acute thrombophlebitis

The ATLANT'S device is a powered, inflatable tube massager intended for medical purposes, such as to relieve minor muscle aches and pains and to increase circulation. The front panel includes a visual display which shows the pressure valves.

This pressure therapy apparatus creates a linear and dynamic pressure gradient over the limbs. The device provides a range of massaging programs, which are chosen by pushing the digit switch. Three are three actions: massage, lymphatic node drainage and complete drainage. These programs are based on three different pressure curves. All the three modes can be used at three different speeds: slow (T1), medium (T2) and fast (T3).

ATLANT'S has an exclusive technology using inflatable boots and sleeves made of a layer of micro-porous foam encapsulated between two layers of neoprene covering. When air is forced into the distal part of the boots, it creates a positive pressure which decreases as air diffuses through the foam particles creating a perfect linear gradient of pressure. Therefore, lymph is moved toward the proximal part of the limb, due to the pressure difference and mechanical stimulation of the lymph vessels. The pump has sequential programs that allow for the generation of a pulsating flow of air to move the lymph in the appropriate physiological direction.

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The CelluM6 Keymodule i

The CelluM6 Keymodule i is a Class I device and is classified as a therapeutic massager. Its current clearances are:

1. Temporarily improves the appearance of cellulite and circumferential body measurements of cellulite treated areas
2. Temporary improvement in local blood circulation
3. Relieves DOMS (Delayed Onset Muscle Soreness)
4. Relieves minor muscle aches and pains
5. Relieves muscle spasm
6. Relieves minor muscle aches and pains, relieves muscle spasm, and improves local circulation during burn rehabilitation (prescriptive use only)

Use of the Keymodule device is contraindicated for:

1. Known sensitivity to the device
2. Skin cancer in the treated area
3. Open wounds, infected areas, skin tumors, scars from recent surgery
4. Patients with infectious progressive illnesses
5. Pregnant women
6. Anyone under medical care for circulatory conditions without first consulting a physician

The CelluM6 Keymodule i therapeutic massager is comprised of a program console housing a vacuum pump and a regulation system. The main treatment head consists of two parallel motorized rollers housed in a chamber which produces both negative pressure above the rollers and positive pressure below the rollers. This technology creates a skin fold between the two rollers in the suction chamber, thus mimicking the "rolled palpation" of manual massage techniques.

The device has the capability to produce both constant and sequential aspiration. Constant aspiration provides a deeper massage, which also mobilizes the muscle fascia. With sequential aspiration, the suction power is cyclically interrupted to provide pulsation to the skin fold between the two rollers and a softer, gentler stroking action of the tissues. This action mobilizes the more superficial layers where the lymph vessels lie and can facilitate their one-way movement.

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The treatment head can be applied to most areas of the body including the limbs. When applied as a full body treatment, however, a larger portion of the lymphatic system is mobilized for greater movement and elimination of fluid accumulation.

Summary

As discussed earlier, any factor that tends to increase interstitial hydrostatic pressure increases the rate of lymph flow. When inflated to the proper level, the intermittent compression and increase of pressure on the edematous limbs provided by the compression devices decrease vascular pressure, which regulates edema by increasing filtration and increasing resorption. With the CelluM6 Keymodule i(b)(4) [redacted] Maneuvers performed in the manner of the manual lymphatic drainage technique, from distal to proximal, facilitate the movement of lymph in the direction of its proper flow, with the goal of(b)(4) [redacted]

Similar to the Multipulse and ATLANT'S devices, the skinfold process performed by the Keymodule treatment head utilizing two rollers and aspiration also creates a wave-like action and releases pressure on the tissue behind it as it moves up the limb. Further, this device can be set to a sequential program which contains cyclically interrupted aspiration creating a pulsation on the tissue captured within the treatment head's chamber allowing for (b)(4) [redacted]

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Substantial Equivalence Comparison Table

CRITERIA	**CelluM6 Keymodule i**	**Sport Pump**	**Multipulse PT101**	**ATLANT'S**
Manufacturer	LPG	Shepard	Talley Group	Grad-Line
Therapy Session Timer	Yes	Yes	Yes	Yes
Sequential	Yes	Yes	Yes	Yes
Duty Cycle Programmable	Yes	Yes	Yes	Yes
Frequency Programmable	Yes	N/A	Yes	Yes
Pressure Programmable	Yes	Yes	Yes	Yes
Weight	90 kg	N/A	11.2 kg	5.5 kg
Amperage	8.7 amp	N/A	5 amp	0.5 amp
Voltage	115V, 60 Hz	120V	200/250V, 50 Hz	110V, 60 Hz
Length, width, height	60 x 46 x 210 cm	N/A	43 x 26 x 31 cm	N/A
Pressure	50-500 mmHg (negative pressure)	N/A	0-130 mmHg	10-100 mmHg

5.6

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Section 6 – Conclusion

The objective of this paper is to substantiate specific claims for the CelluM6 Keymodule i for the treatment of lymphedema. As shown in its various peer-reviewed published clinical studies and specification comparison, the device is substantially equivalent to other methods proven to be effective in the treatment of lymphedema-related conditions such as, reduction of secondary lymphedema of the arm (SLA) post mastectomy and lymphedematous fibrotic induration, improvement of primary and secondary lymphedema, prevention of venous stasis and venous insufficiency, prevention of deep vein thrombosis (DVT) and improvement of lymphatic circulation in the treated areas.

The mechanical aspect of the LPG massager allows for consistency and reproducibility of treatment for optimal effectiveness. A range of different size treatment heads makes the treatment completely adaptable to all areas of the body. The variety of programs and their parameter settings allow for the direct targeting of tissue conditions.

LPG massagers have a 20-year history globally with six already cleared claims. Two of these claims, "improves circumferential body measurements of the treated areas" and "improves local blood circulation" have a direct effect on its ability to also mobilize the lymphatic system and reduce lymphedema accumulation in the tissues, as demonstrated in this paper. The CelluM6 Keymodule i, as the most current and state of the art version of the LPG mechanical massagers, is truly a safe and effective product in the treatment of lymphedema.

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References

[1]Hocult JE Jr, Jaffie R, Rylander CR, et al. Cryotherapy in ankle sprains. Am J Sports Med, 1982, 10 (Sept-Oct): 316-319.

[2]Tortora GJ, Anagnostakos NP. Principles of Anatomy and Physiology, Ed 3, New York City, Harper and Row Publishers, 1981:98-100, 324, 529.

[3]Elkins EC, Effect of various procedures on the flow of lymph. Arch Phys Med Rehabil, 1953(34): 31-39.

[4]Guyton AC. Textbook of Medical Physiology, Ed. 6, Philadelphia, WB Saunders Co., 1981(70): 358-380.

[5]Starkey JA. Treatment of ankle sprains by simultaneous use of intermittent compression and ice packs, Am J Sports Med, 1976 (4), July-August:142-144.

[6]Brown S. Ankle edema and galvanic muscle stimulation. Phys Sportsmed, 1981(9), November:137.

[7]Wilkerson J. Contrast baths and pressure treatment for ankle sprains. Phys Sportsmed, 1979(7), April:143.

[8]Sabri S, Roberts VC, Cotton LT. Prevention of early deep vein thrombosis by intermittent compression of he leg during surgery, BMJ, 1971(4):394.

[9]Weissleder H & Schuchhardt C, Lymphedema Diagnosis and Therapy, 2nd Edition, 1997, Kagerer Kommunikation, Germany:166.

[10]Berlin E, Gjores J, Ivarsson et al., Postmastectomy lymphedema. Treatment and a five-year follow-up study. Int Angiol, 1999; 18(4):294-8.

[11]Erickson V, Pearson M, Ganz P, et al. Arm edema in breast cancer patients. J Nat Cancer Inst, 2001; 93(2):96-111.

[12]Browning C. Lymphedema: Prevalence, risk factors and management: A review of research. NHMRC National Breast Cancer Centre, 1997.

[13]Perlund C. Prevalence and incidence of chronic lymphedema in a Western Europe country. In Nishi M, Uchino S & Yabuki (Eds) Progress in Lymphology XII, 1990:391-394.

[14]Vignes S, Champagne A, Poisson O. Management of lymphedema: experience of the Cognacq-Jay Hospital. [French] [Abstract] Revue de Medecine Interne, 2002; 23 (Suppl):414-20.

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Records processed under FOIA Request 2013-1897; Released 9/15/14

[15] Kriederman B, Myloyde T, Bernas M, et al. Limb volume reduction after physical treatment by compression and/or massage in a rodent model of peripheral lymphedema. Lymphology, 2002 (35):23-7.

[16]Piller NB, Harris R. Where does he fluid go? Objective measurement of fluid movement around the body using perometry and bio-impedance in two cases of chronic primary and secondary lymphedema. In: Proceedings of the 4th Australian Lymphology Association Conference 2001, Adelaide, 2001:85-91.

[17]Williams AF, Vadgama A, Franks A, et al. A randomized controlled crossover study of manual lymphatic drainage therapy in women with breast cancer-related lymphoedema. Euro J Cancer Care, 2002; 11:254-61.

[18]Johansson K, Lie E, Ekdahl C, et al. A randomized study comparing manual lymph drainage with sequential pneumatic compression for treatment of postoperative arm lymphedema. Lymphology, 1998; 31:56-64.

[19]Franzeck UK, Spiegel I, Fischer M, et al. Combined physical therapy for lymphedema evaluated by fluorescence microlymphography and lymph capillary pressure measurements. J Vasc Res, 1997; 34:306-11.

[20]Földi E, Sauerwald A, Hennig B. Effect of complex decongestive physiotherapy on gene expression for the inflammatory response in peripheral lymphedema. Lymphology, 2000; 33:19-23.

[14]Bartolo M & Allegra C. Microlymphatic system and LPG technique. Proceedings of the 14th World Congress of the 'Union Internationale de Phlebologie" Sept, 2001, Rome.

[15]Leduc A, Bourgeois P, Leduc O. LPG systems and lymphatic activity. Proceedings of the XV International Congress of Lymphology, Sep 1995, Sao Paulo.

[16]Campisi C, Boccardo F, Azevedo WF, Gomes CS, Couto EM, Napoli E, Zilli A, Maccio A. LPG system in the treatment of peripheral lymphoedema: Clinical preliminary results and perspectives. Euro J Lymphology, 2001; 9(34):78.

[17]Guillot B. Prospective study of the use of LPG technique in the treatment of cutaneous fibrosis induced by radiotherapy. XXII Congress National de Medecine Esthetique, 2001, Rome.

[25]P. S. Mortimer. Therapy approaches for lymphedema. Angiology. 1997, 48 (1):87-91.

[26]J. C. Ferrandez, Le DLM est-il efficace sous sa forme actuelle? Ann. Kinesithér. 1998, 25 (2):71-76.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

[27]O. Eliska, M. Eliskova. Are peripheral lymphatics damaged by high-pressure manual massage? Lymphology, 1995, 28 (1):1-3.

[28]W. Olszewski, A. Engeset, P. M. Jaeger, J. Sokoloski, L. Theodorsen. Flow and composition of leg lymph in normal men during venous stasis, muscular activity and local hyperthermia. Acta-Physiol-Scand. 1977, 99 (2):149-155.

[29]Yasuda A., Ohshima N., In situ observations of spontaneous contractions of the peripheral lymphatic vessels in the rat mesentery: effects of temperature. Experientia 1984, 15, 40 (4):342-3.

[30]G. Thibaut, A. Durand, P. Folligni, A. Bertrnad. Measurement of lymphatic flow variation by noninvasive method cases of lymphedema. Angiology, 1992, 43 (7):567-71.

[31]E. Kuhnke. Statistical demonstration of the effectiveness of the Vodder-Asdonk method of manual drainage of lymph. Experientia Suppl. 1978, 33:33-46.

[32]U. Herpetz. Outcome of various impatient lymph drainage procedures. Z. Lymphol. 1996, 20 (1):27-30.

[33]Leduc O, Bourgeois P, Leduc A. Manual lymphatic drainage: Scintigraphic demonstration of its efficacy on colloidal protein reabsorption, Progress in Lymphology XI, Partsch Ed. Excerpta Medica, 1998.

[34]Watson J., Fodor P. B., Cutliffe B., Sayah D., Shaw W.: Physiological effects of Endermologie: a preliminary report. Aesthetic Surgery Journal. January/February 1999:27-33.

[35]G.W. Schmid-Schonbein, Microlymphatics and lymph flow. Pysiol-Rev, 1990, 70(4):987-1028.

[36]F. Ikomi, Schmid-Schonbein, Lymph pump mechanics in he rabbit hind leg. Am-J-Physiol. 1996, 271(1 Pt 2):H173-83.

[37]J.C. Ferrandez, Le DLM est-il efficace sous sa forme actuelle? Ann. Kinésithèr. 1998, 25, 2:71-76.

[38]Z. Yamazaki, Y. Fujimori, T. Wada, T. Togawa, K. Yamakoshi, H. Shimazu. Admittance plethysmographic evaluation of undulatory massage for the edematous limb. Lymphology,1979,12(1):40-2.

[39]K.Johansson, E. Lie, C. Ekdahl, J. Lindfeldt, A randomized study comparing manual lymph drainage with sequential pneumatic compression for treatment of postoperative arm lymphedema. Lymphology, 1998, 31(2):56-64.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

[40]F. Ikomi, J. Hunt, G. Hanna, GW Schmid-Schonbein. Interstitial fluid, plasma protein, colloid and leukocyte uptake into initial lymphatics. J Appl Physiol. 1996, 81 (5):2060-7.

[41]C. Janbon, JC Ferrandez, JM Vinot, D. Serin. A comparative lymphoscintigraphic evaluation of manual lymphatic drainage and pressotherapy in edema of the arm following the treatment of a breast tumor. J Mal Vasc 1990, 15(3):287-8.

[42]J. Gournay, Lymphostatis and the venous wall. Therapeutic implications. Phlebologie, 1984, 37(2):201-5.

[43]LV Leak, JF Burke. Fine structure of the lymphatic capillary and he adjoining connective tissue area. Am J Anat, 1968(118):785-810.

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Vascular problems

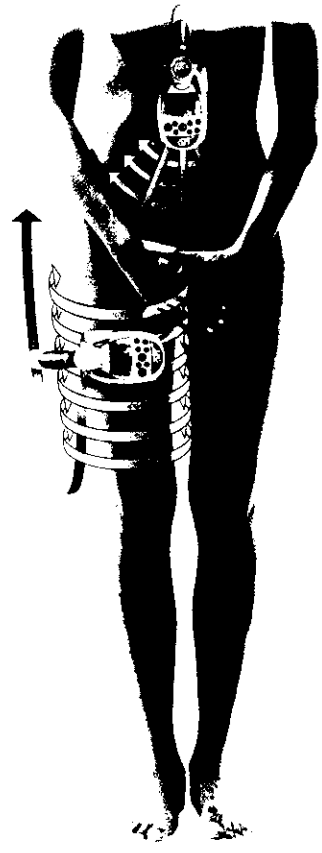
venous inssuficiency

to drain

EVALUATION ■ TIRED LEGS, EDEMA, SPIDER VEINS
OBJECTIVE ■ TO DRAIN
PRACTICE ■ **TRANSVERSAL**
DIRECT LINE

to mobilize

OBJECTIVE ■ TO MOBILIZE
PRACTICE ■ **TRANSVERSAL**
DIRECT LINE
BOUNCING

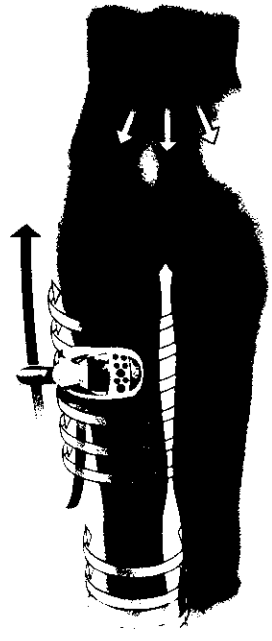


to drain

EVALUATION ■ TIRED LEGS, EDEMA, SPIDER VEINS
OBJECTIVE ■ TO DRAIN
PRACTICE ■ **TRANSVERSAL**
DIRECT LINE

to mobilize

OBJECTIVE ■ TO MOBILIZE
PRACTICE ■ **TRANSVERSAL**
BOUNCING
DIRECT LINE



➜ + Foot sole

7·1

The treatment head is chosen according to the morphology of the treated area

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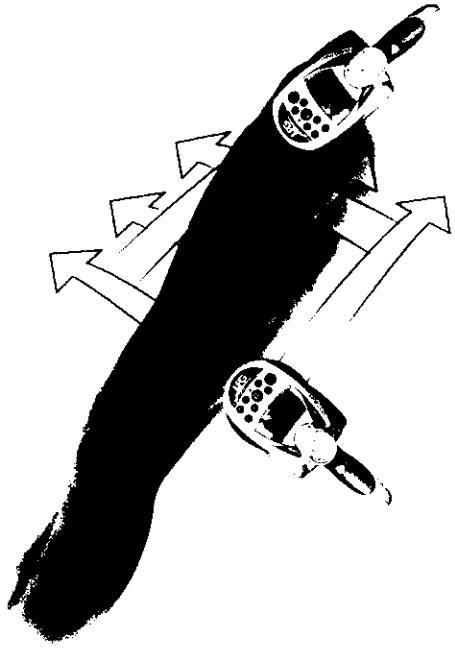
Vascular problems

traumatic edema

to collect

EVALUATION ■ EDEMA
OBJECTIVE ■ TO COLLECT
PRACTICE ■ GRID
DIRECT LINE



to drain

EVALUATION ■ EDEMA
OBJECTIVE ■ TO DRAIN
PRACTICE ■ LYMPHATIC PATHWAY
DIRECT LINE

7.2

The treatment head is chosen according to the morphology of the treated area

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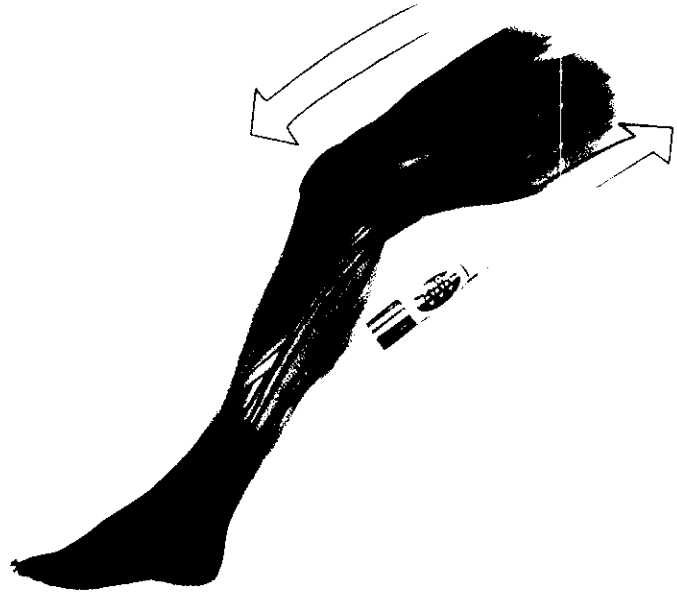
Stiffness

Fibrosis

to mechanize

EVALUATION ■ NON INFLAMMATORY
OBJECTIVE ■ TO MECHANIZE
PRACTICE ■ LONGITUDINAL
DIRECT LINE, SLIDE
MUSCLE, TENDON, LIGAMENT

MODE A ■ ROLL'UP
MODE B ■ ROLL'IN/OUT



to mobilize

EVALUATION ■ LOSS OF MOBILITY, FIBROSIS
OBJECTIVE ■ TO MOBILIZE
PRACTICE ■ LONGITUDINAL
DIRECT LINE, SLIDE
BOUNCING + TWIST
MUSCLE, TENDON

MODE A ■ ROLL'UP
MODE B ■ ROLL'IN/OUT

→ **Specificity:**
• With limitation of joint amplitude

7.3

The treatment head is chosen according to the morphology of the treated area

Réf. : 100 58 65

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LPG® technique efficacy on Secondary Lymphedema of the Arm (SLA)

not published.
no comparison
to predicate
Pilinsky / conventional therapy

[redacted] (b)(4)

LPG

INTRODUCTION

- Breast Cancer: surgical treatment = 1 woman in 15
- Secondary Lymphedema of the Arm (SLA) surgical treatment = 20-30% of cases
- Lymphedema = Great discomfort, more than an aesthetic problem, affects one's quality of life

LPG

[redacted] (b)(4) STUDY/ LYMPHEDEMA

8.1

Investigator/ Study Location:

[redacted] (b)(4)

Objective: Compare and contrast the efficacy of the LPG technique to MLD control group (Manual Lymphatic Drainage)

Total Number of Study Subjects: 45

- 24 in LPG study group
- 21 in MLD group

LPG

8.13

PILLER STUDY/LYMPHEDEMA

Subject Criteria:

- Women > 18 years (average age: 64 years)
- Having SLA from breast cancer surgery (post-chemotherapy and/or radiotherapy)
- Lymphedema > 1 year (fibrosis)
- Difference in volume between healthy and unhealthy arm of > 200 ML (10%)
- Consent to study with explanation

Subject Omission Criteria:
Lymphedema treatment in the preceding month, pregnancy, underlying primary lymphedema, uncontrolled cancer or hypertension

LPG

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[redacted] (b)(4)

STUDY/LYMPHEDEMA

Evaluation Criteria:

- [redacted] (b)(4) imaging device used to measure volume and circumference of treated area
- [redacted] (b)(4) measurement, multi-frequence – fluid levels
- [redacted] (b)(4) resistance of tissues > fibrosis
- Valid questionnaires– impact on QdV
- [redacted] (b)(4) – thickness tissues and structural modifications
- Lymphoscintigraphy – functional Modifications

LPG

[redacted] (b)(4)

STUDY/LYMPHEDEMA

Treatments:

MLD – Control Group/ Technique of Reference

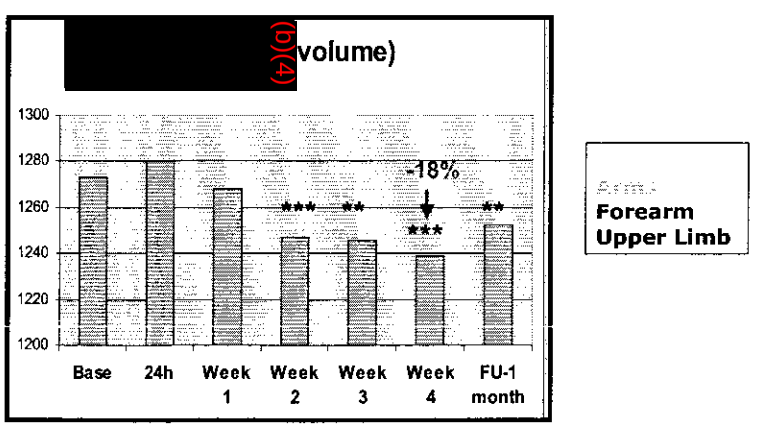
- 45 min
- 4 times a week over 4 weeks (16 sessions)
- Unaffected and affected arms; also the neck, back, upper arm and torso

LPG – Test Group

- 25 min
- 4 times week for 4 weeks (16 sessions)
- 3 aspects– preparation of the
- Anastomosis, mobilization and drainage (Cf MR. Massiot)

LPG

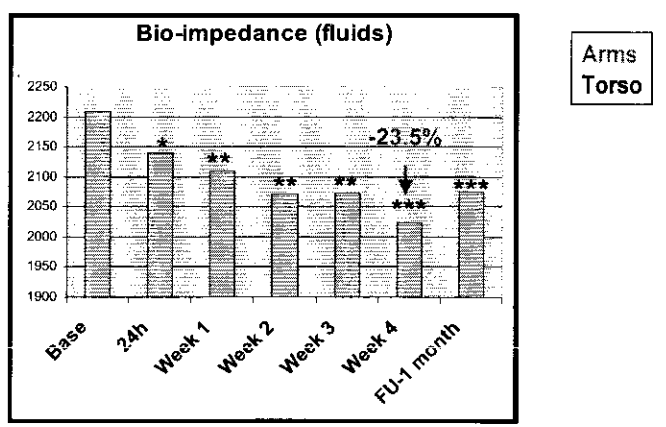
LPG's KEY FINDINGS



Significant decrease of edema after 16 sessions (Week 4)
(Arms: LPG > MLD; Before arms and mb sup: LPG = MLD)

LPG

LPG's KEY FINDINGS



Significant decrease in edema after 16 sessions (Week 4)
(Arms, torso: LPG = MLD)

LPG

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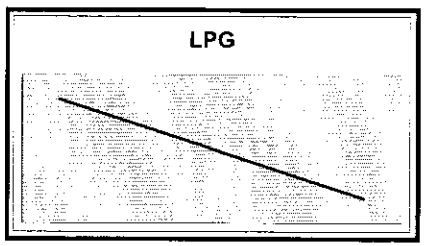
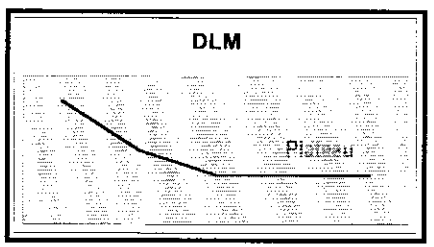
COMPARISON LPG/MLD

Tendency Curve:
(perometry and bio-impedance measurement, between 0 and 4 weeks) :



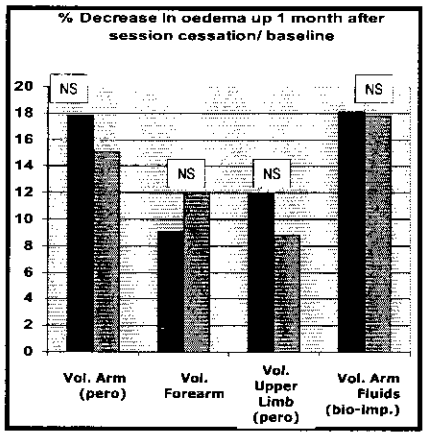


Linear Digression
Effect duration-dependant
(improvement of protocols)

Asymptotic Decrease
Effect threshhold

LPG

COMPARAISON LPG/MLD



Effect persists up to one month after cessation of treatment

LPG

LPG's KEY FINDINGS

8.3

Tonometry

Anti-Fibrosis Effect on
(previous Thorax, before arms: LPG > MLD)

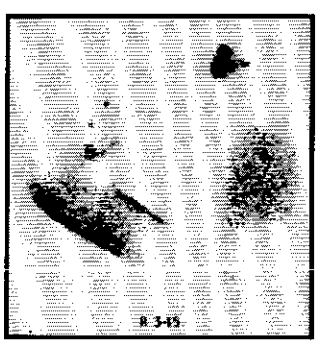
Questionnaires

- **Significant decrease in associated symptoms: pain, heaviness, hardness (LPG = MLD 2)**
- **Better compliance for the LPG technique**

8/15

LPG

LPG's KEY FINDINGS



Echographie

- **4 LPG/ 7 MLD**
  Reduction tissue thickness / posterior thorax and arms
- **Correlation with Tonometry**

Lymphoscintigraphy

- **4 LPG/ 2 MLD**
- **No significant modifications**

LPG

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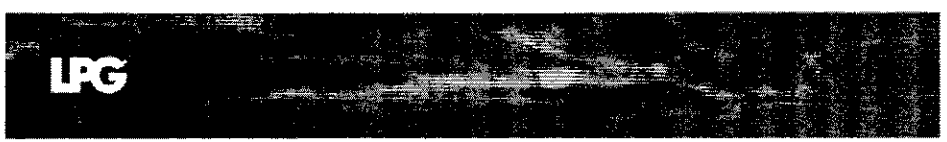
CONCLUSIONS

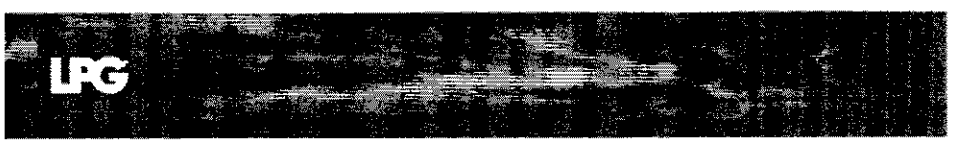
- Cumulative effect **16 treatments (4 weeks)**
- Significant Decrease **in fluid volume**
- Softening **of tissues (thorax post. and arms)**
- Significant improvement **in associated symptoms**



CONCLUSIONS

- **Sustained effect (at least a month) (MLD and LPG)**
- **LPG Treatment (secondary lymphedema in arms) much more effective for some parameters than the reference treatment.**
- ***BUT* treatment times decreased by almost of 50%, meaning**

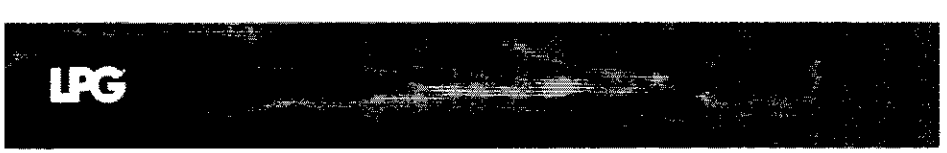
→ **LPG Technique > MLD**



FINAL CONCLUSIONS

LPG Technique:

- Complimentary, all inclusive therapeutic treatment for the traditional treatment(s) of the SLA pathology
- Allows a standardization of the therapeutic approach (less operator – dependant than MLD)
- Possibility of protocol optimization



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Breast cancer related secondary arm lymphedema

Practice Protocol

Lymphedema study, (b)(4) [redacted]

Breast cancer related secondary arm lymphedema

You have to set up the following protocol in a free menu (see the operator's manual)
- Program 1: (b)(4) [redacted]
- Program 2:
- Program 3:

Protocol.

1. To prepare the anastomosis (7 minutes)

Developpment of the trans-thoracic back and front anastomosis with the active auxiliary head: from the borderline of the oedema to the lymph nodes area.

- Program 1.
- **Active** auxiliary head.

The treatment head is chosen according to the morphology of the treated area :
T 644 A or T 630 A.

- Direct line.
- Layouts : to the node area : opposed axillary nodes, thoracics back, cervicals, abdominothoracics nodes.
- Intensity : 1 - 3 (never be painful).

Caution : decrease the intensity if the skin shows any signs of durable hyperaemia, pain or inflammatory reaction.

Over irradiated area towards the lymph nodes area.

8.5

817

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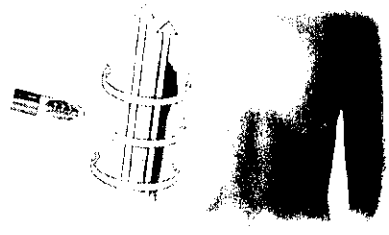
2. To mobilize the fibrosis tissue.(12 minutes)

On the oedemea.

- Program 2.
- **Fixed** auxiliary head; the treatment head is chosen according to the morphology of the treated area : - T 644 - T 630 - T 615
- Direct line.
- Layouts : longitudinal ascending and transversely. Finish always with longitudinal layouts
- Order : proximo-distal by segment of limb : arm → forearm → hand, then disto-proximal back up to the shoulder and to the breast.
- Intensity : 1 - 3

Caution : decrease the intensity if the skin shows any signs of durable hyperaemia, pain or inflammatory reaction.



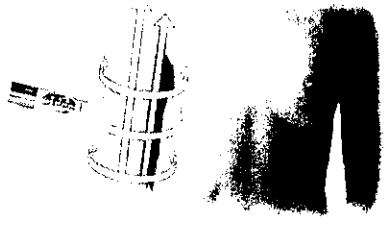
Proximo-disto-proximal progression over the oedema.

3.To drain the upper limb.(6 minutes)

On the oedemea.

- Program 3.
- **Active** auxiliary head; the treatment head is chosen according to the morphology of the treated area : - T 644 A or - T 630 A-T 615 A
- Direct line.
- Layouts : longitudinal ascending and transversely. Finish always with longitudinal layouts
- Order : proximo-distal by segment of limb : arm → forearm → hand, then disto-proximal back up to the shoulder and to the breast.
- Intensity : 2 - 4

Caution : decrease the intensity if the skin shows any signs of durable hyperaemia, pain or inflammatory reaction.



Complete session : 25 minutes.

8.6

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not published
10 healthy subjects

Research report (confidential)

Lymphoscintigraphic study of L.P.G. systems

Part 1

Ten healthy subjects.

Study conducted by: (b)(4) [redacted]

(b)(4) [redacted]

9.1

819

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Results

- Lower right limbs
- Lower left limbs

Discussion/interpretation

- Lower right limb
- Lower left limb

Conclusion

- General conclusion

9.2

820

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Purpose

The L.P.G. device is used at the skin level (the skin being drawn by suction).
The primary or secondary edemas we encounter during lymphological consultation affect the limbs and are essentially superficial.
Return circulation deficiency, which is responsible for stasis, pertains to superficial circulation.
The proposed techniques to treat edema all act upon the superficial circulation network.
The procedures used in manual lymphatic drainage, pressotherapy and the multilayered bandage techniques, were developed on the basis of experiments conducted first in animal clinics and later in human clinics (ref: 1,2,3,4,5).
We set out to test the effect of L.P.G. on the lymphatic system using a population of 10 healthy subjects. We will later conduct the same study on a population displaying lymphatic deficiency.

References:

1. Leduc, A., Bourgeois, P., Bastin, R.: Lymphatic resorption of proteins and pressotherapies. VIème Congrès Groupement Européen de Lymphologie (G.E.L.). Porto 05/31/95.

2. Leduc, O., Bourgeois, P., Leduc, A.: Manual lymphatic drainage: scintigraphic demonstration of its efficacy on colloidal protein reabsorption. Progress in Lymphology-XI-Partsch Ed. Excerpta Medica 1988.

3 Leduc, O., Derreppe, H., Hoeylaerts, M., Renard, M., Bernard, R.: Hemodynamic effects of pressotherapy. Progress in Lymphology, Elsevier Science Publishers B.V., 1990, pp. 431, 432, 433, 434.

4 Leduc, O., Klein, P., Demaret, P. and Belgrado, J.P.: Dynamic pressure variation under bandages with different stiffness. Elsevier Science Publishers B.V. Vascular Medicine. H. Boccalon editor. pp. 465-468. 1993.

5 Leduc. O., Peeters, A., Bourgeois, P.: Scintigraphic demonstration of its efficacy on colloidal protein reabsorption during muscle activity. Progress in Lymphology. Elsevier Science Publishers B.V., pp. 421-423. 1990.

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Method

Lymphoscintigraphy:

The chemical used is "Human Serum Albumin" (H.S.A.) a nanocolloid marked with Technetium (Tc) 99 m.
Due to the size of its molecules, the H.S.A. nanocolloid has the particularity of being absorbed only by lymphatic vessels.
For the lower right limb, 0,2 ml of H.S.A. nanocolloid are injected subcutaneously in the first interdigital space. For the lower left limb, the injection will be performed on the distal tierce of the thigh (antero-external part).
Two regions of "dynamic" evaluation (areas of study) are proposed:

-in the thigh area

"Static" evaluations are performed at the injection sites and around the inguinal ganglia before and after the experiment.

The L.P.G. device:

It is set as follows:

-suction level: (b)(4) type of suction

-Use of heads

For the lower right limb:

T44 on the antero-internal surface of the thigh

T33 on the antero-internal surface of the leg

T15 on the injection site and on the back of the foot

T44 on the antero-external surface of the thigh all the way to the inguinal ganglia.

T44 on the injection site

9.4

822

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Development of a treatment protocol:

The L.P.G. company offers a treatment protocol for the lower limbs (based on empirical research).
After testing with lymphoscintigraphy the treatment protocol developed by therapists sent by the L.P.G. company, we decided, in agreement with [redacted] (b) (6) [redacted], to offer a treatment therapy based on our anatomical and physiological knowledge of lymphatic vessels.
Sequence of treatment: see chapter on "experiment".

Method of analysis of results:

The analysis of results is qualitative and based on graphs.

Example: figures 1 and 2.
The x axis measures time, which is divided into intervals, each corresponding to a specific procedure.
The y axis measures nuclear activity over time.

Fig. 1.

In blue: nuclear activity over time in the right thigh area.

In green: nuclear activity over time in the right inguinal ganglia area.

9.5

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Fig. 2.

In red: nuclear activity over time in the left thigh area.
In green: nuclear activity over time in the left inguinal ganglia area.

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Population

We studied the two lower limbs of 10 healthy subjects.
The subjects are about 23 years old and show no circulation deficiency of the lower limbs.
None was under medication.
All are volunteer subjects.

9.7

825

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Experiment

Injections are performed on the lower limbs and the study is divided into two stages. An experimental protocol is developed for the lower right limb, as well as for the left. We first try out techniques (offered by LPG demonstrators) which are performed at the abdominal level in order to influence the lymphatic vessels. Once we have witnessed the [redacted] (b) (6) impact resulting from these procedures, we develop the experimental protocol based on our findings (see Elaboration of a treatment protocol on page 6).

On the right side, the injection is performed subcutaneously in the first interdigital space in order to visualize the internal saphenous lymphatic peduncle.

The procedure chronology is as follows:

The completion of the injection on the left and right sites corresponds to zero time.

0 end of injection
10 minutes of rest
5 minutes of L.P.G. on the thigh* at T.44
5 minutes of L.P.G. on the leg at T.30
5 minutes of rest (to isolate the procedure on the experimental edema)
5 minutes of L.P.G. on the injection site at T.15
5 minutes of rest
5 minutes of L.P.G. on the leg at T. 30
5 minutes of L.P.G. on the thigh* at T.44
5 minutes of rest

On the left side, the injection is performed on the antero-external surface of the distal tierce of the thigh.
In this case also, the visualized lymphatic peduncle is the internal saphenous peduncle.

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The procedure chronology is as follows:

50 minutes of rest (length of protocol on the right side)
5 minutes of L.P.G. on the thigh* at T.44
5 minutes of rest (to isolate the procedure on the experimental edema)
5 minutes of L.P.G. on the injection site at T.44
5 minutes of rest
5 minutes of L.P.G. on the thigh* at T.44.

*All procedures conducted on the thigh follow along the route of the internal saphenous lymphatic vessels and end at the lymphatic inguinal ganglia.

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Results

Lower right limb:

1) During the rest period following the injection, we can observe among all our subjects a normal physiological pick up of the tracer within the two evaluation zones.

2) Procedures in the thigh region do not modify the evolution of the lymphatic flow measured during the rest period, regardless of the area of study.

3) a- Use of L.P.G. on the leg always brings about an increase in the flow of traced proteins in the thigh area under study. This flow increase is followed by a decrease.

b- Upon evaluation of the inguinal ganglionic activity, an accumulation of tracers is always noticed.

4) During the rest period preceding the procedure performed on the injection site, the migration of the tracer over the two areas under study is comparable to the one observed during the first rest period: therefore there is no residual flow increase as a result of this procedure.

5) When using L.P.G. over the injection site, we notice only slight variations in radioactivity within the two areas of study.

6) During the rest period, subjects who showed slight variations in radioactivity during the preceding time period continue to display the same evolution in the two areas under study. Subjects who remained unaffected during the procedure performed on the foot are experiencing a lymphatic flow increase comparable to the one experienced by the other subjects during the preceding time period.

7) a- The L.P.G. procedure performed on the leg systematically leads to an increase followed by a decrease in radioactivity in the thigh region. The decline corresponds to the time period following the procedures.

b- The inguinal ganglia increase their nanocolloid overtake.

8) During the final rest period, activity within the evaluation sites stabilizes.

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1) The 50-minute rest period following the injection allows us to observe among all our subjects a normal physiological pick up of the tracer within the two evaluation sites.

2) a- Procedures in the thigh region increase the radioactivity level of the thigh.
b- Inguinal ganglia are only slightly affected.

3) Thigh procedures using L.P.G. do not modify the evolution of the lymphatic flow recorded during the rest period regardless of the area of study.

4) a- Use of L.P.G. on the injection site leads to a systematic increase in activity in the thigh region under study sometimes followed by a decrease.
b- The inguinal region shows an accumulation of traced molecules.

5) a- Slight decrease in nuclear activity in the thigh region during the rest period.
b- Causing an increase in inguinal activity.

6) a- Marked decrease in radioactivity in the thigh region during the thigh procedures.
b- Marked increase in inguinal radioactivity during the L.P.G. procedure on the thigh.

7) During the final rest period, activity within the two evaluation sites stabilizes.

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Discussion-Interpretation

Lower right limb:

Point 1 of page 11 "results".

Drainage at rest is normal, which eliminates all pathology among the population.

Point 2

Procedures on the thigh are performed on empty lymphatic collectors, producing no fluctuations.

Point 3

a- During L.P.G. leg application, lymphatic collectors from the leg region, already physiologically filled with tracers, pour empty into collectors from the thigh region. As soon as the leg is empty, collectors from the thigh region, which are no longer receiving the tracing chemical, display a drop in radioactivity.

b- Inguinal ganglia are affected in the same manner as in (a-) by the leg procedures but there is no drop in radioactivity when the tracer no longer reaches the ganglia. The latter have the ability to accumulate H.S.A. Technecie through their mucous membranes.

Point 4

Rest periods enable us to distinguish the separate effects of various procedures administered in sequence.

Point 5

The effect of the small L.P.G. head on the injection site is limited because the head is ill-suited for the first interdigital space and because the two areas under study are far away from the injection site.

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Point 6

A slight L.P.G. effect, enduring or recent, is registered in the two areas of study during the rest period. This shows the impact of distance between the area in which the procedure is performed and the evaluation zone. In this case, the distance separating these two points is so great that the effect of one upon the other is lessened.

Point 7

Same observations as in Point 3 (-a and b-) but this time, leg collectors have been filled by the procedures performed on the injection site.

Point 8

Nuclear activity as measured during the final rest period has reached a plateau. This stability means that after procedures have been performed, their effect does not perpetuate itself.

9.13

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Lower left limb

Point 1

Drainage at rest is normal among all subjects.

Point 2

The thigh fills up little by little thanks to procedures performed between the injection site and the inguinal ganglia. We have a sort of tracer suction.
The inguinal ganglia are only slightly affected because there is little chemical in the lymphatic thigh vessels before the procedure.

Point 3

The rest period enables use to isolate the effect of L.P.G. on the injection site.

Point 4

During the injection site procedure, the tracer penetrates the collectors of the thigh region and then moves toward the inguinal ganglia. The ganglia take in the chemical on their mucous membranes while the collectors of the thigh region, which were filled, are becoming empty.

Point 5

The thigh completes the draining process to fill up the ganglia.

Point 6

Procedures in the thigh region cause the collectors, which are filled with chemical, to empty. The inguinal ganglia fill up at the same rate as the drainage taking place in the thigh.

Point 7
During the rest period, the effects fade.

9.14

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RESULTS

1/ The application of L.P.G. systems to activate superficial lymphatic circulation of the lower limbs is useless and inefficient when performed far from the saphenous lymphatic flow.

2/ To be efficient, procedures must be performed on collectors which are filled with tracers or are located close to the injection site.

3/ After drainage of the collectors located farther from the injection site, it is recommended to overload again the collectors that are closer to the injection site by applying L.P.G. to the experimental edema.

CONCLUSION

It is necessary to follow the lymphatic routes and to adopt an L.P.G. application sequence consistent with points 2 and 3 described above.

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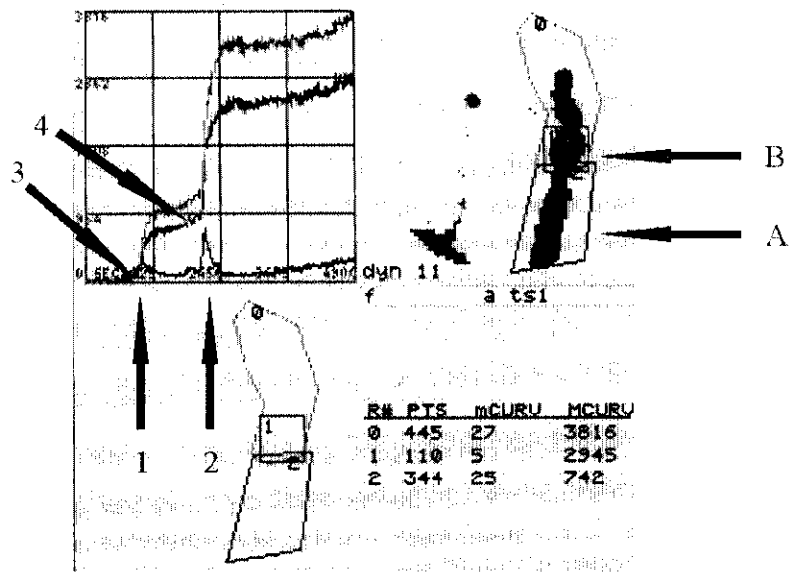
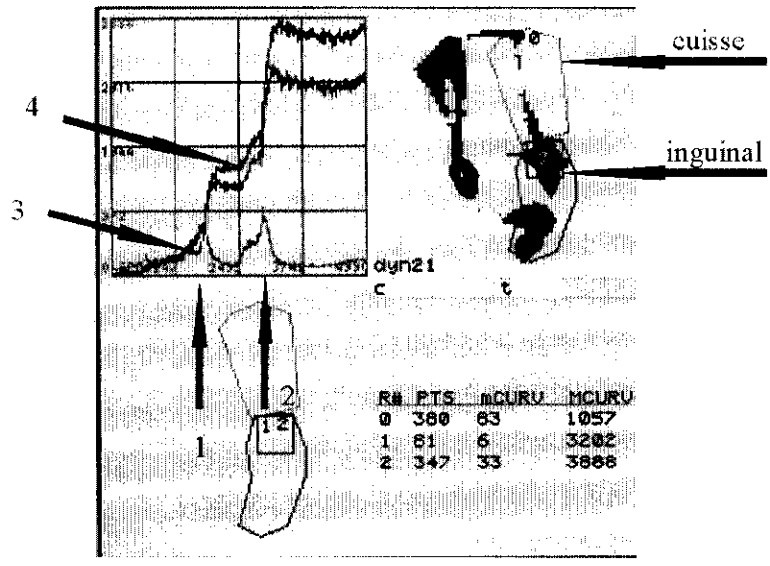
(b)(4) [redacted] (b)(4) [redacted]

Nuclear activity of the inguinal and leg regions (activity count) in normal human subjects exposed to the medical Cellu M6® by LPG®.

A 0.2 ml injection, tc 99m marked colloid, is performed in the foot first inter-digital space. The graphs hereafter are the lympho-scintigraphy recordings of the manoeuvres performed with the medical Cellu M6® by LPG® on the lower limb. The headset of the Cellu M6® by LPG® is applied consecutively on the leg and at the colloid point of injection.
"A" delimits the activity count at the thigh level (arrow A).
"B" delimits the activity count at the inguinal level (arrow B).





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(b)(4) [redacted]

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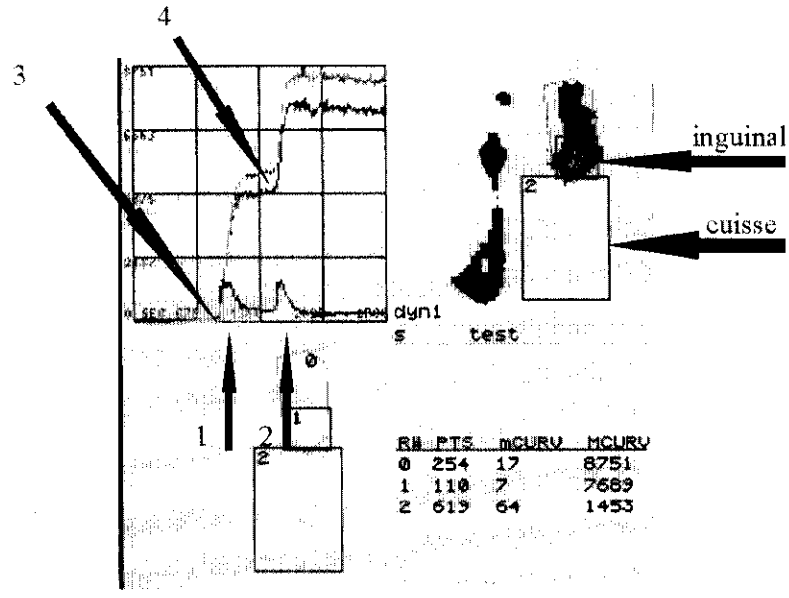
(b)(4) [redacted]

(b)(4) [redacted]



The blue arrow 1 (1st peak) defines the increase of the thigh nuclear activity during the application of the Cellu M6® LPG® head set on the leg (the colloids in the greater saphenous vein are pushed into the thigh).

Note 1: Once the manoeuvre on the leg is ended, the thigh nuclear activity returns to the pre-peak value. This is only possible because there is no lymph nodes in the nuclear activity.

The blue narrow 2 corresponds to the recording of the thigh nuclear activity after the application of the Cellu M6® LPG® at the injection site (the interstitial colloids penetrate and are pushed into the lymphatic vessels). The recording of the peak is delayed by the same amount of time the colloids take to migrate from the foot to the thigh.

Note 2 : identical to the note 1.

The red arrow 3 corresponds to the blue arrow 1 manoeuvre but the recording is made at the level of the inguinal lymph nodes.

Note 3 : the increase in the inguinal radioactivity persists even though the application of the Cellu M6® LPG® has been ended. Indeed, the lymph node mucous membrane captured the colloid.

The red arrow 4 corresponds to the blue arrow 2 manoeuvre but the recording is made at the level of the inguinal lymph nodes.

Note 4 : identical to the note 3.

Conclusion: With the application of the Cellu M6® de LPG® on the lower extremity an increase in the marked colloid is observed at the level of the activity count. Fodor **made the same observations.**

Return

(b)(4) [redacted]

(b)(4) [redacted]

9.17

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Physiological Effects of Endermologie®: A Preliminary Report

James Watson, MD[a]; Peter Bela Fodor, MD[b]; Brian Cutcliffe, BA[a]; David Sayah, MD[a]; and William Shaw, MD[a]

Background: *Endermologie® is a noninvasive, suction-assisted massage technique that has been advocated for body contouring and cellulite treatment. Theories with regard to the mechanism of action remain unproven.*
Objective: *This investigation was designed to elucidate the mechanism of action by observing the physiological effects of Endermologie® based on both animal and human studies.*
Methods: *In the SUS scorfa pig model, Endermologie® was studied by use of subcutaneous endoscopy (original magnification × 80), photography, gross tissue examination, and histologic examination. In human volunteers, Endermologie® was studied with lymphoscintigraphy, venous color-flow Doppler ultrasonography, and laser Doppler blood flow analysis of skin perfusion.*
Results: *Endoscopic and gross analysis of treated fat failed to conclusively demonstrate that Endermologie® can actually redistribute fat in vivo, but we were able to demonstrate that Endermologie® can redistribute free, autologous fat after autologous fat injections. Laser Doppler measurements showed a 4-fold increase in cutaneous blood flow. This increase in skin perfusion peaked approximately 10 minutes after treatment and lasted for more than 6 hours. Color-flow Doppler measurements showed increases in the flow velocities of the subcutaneous veins within the adipose tissue and a concomitant decrease in flow velocities of the deep muscluar veins. These effects were also noted to be prolonged, lasting for at least 6 hours after the Endermologie® treatment was completed. Lymphoscintigraphy studies revealed a 3-fold increase in lymphatic flow in the treated limb, as compared with the untreated limb. This increase in lymphatic flow was prolonged, lasting at least 3 hours after the treatment was completed.*
Conclusions: *We conclude that Endermologie® has a profound physiological effect that can be easily measured, but its anatomic effects are more difficult to identify. This suggests that Endermologie® may exert its effects by altering the physiological and metabolic activity of fat. Whether Endermologie® has a measurable anatomic effect of redistributing fat cells is yet to be proven.*

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Endermologie® (LPG Endermologie USA, Fort Lauderdale, FL) is a noninvasive, suction-assisted massage technique that was initially developed in the late 1970s by the French inventor Louis Paul Guitay to standardize scar massage therapy.[1] This mechanical device consists of two moving rollers that travel across the skin with a suction-generated vacuum between the rollers (Figure 1). The rollers exert a positive

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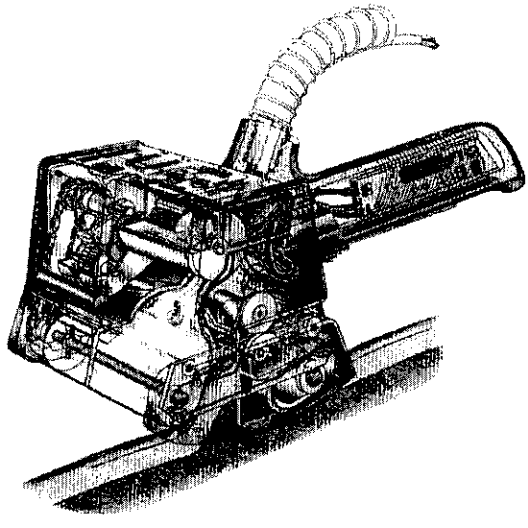

Figure 1. *Mechanical drawing of the Endermologie® handpiece. Courtesy LPG Endermologie USA.*

force on the skin and subcutaneous tissues, and the suction draws a fold of skin and fat into the vacuum space (Figure 2). With roller motion, this produces a "moving fat roll," massaging the tissues much more effectively than manual massage.

This device was initially used in Europe for burn and traumatic scars; many users noted the additional improvement in the appearance of cellulite and an apparent alteration in fat distribution. As a consequence, Endermologie® has been used in Europe, Japan, and South America for cosmetic purposes for more than a decade. Recently it was approved by the Food and Drug Administration for use in the United States.[2] In spite of the widespread use of this device, the mechanism of action is still unclear. Many theories have been advocated but remain unproven (Table).

Table. Theories regarding the mechanism of action of Endermologie®

Vertical stretching of connective tissue (retinaculae cuti)
Increased metabolism of fat cells
Stimulation of lymphatic flow
Increased skin tone and elasticity
Stimulation of subcutaneous collagen production

Purpose

This investigation was designed to elucidate the mechanism of action by observing the physiological and anatomic effects of Endermologie®. Two separate experimental studies were carried out in laboratory animals and human volunteers. The animal study was performed by use of SUS scorfa swine with Institutional Review Board (IRB) approval by the Animal Research Committee

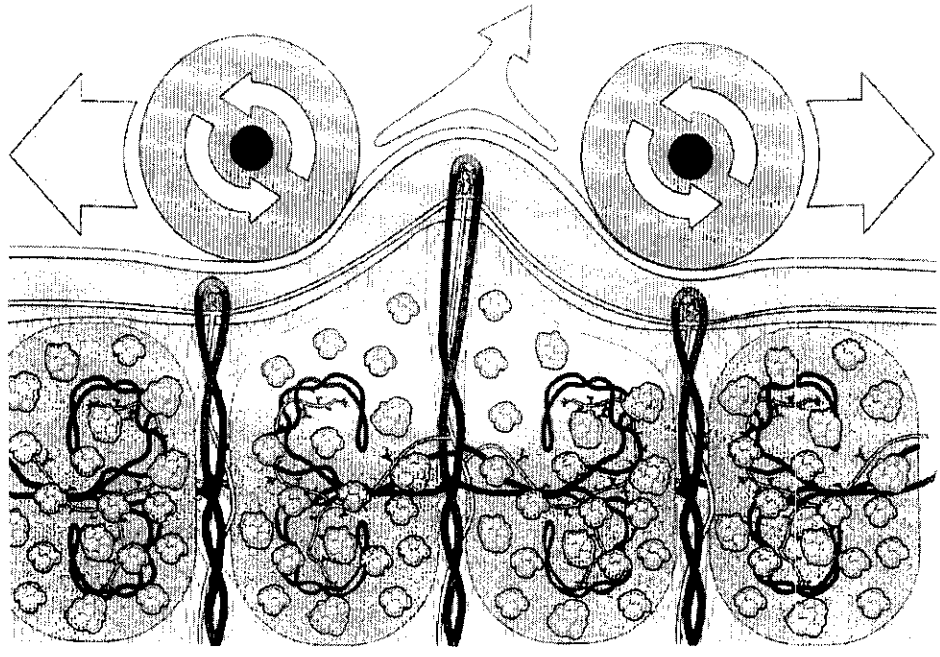

Figure 2. *Stylized illustration of the effect of the mechanical rollers and suction on the skin, retinaculae cuti, and adipose tissue.*

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at the University of California at Los Angeles (UCLA). Animals were housed in the UCLA animal care facility in accordance with National Institutes of Health guidelines for the care of experimental animals. The human study was performed with the approval of the Human Subject Protection Committee.

Animal Study

Rationale

To elucidate the exact mechanism of action of Endermologie® in subcutaneous tissue, we believed that real time visualization of the tissues during the treatment sessions would be necessary. For this reason, a model was developed that would give us near-microscopic, in vivo pictures of the blood vessels, lymphatics, adipocytes, and retinaculae cuti during Endermologie®. Animal studies are also required to obtain tissue samples for gross and microscopic analysis. For this reason, we developed the following protocol.

Methods

Four female SUS scorfa swine weighing 100 kg were used in the laboratory study of Endermologie®. With the pigs under general anesthesia, matching rectangular test sites measuring 5 × 9 cm were marked out on each swine's back, with contralateral sites serving as the controls. Each test site was photographically documented before and after treatments. Test sites were divided into three groups to evaluate the following: group 1, Endermologie® versus no Endermologie® on normal, undisturbed subcutaneous tissue; group 2, Endermologie® versus no Endermologie® in test spots that had been treated with liposuction just before treatment; and group 3, Endermologie® versus no Endermologie® in test spots where autologous fat had been injected just before Endermologie®.

Group 1: Endermologie® versus no Endermologie®. This portion of the experiment was designed to determine whether fat redistribution could be documented by endoscopy, autopsy, or light microscopy with Endermologie® treatments. In matching test spots, Endermologie® was performed on one side of the pig's back and no Endermologie® was performed on the opposite side. Endermologie® treatments were performed with the standard handpiece by use of suction settings of 6 to 7. Standard Endermologie® techniques were used, with "smoothing," "bouncing," and "figure-eight" motions for 20 minutes per test site. To ensure quality control, the treatments were monitored by an experienced Endermologie® instructor from LPG to ensure that the technique was properly performed. During the Endermologie® treatment, real-time endoscopic visualization of subcutaneous tissue was achieved by use of a high-powered endoscope, an image intensifier, and a three-chip CCD camera (Karl Storz GmbH & Co., Tuttlingen, Germany). Video recordings of these endoscopic findings were taken, and 35 mm photographic slides were taken of the test sites before and after treatments. After the experiment was completed, the pig was euthanized. The skin and fat of each test site were harvested "en bloc," photographed, and sent for microscopic analysis.

Group 2: Endermologie® versus no Endermologie® with suction-assisted lipoplasty. This portion of the experiment was designed to determine whether Endermologie® could redistribute fat in areas treated by suction-assisted lipoplasty (SAL). Contour defects were deliberately created to determine whether Endermologie® could correct these depressions. Traditional SAL was performed with the "super-wet technique" of subcutaneous infusion.[3] SAL was performed in the deep layer of the pig's subcutaneous fat, with a 3-mm, single-hole cannula.* Within this treatment area, a large 5-mm cannula was used in a 3 × 3 cm area to create an "iatrogenic" contour deformity. Matching contour defects were created on each side in this group of test sites (group 2). Photographs were taken of these contour defects before and after the Endermologie® treatments were performed. Endermologie® was performed with the same parameters used in group 1 test sites, except that the "smoothing" technique was primarily used to "redistribute" the fat into the contour deformity that had been created with the 5-mm SAL cannula. High-powered endoscopy was also used to catch real-time images of the SAL being performed, as well as the "intraoperative" Endermologie®. Postmortem gross and microscopic examinations of these test spots were performed just as they were in group 1.

Group 3: Endermologie® versus no Endermologie® in autologous fat transfers. This portion of the experiment was designed to determine whether Endermologie® could redistribute autologous fat that had been transferred by use of standard fat grafting techniques. Autologous fat was harvested by use of the syringe technique with a mercedes-tipped 2-mm cannula. The

*SUS scorfa pigs have a dense superficial layer of fat that does not resemble any fat seen in human beings. Below this layer, there is a thin, superficial fascial layer similar to Scarpa's fascia in human beings, and below that, there is a loose layer of subcutaneous fat that closely resembles the density of fat seen in human beings. That is why we chose this layer for the experimental model.

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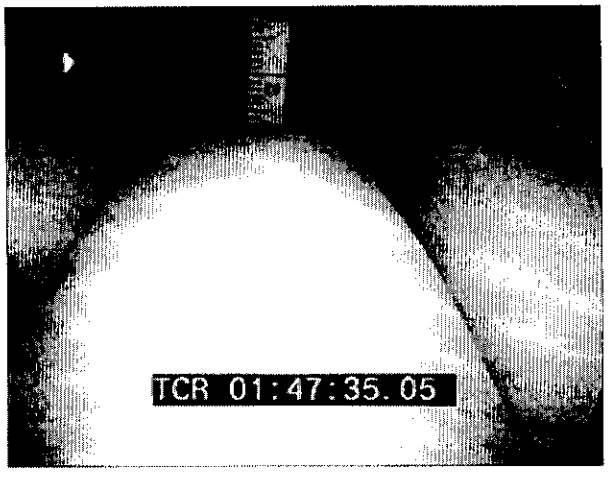

Figure 3. *Endoscopic view of skin roll between the rollers within the Endermologie® handpiece.*

harvested fat was allowed to settle, and the infranatant fluid was decanted. The remaining fat was then rinsed with saline solution decanted three times. The remaining fat was then stained with methylene blue and reinjected into the contour defects in the group 3 test sites. Ten minutes of Endermologie® was then performed on the experimental side; no Endermologie® was performed on the opposite control side. These two test sites were then harvested immediately after the pig was euthanized. The methylene blue–stained autologous fat was then evaluated by gross examination and photographically documented.

Results

In group 1, high-powered endoscopy, gross examination, and histologic examination were performed to compare areas treated with Endermologie® with those not treated (Figure 3). With high-powered subcutaneous endoscopy (original magnification × 80), we were able to demonstrate actual blood flow in transilluminated small blood vessels (<1 mm) within the fat. The blood flow was documented by use of videotape recording before, during, and after Endermologie® treatments. During Endermologie® treatments, a significant increase in subcutaneous blood flow was noted. This seemed to be a direct mechanical effect (massaging) to the treated area, because we did not see increases in blood flow in the contralateral (untreated) area. With endoscopy, we were unable to demonstrate any fat "redistribution." The animals were sacrificed immediately after the treatment session, so no long-term follow-up was done in this preliminary study, which was designed primarily to examine the immediate physiological effects of Endermologie®. Direct examination and histologic examination of the treatment sites and control sites showed no gross or histologic differences between specimens.

In group 2, high-powered endoscopy, gross examination, and histologic examination were also performed to compare Endermologie®-treated sides with those not treated in areas on which SAL had been performed. One significant finding in this portion of the study was the effect of the wetting solution on subcutaneous blood flow. After infusion of a super-wet solution before performing SAL, blood flow nearly ceased in the small subcutaneous vessels (this had been well visualized in group 1). Sludging of blood within the small venules occurred, and extreme vasoconstriction of the small arteries was observed. As a consequence of the sludging and vasoconstriction, no changes in blood flow with Endermologie® treatments could be videographically documented. In the iatrogenically produced contour deformities, we were able to demonstrate smoothing of these contours with Endermologie® by use of still photography. Endoscopic and autopsy findings failed to show actual fat redistribution into the contour deformities, however. Instead, they showed evidence of fluid mobilization (wetting solution and edema) into these depressions. The animals were sacrificed immediately after the treatment session, so no long-term follow-up was done in this preliminary study to determine whether these contour deformities improved with time.

In group 3, only gross examination at autopsy was done to examine the effects of Endermologie® on autologous fat grafting. The methylene blue–stained fat that had been reinjected into the test sites could be easily visualized on gross examination to determine whether any fat redistribution occurred. When Endermologie® test sites were compared with untreated autologous fat transfer sites, we noted a significant fat redistribution into a larger area. This seemed to be a direct mechanical effect (massage) that had spread the autologous fat transfer over a larger area in the subcutaneous space.

Human Study

Rationale

Because the animal study portion of this research was primarily qualitative in nature, the primary purpose of the human portion of the study was to obtain some quantitative information about the physiological effects of Endermologie®. The study was designed to be a noninvasive study with proven diagnostic modalities currently

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used clinically to evaluate the effect of Endermologie® on lymphatic flow, skin perfusion, and venous flow in both muscles and subcutaneous tissue. With proven techniques used to measure these effects, the data obtained would better substantiate the clinical significance of the animal study.

Methods

Five human volunteers with no lymphedema, surgical incisions, or previous liposuction were recruited to participate in this IRB-approved human study. Skin perfusion was measured on the ipsilateral thigh, before and after Endermologie® treatments with a laser Doppler flowmeter (Transonics, Ithaca, NY). Venous return was measured by color-flow ultrasound Doppler imaging of the greater saphenous vein, superficial femoral vein, and the deep femoral vein. Lymphatic flow was measured by lymphoscintigraphy, with a technetium-labeled dextran clearance from a first web space injection. Exact methods used for each limb of the study are described as follows.

Skin perfusion. Baseline cutaneous blood flow was established by placing the laser Doppler flow probe over the skin of the volunteer's left anterior thigh. Contralateral blood flow measurements of the exact same spot on the right thigh were also obtained for control subjects. Twenty minutes of Endermologie® treatments were performed by a trained Endermologie® technician, using smoothing, kneading, bouncing, and figure-eight motions. Immediately on completion of the treatment session, skin perfusion was remeasured every 30 seconds for the next 30 minutes.

Venous return. Baseline venous return was measured by use of color-flow Doppler imaging in the vicinity of the femoral triangle. Velocity measurements (cm/sec) could be accurately and reproducibly obtained from the greater saphenous vein, the superficial femoral vein, and the deep femoral vein at their confluence in the groin. Measurements were made by a trained, certified ultrasound technologist with the standard techniques used for clinical, diagnostic use. Contralateral simultaneous flow velocities of the untreated extremity could not be done (because of the lack of two separate color-flow Doppler machines to measure simultaneous flow velocities).

Lymphoscintigraphy. In selected patients who were undergoing lymphoscintigraphy for diagnostic purposes, Endermologie® was performed while the lymphoscintigraphy nuclear medicine scan was carried out. Technetium-labeled dextran was injected into the first

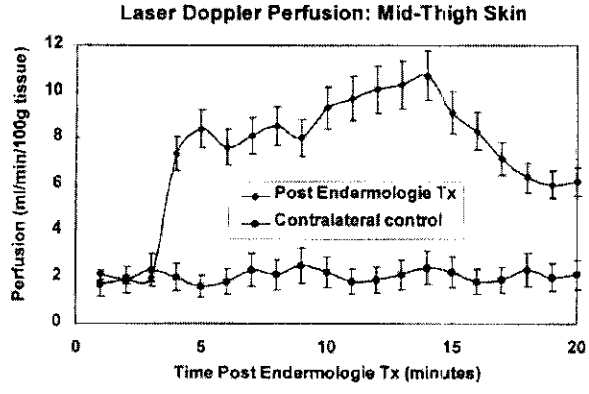

Figure 4. *Laser Doppler skin perfusion of right thigh skin after 20 minutes of Endermologie® (patient 2).*

web space of both lower extremities, and a gamma camera was used to collect images over a 5-hour time period. Endermologie® was performed twice on one lower extremity for a total of 20 minutes. The scanning continued for 3 hours after the completion of the last Endermologie® session. The lymphoscintigraphy test was performed by a licensed nuclear medicine technologist under the supervision of a radiologist. The interpretation of the results was made by a radiologist who did not know which extremity had been treated with Endermologie®.

Results

Laser Doppler skin perfusion showed a dramatic increase in perfusion after the completion of Endermologie® (Figure 4). Skin perfusion increased 4- to 5-fold over baseline measurements, with the peak perfusion occurring 6 to 10 minutes after the Endermologie® treatment. Although this peak was transient, the perfusion remained elevated for more than 6 hours after the completion of the treatment session. This effect was reproducible in all of the treatment sessions performed on different patients and in subsequent treatment sessions in the same patient. Venous flow velocity in the lower extremity veins showed a 2- to 3-fold increase in flow in the veins within the fat (Figure 5). Flow velocities increased 2- to 3-fold over baseline, with the peak flow occurring 8 to 10 minutes after the completion of the Endermologie® treatment. In contrast, the venous flow in the deeper muscular veins (deep femoral, superficial femoral, and common femoral vein proximal to the confluence of the saphenous vein) showed a decrease in flow velocity (Figure 6). This decrease peaked at 10 to 14 minutes after the Endermologie® treatment was completed. These effects were also noted to be prolonged and did not

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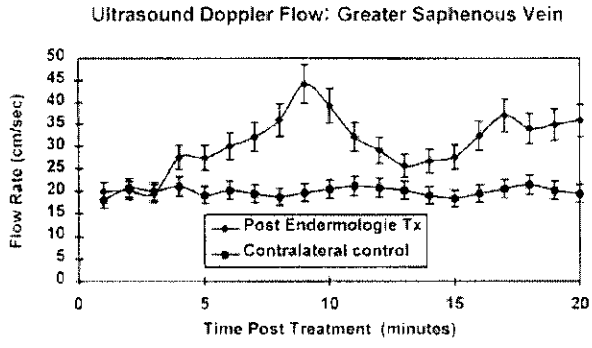

Figure 5. *Color-flow ultrasound Doppler velocity of greater saphenous vein after 20 minutes of Endermologie® (patient 3).*

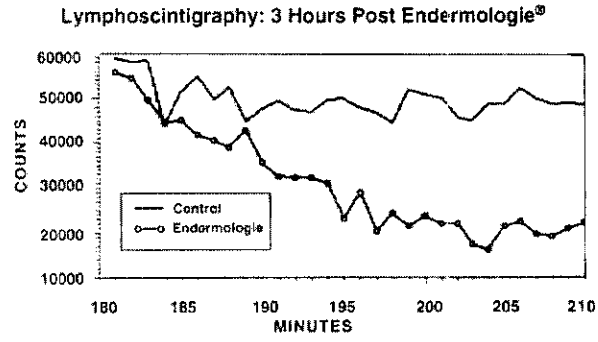

Figure 7. *Lymphoscintigraphy quantitative counts of technetium-labeled dextran 3 hours after Endermologie® treatment, with untreated control (opposite lower extremity).*

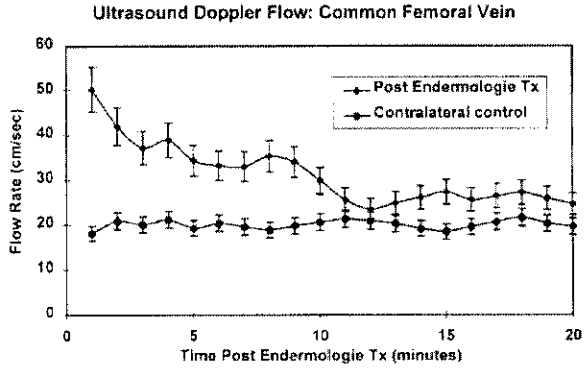

Figure 6. *Color-flow ultrasound Doppler velocity of right common femoral vein proximal to confluence of the saphenous vein (patient 2).*

return to baseline throughout the 6-hour period of observation. Lymphoscintigraphy measurements in treated and untreated lower extremities showed a dramatic increase in lymphatic flow. When compared with the opposite, untreated extremity, there was a 3-fold increase in lymphatic flow (Figure 7). Although this effect was observed as early as 30 minutes after the Endermologie® treatment session, the most dramatic change in lymphatic flow occurred more than 3 hours after Endermologie® treatment. This effect was reproducible in all of the patients who were studied. With laser Doppler, ultrasound Doppler, and lymphoscintigraphy, we were unable to document any systemic effect of Endermologie®, however.

Conclusions

On the basis of our animal studies, we conclude that Endermologie® can produce physiological alterations in cutaneous blood flow. This effect seemed to be local, rather than a systemic effect. Although we attempted to document actual fat mobilization in normal subcutaneous tissue and fat mobilization into contour defects, we failed to show any fat translocation on gross and microscopic analysis. The fact that we were able to demonstrate that free autologous fat could be mobilized comes as no surprise, because this can be done with manual massage as well. However, because this study was designed to examine the immediate effects of Endermologie®, we cannot conclude that Endermologie® does not produce any long-term anatomic effects. This is an ongoing study, and we hope to ultimately answer this question.

On the basis of our human study, we conclude that Endermologie® produces a profound physiological alteration in cutaneous perfusion, subcutaneous perfusion, and lymphatic flow. This effect seems to be delayed and prolonged, lasting for hours after the completion of the treatment. Of interest is the observation that Endermologie® increased blood flow in the subcutaneous tissue (greater saphenous vein flow) and skin (laser Doppler flow), but decreased blood flow in the deep veins within the muscles (superficial femoral vein, deep femoral veins). In our human studies, we looked for changes in the untreated areas (controls) to determine whether we could document a systemic physiological effect.

Discussion

It must be emphasized that this study is a preliminary report that was designed to examine the immediate—not the long-term—effects of Endermologie®. Because any long-term study of Endermologie® would have to account for changes in diet and exercise, it may be difficult to prove conclusively that Endermologie® alters fat metabolism. Nevertheless, we believe that this study leaves little doubt that Endermologie® has a measurable

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physiological effect on local skin and subcutaneous tissue. Some may argue that these effects can be reproduced with exercise. We are currently duplicating this study to answer this question; however, on the basis of our observations to date, the physiological effects of exercise seem to be targeted toward muscle, not fat or skin. There also seems to be a significant systemic effect of exercise, whereas the only measurable effects of Endermologie® seem to be confined to the treated area. In this aspect, Endermologie® may prove to be a simple method of targeting physiologic changes to a localized area, rather than affecting total body fat metabolism. ■

References

1. Fodor PB. Endermologie (LPG): does it work? Aesthetic Plast Surg 1997;21:68-71.
2. Steven Budabin, FDA bulletin to LPG, Inc., April 23, 1998.

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Not controlled 12 arms 8 legs

LPG® Technique in the Treatment of Peripheral Lymphedema: Clinical Preliminary Results and Perspectives

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INTRODUCTION

Lymphedema is a chronic worsening disease with progressive appearance of fibrosis in the interstitial tissue involving dermal and hypodermal layers.

LPG technique supplies a sort of standardized massage procedure by means of two moving rollers, shifting over the skin. This method creates a kind of traction on the tissue together with an aspiration effect, that can be continuous or intermittent. The mechanical action on the skin represents a stimulation on the most superficial layers allowing to soften fibrosis.

We tried to use LPG technique to reduce fibrosis in lymphedemas at advanced stages, from the 3rd to 5th, after treating them by combining complex decongestive physical therapies and microsurgical operation.

MATERIALS AND METHODS

We performed a prospective study in twenty patients affected from secondary lymphedema of arms (12) and legs (8) treated by combining physical therapies and microsurgical operations. After a period variable from 1 to 3 months from microsurgery, patients underwent a standardized protocol of therapy by LPG technique to cure the remaining less responsive fibrosis. We used Cell M6-IP device.

The protocol of therapy by LPG consisted in a treatment of 25 minutes, 3 times a week, for 5 weeks.

The results were assessed by photographs, volumetric measurements, US, lymphoscintigraphy, MR and Laser-Doppler.

RESULTS

By comparing photographs before and after LPG treatment, we could notice an evident improvement in terms of reduction in size of the treated part of the limb.

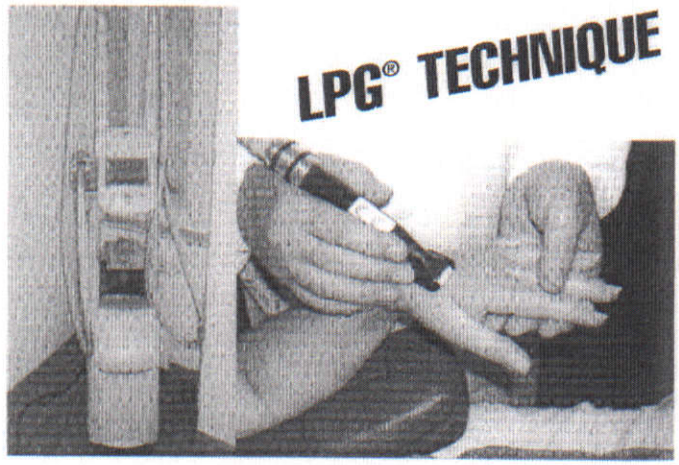
Volumetric measurements showed a decrease of excess volume from 5% to 10% after LPG therapy.

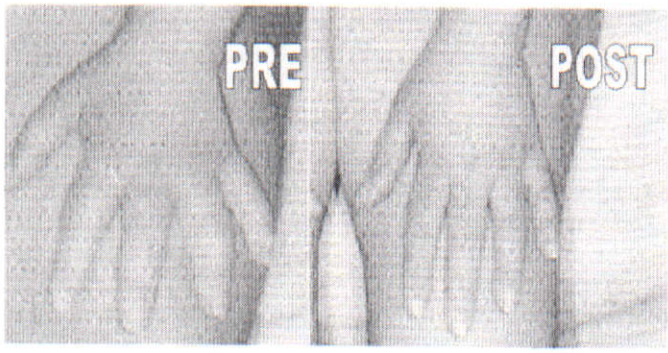
Ultrasounds allowed to obtain a better assessment of fibrosis of tissues and follow results obtained by LPG treatment. Echo-scanning performed by the same operator demonstrated a significant reduction of fibrosis together with a consequent decrease of the thickness of superficial layers after LPG therapy.

Lymphoscintigraphy showed a reduction of dermal back flow at the site of fibrosis after treating the area by LPG technique.

MR proved to be useful to assess the reduction of fibrosis but is too expensive to be performed routinely.

Laser-Doppler evaluated perfusion of blood microcirculation of superficial tissues and showed a significant improvement of perfusion after LPG treatment of fibrosis.





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DISCUSSION AND CONCLUSIONS

Lymphedema is assumed to increase in amount and stage with time. These increases together with that of fibrosis were caused mostly by duration rather than by patient aging[1].

Due to pathophysiological changes that occur in chronic extremity lymphedema, fibrosis progressively appear, resulting also from overexpressions of relevant genes like TGF-beta in the dermal and subcutaneous tissue fibroblasts and subsequent extracellular matrixes syntheses and deposition.

Thus, patients should be persuaded to undergo treatment early, starting with complex physical therapies for 2 intensive weeks of treatment. If after 3-6 months there is the relapse or worsening of lymphedema, notwithstanding proper elastic support (stockings, sleeves, etc.) another cycle of therapy of other 2 weeks is performed. If after 3-6 months after this second treatment lymphedema relapse of increases it is recommended to refer to microsurgical operations, in order to create new pathways of drainage of lymph. This way, the appearance of fibrosis is prevented or at least reduced at the utmost[2]. For those cases addressed to this kind of combined treatment physical and microsurgical late, at the most advanced stages, with a lot of fibrosis already present, LPG technique proved to be extremely useful to greatly reduce and soften fibrosis.

Lymphedema is characterized by complications consisting of infections followed by fibrosis and occlusion of the collecting lymphatic vessels. Lymphedema is worsened by fibrosis.

Manual lymph drainage, through a constant change in pressure, moves fluid in the skin, increases lymphomotricity and softens fibrosis[3]. But, often fibrosis is not enough responsive to this kind of physical therapy, also if associated with compression, and requires some other method of treatment.

Microsurgery offers valid solutions in allowing the drainage of the obstructed lymph flow by carrying out lymphatic-venous shunts[4] or by reconstructing lymphatic-pathways where obstructed by means of autologous venous grafts interposed between lymphatic collectors above and below the obstacle to lymph circulation[5]. This drainage, if applied precociously, can prevent the formation of fibrosis and the progressive evolution of extremity lymphedemas. Unfortunately, several patients are addressed to microsurgical solutions lately when fibrosis is present at a certain amount.

In these cases, LPG technique helped us in reducing fibrotic tissural component, allowing to softening skin and superficial tissues, further improving lymphatic drainage of the affected limb.

As concerns the objective assessment of fibrosis, among different clinical and instrumental criteria, we think that ultrasounds can show better the amount of reduction of fibrosis in lymphedematous tissues from the morphological point of view. Lymphoscintigraphy is useful to evaluate the functional improvement of the drainage of lymph at the areas of fibrosis (reduction of dermal back flow)[6]. Laser-Doppler gives precise information on the benefit effects of the therapy on blood microcirculation and thus is considered an indirect sign of decrease of fibrotic component of tissues.

In conclusion, in our preliminary clinical experience, LPG technique showed to be a valid method to reduce and soften fibrosis in chronic extremity lymphedemas after reducing edema volume by physical therapies associated to microsurgery.

REFERENCES

1. Casley-Smith JR. Alterations of untreated lymphedema and it's grades over time. Lymphology 1995 Dec; 28 (4): 174-85.
2. Campisi C, Boccardo F. Frontiers in Lymphatic Microsurgery. *Microsurgery* 1998; 18: 462-71.
3. Kasseroller RG. The Vodder School: the Vodder method. Cancer 1998 Dec 15; 83 (12 Suppl American): 2840-2.
4. Campisi C. Lymphoedema: modern diagnostic and therapeutic aspects. International Angiology 1999 March; 18,1: 14-24.
5. Campisi C. Use of autologous interposition vein graft in management of lymphoedema. Lymphology 1991; 24: 71-76.
6. Mariani G, Campisi C, Taddei G, Boccardo F. The current role of lymphoscintigraphy in the diagnostic evaluation of patients with peripheral lymphoedema. *Lymphology* 1998; 31 S: 316-9.

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U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Establishment Registration Database

Establishment:
LPG ONE, INC
701 Brickell Ave.
Suite 2550
Miami, FL 33131
Registration Number: 3004887948

Operations: Initial Distributor
Status: Active
Date Of Registration Status: 2005

Owner/Operator:
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Database Updated 11/07/2005

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A randomised, single-blinded trial of the effectiveness of manual lymphatic massage (MLD) and machine based massage (LPG) on post mastectomy arm lymphoedema.

FINAL REPORT

For
LPG Systems

From a Consortium of

(b)(4)

[redacted]

(b)(4)

[redacted]

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BACKGROUND.

Secondary Lymphoedema of the Arm (SLA) Post Mastectomy

The pathophysiology of SLA is related to the disruption of lymph flow following severance or ligation of lymph vessels, lymph node removal and/or structural changes related to radiation therapy. These changes cause transport impairment in the afferent lymphatics of the affected drainage area[1]. The body's inability to compensate for the mechanical obstruction of the lymph circulation results in excessive interstitial accumulation of protein rich fluid and subsequent swelling of the affected arm.

Chronic SLA is a frequent and distressing complication associated with breast cancer treatments[2-3] with an estimated 20-30%[2,5-6] of women developing it. Secondary lymphoedema of the arm usually develops after an average latent period of 3.5 years. Often the arm swells to 150-200% of normal limb volume, with the excess fluid largely restricted to the subcutaneous tissue. Untreated, the condition progressively worsens, with patients experiencing symptoms of:

- arm heaviness and weakness;
- restricted arm movement
- tightness/hardness of the arm
- burning pains and elevated skin temperatures;
- obvious swollen limb disfigurement
- psychological morbidity.

Manual Lympatic Massage (MLD)

MLD is a specific form of massage which is designed to move fluid out of the lymphoedematous arm. It involves massaging the whole upper body (torso and neck) plus the lymphoedema arm using light skin stroking. MLD has been proven to reduce limb volume[7-8], improve limb tissues[9-10], subjective complaints like pain[11] and emotional well being[10]. Physiologically, it reduces micro-lymphatic hypertension[12] and decreases expression of the pro-inflammatory genes responsible for the fibro-sclerotic reactivity[13].

LPG technique (mechanised massage)

The LPG technique uses a mechanised massage piece of equipment which uses two moving rollers that shift over the skin and exert small negative pressure to deliver a light massage to the area being treated. This massage is delivered to the upper body, upper-arm and then to the lower arm and then from the lower arm to the upper arm and finally to the upper body. Pilot studies of this equipment have shown that it improves superficial lymphatic drainage[14] and lymphatic transport capacity[15], decreases fibrotic induration[16], and decreases functional discomfort[17]. Based upon these preliminary studies it was hypothesized that the mechanised massage would result in an increase in lymphatic drainage with an accompanying reduction in arm volume, fibrotic induration and subjective symptoms.

AIM.

To establish the effectiveness of LPG and then compare this to the effect obtained from MLD, using the following;

- Objective physiological measures (arm volume, fluids, fibrotic induration)
- Lymphoscintigraphy & ultrasound (in those who volunteered)
- Subjective patient report

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METHODS.

Participants were sourced from the (b)(4) [redacted] Before the commencement of the study all prospective participants were assessed in terms of their medical diagnosis and their suitability for the study via phone screening (see criteria below);

Inclusion criteria:

- those presenting, or diagnosed with clinically manifest chronic secondary unilateral arm lymphoedema. With the onset of the lymphoedema being associated with previous breast cancer treatment (surgery ± radiotherapy ± chemotherapy)
- all radiotherapy and chemotherapy completed.
- a duration of disease > 1 year or who have significant indications of fibrotic induration of the major lymphatic territories (as detected by tonometry).
- a volume difference between the arms of at least 200mls (10%) or greater (with arm dominance being corrected for)

Exclusion criteria:

- People under the age of 18.
- Current uncontrolled cancer.
- Uncontrolled hypertension (cardiovascular disease).
- Underlying primary lymphoedema.
- Underlying lipoedema.
- Severe immobility.
- Pregnancy or suspicion of pregnancy.
- Received treatment for the lymphoedema arm in the last month.

Once recruited, all participants were given verbal and written explanation about the trial and given a consent form to sign.

The participants were then allocated into two groups using a randomised number table*:

Group 1: received 45 minutes of manual lymphatic drainage plus short stretch elastic bandaging 4 times a week for 4 weeks (16 sessions in total) then 1 month follow up measurement.

Group 2: received 25 minutes of LPG plus short stretch elastic bandaging 4 times a week for 4 weeks (16 sessions in total) then 1 month follow up measurement.

* All attempts were made to randomize participants, however due to clinical needs the randomization process was sometimes broken.

A qualified (b)(4) [redacted] therapist performed the manual lymphatic massage. According to the following protocol:

1. Neck
2. Unaffected side
3. Affected side
4. Back
5. Upper arm (affected side)
6. Forearm (affected side)
7. Affected side
8. Back

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An occupational therapist administered the LPG according to the following protocol:

1. Prepare anastomosis
2. Mobilization
3. Drainage

All participants were asked not to undertake any new treatments whilst undergoing the 4 week treatment phase and during the 1 month follow up.

The elastic bandaging consisted off:

1. Gauze Sleeve
2. High density foam
3. 2 – 3 layers of short stretch bandaging

Participants were encouraged to wear the elastic bandaging as long as possible and to remove it before showering the following day. However, if the participant experienced any discomfort, pins & needles, itchiness, or finger discolouration they were instructed to remove the bandaging. Participants' were asked to keep a log book of when they removed the bandaging so compliance could be monitored.

For those participants who worked during the day, the participant was asked to remove the bandaging but to wear their compression sleeve.

At the end of 4 weeks of treatment all women were encouraged to purchase a new compression garment that fitted the arm and were asked to wear this garment and continue daily skincare over the 1 month period.

MEASUREMENTS.

Measurements were taken on the following occasions:

- Baseline
- Directly after the first treatment session (before bandaging)
- 24 hours after the first treatment session (before the 2nd treatment session)
- End of week 1
- Beginning of week 2
- End of week 2
- Beginning of week 3
- End of week 3
- Beginning of week 4
- End of week 4
- 1 month post treatment follow up

The measurements that were taken were as follows:

- (b)(4) [redacted]. Is a previously validated[18-19] piece of equipment which uses optoelectronics to measure arm circumference at every 3mm, giving an accurate picture of variations in circumference compared with the other side. It also gives an accurate indication of arm volume.

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- (b)(4) [redacted]. Resistance of subdermal tissues to standardized mechanical compression was measured using a skin tonometer[20]. Measurements were taken at the anterior forearm (10cm down from cubital fossa), upper arm (10cm up from the cubital fossa), mid-clavicular line (5cm down from the clavicle) and posterior scapula (3cm up from the top of the scapula).

- Bio-impedance. Indices of arm and truncal fluid volumes were derived from the Inbody-3, a multi-frequency bio-impedance (5 – 500Hz) machine. This method has been previously validated[21-22], with Inbody-3 limb measurements being shown to correlate with perometry measurements[23].

- Subjective examination. participants were asked to indicate on a 10 point likert scale[24] their perception of subjective arm symptoms, this included; pain, heaviness, tightness, arm hardness, arm temperature, cramps, pins & needles, arm size difference and range of movement.

- Blood pressure and pulse rate. blood pressure was taken with a standard cuff on the unaffected arm. The radial pulse was taken for 1 minute.

- General Questionnaire. this was taken at the beginning of the trial only and recorded breast cancer surgery & treatment, general medical conditions and lymphoedema history (including onset and previous treatments).

Voluntary Measurements.

- Ultrasound. This procedure was performed before treatment and at the end of 4 weeks of treatment and assessed the superficial and deep fascia, including thickness and distance between the fascias in the lymphatic territories. It involved the application of thick gel and the ultrasound head (compressed against the skin) to the lymphatic territories in the affected and normal arm, including the: anterior forearms, anterior upper arms, the anterior thorax (below the collarbones) and the posterior thorax (on the back above the scapulas). The ultrasounds were performed by the same Sonographer each time for consistency.

- Lymphoscintigraphy. This procedure involved the injection of radioactive dye into the web space in between the middle and index finger of the lymphoedematous and normal arm. The dye is picked up by the lymphatic system and moved up the arm, with the movement of the dye being photographed by a gamma camera over a 4-5 hour period. This technique helps to determine the disruption in lymphatic transport capacity, how this maybe optimized by massage and whether an increase in lymphatic trasport capacity can be detected and correlates with a reduction in arm volume, arm segmental fluids or improvements in subjective arm symptoms.This measurement was performed before and after the 4 weeks of treatment.

- Clinical photography. A standardised photo was taken of the lymphoedematous and normal arm before and after 4 weeks of treatment.

ANALYSIS

Only those who completed the whole trial (including the 1 month follow up) were included in the analysis.

Both groups were evenly distributed in terms of arm volume at baseline, therefore a parametric analysis was used. The Independent-Samples T Test was used to compare the difference between the two groups by comparing the means. For this test patients are randomly assigned to two treatment groups, so that any difference in response is due to the treatment and not to other factors.

The Paired-Samples T Test was used to compare the change of a particular variable within the treatment group. This procedure computes the differences between values of the two variables for each case by comparing the means.

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The percentage change for arm volume (as measured by bioimpedance and perometry) was calculated using the following equations[25]:

Actual oedema at time$_{(x)}$ (b)(4) [redacted]

The percentage change in actual oedema was then calculated as follows:

% oedema change at time(x) (b)(4) [redacted]

RESULTS.

Table 1. Breast Cancer Treatment & General Medical History

	LPG	MLD	p
Number	24	21	0.927
Age	**63.3yrs** (± 10.7) (38 - 84yrs)	**62.1yrs** (± 9.8) (46 - 79yrs)	0.727
Part. Mastectomy + Axillary Cl. Tot. Mastectomy + Axillary Cl.	9 (37.5%) 15 (62.5%)	5 (23.8%) 16 (76.2%)	0.056
Nodes removed: 1 – 10	2 (8.3%)	1 (4.8%)	0.347
11 – 20	6 (25%)	9 (42.9%)	0.857
21 – 30	1 (4.2%)	1 (4.8%)	0.851
> 30	1 (4.2%)	1 (4.8%)	0.851
all	2 (8.3%)	4 (19%)	0.251
K/N	12 (50%)	5 (23.5%)	**0.005**
Positive nodes: none	13 (54.2%)	10 (47.6%)	0.825
1 – 5	2 (8.3%)	3 (14.3%)	0.251
6 – 10	4 (16.7%)	1 (4.8%)	**0.009**
11 – 15	-	1 (4.8%)	**0.029**
> 20	-	1 (4.8%)	**0.029**
K/N	4 (16.7%)	5 (23.8%)	0.247
All	1 (4.2%)	-	**0.029**
Chemotherapy: Yes No	12 (50%) 12 (50%)	12 (57.1%) 9 (42.9%)	0.493
Radiotherapy: Yes No	20 (83.3%) 4 (16.7%)	15 (71.4%) 6 (28.6%)	0.064
Area: Breast only	8 (33.3%)	5 (23.8%)	0.169
Axilla only	1 (4.2%)	-	0.057
Breast + axilla	5 (20.8%)	6 (28.6%)	0.246
Breast + axilla + supra-			

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clavicular	4 (16.7%)	2 (9.8%)	0.064
Breast + axilla + lateral	-	2 (9.8%)	**0.001**
Supraclavicular only	1 (4.2%)	-	0.057
Supraclavicular + breast	1 (4.2%)	-	0.057
Hypertension: Yes	11 (45.8%)	12 (57.1%)	0.701
No	13 (54.2%)	9 (42.9%)	
Heart Disorders: Yes	1 (4.2%)	-	0.057
No	23 (95.8%)	21 (100%)	
Thyroid Dysfunction: Yes	6 (25%)	3 (14.3%)	0.074
No	18 (75%)	18 (85.7%)	
Diabetes:			
Borderline	2 (8.3%)	1 (4.8%)	0.347
Yes – diet controlled	7 (29.2%)	4 (19%)	0.120
Yes – medication controlled	-	1 (4.8%)	**0.029**
No	15 (62.5%)	15 (71.4%)	0.220
Arthritis (in aff. arm): Yes	12 (50%)	7 (50.0%)	0.493
No	12 (50%)	7 (50.0%)	
Post-menopausal: Yes	23 (95.8%)	20 (95.2%)	0.064
No	1 (4.2%)	1 (4.8%)	
HRT Tx: Yes	-	1 (4.8%)	**0.029**
No	24 (100%)	20 (95.2%)	

Table 2. Lymphoedema History

	LPG	MLD	p
Lymphoedema Onset After Tx:	**30.6mths** (± 43.2) (2 – 192mths)	**37.4 mths** (± 47.1) (2 – 168mths)	0.540
Cause of Lymphoedema:			
Work related	2 (8.3%)	-	**0.005**
Flight	1 (4.2%)	2 (9.5%)	0.158
Over use	6 (25%)	4 (19%)	0.347
Insect bite	1 (4.2%)	1 (4.8%)	0.851
Radiotherapy	1 (4.2%)	1 (4.8%)	0.851
Post Surgery	1 (4.2%)	1 (4.8%)	0.851
Hot weather	-	1 (4.8%)	**0.029**
Venepuncture	1 (5.9%)	-	**0.057**
Infection	-	1 (4.8%)	**0.029**
Scratch from gardening	2 (8.3%)	-	**0.005**
Fall on affected side	-	1 (4.8%)	**0.029**

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K/N	9 (37.5%)	6 (42.9%)	0.498
Worse in evening: Yes	16 (66.7%)	13 (61.9%)	0.202
No	8 (33.3%)	7 (33.3%)	
Worse in hot weather: Yes	15 (62.5%)	14 (66.7%)	0.570
No	9 (37.5%)	7 (33.3%)	
Previous arm injury: Yes	8 (33.3%)	8 (38.1%)	0.526
No	16 (66.7%)	13 (61.9%)	
Lymphoedema Status:			
Mild	6 (25%)	6 (28.6%)	0.601
Moderate	16 (66.7%)	11 (52.4%)	0.132
Severe	2 (8.3%)	4 (19%)	**0.037**

Table 3. Previous Lymphoedema Treatment

	LPG	MLD	p
Last Tx: 1mth	5 (20.8%)	8 (38.1%)	**0.019**
2 – 6mths	4 (16.7%)	3 (14.3%)	0.668
> 6mths	4 (16.7%)	2 (9.5%)	0.164
> 1 yr	10 (41.7%)	7 (33.3%)	0.274
N/A	1 (4.2%)	1 (4.8%)	0.851
Previous Tx Received:			
Complete Physical Therapy	4 (16.7%)	3 (14.3%)	0.606
Manual Lymphatic Drainage	21 (87.5%)	17 (81.0%)	0.864
Laser Therapy	17 (70.8%)	15 (71.4%)	0.403
Tai Chi Trial	5 (20.8%)	4 (19.0%)	0.659
Wears a Compression Sleeve			
Yes	6 (25%)	5 (23.8%)	0.857
Sometimes	5 (20.8%)	4 (21.4%)	
No	11 (54.2%)	12 (57.1%)	0.701

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Figure 1A. Change in affected whole arm volume (as measured via (b)(4) over trial duration (**LPG**)

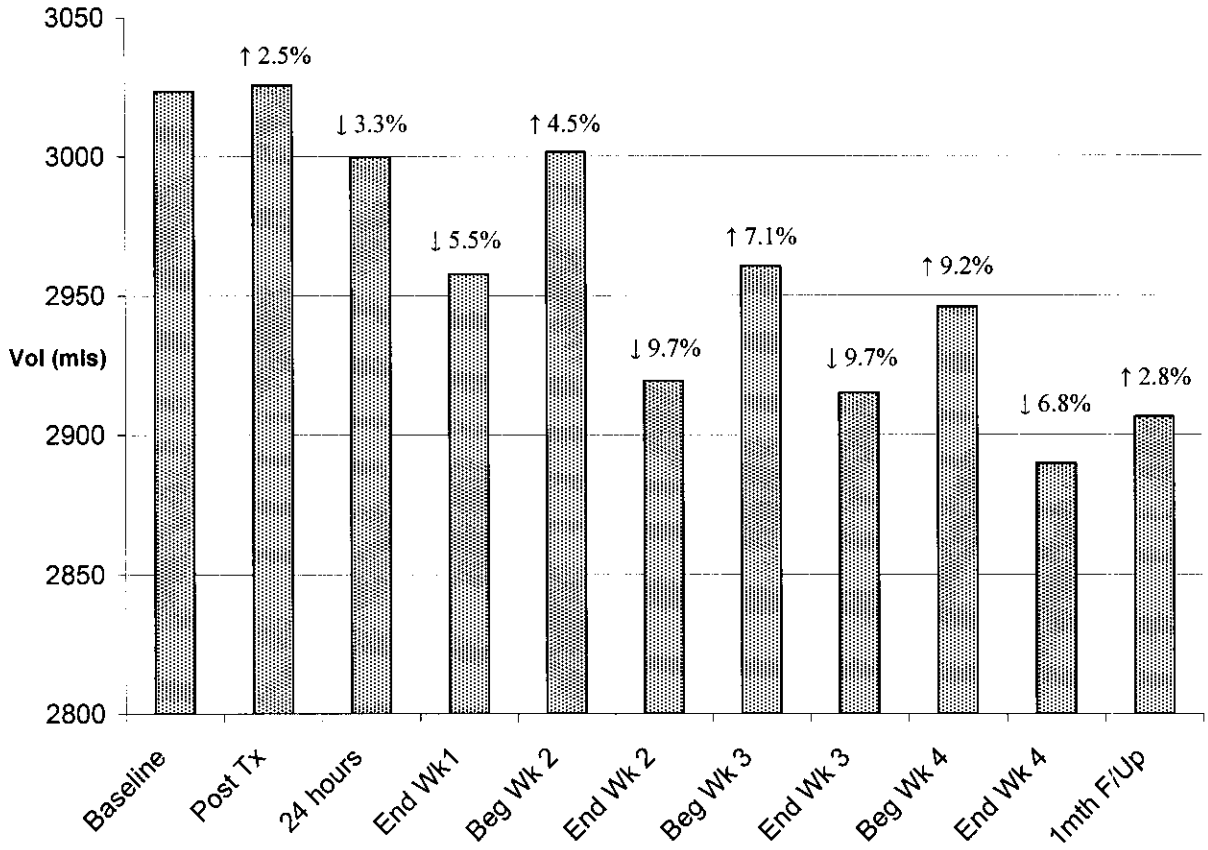

Table 1A. Change in affected whole arm volume (as measured via (b)(4) over trial duration (**LPG**)

	Mean Change (mls)	**Std. Dev. (±)**	**Mean Change (%)**	**Std. Dev. (±)**	**p**
Baseline v's After 1st treatment	+ 2.1	43.3	+ 2.5	12.8	0.811
Baseline v's After 24 hours	- 23.7	84.9	- 3.3	19.8	0.184
Baseline v's End of week 1	- 65.7	77.2	- 5.5	17.5	**0.000**
End wk 1 v's Beginning wk 2	+ 43.8	78.7	+ 4.5	18.9	**0.012**
Beginning wk 2 v's End of week 2	- 82.2	76.7	- 9.7	13.6	**0.000**
End wk 2 v's Beginning wk 3	+ 41.3	64.2	+ 7.1	21.2	**0.004**
Beginning wk 3 v's End of week 3	- 45.6	56.0	- 9.7	12.8	**0.001**
End wk 3 v's Beginning wk 4	+ 30.9	52.3	+ 9.2	21.5	**0.008**
Beginning wk 4 v's End of week 4	- 56.1	47.8	- 6.8	11.5	**0.000**
Baseline v's End of week 4	- 133.6	87.6	- 18.2	18.1	**0.000**
End wk 4 v's 1 mth follow up	+ 16.6	90.6	+ 2.8	17.4	0.377
Baseline v's 1 mth follow up	- 117.0	109.2	- 17.8	30.6	**0.000**

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Figure 1B. Change in affected whole arm volume (as measured via [redacted] (b)(4) over trial duration (**MLD**)

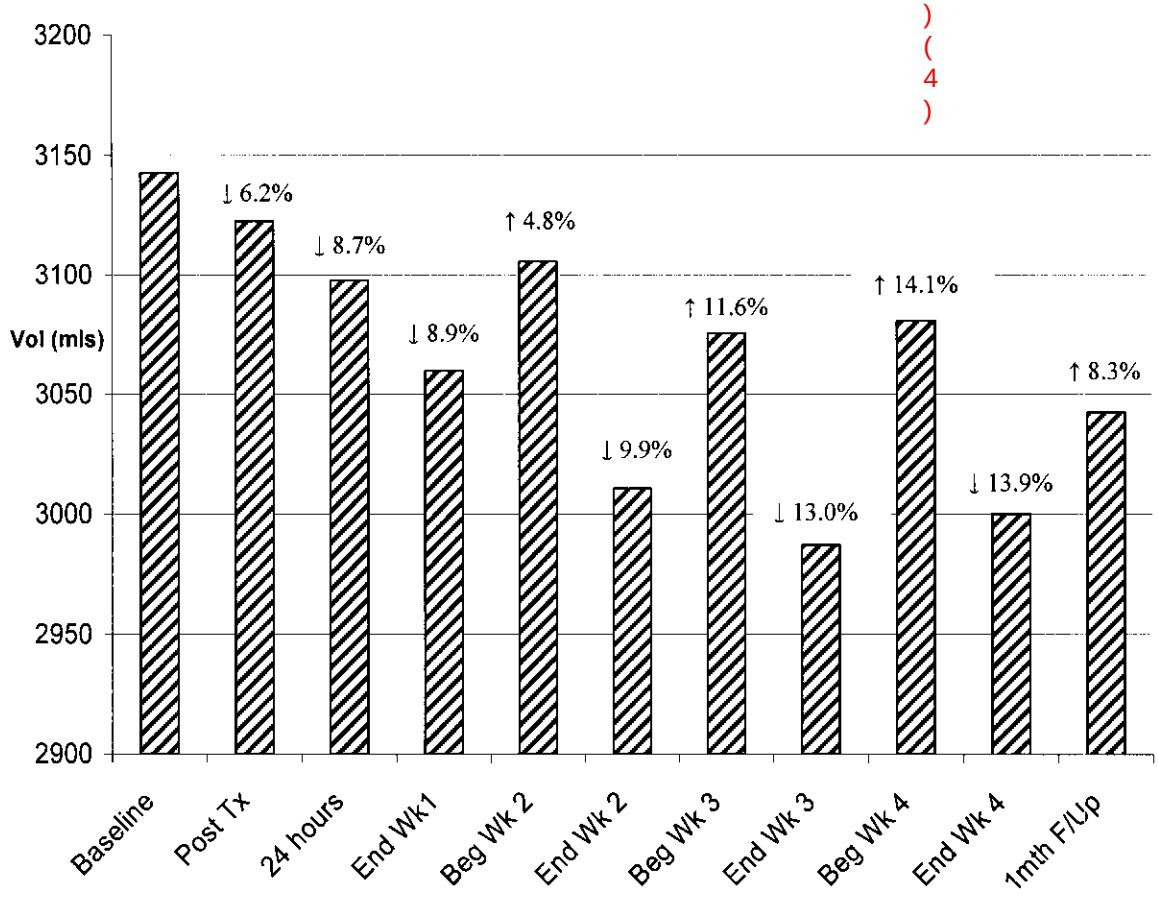

Table 1B. Change in affected whole arm volume (as measured via (b)(4) [redacted] over trial duration (**MLD**)

	Mean Change (mls)	**Std. Dev. (±)**	**Mean Change (%)**	**Std. Dev. (±)**	**p**
Baseline v's After 1st treatment	- 20.2	49.9	- 6.2	9.6	0.078
Baseline v's After 24 hours	- 45.7	93.7	- 8.7	8.9	**0.039**
Baseline v's End of week 1	- 83.0	78.1	- 8.9	7.6	**0.000**
End wk 1 v's Beginning wk 2	+ 45.9	120.3	+ 4.8	11.9	0.096
Beginning wk 2 v's End of week 2	- 95.0	124.0	- 9.9	10.0	**0.002**
End wk 2 v's Beginning wk 3	+ 64.9	62.7	+ 11.6	12.8	**0.000**
Beginning wk 3 v's End of week 3	- 88.4	96.9	- 13.0	16.1	**0.000**
End wk 3 v's Beginning wk 4	+ 93.4	99.6	+ 14.1	17.5	**0.000**
Beginning wk 4 v's End of week 4	- 80.6	89.7	- 13.9	11.6	**0.001**
Baseline v's End of week 4	- 142.7	156.8	- 21.3	13.0	**0.000**
End wk 4 v's 1 mth follow up	+ 42.5	114.4	+ 8.3	15.1	0.106
Baseline v's 1 mth follow up	- 100.4	186.3	- 15.1	11.8	**0.023**

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Table 1C. Between group analysis: affected whole arm volume: LPG v's MLD

	mls	**%**
	p =	**p =**
Arm volume at baseline	0.440	-
Change after 1st treatment	0.158	0.756
Change after 24 hours	0.609	**0.001**
Change at end of week 1	0.983	0.107
Change over 1st weekend	0.365	0.146
Change at end of week 2	0.158	0.267
Change over 2nd weekend	0.873	0.060
Change at end of week 3	0.229	0.853
Change over 3rd weekend	**0.023**	0.759
Change at end of week 4	**0.008**	0.286
Change over whole trial	0.246	0.516
Change at end of 1 month F/U	0.190	0.145

SUMMARY

Both the LPG and MLD group experienced statistically significant reductions in whole arm volume over the duration of the trial. Both groups also showed significant increases in volume over the weekends when no compression bandaging was applied. Over the 4 weeks both groups had a very similar reduction in whole arm volume, with LPG demonstrating a loss of 13.6mls (18.2% in actual oedema), p = 0.000 and MLD a loss of 142.7mls (21.3% in actual oedema), p = 0.000. The LPG group only had a slight increase at 1 month follow up (16.6mls, n.s.) whilst the MLD group had slightly more of an increase (42.5mls, n.s).

At 24 hours the reduction in actual oedema was greater in the MLD group (p = 0.001), this is probably related to the generally trend of the LPG group having a slight volume increase and the MLD group having a decrease. In the MLD group, whole arm volume increased significantly more over the 3rd weekend and due to this decreased significantly more at the end of week 4 in comparison to the LPG group. Apart from this, there were no other statistically significant differences.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Figure 2A. Change in affected forearm volume (as measured via (b)(4)) over trial duration (**LPG**)

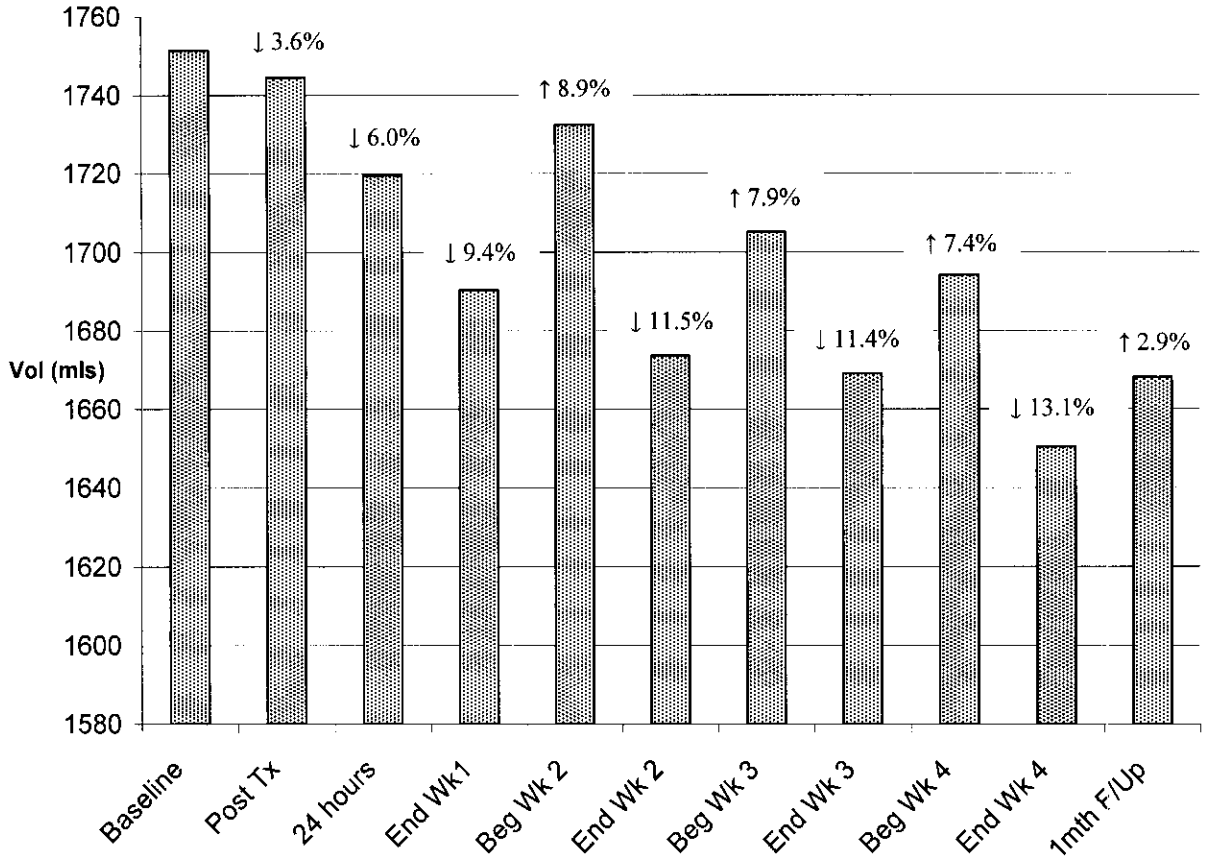

Table 2A. Change in affected forearm volume (as measured via (b)(4)) over trial duration (**LPG**)

	Mean Change (mls)	**Std. Dev. (±)**	**Mean Change (%)**	**Std. Dev. (±)**	**p**
Baseline v's After 1st treatment	- 6.8	39.5	- 3.6	7.9	0.410
Baseline v's After 24 hours	- 31.9	56.7	- 6.0	12.1	**0.011**
Baseline v's End of week 1	- 61.1	60.4	- 9.4	14.1	**0.000**
End wk 1 v's Beginning wk 2	+ 42.1	59.6	+ 8.9	15.3	**0.002**
Beginning wk 2 v's End of week 2	- 58.8	56.3	- 11.5	11.5	**0.000**
End wk 2 v's Beginning wk 3	+ 31.5	52.3	+ 7.9	15.5	**0.007**
Beginning wk 3 v's End of week 3	- 36.0	39.2	- 11.4	12.5	**0.000**
End wk 3 v's Beginning wk 4	+ 25.1	40.0	+ 7.4	12.1	**0.005**
Beginning wk 4 v's End of week 4	- 43.8	38.5	- 13.1	9.5	**0.000**
Baseline v's End of week 4	- 101.1	66.8	- 19.4	15.3	**0.000**
End wk 4 v's 1 mth follow up	+ 17.7	54.1	+ 2.9	7.3	0.122
Baseline v's 1 mth follow up	- 83.3	70.0	- 9.1	18.7	**0.000**

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Figure 2B. Change in affected forearm volume (as measured via (b)(4) [redacted]) over trial duration (**MLD**)

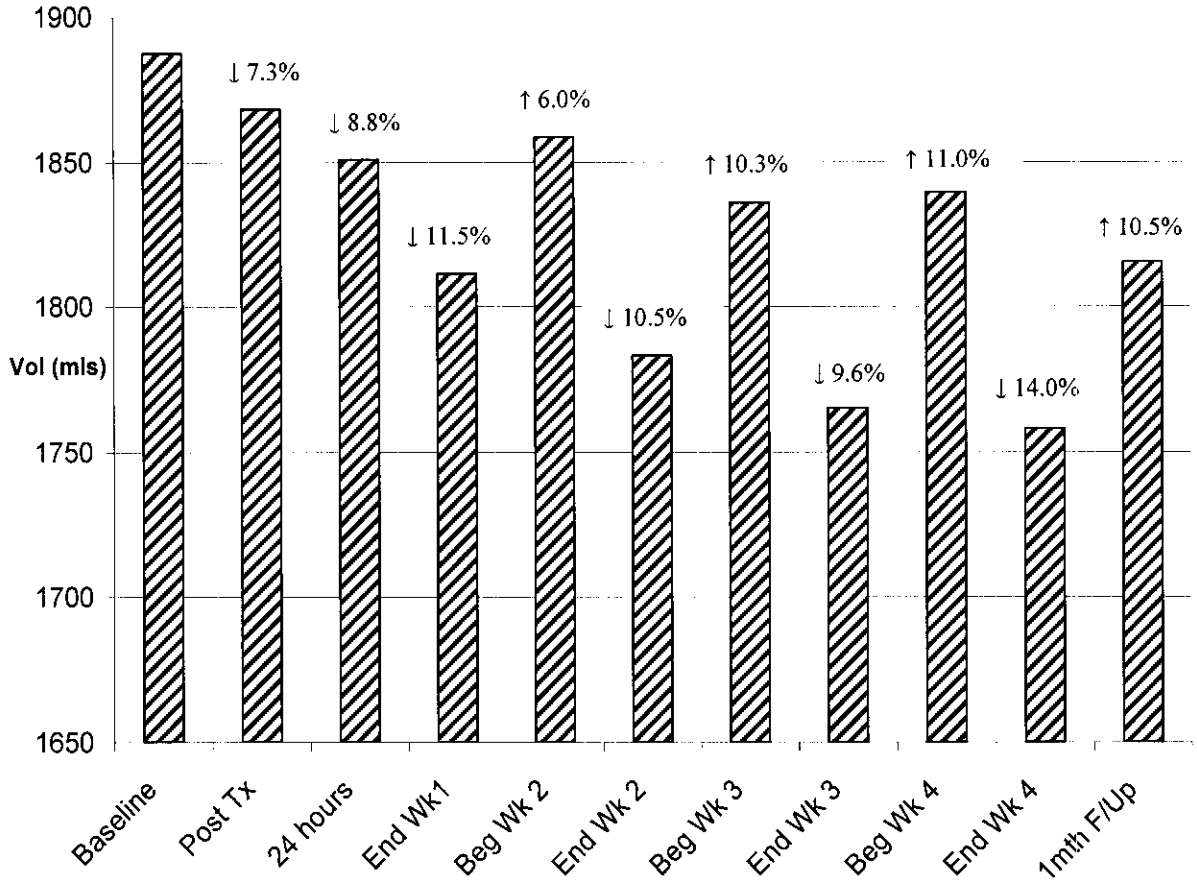

Table 2B. Change in affected forearm volume (as measured via (b)(4) [redacted]) over trial duration (**MLD**)

	Mean Change (mls)	Std. Dev. (±)	Mean Change (%)	Std. Dev. (±)	p
Baseline v's After 1st treatment	- 19.1	38.4	- 7.3	12.8	**0.034**
Baseline v's After 24 hours	- 36.5	74.2	- 8.8	9.4	**0.035**
Baseline v's End of week 1	- 76.2	60.6	- 11.5	8.1	**0.000**
End wk 1 v's Beginning wk 2	+ 47.4	85.4	+ 6.0	13.0	**0.019**
Beginning wk 2 v's End of week 2	- 75.7	92.8	- 10.5	12.2	**0.001**
End wk 2 v's Beginning wk 3	+ 52.7	46.5	+ 10.3	12.0	**0.000**
Beginning wk 3 v's End of week 3	- 70.7	63.3	- 9.6	10.3	**0.000**
End wk 3 v's Beginning wk 4	+ 74.4	72.0	+ 10.9	12.5	**0.000**
Beginning wk 4 v's End of week 4	- 81.3	98.8	- 14.0	12.0	**0.001**
Baseline v's End of week 4	- 129.4	118.6	- 19.1	15.7	**0.000**
End wk 4 v's 1 mth follow up	+ 57.3	98.8	+ 10.6	15.6	**0.015**
Baseline v's 1 mth follow up	- 72.1	114.2	- 12.1	17.3	**0.009**

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Table 2C. Between group analysis: affected forearm volume: LPG v's MLD

	mls	**%**
	p =	**p =**
Arm volume at baseline	0.906	-
Change after 1st treatment	0.443	0.210
Change after 24 hours	0.287	0.425
Change at end of week 1	0.633	**0.038**
Change over 1st weekend	0.657	0.245
Change at end of week 2	0.395	0.660
Change over 2nd weekend	0.249	0.560
Change at end of week 3	0.204	0.439
Change over 3rd weekend	**0.038**	0.939
Change at end of week 4	**0.013**	0.532
Change over whole trial	0.114	0.459
Change at end of 1 month F/U	**0.036**	0.359

SUMMARY

Both the LPG and MLD group demonstrated significant reductions and increases in the forearm (over the weekends) during the trial period. At the end of week one the reduction in the forearm was greater in the MLD group in comparison to the LPG group (76.2mls v's 61.1mls, p = 0.038). Interestingly the reduction in actual oedema was not statistically significantly different at this time point.

Both groups experienced similar reductions in the forearm after 4 weeks of treatment, with LPG demonstrating a reduction of 101mls (19.4%), p = 0.000 and MLD a reduction of 129.1mls (19.1%), p = 0.000. At one month follow up there had only been a slight increase in the forearm volume in the LPG group (17.7mls, p = 0.122) whilst the MLD had a statistically significant increase of 57.3mls (p = 0.015), this was also significant in comparison to the MLD group (p = 0.036)

Again there was a greater increase in the MLD group in forearm volume over the 3rd weekend which resulted in a greater decrease in this group at the end of week 4.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Figure 3A. Change in affected upper arm volume (as measured via (b)(4)) over trial duration (**LPG**)

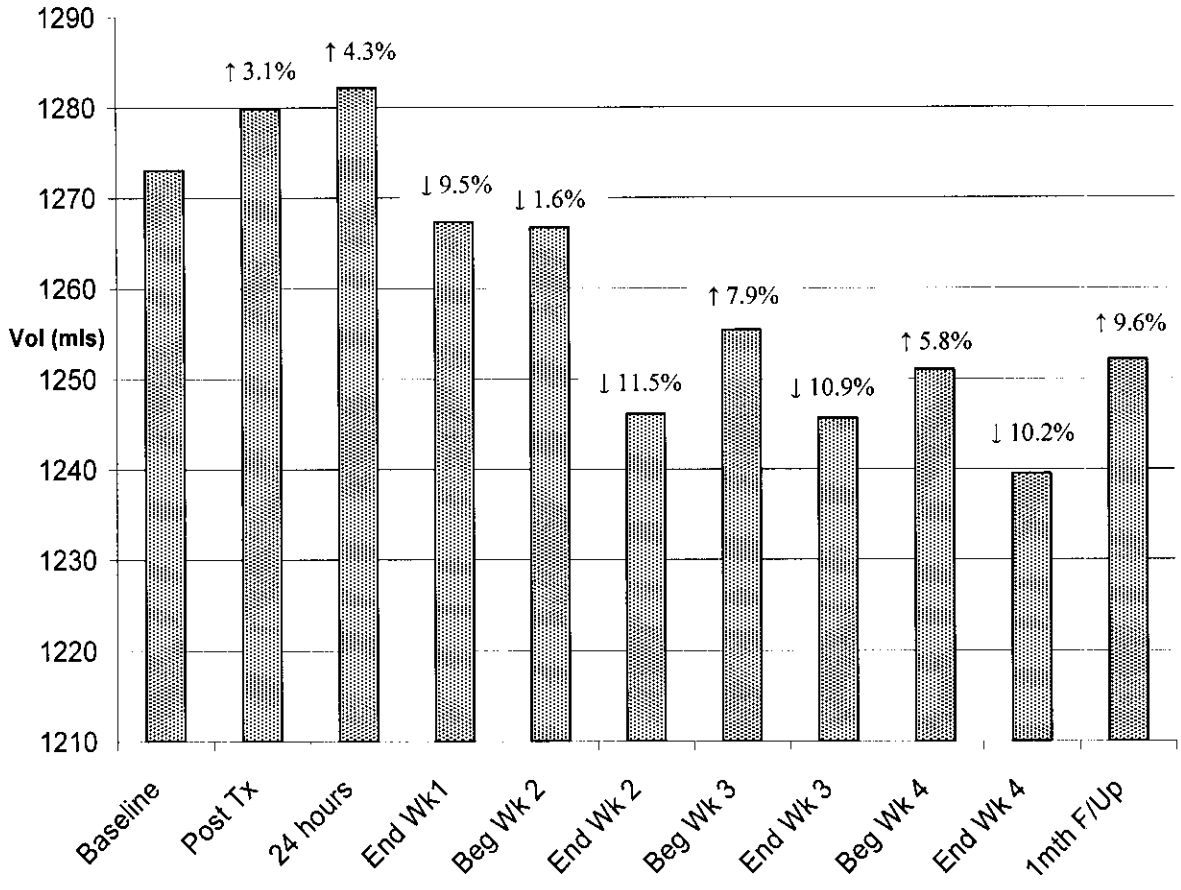

Table 3A. Change in affected upper arm volume (as measured via (b)(4) over trial duration (**LPG**)

	Mean Change (mls)	**Std. Dev. (±)**	**Mean Change (%)**	**Std. Dev. (±)**	**p**
Baseline v's After 1st treatment	+ 6.8	18.8	+ 3.1	11.7	0.089
Baseline v's After 24 hours	+ 9.2	37.2	+ 4.3	14.0	0.240
Baseline v's End of week 1	- 5.7	33.8	- 9.5	16.8	0.417
End wk 1 v's Beginning wk 2	- 0.6	26.1	- 1.6	5.3	0.911
Beginning wk 2 v's End of week 2	- 20.6	24.2	- 11.5	11.6	**0.000**
End wk 2 v's Beginning wk 3	+ 9.3	28.5	+ 7.9	17.3	0.124
Beginning wk 3 v's End of week 3	- 9.7	29.8	- 10.9	13.7	0.124
End wk 3 v's Beginning wk 4	+ 5.3	33.2	+ 5.8	6.7	0.438
Beginning wk 4 v's End of week 4	- 11.5	26.8	- 10.2	13.2	**0.046**
Baseline v's End of week 4	- 33.5	30.1	- 17.9	18.7	**0.000**
End wk 4 v's 1 mth follow up	+ 12.6	32.0	+ 9.6	14.7	0.065
Baseline v's 1 mth follow up	- 20.8	36.2	- 11.9	14.3	**0.010**

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Figure 3B. Change in affected upper arm volume (as measured via (b)(4)) over trial duration (**MLD**)

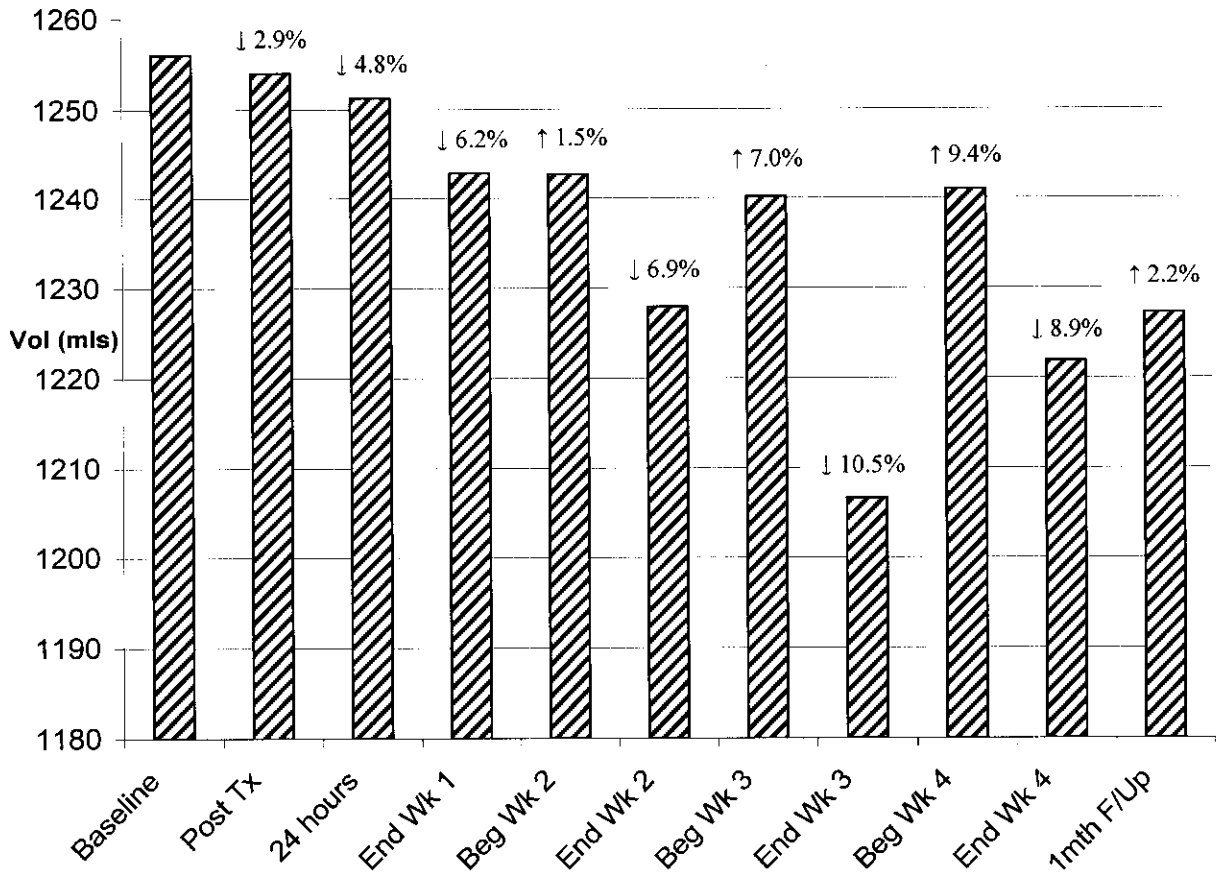

Table 3B. Change in affected upper arm volume (as measured via (b)(4)) over trial duration (**LPG**)

	Mean Change (mls)	**Std. Dev. (±)**	**Mean Change (%)**	**Std. Dev. (±)**	**p**
Baseline v's After 1st treatment	- 1.9	26.2	- 2.9	14.4	0.746
Baseline v's After 24 hours	- 4.7	39.4	- 4.8	13.1	0.593
Baseline v's End of week 1	- 13.2	35.9	- 6.2	15.3	0.108
End wk 1 v's Beginning wk 2	- 0.07	42.1	+ 1.5	8.6	0.994
Beginning wk 2 v's End of week 2	- 14.8	42.7	- 6.9	15.4	0.127
End wk 2 v's Beginning wk 3	+ 12.3	31.0	+ 7.0	13.3	0.083
Beginning wk 3 v's End of week 3	- 33.6	88.0	- 10.5	11.6	0.096
End wk 3 v's Beginning wk 4	+ 34.4	87.0	+ 9.4	13.2	0.085
Beginning wk 4 v's End of week 4	- 19.1	43.7	- 8.9	13.0	0.060
Baseline v's End of week 4	- 34.0	74.9	- 13.4	17.6	**0.051**
End wk 4 v's 1 mth follow up	+ 5.3	32.0	+ 2.2	6.3	0.627
Baseline v's 1 mth follow up	- 28.8	82.3	- 8.8	11.9	**0.169**

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Table 3C. Between group analysis: affected upper arm volume: LPG v's MLD

	mls	%
	p =	p =
Arm volume at baseline	0.906	-
Change after 1st treatment	0.171	0.333
Change after 24 hours	0.891	0.833
Change at end of week 1	0.495	0.520
Change over 1st weekend	0.121	0.664
Change at end of week 2	**0.032**	0.162
Change over 2nd weekend	0.516	0.314
Change at end of week 3	**0.049**	0.826
Change over 3rd weekend	0.068	0.955
Change at end of week 4	**0.018**	0.967
Change over whole trial	0.107	**0.033**
Change at end of 1 month F/U	0.265	0.139

SUMMARY

The upper arm volume increased in the LPG group both post treatment and at 24 hours (6.8mls and 9.2mls respectively). This increase did not occur in the MLD group and suggests that the fluid is drained into this area but not adequately cleared out. At the end of 4 weeks treatment there were again similar reductions, with LPG demonstrating a reduction of 33.5mls (p = 0.000) and the MLD group a reduction of 34mls (p = 0.051). There were again increases at 1 month follow up, with the LPG group experiencing an increase of 12.6mls (p = 0.065) and the MLD group an increase of 5.3mls (p = 0.627).

The reduction in the upper arm was greater in the MLD group at the end of weeks 3 and 4. Interestingly the percentage reduction in actually oedema (which takes in to account the response in the normal upper arm) was greater at the end of 4 weeks in the LPG group in comparison to the MLD group (p = 0.033).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Figure 4A. Change in affected arm fluid (as measured via (b)(4) [redacted]) over trial duration (**LPG**)

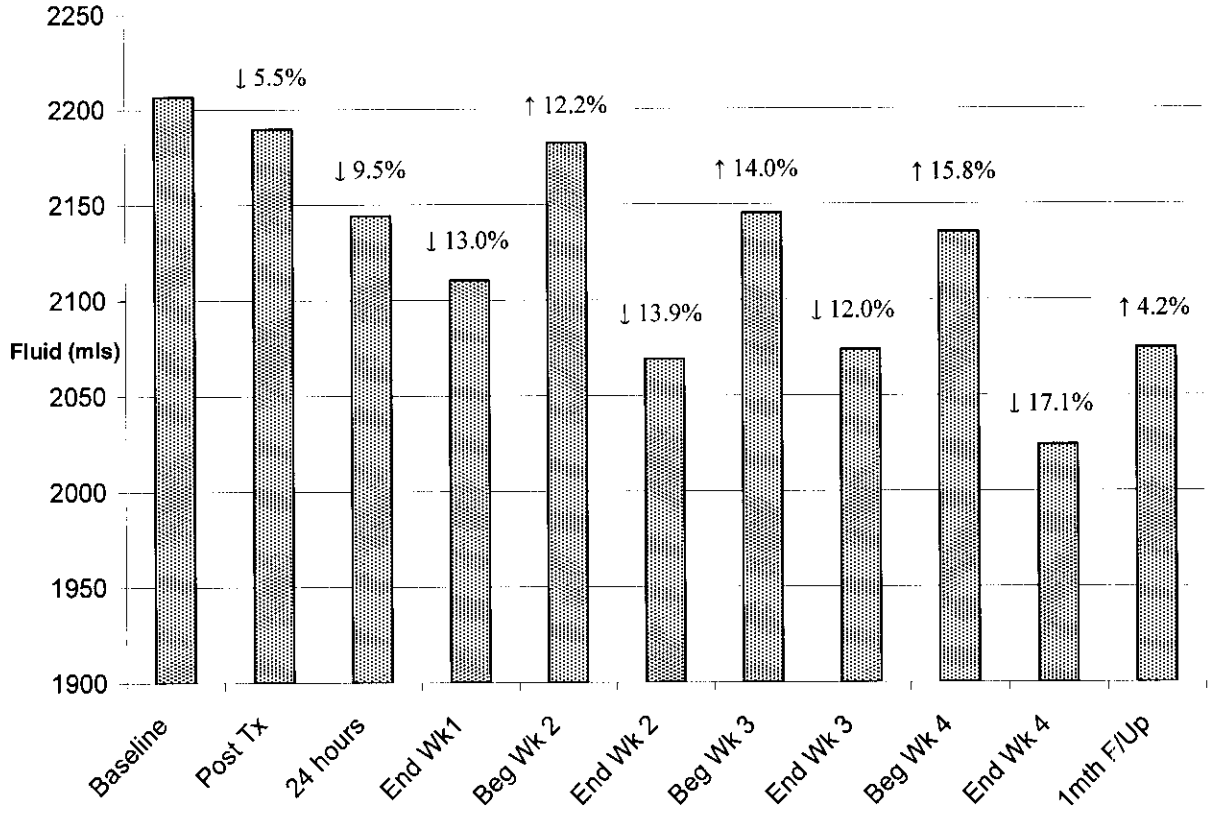

Table 4A. Change in affected arm fluid (as measured via (b)(4) [redacted]) over trial duration (**LPG**)

	Mean Change (mls)	**Std. Dev. (±)**	**Mean Change (%)**	**Std. Dev. (±)**	**p**
Baseline v's After 1st treatment	- 17.1	46.9	- 5.5	8.4	0.088
Baseline v's After 24 hours	- 62.5	138.7	- 9.5	15.3	**0.038**
Baseline v's End of week 1	- 96.2	136.8	- 13.0	19.1	**0.002**
End wk 1 v's Beginning wk 2	+ 71.7	111.6	+ 12.2	15.6	**0.005**
Beginning wk 2 v's End of week 2	- 112.9	116.1	- 13.9	15.7	**0.000**
End wk 2 v's Beginning wk 3	+ 76.2	138.9	+ 14.0	22.1	**0.013**
Beginning wk 3 v's End of week 3	- 71.4	105.9	- 12.0	16.0	**0.003**
End wk 3 v's Beginning wk 4	+ 61.5	117.1	+ 15.8	14.8	**0.017**
Beginning wk 4 v's End of week 4	- 111.2	115.3	- 17.1	11.5	**0.000**
Baseline v's End of week 4	- 182.5	169.6	- 23.5	22.2	**0.000**
End wk 4 v's 1 mth follow up	+ 50.6	125.4	+ 4.2	17.9	0.060
Baseline v's 1 mth follow up	- 131.9	141.2	- 18.1	19.9	**0.000**

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Figure 4B. Change in affected arm fluid (as measured via (b)(4) [redacted]) over trial duration (**MLD**)

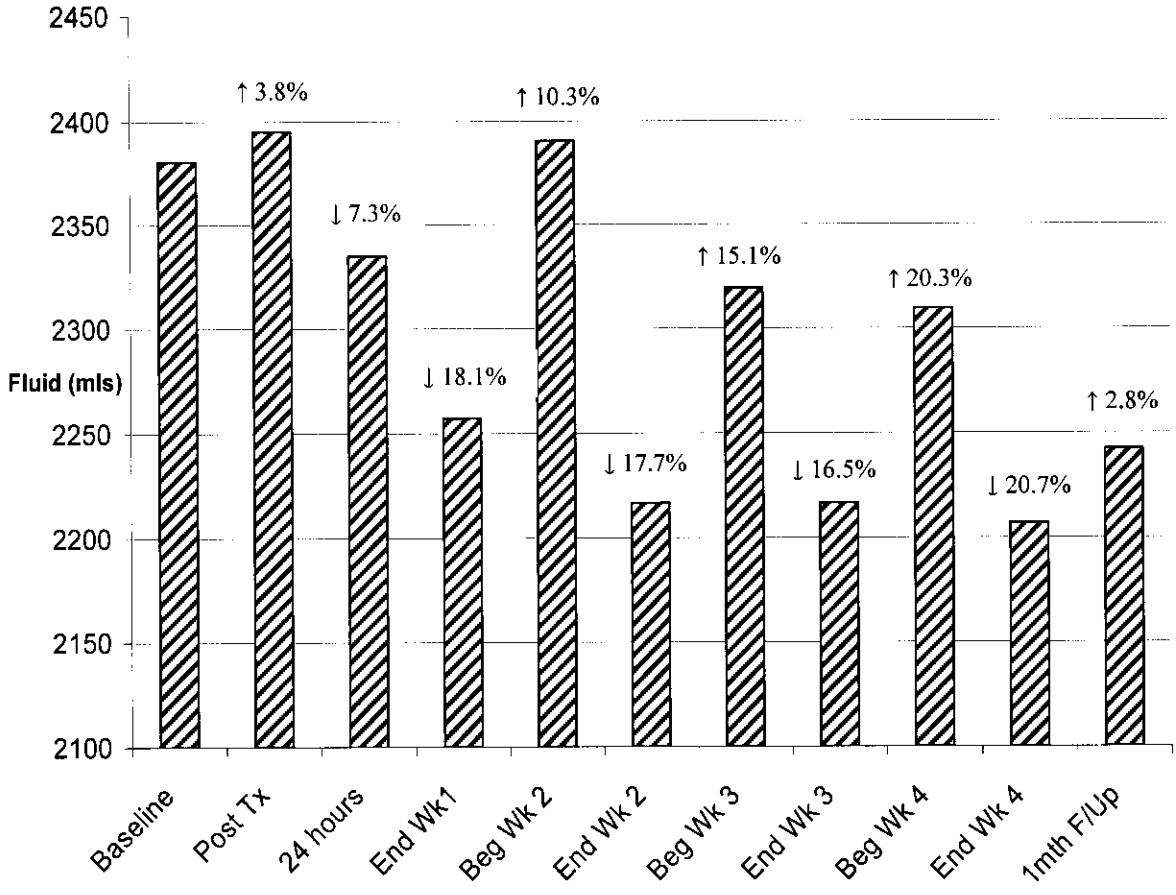

Table 4B. Change in affected arm fluid (as measured via (b)(4) [redacted]) over trial duration (**MLD**)

	Mean Change (mls)	Std. Dev. (±)	Mean Change (%)	Std. Dev. (±)	p
Baseline v's After 1st treatment	+ 14.8	66.1	+ 3.8	13.3	0.318
Baseline v's After 24 hours	- 45.7	134.7	- 7.3	13.9	0.135
Baseline v's End of week 1	- 123.3	177.2	- 18.1	17.8	**0.005**
End wk 1 v's Beginning wk 2	+ 133.3	204.7	+ 10.3	21.7	**0.007**
Beginning wk 2 v's End of week 2	- 173.8	186.7	- 17.7	15.5	**0.000**
End wk 2 v's Beginning wk 3	+ 102.8	97.1	+ 15.1	23.3	**0.000**
Beginning wk 3 v's End of week 3	- 102.8	101.8	- 16.5	13.4	**0.000**
End wk 3 v's Beginning wk 4	+ 92.8	100.5	+ 20.3	20.8	**0.000**
Beginning wk 4 v's End of week 4	- 102.4	122.1	- 20.7	15.7	**0.001**
Baseline v's End of week 4	- 173.3	230.4	- 26.6	20.2	**0.003**
End wk 4 v's 1 mth follow up	+ 35.2	179.2	+ 2.8	18.3	0.378
Baseline v's 1 mth follow up	- 138.1	191.9	- 17.8	19.5	**0.042**

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Table 4C. Between group analysis: affected arm fluid: LPG v's MLD

	mls	%
	p =	p =
Arm fluid at baseline	0.631	-
Change after 1st treatment	0.418	0.558
Change after 24 hours	0.559	0.915
Change at end of week 1	0.426	0.765
Change over 1st weekend	0.187	0.081
Change at end of week 2	0.112	0.805
Change over 2nd weekend	0.423	0.806
Change at end of week 3	0.577	0.889
Change over 3rd weekend	0.630	0.196
Change at end of week 4	0.914	0.084
Change over whole trial	0.260	0.805
Change at end of 1 month F/U	**0.050**	0.126

SUMMARY

The trend in arm fluid reductions and increases is similar to what occurred in the whole arm volume as measured via (b)(4) that is there were significant decreases over the weeks of treatment but increases over the weekends. At the end of 4 weeks of treatment there was a decrease in arm fluid of 182.5mls (p = 0.000) in the LPG group and 173.3mls (p = 0.003) in the MLD group. At 1 month follow up there was an increase of 50.6mls (p = 0.06) in the LPG group and 35.2mls (p = 0.378) in the MLD group. The increase in the LPG group was significant at 1 month in comparison to the MLD group (p = 0.050).

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Figure 5A. Change in truncal fluid (as measured via (b)(4) [redacted]) over trial duration (**LPG**)

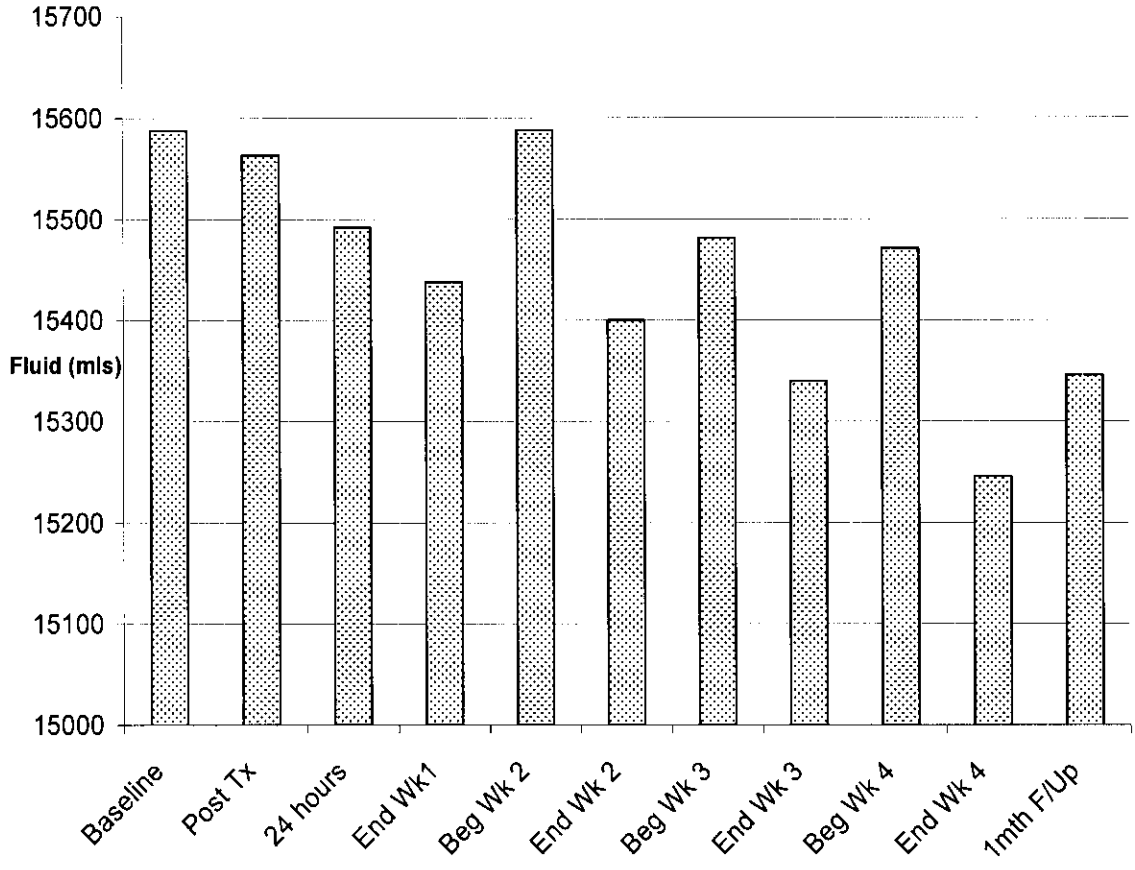

Table 5A. Change in truncal fluid (as measured via (b)(4) [redacted]) over trial duration (**LPG**)

	Mean Change	**Std. Dev. (±)**	**p**
Baseline v's After 1st treatment	- 24.6	218.0	0.586
Baseline v's After 24 hours	- 95.8	432.9	0.289
Baseline v's End of week 1	- 150.0	404.0	0.082
End wk 1 v's Beginning wk 2	+ 150.0	365.0	0.056
Beginning wk 2 v's End of week 2	- 187.5	409.2	**0.035**
End wk 2 v's Beginning wk 3	+ 81.2	407.7	0.339
Beginning wk 3 v's End of week 3	- 141.7	314.7	**0.038**
End wk 3 v's Beginning wk 4	+ 131.2	302.1	**0.044**
Beginning wk 4 v's End of week 4	- 225.0	298.8	**0.001**
Baseline v's End of week 4	- 341.7	487.1	**0.002**
End wk 4 v's 1 mth follow up	+ 100.0	459.7	0.298
Baseline v's 1 mth follow up	- 341.7	495.1	**0.025**

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Figure 5B. Change in truncal fluid (as measured via (b)(4) [redacted]) over trial duration (**MLD**)

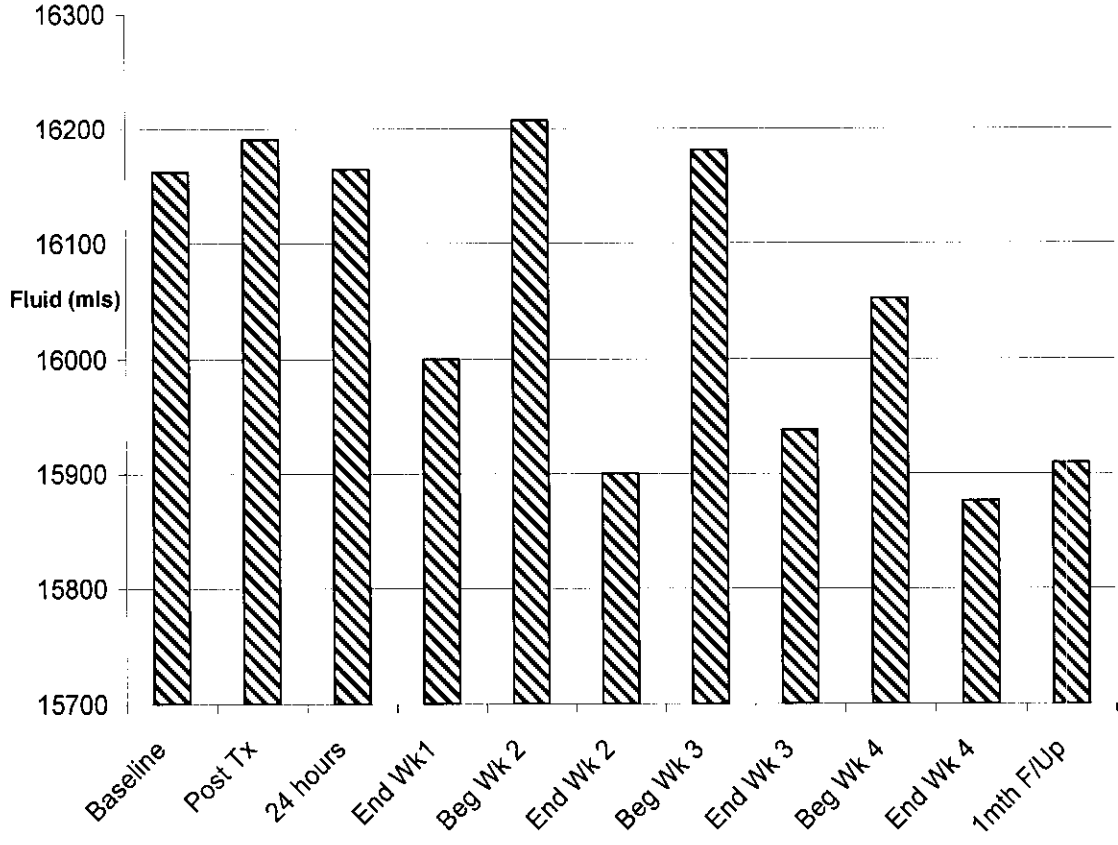

Table 5B. Change in truncal fluid (as measured via (b)(4) [redacted]) over trial duration (**MLD**)

	Mean Change	**Std. Dev. (±)**	**p**
Baseline v's After 1st treatment	+ 28.6	246.6	0.601
Baseline v's After 24 hours	+ 2.4	364.2	0.976
Baseline v's End of week 1	- 161.9	339.8	**0.041**
End wk 1 v's Beginning wk 2	+ 207.1	247.6	**0.001**
Beginning wk 2 v's End of week 2	- 307.1	291.7	**0.000**
End wk 2 v's Beginning wk 3	+ 280.9	337.1	**0.001**
Beginning wk 3 v's End of week 3	- 242.8	350.4	**0.005**
End wk 3 v's Beginning wk 4	+ 114.3	265.6	0.063
Beginning wk 4 v's End of week 4	- 176.2	334.5	**0.026**
Baseline v's End of week 4	- 285.7	491.5	**0.015**
End wk 4 v's 1 mth follow up	+ 33.3	344.0	0.662
Baseline v's 1 mth follow up	- 252.4	463.5	**0.021**

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Table. Between group analysis: Truncal fluid: LPG v's MLD

	p =
Truncal Fluid at baseline	0.935
Change after 1st treatment	0.726
Change after 24 hours	0.453
Change at end of week 1	0.856
Change over 1st weekend	0.152
Change at end of week 2	0.180
Change over 2nd weekend	0.316
Change at end of week 3	0.897
Change over 3rd weekend	0.498
Change at end of week 4	0.592
Change over whole trial	0.782
Change at end of 1 month F/U	0.199

SUMMARY

The truncal fluid also decreased over the treatment weeks in both groups and also increased over the weekends when no treatment was instigated. At the end of 4 weeks of treatment there was a 341.7mls (p =0.002) reduction in truncal fluid in the LPG group and a 285.7mls (p = 0.015) reduction in the MLD group. The truncal fluid increased at the one month follow up in both groups, in the LPG group this increase was 100mls (p = 0.298) and in the MLD group it was 33.3.mls (p = 0.662). Although the increase at 1 month was greater in the LPG group, it was not statistically significant in comparison to the MLD group (p = 0.199).

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Table 6A. Changes in Weight (Kg's), Fat mass (Kg's) & Percentage body fat (%) at the end of trial and at 1 month follow up (**LPG**)

Parameter	Pre	Post	p =
Weight (Kg's)			
Baseline v's after 1st treatment	74.1 (± 16.0)	73.9 (± 16.0)	**0.001**
Baseline v's 24 hours	74.1 (± 16.0)	73.9 (± 16.1)	**0.046**
Baseline v's end of wk 1	74.1 (± 16.0)	73.9 (± 16.2)	0.254
Beginning wk 2 v's end wk 2	74.0 (± 16.3)	73.8 (± 16.2)	**0.003**
Beginning wk 3 v's end wk 3	73.8 (± 16.2)	73.7 (± 16.2)	0.132
Beginning wk 4 v's end wk 4	73.7 (± 16.1)	73.5 (± 16.1)	**0.004**
Baseline v's End of trial	74.1 (± 16.0)	73.5 (± 16.1)	**0.000**
End of trial v's 1mth follow up	73.5 (± 16.1)	73.7 (± 16.2)	0.352
Baseline v's 1mth follow up	74.1 (± 16.0)	73.7 (± 16.2)	0.107
Fat Mass (Kg's)			
Baseline v's end of trial	27.4 (± 12.2)	27.8 (± 11.8)	**0.019**
End of trial v's 1mth follow up	27.8 (± 11.8)	27.5 (± 12.2)	0.084
Baseline v's 1mth follow up	27.4 (± 12.2)	27.5 (± 12.2)	0.908
Percentage Body Fat (%)			
Baseline v's end of trial	35.7 (± 8.9)	36.5 (± 8.1)	**0.001**
End of trial v's 1mth follow up	36.5 (± 8.1)	35.8 (± 8.6)	**0.013**
Baseline v's 1mth follow up	35.7 (± 8.9)	35.8 (± 8.6)	0.437

MLD

Parameter	Pre	Post	p =
Weight (Kg's)			
Baseline v's after 1st treatment	78.4 (± 14.7)	78.2 (± 14.7)	**0.000**
Baseline v's 24 hours	78.4 (± 14.7)	78.1 (± 14.6)	**0.027**
Baseline v's end of wk 1	78.4 (± 14.7)	78.1 (± 14.5)	0.068
Beginning wk 2 v's end wk 2	78.4 (± 14.7)	78.1 (± 14.6)	**0.032**
Beginning wk 3 v's end wk 3	78.1 (± 14.7)	77.9 (± 14.7)	0.079
Beginning wk 4 v's end wk 4	78.1 (± 14.7)	78.2 (± 14.9)	0.624
Baseline v's End of trial	78.4 (± 14.7)	78.2 (± 14.9)	0.399
End of trial v's 1mth follow up	78.2 (± 14.9)	78.0 (± 14.5)	0.509
Baseline v's 1mth follow up	78.4 (± 14.7)	78.0 (± 14.5)	0.136
Fat Mass (Kg's)			
Baseline v's end of trial	29.9 (± 11.1)	30.6 (± 11.4)	**0.018**
End of trial v's 1mth follow up	30.6 (± 11.4)	30.1 (± 11.1)	0.067
Baseline v's 1mth follow up	29.9 (± 11.1)	30.1 (± 11.1)	0.356

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Percentage Body Fat (%)			
Baseline v's end of trial	36.5 (± 7.6)	38.2 (± 6.5)	**0.048**
End of trial v's 1mth follow up	38.2 (± 6.5)	37.8 (± 6.3)	0.195
Baseline v's 1mth follow up	36.5 (± 7.6)	37.8 (± 6.3)	0.121

Both LPG & MLD group showed a reduction in weight but in the overall trial both groups increased in fat mass and percentage body fat. Therefore the changes in weight are most likely related to the reductions in arm and truncal fluid.

Table 6B. Between group analysis: Weight, Body fat mass & Percentage body fat: LPG v's MLD

Parameter	**p =**
Weight (Kg's)	
Weight at baseline	0.676
Baseline v's after 1st treatment	0.331
Baseline v's 24 hours	0.386
Baseline v's end of wk 1	0.814
Beginning wk 2 v's end wk 2	**0.026**
Beginning wk 3 v's end wk 3	0.315
Beginning wk 4 v's end wk 4	0.072
Baseline v's End of trial	0.078
End of trial v's 1mth follow up	0.428
Baseline v's 1mth follow up	0.771
Fat Mass (Kg's)	
Fat mass at baseline	0.457
Baseline v's end of trial	0.121
End of trial v's 1mth follow up	0.363
Baseline v's 1mth follow up	0.077
Percentage Body Fat (%)	
Percentage body fat at baseline	0.274
Baseline v's end of trial	0.171
End of trial v's 1mth follow up	0.429
Baseline v's 1mth follow up	0.275

SUMMARY

Both the LPG and MLD groups experienced a reduction in body weight over the whole trial (0.6kgs and 0.2kgs respectively). However, both groups also experienced significant increases in body fat mass and percentage body fat, therefore the weight loss most likely related to the reductions in arm and truncal fluid.

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Table 7A. Change (b)(4) [redacted] measurements over trial duration (**LPG**)

Parameter	Pre	Post	p =
Forearm (anterior)			
Baseline v's after 1st treatment	4.79 (± 0.69)	4.72 (± 0.68)	0.646
Baseline v's 24 hours	4.79 (± 0.69)	4.84 (± 0.67)	0.712
Baseline v's end of wk 1	4.79 (± 0.69)	5.02 (± 1.02)	0.207
Beginning wk 2 v's end wk 2	4.83 (± 0.96)	4.73 (± 0.78)	0.540
Beginning wk 3 v's end wk 3	4.94 (± 0.72)	4.87 (± 0.68)	0.653
Beginning wk 4 v's end wk 4	4.95 (± 0.79)	4.84 (± 0.90)	0.317
Baseline v's End of trial	4.79 (± 0.69)	4.84 (± 0.90)	0.792
End of trial v's 1mth follow up	4.84 (± 0.90)	4.97 (± 0.83)	0.366
Baseline v's 1mth follow up	4.79 (± 0.69)	4.97 (± 0.83)	0.313
Upper Arm (anterior)			
Baseline v's after 1st treatment	5.82 (± 1.30)	5.87 (± 1.15)	0.813
Baseline v's 24 hours	5.82 (± 1.30)	5.85 (± 1.12)	0.906
Baseline v's end of wk 1	5.82 (± 1.30)	5.91 (± 1.43)	0.614
Beginning wk 2 v's end wk 2	5.74 (± 1.47)	5.85 (± 1.04)	0.661
Beginning wk 3 v's end wk 3	5.94 (± 1.24)	5.83 (± 1.20)	0.508
Beginning wk 4 v's end wk 4	5.97 (± 1.19)	5.84 (± 1.25)	0.296
Baseline v's End of trial	5.82 (± 1.30)	5.84 (± 1.25)	0.965
End of trial v's 1mth follow up	5.84 (± 1.25)	5.65 (± 1.29)	0.428
Baseline v's 1mth follow up	5.82 (± 1.30)	5.65 (± 1.29)	0.454
Anterior Thorax			
Baseline v's after 1st treatment	8.27 (± 1.81)	8.44 (± 1.68)	0.813
Baseline v's 24 hours	8.27 (± 1.81)	8.23 (± 1.96)	0.906
Baseline v's end of wk 1	8.27 (± 1.81)	8.49 (± 1.76)	0.614
Beginning wk 2 v's end wk 2	8.87 (± 1.56)	8.90 (± 1.59)	0.841
Beginning wk 3 v's end wk 3	8.90 (± 1.48)	8.88 (± 1.48)	0.931
Beginning wk 4 v's end wk 4	9.04 (± 1.52)	9.03 (± 1.40)	0.938
Baseline v's End of trial	8.27 (± 1.81)	9.03 (± 1.40)	**0.006**
End of trial v's 1mth follow up	9.03 (± 1.40)	8.59 (± 1.63)	0.058
Baseline v's 1mth follow up	8.27 (± 1.81)	8.59 (± 1.63)	0.298

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Table 7A. Change (b)(4) measurements over trial duration (**LPG**)

Parameter	Pre	Post	p =
Posterior Thorax			
Baseline v's after 1st treatment	3.99 (± 0.55)	4.04 (± 0.47)	0.621
Baseline v's 24 hours	3.99 (± 0.55)	3.96 (± 0.55)	0.747
Baseline v's end of wk 1	3.99 (± 0.55)	4.03 (± 0.41)	0.492
Beginning wk 2 v's end wk 2	3.87 (± 0.60)	4.02 (± 0.90)	0.141
Beginning wk 3 v's end wk 3	3.82 (± 0.72)	3.96 (± 0.54)	0.311
Beginning wk 4 v's end wk 4	3.99 (± 0.44)	4.02 (± 0.40)	0.826
Baseline v's End of trial	3.99 (± 0.55)	4.02 (± 0.40)	0.825
End of trial v's 1mth follow up	4.02 (± 0.40)	3.81 (± 0.62)	0.178
Baseline v's 1mth follow up	3.99 (± 0.55)	3.81 (± 0.62)	0.339

Table 7B. Change in (b)(4) measurements over trial duration (**MLD**)

Parameter	Pre	Post	p =
Forearm (anterior)			
Baseline v's after 1st treatment	4.92 (± 1.23)	4.92 (± 1.13)	0.969
Baseline v's 24 hours	4.92 (± 1.23)	4.79 (± 1.14)	0.492
Baseline v's end of wk 1	4.92 (± 1.23)	4.97 (± 0.97)	0.824
Beginning wk 2 v's end wk 2	4.89 (± 0.87)	4.85 (± 0.95)	0.719
Beginning wk 3 v's end wk 3	4.70 (± 0.77)	4.69 (± 0.85)	0.913
Beginning wk 4 v's end wk 4	4.75 (± 0.78)	4.83 (± 1.08)	0.432
Baseline v's End of trial	4.92 (± 1.23	4.83 (± 1.08)	0.452
End of trial v's 1mth follow up	4.83 (± 1.08)	4.77 (± 0.92)	0.683
Baseline v's 1mth follow up	4.92 (± 1.23)	4.77 (± 0.92)	0.370
Upper Arm (anterior)			
Baseline v's after 1st treatment	5.93 (± 1.07)	5.98 (± 1.09)	0.755
Baseline v's 24 hours	5.93 (± 1.07)	6.00 (± 1.23)	0.602
Baseline v's end of wk 1	5.93 (± 1.07)	6.22 (± 1.30)	0.097
Beginning wk 2 v's end wk 2	5.90 (± 1.21)	6.02 (± 1.14)	0.297
Beginning wk 3 v's end wk 3	6.02 (± 0.93)	5.90 (± 1.00)	0.145
Beginning wk 4 v's end wk 4	6.15 (± 1.16)	6.03 (± 1.02)	0.315
Baseline v's End of trial	5.93 (± 1.07)	6.03 (± 1.02)	0.588
End of trial v's 1mth follow up	6.03 (± 1.02)	5.82 (± 1.26)	0.343
Baseline v's 1mth follow up	5.93 (± 1.07)	5.82 (± 1.26)	0.633

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Parameter	Pre	Post	p =
Anterior Thorax			
Baseline v's after 1st treatment	8.96 (± 1.27)	9.08 (± 1.34)	0.359
Baseline v's 24 hours	8.96 (± 1.27)	8.86 (± 1.30)	0.475
Baseline v's end of wk 1	8.96 (± 1.27)	8.99 (± 1.29)	0.795
Beginning wk 2 v's end wk 2	9.26 (± 0.87)	9.44*(± 1.13)	0.123
Beginning wk 3 v's end wk 3	9.36 (± 1.18)	9.29 (± 1.35)	0.585
Beginning wk 4 v's end wk 4	9.01 (± 1.19)	9.26 (± 1.10)	0.093
Baseline v's End of trial	8.96 (± 1.27)	9.26 (± 1.10)	0.053
End of trial v's 1mth follow up	9.26 (± 1.10)	9.03 (± 1.54)	0.781
Baseline v's 1mth follow up	8.96 (± 1.27)	9.03 (± 1.54)	0.275
Posterior Thorax			
Baseline v's after 1st treatment	3.91 (± 0.44)	4.04 (± 0.44)	**0.039**
Baseline v's 24 hours	3.91 (± 0.44)	4.02 (± 0.40)	0.182
Baseline v's end of wk 1	3.91 (± 0.44)	4.03 (± 0.37)	0.148
Beginning wk 2 v's end wk 2	3.83 (± 0.40)	3.93 (± 0.51)	0.157
Beginning wk 3 v's end wk 3	4.03 (± 0.55)	4.07 (± 0.38)	0.683
Beginning wk 4 v's end wk 4	3.98 (± 0.44)	4.14 (± 0.44)	0.083
Baseline v's End of trial	3.91 (± 0.44)	4.14 (± 0.44)	**0.041**
End of trial v's 1mth follow up	4.14 (± 0.44)	3.89 (± 0.67)	0.147
Baseline v's 1mth follow up	3.91 (± 0.44)	3.89 (± 0.67)	0.903

* Baseline v's end of week 2 for the anterior thorax was statistically significant, p = **0.014**

Table 7C. Between group analysis: [redacted] (b)(4) LPG v's MLD

Time Period	Fore arm	Upper arm	Anterior thorax	Posterior thorax
At Baseline	**0.011**	0.264	0.077	0.639
Baseline v's after 1st treatment	0.162	0.136	0.079	0.064
Baseline v's 24 hours	**0.047**	0.150	**0.005**	0.604
Baseline v's end of wk 1	0.538	0.444	**0.006**	**0.017**
Beginning wk 2 v's end wk 2	0.103	**0.007**	0.086	**0.048**
Beginning wk 3 v's end wk 3	**0.018**	**0.001**	0.087	0.090
Beginning wk 4 v's end wk 4	0.589	0.257	0.644	0.338
Baseline v's End of trial	0.258	0.783	**0.002**	0.391
End of trial v's 1mth follow up	0.390	0.567	0.505	0.734
Baseline v's 1mth follow up	0.410	0.898	0.438	0.317

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SUMMARY

Forearm

The baseline measurement of the anterior forearm revealed that this area was slightly harder in the LPG group in comparison to the MLD group ($p = 0.011$). At 24 hours there was a slight softening in the forearm territory in the LPG group but not the MLD group ($p = 0.047$). At the end of week 3 there was no real change in the MLD group but a slight deterioration in the forearm territory in the LPG group ($p = 0.018$). In the overall trial, there was a softening in the forearm in the LPG group but not in the MLD group.

Upper arm

At the end of week 2 both groups experienced a softening in the upper arm territory, with the improvement in the MLD group being greater ($p = 0.007$). At the end of week 3 both groups experienced a deterioration in this territory with the deterioration being worse in the MLD group ($p = 0.001$). In the overall trial, there was softening in the upper arm in both groups (n.s.)

Anterior thorax

At 24 hours there was no real change in the anterior thorax in the LPG group but a slight deterioration in the MLD group ($p = 0.005$). At the end of week 1 both groups experienced a softening in this territory but the improvement was greater in the LPG group ($p = 0.006$). Both groups also experienced a softening in this area over the whole trial, again the softening was greater in the LPG group ($p = 0.002$).

Posterior thorax

At the end of week 1 both groups experienced softening in the posterior thorax, with the improvement being greater in the MLD group ($p = 0.017$). Interestingly at the end of week 2 the softening was slightly greater in this territory in the LPG group ($p = 0.048$). In the overall trial, there was softening in the posterior thorax in both groups, but the softening was greater in the MLD group.

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Table 8A: Change in Blood pressure (mmHg) & Pulse (bpm) over trial duration **(LPG)**

Parameter	Pre	Post	p =
Systolic Blood Pressure (mmHg)			
Baseline v's after 1st treatment	122.6 (± 14.9)	123.1 (± 13.1)	0.758
Baseline v's 24 hours	122.6 (± 14.9)	120.8 (± 14.7)	0.496
Baseline v's end of wk 1	122.6 (± 14.9)	122.7 (± 14.7)	0.953
Beginning wk 2 v's end wk 2	122.7 (± 14.7)	120.8 (± 12.9)	0.328
Beginning wk 3 v's end wk 3	119.6 (± 13.5)	123.3 (± 13.9)	0.065
Beginning wk 4 v's end wk 4	123.5 (± 14.2)	125.4 (± 12.1)	0.288
Baseline v's End of trial	122.6 (± 14.9)	125.4 (± 12.1)	0.265
End of trial v's 1mth follow up	125.4 (± 12.1)	125.0 (± 13.1)	0.397
Baseline v's 1mth follow up	122.6 (± 14.9)	125.0 (± 13.1)	0.848
Dystolic Blood Pressure (mmHg)			
Baseline v's after 1st treatment	76.7 (± 7.2)	76.4 (± 6.3)	0.883
Baseline v's 24 hours	76.7 (± 7.2)	76.6 (± 7.7)	0.950
Baseline v's end of wk 1	76.7 (± 7.2)	77.1 (± 7.9)	0.802
Beginning wk 2 v's end wk 2	76.2 (± 7.4)	77.3 (± 7.6)	0.540
Beginning wk 3 v's end wk 3	74.4 (± 8.1)	77.7 (± 5.9)	**0.015**
Beginning wk 4 v's end wk 4	76.7 (± 7.9)	79.7 (± 7.6)	**0.014**
Baseline v's End of trial	76.7 (± 7.2)	79.7 (± 7.6)	**0.047**
End of trial v's 1mth follow up	79.7 (± 7.6)	76.7 (± 7.2)	**0.027**
Baseline v's 1mth follow up	76.7 (± 7.2)	76.7 (± 7.2)	0.996
Pulse (bpm)			
Baseline v's after 1st treatment	80.6 (± 7.0)	77.1 (± 8.7)	**0.002**
Baseline v's 24 hours	80.6 (± 7.0)	81.5 (± 8.1)	0.724
Baseline v's end of wk 1	80.6 (± 7.0)	78.5 (± 8.1)	0.301
Beginning wk 2 v's end wk 2	81.1 (± 7.5)	77.7 (± 7.9)	0.068
Beginning wk 3 v's end wk 3	79.2 (± 7.9)	78.2 (± 6.6)	0.161
Beginning wk 4 v's end wk 4	79.3 (± 8.2)	78.2 (± 6.3)	0.094
Baseline v's End of trial	80.6 (± 7.0)	78.2 (± 6.3)	0.184
End of trial v's 1mth follow up	78.2 (± 6.3)	80.9 (± 5.9)	0.091
Baseline v's 1mth follow up	80.6 (± 7.0)	80.9 (± 5.9)	0.858

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Table 8B: Change in Blood pressure (mmHg) & Pulse (bpm) over trial duration **(MLD)**

Parameter	Pre	Post	p =
Systolic Blood Pressure			
Baseline v's after 1st treatment	129.3 (± 9.8)	130.9 (± 9.7)	0.491
Baseline v's 24 hours	129.3 (± 9.8)	131.2 (± 10.1)	0.337
Baseline v's end of wk 1	129.3 (± 9.8)	132.1 (± 10.5)	0.130
Beginning wk 2 v's end wk 2	131.7 (± 12.1)	131.0 (± 11.2)	0.679
Beginning wk 3 v's end wk 3	129.6 (± 9.0)	133.1 (± 10.2)	0.068
Beginning wk 4 v's end wk 4	132.4 (± 10.9)	132.4 (± 12.7)	1.000
Baseline v's End of trial	129.3 (± 9.8)	132.4 (± 12.7)	0.230
End of trial v's 1mth follow up	132.4 (± 12.7)	132.4 (± 7.8)	1.000
Baseline v's 1mth follow up	129.3 (± 9.8)	132.4 (± 7.8)	0.142
Dystolic Blood Pressure			
Baseline v's after 1st treatment	80.0 (± 5.0)	81.9 (± 6.4)	**0.042**
Baseline v's 24 hours	80.0 (± 5.0)	81.7 (± 5.5)	**0.031**
Baseline v's end of wk 1	80.0 (± 5.0)	79.8 (± 6.6)	0.877
Beginning wk 2 v's end wk 2	80.9 (± 9.4)	82.1 (± 7.3)	0.459
Beginning wk 3 v's end wk 3	80.2 (± 4.9)	82.6 (± 8.0)	0.096
Beginning wk 4 v's end wk 4	82.6 (± 7.2)	83.8 (± 8.8)	0.459
Baseline v's End of trial	80.0 (± 5.0)	83.8 (± 8.8)	**0.032**
End of trial v's 1mth follow up	83.8 (± 8.8)	82.6 (± 7.5)	0.470
Baseline v's 1mth follow up	80.0 (± 5.0)	82.6 (± 7.5)	**0.030**
Pulse			
Baseline v's after 1st treatment	80.3 (± 7.3)	75.6 (± 7.8)	**0.002**
Baseline v's 24 hours	80.3 (± 7.3)	81.0 (± 7.9)	0.446
Baseline v's end of wk 1	80.3 (± 7.3)	77.9 (± 9.1)	0.171
Beginning wk 2 v's end wk 2	81.2 (± 7.7)	77.1 (± 7.5)	**0.025**
Beginning wk 3 v's end wk 3	78.3 (± 7.3)	76.4 (± 9.9)	0.532
Beginning wk 4 v's end wk 4	76.1 (± 8.4)	78.0 (± 7.4)	0.457
Baseline v's End of trial	80.3 (± 7.3)	78.0 (± 7.4)	0.083
End of trial v's 1mth follow up	78.0 (± 7.4)	79.1 (± 5.9)	0.546
Baseline v's 1mth follow up	80.3 (± 7.3)	79.1 (± 5.9)	0.487

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Table 8C. Between group analysis: Blood Pressure & Pulse: LPG v's MLD

Time Period	Systolic	Dystolic	Pulse
At Baseline	**0.024**	**0.017**	0.810
Baseline v's after 1st treatment	0.231	0.143	0.904
Baseline v's 24 hours	0.224	0.155	0.150
Baseline v's end of wk 1	0.833	0.965	0.095
Beginning wk 2 v's end wk 2	0.161	0.338	0.122
Beginning wk 3 v's end wk 3	0.533	0.742	0.382
Beginning wk 4 v's end wk 4	0.809	0.597	0.680
Baseline v's End of trial	0.863	0.744	0.930
End of trial v's 1mth follow up	0.331	0.714	0.722
Baseline v's 1mth follow up	0.073	0.498	0.879

SUMMARY

The blood pressure at baseline was lower in the LPG group in comparison to the MLD group. The changes in blood pressure and pulse was not significantly different between the two groups.

Table 9A. Change in Subjective Symptoms over trial duration (LPG)

(based upon a 10 point likert scale, 1 = no problem, 10 = worse imaginable problem)

	Pre	Post	p =
Pain			
Baseline v's after 1st treatment	1.8 (± 1.5)	1.1 (± 0.4)	**0.030**
Baseline v's 24 hours	1.8 (± 1.5)	1.4 (± 1.1)	0.144
Baseline v's end of wk 1	1.8 (± 1.5)	1.6 (± 1.3)	0.454
Beginning wk 2 v's end wk 2	1.5 (± 1.1)	1.1 (± 0.5)	0.139
Beginning wk 3 v's end wk 3	1.2 (± 0.5)	1.1 (± 0.4)	0.479
Beginning wk 4 v's end wk 4	1.5 (± 1.3)	1.0 (± 0.1)	0.112
Baseline v's End of trial	1.8 (± 1.5)	1.0 (± 0.1)	**0.010**
End of trial v's 1mth follow up	1.0 (± 0.1)	1.0 (± 0.0)	0.328
Baseline v's 1mth follow up	1.8 (± 1.5)	1.0 (± 0.0)	**0.010**
Heaviness			
Baseline v's after 1st treatment	3.2 (± 2.4)	2.2 (± 2.0)	0.057
Baseline v's 24 hours	3.2 (± 2.4)	2.2 (± 1.8)	**0.036**
Baseline v's end of wk 1	3.2 (± 2.4)	1.8 (± 1.4)	**0.004**
Beginning wk 2 v's end wk 2	1.9 (± 1.5)	1.5 (± 1.1)	0.158
Beginning wk 3 v's end wk 3	1.7 (± 1.4)	1.4 (± 0.8)	0.319
Beginning wk 4 v's end wk 4	1.5 (± 0.9)	1.1 (± 0.1)	0.064
Baseline v's End of trial	3.2 (± 2.4)	1.1 (± 0.4)	**0.000**

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End of trial v's 1mth follow up	1.1 (± 0.4)	2.0 (± 1.4)	**0.004**
Baseline v's 1mth follow up	3.2 (± 2.4)	2.0 (± 1.4)	**0.013**
Tightness			
Baseline v's after 1st treatment	2.8 (± 2.3)	1.6 (± 1.2)	**0.015**
Baseline v's 24 hours	2.8 (± 2.3)	1.4 (± 0.9)	**0.004**
Baseline v's end of wk 1	2.8 (± 2.3)	1.3 (± 1.1)	**0.008**
Beginning wk 2 v's end wk 2	1.7 (± 1.5)	1.2 (± 0.6)	0.126
Beginning wk 3 v's end wk 3	1.7 (± 1.2)	1.0 (± 0.2)	**0.018**
Beginning wk 4 v's end wk 4	1.5 (± 1.2)	1.1 (± 0.3)	0.106
Baseline v's End of trial	2.8 (± 2.3)	1.1 (± 0.3)	**0.001**
End of trial v's 1mth follow up	1.1 (± 0.3)	1.9 (± 1.9)	0.102
Baseline v's 1mth follow up	2.8 (± 2.3)	1.9 (± 1.9)	**0.027**
Tissue Hardness			
Baseline v's after 1st treatment	3.3 (± 2.5)	2.1 (± 1.8)	**0.004**
Baseline v's 24 hours	3.3 (± 2.5)	2.2 (± 1.6)	**0.014**
Baseline v's end of wk 1	3.3 (± 2.5)	1.7 (± 1.3)	**0.001**
Beginning wk 2 v's end wk 2	2.0 (± 1.4)	1.5 (± 0.9)	0.118
Beginning wk 3 v's end wk 3	1.5 (± 1.1)	1.5 (± 1.1)	**0.935**
Beginning wk 4 v's end wk 4	1.3 (± 0.6)	1.2 (± 0.5)	0.597
Baseline v's End of trial	3.3 (± 2.5)	1.2 (± 0.5)	**0.000**
End of trial v's 1mth follow up	1.2 (± 0.5)	1.9 (± 1.5)	**0.029**
Baseline v's 1mth follow up	3.3 (± 2.5)	1.9 (± 1.5)	**0.003**
Arm Temperature			
Baseline v's after 1st treatment	1.7 (± 1.5)	1.3 (± 1.5)	0.111
Baseline v's 24 hours	1.7 (± 1.5)	1.2 (± 0.8)	0.223
Baseline v's end of wk 1	1.7 (± 1.5)	1.1 (± 0.4)	0.065
Beginning wk 2 v's end wk 2	1.4 (± 1.0)	1.1 (± 0.3)	0.171
Beginning wk 3 v's end wk 3	1.2 (± 0.6)	1.2 (± 1.8)	0.575
Beginning wk 4 v's end wk 4	1.1 (± 0.3)	1.1 (± 0.4)	1.000
Baseline v's End of trial	1.7 (± 1.5)	1.1 (± 0.4)	0.065
End of trial v's 1mth follow up	1.1 (± 0.4)	1.2 (± 0.8)	0.328
Baseline v's 1mth follow up	1.7 (± 1.5)	1.2 (± 0.8)	0.147
Cramping	No change	No change	No change
Pins & Needles (P&N's)			
Baseline v's after 1st treatment	1.8 (± 1.9)	1.3 (± 1.0)	0.152
Baseline v's 24 hours	1.8 (± 1.9)	1.6 (± 1.8)	0.563
Baseline v's end of wk 1	1.8 (± 1.9)	1.5 (± 1.4)	0.502
Beginning wk 2 v's end wk 2	1.4 (± 1.1)	1.2 (± 0.8)	0.129
Beginning wk 3 v's end wk 3	1.4 (± 1.4)	1.2 (± 0.9)	0.328
Beginning wk 4 v's end wk 4	1.2 (± 0.9)	1.1 (± 0.6)	0.479
Baseline v's End of trial	1.8 (± 1.9)	1.2 (± 0.6)	0.095

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End of trial v's 1mth follow up	1.2 (± 0.6)	1.5 (± 1.8)	0.321
Baseline v's 1mth follow up	1.8 (± 1.9)	1.5 (± 1.8)	0.640
Arm Size			
Baseline v's after 1st treatment	5.7 (± 2.1)	5.3 (± 2.2)	**0.006**
Baseline v's 24 hours	5.7 (± 2.1)	4.8 (± 2.0)	**0.005**
Baseline v's end of wk 1	5.7 (± 2.1)	4.3 (± 1.7)	**0.000**
Beginning wk 2 v's end wk 2	4.5 (± 1.6)	3.8 (± 1.9)	**0.006**
Beginning wk 3 v's end wk 3	4.0 (± 2.0)	3.4 (± 2.0)	**0.012**
Beginning wk 4 v's end wk 4	3.9 (± 2.1)	3.2 (± 2.1)	**0.001**
Baseline v's End of trial	5.7 (± 2.1)	3.2 (± 2.1)	**0.000**
End of trial v's 1mth follow up	3.2 (± 2.1)	3.9 (± 2.1)	**0.011**
Baseline v's 1mth follow up	5.7 (± 2.1)	3.9 (± 2.1)	**0.000**
Arm Range of Movement			
Baseline v's after 1st treatment	1.8 (± 1.9)	1.3 (± 1.0)	0.152
Baseline v's 24 hours	1.8 (± 1.9)	1.6 (± 1.8)	0.563
Baseline v's end of wk 1	1.8 (± 1.9)	1.5 (± 1.4)	0.502
Beginning wk 2 v's end wk 2	1.4 (± 1.1)	1.2 (± 0.8)	0.129
Beginning wk 3 v's end wk 3	1.4 (± 1.4)	1.2 (± 0.9)	0.328
Beginning wk 4 v's end wk 4	1.2 (± 0.9)	1.1 (± 0.6)	0.479
Baseline v's End of trial	1.8 (± 1.9)	1.2 (± 0.6)	0.095
End of trial v's 1mth follow up	1.2 (± 0.6)	1.6 (± 1.2)	0.788
Baseline v's 1mth follow up	1.8 (± 1.9)	1.6 (± 1.2)	0.536

Table 9B. Change in Subjective Symptoms over trial duration (MLD)

	Pre	**Post**	**p =**
Pain			
Baseline v's after 1st treatment	2.6 (± 2.5)	1.6 (± 1.7)	**0.039**
Baseline v's 24 hours	2.6 (± 2.5)	1.4 (± 1.2)	**0.020**
Baseline v's end of wk 1	2.6 (± 2.5)	1.2 (± 0.8)	**0.034**
Beginning wk 2 v's end wk 2	2.1 (± 2.1)	1.3 (± 1.1)	0.101
Beginning wk 3 v's end wk 3	1.7 (± 1.7)	1.1 (± 0.5)	0.138
Beginning wk 4 v's end wk 4	1.3 (± 0.9)	1.2 (± 0.6)	0.432
Baseline v's End of trial	2.6 (± 2.5)	1.2 (± 0.6)	**0.023**
End of trial v's 1mth follow up	1.2 (± 0.6)	1.3 (± 1.3)	0.611
Baseline v's 1mth follow up	2.6 (± 2.5)	1.3 (± 1.3)	0.063
Heaviness			
Baseline v's after 1st treatment	3.5 (± 2.5)	2.6 (± 2.6)	**0.033**
Baseline v's 24 hours	3.5 (± 2.5)	3.1 (± 3.0)	0.366
Baseline v's end of wk 1	3.5 (± 2.5)	2.1 (± 2.1)	**0.004**
Beginning wk 2 v's end wk 2	2.6 (± 2.4)	1.4 (± 1.5)	**0.020**

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Beginning wk 3 v's end wk 3	2.3 (± 2.4)	2.0 (± 1.9)	0.218
Beginning wk 4 v's end wk 4	2.3 (± 1.9)	1.8 (± 1.9)	0.069
Baseline v's End of trial	3.5 (± 2.5)	1.8 (± 1.9)	**0.009**
End of trial v's 1mth follow up	1.8 (± 1.9)	2.1 (± 2.1)	0.386
Baseline v's 1mth follow up	3.5 (± 2.5)	2.1 (± 2.1)	**0.006**
Tightness			
Baseline v's after 1st treatment	3.7 (± 3.3)	2.5 (± 3.0)	**0.015**
Baseline v's 24 hours	3.7 (± 3.3)	2.6 (± 2.5)	**0.004**
Baseline v's end of wk 1	3.7 (± 3.3)	1.5 (± 1.7)	**0.008**
Beginning wk 2 v's end wk 2	3.1 (± 2.6)	2.3 (± 2.3)	0.126
Beginning wk 3 v's end wk 3	1.6 (± 1.5)	1.6 (± 1.6)	0.950
Beginning wk 4 v's end wk 4	1.5 (± 1.0)	1.5 (± 1.5)	0.744
Baseline v's End of trial	3.7 (± 3.3)	1.5 (± 1.5)	**0.004**
End of trial v's 1mth follow up	1.5 (± 1.5)	2.4 (± 2.4)	0.054
Baseline v's 1mth follow up	3.7 (± 3.3)	2.4 (± 2.4)	0.144
Tissue Hardness			
Baseline v's after 1st treatment	4.5 (± 3.1)	2.9 (± 3.0)	**0.001**
Baseline v's 24 hours	4.5 (± 3.1)	2.9 (± 2.6)	**0.020**
Baseline v's end of wk 1	4.5 (± 3.1)	2.0 (± 2.0)	**0.000**
Beginning wk 2 v's end wk 2	2.5 (± 2.6)	2.5 (± 2.2)	0.906
Beginning wk 3 v's end wk 3	2.2 (± 1.9)	2.2 (± 1.8)	**0.897**
Beginning wk 4 v's end wk 4	2.2 (± 1.8)	1.9 (± 1.9)	0.262
Baseline v's End of trial	4.5 (± 3.1)	1.2 (± 0.5)	**0.002**
End of trial v's 1mth follow up	1.9 (± 1.9)	2.5 (± 2.3)	0.210
Baseline v's 1mth follow up	4.5 (± 3.1)	2.5 (± 2.3)	**0.025**
Arm Temperature			
Baseline v's after 1st treatment	2.4 (± 1.9)	1.4 (± 0.9)	0.111
Baseline v's 24 hours	2.4 (± 1.9)	1.8 (± 1.6)	0.223
Baseline v's end of wk 1	2.4 (± 1.9)	1.3 (± 0.6)	0.065
Beginning wk 2 v's end wk 2	2.0 (± 1.8)	1.4 (± 1.5)	0.171
Beginning wk 3 v's end wk 3	1.6 (± 1.6)	1.3 (± 1.0)	0.575
Beginning wk 4 v's end wk 4	1.2 (± 0.4)	1.2 (± 0.4)	1.000
Baseline v's End of trial	2.4 (± 1.9)	1.2 (± 0.4)	**0.004**
End of trial v's 1mth follow up	1.2 (± 0.4)	1.8 (± 1.8)	0.090
Baseline v's 1mth follow up	2.4 (± 1.9)	1.8 (± 1.8)	0.285
Cramping			
Baseline v's after 1st treatment	1.6 (± 1.7)	1.0 (± 0.0)	0.118
Baseline v's 24 hours	1.6 (± 1.7)	1.3 (± 1.3)	0.221
Baseline v's end of wk 1	1.6 (± 1.7)	1.0 (± 0.1)	0.135
Beginning wk 2 v's end wk 2	1.4 (± 1.2)	1.0 (± 0.2)	0.167
Beginning wk 3 v's end wk 3	1.4 (± 1.3)	1.0 (± 0.0)	0.181

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Beginning wk 4 v's end wk 4	No change	No change	No change
Baseline v's End of trial	1.6 (± 1.7)	1.0 (± 0.0)	0.118
End of trial v's 1mth follow up	1.0 (± 0.0)	1.3 (± 1.3)	0.329
Baseline v's 1mth follow up	1.6 (± 1.7)	1.3 (± 1.3)	0.221
Pins & Needles (P&N's)			
Baseline v's after 1st treatment	1.1 (± 0.5)	1.0 (± 0.0)	0.329
Baseline v's 24 hours	1.1 (± 0.5)	1.0 (± 0.0)	0.329
Baseline v's end of wk 1	1.1 (± 0.5)	1.2 (± 0.9)	0.847
Beginning wk 2 v's end wk 2	1.2 (± 0.6)	1.0 (± 0.1)	0.232
Beginning wk 3 v's end wk 3	1.1 (± 0.3)	1.0 (± 0.0)	0.329
Beginning wk 4 v's end wk 4	No change	No change	No change
Baseline v's End of trial	1.1 (± 0.5)	1.0 (± 0.0)	0.329
End of trial v's 1mth follow up	1.0 (± 0.0)	1.1 (± 0.6)	0.190
Baseline v's 1mth follow up	1.1 (± 0.5)	1.1 (± 0.6)	0.377
Arm Size			
Baseline v's after 1st treatment	6.3 (± 2.4)	5.8 (± 2.4)	**0.029**
Baseline v's 24 hours	6.3 (± 2.4)	5.6 (± 2.6)	0.089
Baseline v's end of wk 1	6.3 (± 2.4)	4.7 (± 2.0)	**0.000**
Beginning wk 2 v's end wk 2	4.9 (± 2.5)	4.1 (± 2.0)	0.090
Beginning wk 3 v's end wk 3	4.0 (± 2.4)	3.3 (± 1.6)	**0.032**
Beginning wk 4 v's end wk 4	3.5 (± 1.9)	2.9 (± 2.0)	**0.049**
Baseline v's End of trial	6.3 (± 2.4)	2.9 (± 2.0)	**0.000**
End of trial v's 1mth follow up	2.9 (± 2.0)	4.1 (± 2.2)	**0.001**
Baseline v's 1mth follow up	6.3 (± 2.4)	4.1 (± 2.2)	**0.000**
Arm Range of Movement			
Baseline v's after 1st treatment	3.3 (± 2.9)	3.2 (± 2.8)	0.215
Baseline v's 24 hours	3.3 (± 2.9)	2.5 (± 2.2)	**0.046**
Baseline v's end of wk 1	3.3 (± 2.9)	1.7 (± 1.5)	**0.007**
Beginning wk 2 v's end wk 2	2.0 (± 2.1)	1.6 (± 1.7)	0.295
Beginning wk 3 v's end wk 3	1.8 (± 2.1)	1.6 (± 1.5)	0.143
Beginning wk 4 v's end wk 4	1.8 (± 1.9)	1.5 (± 1.8)	0.479
Baseline v's End of trial	3.3 (± 2.9)	1.5 (± 1.8)	**0.006**
End of trial v's 1mth follow up	1.5 (± 1.8)	1.9 (± 2.4)	0.239
Baseline v's 1mth follow up	3.3 (± 2.9)	1.9 (± 2.4)	**0.026**

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Table 9C. Between group analysis: Subjective Symptoms: LPG v's MLD

Time Period	Pain	Heaviness	Tightness	Hardness	Arm Tem.
At baseline	**0.013**	0.656	**0.018**	0.652	0.124
Change after 1st treatment	0.238	0.458	0.291	0.890	**0.019**
Change after 24 hours	**0.023**	0.657	0.373	0.804	0.964
Change at end of week 1	**0.003**	0.365	0.215	0.863	0.478
Change at end of week 2	0.053	0.170	**0.024**	0.880	0.135
Change at end of week 3	**0.002**	0.319	0.904	0.531	**0.029**
Change at end of week 4	0.512	0.132	0.848	0.163	0.892
Change over whole trial	**0.007**	0.882	0.268	0.676	0.473
Change at end of 1 month F/U	**0.034**	0.421	0.949	0.503	**0.004**

Time Period	Cramps	P&N's	Size	ROM
At baseline	**0.001**	**0.006**	0.376	0.066
Change after 1st treatment	**0.001**	0.094	0.226	0.694
Change after 24 hours	**0.021**	0.283	0.463	**0.012**
Change at end of week 1	0.243	0.187	0.900	**0.050**
Change at end of week 2	**0.001**	0.477	0.193	0.553
Change at end of week 3	**0.002**	0.453	0.618	0.292
Change at end of week 4	0.057	0.066	0.152	**0.005**
Change over whole trial	**0.001**	**0.029**	0.440	0.068
Change at end of 1 month F/U	**0.949**	0.684	0.883	0.557

SUMMARY

Pain

Both the LPG and MLD group had statistically significant reductions in pain directly after treatment and at the end of 4 weeks of treatment. Only the MLD group had statistically significant reductions at 24 hours and at the end of week one 1st week, end wk3 & whole trial stat in favour of MLD. The reduction in pain over the trial duration was greater in the MLD group in comparison to the LPG group ($p = 0.011$) but the pain rating was significantly greater in the MLD group at baseline which may explain the differences.

Heaviness

Both groups experienced statistically significant reductions in heaviness at 24 hours, week 1, and at the end of trial. The improvements were slightly greater in the LPG group over first week and over whole trial but this was not statistically different in comparison to the MLD group.

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Tightness

Both groups experienced statistically significant reductions in tightness post treatment, at 24 hours, at the end of week 1 and 3 and over the whole trial duration. The tightness rating was statistically significantly greater for the MLD group at baseline but both groups experienced similar reductions. The reduction in heaviness at the end of week 2 was greater in the MLD group in comparison to the LPG group ($p = 0.024$).

Tissue Hardness

Both groups experienced reductions in tissue hardness (ie: the arm felt softer to the women) post treatment, at 24 hours, at the end of week 1 and 3 and the end of the whole trial. The reductions in reported tissue hardness were slightly greater improvement in the MLD group but not statistically different in comparison to LPG group. Both groups reported an increase in tissue hardness at 1 month follow up, with this increase being statistically significant in the LPG group.

Arm Temperature

Both groups reported reductions in arm temperature, in the MLD group the reductions were statistically greater directly after treatment and at the end of week 3 in comparison to LPG group. At the end of the trial this reduction was also statistically significant within the MLD group.

Cramping

The LPG group didn't suffer from this subjective symptom and therefore it didn't alter over the duration of the trial. However, the MLD group did report a slight problem with cramping and therefore the change in the MLD group is statistically significant when compared to the LPG group.

Pins & Needles

Both groups experienced non statistically significant reductions in pins and needles, these reductions were only very slight in the MLD group as this was not a highly rated problem for this group. Therefore the reductions in the LPG group were greater and by the end of the trial statistically significantly greater in comparison to MLD.

Size

Both groups reported similar reductions in perceived arm size during the trial, the majority of which were statistically significant. However, these reductions were not statistically significant in the MLD group at 24 hours or at the end of week 2, the change in perceived size at these time points were not statistically significant in comparison to the LPG group.

Range of Movement

The MLD group rated their decreased arm range of movement as more of a problem in comparison to the LPG group, this may explain why the reductions were greater in the MLD group at 24hours, 1 week post treatment and at the end of the trial.

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VOLUNTARY PROCEDURES

Ultrasound

Table 10A. Change in (b)(4) measurements in the forearm, upper arm, anterior thorax and posterior thorax **(LPG & MLD)**

The following table represents the distance of the sub-fascia to the deep fascia (mm) when the ultrasound head is completely compressed against the skin. The (b)(4) measurements are also included in this table to establish whether these readings also changed in these sub-groups over the same time period.

	Fore arm	Upper arm	Ant Thorax	Post Thorax
LPG (n = 4)				
Ultrasound				
Baseline	11.0 (± 2.3)	7.3 (± 2.1)	9.1 (± 2.1)	13.0 (± 2.1)
End 4wks of Tx	10.9 (± 2.7)	5.8 (± 0.7)	9.2 (± 2.2)	12.3 (± 2.1)
p =	0.756	0.120	0.936	0.153
(b)(4)				
Baseline	4.47 (± 0.61)	5.65 (± 0.98)	8.92 (± 2.85)	3.77 (± 0.80)
End 4wks of Tx	4.87 (± 0.17)	6.05 (± 0.92)	9.52 (± 2.16)	4.00 (± 0.67)
p =	0.305	0.503	0.201	0.717
MLD (n = 7)				
Ultrasound				
Baseline	10.7 (± 5.3)	7.3 (± 3.3)	9.1 (± 4.6)	9.5 (± 2.7)
End 4wks of Tx	10.3 (± 4.6)	6.9 (± 3.2)	9.0 (± 2.9)	8.6 (± 1.6)
p =	0.412	0.317	0.942	0.267
(b)(4)				
Baseline	5.37 (± 1.38)	5.93 (± 1.04)	8.58 (± 1.12)	3.81 (± 0.36)
End 4wks of Tx	5.23 (± 1.01)	6.14 (± 0.56)	9.27 (± 1.15)	4.31 (± 0.27)
p =	0.548	0.470	**0.017**	**0.032**

SUMMARY

At the end of the trial, in the fore arm and anterior thorax area the distance from the sub-fascia to the deep fascia hardly altered in either the LPG or MLD group. In the upper arm and posterior thorax the distance was decreased in both the LPG and MLD group, this indicates a change in the tissue structure and may be a result of less fluid and/or fibre in these territories. In unison with these ultrasound changes, there were also improvements in the measurements taken via (b)(4) in the upper arm and the posterior thorax in both the LPG and MLD group, indicating that these areas had also softened over the trial duration.

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Table 10B. Between group analysis(b)(4) [redacted]: LPG v's MLD

	U/Sound p =	Ton p =
Forearm	0.209	0.983
Upper arm	0.693	0.058
Anterior Thorax	0.545	0.391
Posterior Thorax	0.375	0.106

Both the LPG and MLD group experienced similar changes in both the(b)(4) [redacted] measurements.

VOLUNTARY PROCEDURES

Lymphoscintigraphy

As only a few lymphoscintigraphies were performed (due to the voluntary nature of this aspect of the trial), data can not be combined to do a formal statistical analysis. Instead, a case study of each participant who underwent this procedure before and at the end of 4 weeks of treatment is presented. Each case study will outline the participant's response to treatment and any changes that were detected in the Lymphoscintigraphy scan. Copies of the Lymphoscintigraphy reports and the pre and post treatment scans are contained in appendix I.

MLD

Patient One

A 47 year old women who has had right arm lymphoedema for 1.5 years which developed after a total mastectomy + axillary clearance combined with radiotherapy administered to the surgery area, axilla and lateral side. She also had a significant scar under the collar bone (mid-line) after chemotherapy portal removal which may have been impeding lymphatic drainage and bursitis of the right shoulder which may have been putting an extra fluid load on the lymphatic system in this area.

This lady lost 130mls of fluid from the affected arm and 400mls from the trunk. There was a slight softening in the forearm territory, with little change in the other territories, although she subjectively reported that the arm felt less hard. Lymphoscintigraphy showed minimal change between pre and post scans, with less tracer apparent within the deep channels at 30 minutes, less tracer with in the elbow nodes at this time and slightly less dermal back flow.

Patient Five

A 70 year old women who has had left arm lymphoedema for 6 years which developed after a total mastectomy and axillary clearance was not combined with radiotherapy. This lady was slightly over weight, had high blood pressure which was controlled by medication and suffered from arthritis in the affected arm which may have put an extra load on the lymphatic system.

This lady showed negligible change in both fluid and volume in the affected arm and in truncal fluid at the end of 4 weeks of treatment. This may be related to the fact that this woman only received compression bandaging in the first week of treatment as she developed numbness and pins and needles in the left thumb. Due to this development, it was decided that she would receive massage only (minus the bandaging) for the next 3 weeks.

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(b)(4) [redacted] demonstrated that there had been some softening in the upper arm and posterior thorax territories. She had reported no subjective symptoms at the beginning of the trial and therefore this remained unchanged at the end of the trial. She did subjectively report that the arm looked smaller. (b)(4) [redacted] showed that there was flow via the deep channels to the axillary nodes within 30 minutes bilaterally which did not appear to appreciably change between the pre and post scans.

LPG

Patient Two

A 38 year old women who has had left arm lymphoedema for 2 years which developed after a partial mastectomy and axillary clearance combined with radiotherapy administered to the breast, axillary and supraclavicular areas. She had no other relevant problems.

This lady lost 580mls of fluid from the affected arm and just over a litre of fluid from the trunk. Tonometry showed a softening in the upper arm territory and she reported that the arm felt less hard and heavy. Lymphoscintigraphy showed no appreciable change between the pre and post images.

Patient Three

A 59 year old women who has had right arm lymphoedema for 2 years & 10 months which developed after a partial mastectomy and axillary clearance combined with radiotherapy administered to the breast, and supraclavicular areas. She had no other relevant problems.

This lady lost 310mls of fluid from the affected arm and 500mls from the trunk. Tonometry showed softening in all the lymphatic territories and she reported that the arm felt less hard and tight. Lymphoscintigraphy showed no appreciable differences between the pre and post scans.

Patient Four

A 62 year old women who has had right arm lymphoedema for 7 years & 4 months which developed after a partial mastectomy and axillary clearance combined with radiotherapy administered to the breast only. She had no other relevant problems.

This lady lost 110mls from the affected arm and 400mls from the trunk. Tonometry showed softening in forearm and upper arm territories and she reported improvements in arm heaviness, tightness, hardness and temperature (the arm no longer felt 'hot') (b)(4) [redacted] y showed less dermal backflow in comparison to the pre-treatment scan.

Patient Six

A 53 year old women who has had right arm lymphoedema for 5 months which developed after a total mastectomy and axillary clearance combined with radiotherapy administered to the surgical area, axilla and supraclavicular area. This lady is currently a smoker and her arm was susceptible to increasing in the hot weather (there was some hot weather occurred during the treatment period).

At the end of the trial there was negligible change in arm fluid and a slight decrease in arm volume as measured via perometry. However this woman did experience reductions at different stages in the trial and the negligible difference at the end of treatment may be related to the hot weather.

(b)(4) [redacted] demonstrated a softening in the upper arm and posterior thorax and this woman reported improvements in pain and heaviness. (b)(4) [redacted] showed a slight increase in dermal back flow in the post treatment scan but no other appreciable differences.

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SUMMARY

There is no clearly defined pattern or trend demonstrated by the pre and post (b)(4) [redacted] scans. Although the majority of women who underwent the scans had arm volume reductions (in one case there was quite a significant reduction of 580mls – patient two) and improvements in (b)(4) [redacted] readings and subjective symptoms, this improvement was not seemingly captured by the actual lymphoscintigraphy scan.

The fact there were fluid reductions, tissue softening and therefore less fibrotic induration and the fact the arm felt better to the women all indicate that there was a response to the treatment regime and that the lymphatic system in the affected arm was generally working more effectively. Why these improvements were not demonstrated in the [redacted] is not known. One of our strong hypotheses is that not only are there a range of possibly anatomical configurations of the lymphatic drainage system of the arm and thus the possibility that the tracer did not enter into the ones whose drainage/clearance was actually improved. The other strong hypothesis is that the LPG treatment has its major impact on the vascular system (specifically the venous end) and that this results in firstly a reduced exudation from the vascular system (and thus resulting on a reduced load on the lymphatic system) and secondly that the pressure variations result in an improved uptake from the venous system. Again the overall impact is a reduced load on the lymphatic system.

(b)(4)

Table 11A: Positive Subjective Comments (average percent)

The following tables represent subjective comments that the patients themselves voluntarily made.

Comment	LPG	MLD
Tx relaxing	56%	40%
Tx enjoyable	28%	6%
Tx soothing	7%	-
Felt good post Tx	76%	80%
Slept better post Tx	4%	31%
Limb felt lighter	27%	1%
Limb felt softer	32%	6%
Limb felt normal	18%	-
Limb looked smaller	68%*	8%
Limb looked wrinkled	11%	1%
Area adjacent affected limb less puffy/swollen[a]	16%	5%
Less limb pitting	4%	-
Less neck muscle tension	4%	-
Less arthritic pain	5%	2%
Clothes/jewellery looser Fitting	8%	-
Less focused on affected	9%	-

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Limb		
Improved self image	10%	4%
Less abdominal bloating	2%	1%

* 91.7% of the LPG participants thought their arm looked smaller by week 4.

[a] This area includes: axillary pouch/chest wall/above the scapula

Table 10B: Negative Subjective Comments (average percent)

Comment	LPG	MLD
Tired post Tx	13%	30%
Increased urination	10%*	14%*
Increased thirst	6%*	20%*
Increased bowel motions	-	1%
Restless post Tx	-	1%

* increased urination and thirst was predominantly experienced in the first week of treatment.

Table 11: Bandaging compliance and adverse events

	Week 1		Week 2		Week 3		Week 4	
	LPG	MLD	LPG	MLD	LPG	MLD	LPG	MLD
Bandaging Compliance:								
Not at all*	4.2%	4.8%	8.3%	4.8%	12.5%	9.5%	8.3%	14.3%
Slightly	8.3%	-	-	4.8%	-	-	-	-
Moderately	16.7%	33.3%	12.5%	33.3%	12.5%	42.9%	20.8%	33.3%
Completely	70.8%	61.9%	75.0%	57.1%	70.8%	47.6%	66.7%	52.4%
Wore compression sleeve	-	-	4.2%	-	4.2%	-	4.2%	-
Puffy/swollen fingers	16.7%	28.6%	12.5%	4.8%	16.7%	19.0%	16.7%	19.0%
Disturbed Sleep	4.2%	19.0%	8.3%	4.8%	4.2%	9.5%	4.2%	4.8%
Bandaging uncomfortable	95.8%	47.6%	29.2%	38.1%	29.2%	38.1%	16.7%	42.9%
Itching	20.8%	4.8%	16.7%	4.8%	20.8%	9.5%	-	-
Redness/chaffing/blistering	29.2%	19.0%	12.5%	23.8%	16.7%	28.6%	16.7%	14.3%
Increased thirst	4.2%	4.8%	-	-	-	9.5%	-	-
Increased urination	4.2%	-	-	-	-	-	-	-

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* This includes those patients who couldn't wear bandaging because they had a reaction to the bandaging material itself or had previous conditions (ie: nerve damage) which excluded them from bandaging.

Withdrawals & Drop outs

In total 52 women were recruited to the trial, with 45 women completing the trial. Two women withdrew from the study due to illness (unrelated to treatment), 1 woman withdrew because she didn't like the sensation of the manual lymphatic massage and 4 women withdrew due to being unable to meet the treatment and measurement schedule.

Discussion & Conclusions

Both groups experienced similar reductions in both arm volume, arm fluid and truncal fluid. (b)(4) shows that the majority of this reduction occurs in the forearm area, with a slight reduction in the upper arm. Of particular interest is the fact that the upper arm volume increases slightly in the LPG group post treatment and at 24 hours, which did not occur in the MLD group. This indicates that the fluid is drained to the upper arm but perhaps not drained out of this area effectively, this maybe overcome by either massage to the neck lymph nodes or adding some more drainage time to the end of the LPG protocol to insure that this area is draining at it's optimum.

Both groups experienced increases in arm volume, arm fluid and truncal fluid at 1 month follow up but none of these parameters had returned to the baseline value. Both groups experienced a reduction in body weight but increases in body fat mass and percentage body fat, therefore the weight reduction is most likely related to the arm and truncal fluid reductions.

(b)(4) measurements revealed that at the end of the trial there was softening in the forearm in the LPG group but not the MLD group. Both groups experienced softening in the upper arm at the end of the trial. The LPG group experienced significantly more softening in the anterior thorax at the end of week 1 and the end of the whole trial, whilst the MLD group experienced a greater softening in the posterior thorax at the end of the whole trial. These differences in the anterior and post thorax may be related to technique, with LPG spending more massaging time in the anterior thorax area whilst MLD spending more time in the posterior thorax. At 1 month follow up there was a general hardening in all the lymphatic territories.

The improvements in subjective symptoms were very similar in both groups, with the reductions in pain, heaviness, tightness, hardness and perceived limb size being statistically significant by the end of trial duration. There were also improvements in skin temperature, pins & needles and cramps, but these were generally not statistically significant. Range of movement was statistically improved in the MLD group at 24 hours, end of week 1 and the end of the trial, but this was more of a problem for this particular group. The majority of the subjective symptoms had increased at the 1 month follow up but had not returned to baseline values.

(b)(4) in a sub group of volunteers demonstrated in both the LPG & MLD groups there was less distance between the sub-fascia and deep fascia in both the upper arm and posterior thorax. There were also improvements in tonometry readings in the upper arm and posterior thorax in these areas, indicating less fibrotic induration.

Although (b)(4) was undertaken in 6 women (LPG = 4, MLD = 2), no clear trend could be detected, this was despite reductions in arm volume and fluid, improvements in subjective symptoms and softening in some of the lymphatic territories. Why the clinical improvements were not captured by (b)(4) is uncertain. However, one of our strong hypotheses is that not only are there a range of possibly anatomical configurations of the lymphatic drainage system of the arm and thus the possibility that the tracer did not enter into the ones whose drainage/clearance was actually improved. The other strong hypothesis is that

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the LPG treatment has its major impact on the vascular system (specifically the venous end) and that this results in firstly a reduced exudation from the vascular system (and thus resulting in a reduced load on the lymphatic system) and secondly that the pressure variations result in an improved uptake from the venous system. Again the overall impact is a reduced load on the lymphatic system.

Both LPG and MLD were well received by the women, with a lot of the women indicating that they found it quite relaxing. A small percentage of women reported tiredness after the massage which is most likely related to the release and movement of cell waste products and toxins. Some also reported increased urination and thirst, the increased urination is most likely related to the movement of fluid into the general circulation and therefore increased kidney filtration, with the thirst being a response to the increased urination.

Most of the adverse effects were experienced from the compression bandaging, with both groups reporting finger swelling, disturbed sleep, discomfort, itchiness, redness, chaffing and some blistering. One participant also experienced numbness and pins and needles in the thumb on the affected side. Some women could not tolerate the bandaging, and these women (indicated in the bandaging compliance table) either received massage only or massage and wore their own compression sleeve. Despite this, the majority of these women still experienced improvements.

Overall, both treatment regimes resulted in similar reductions in arm volume, arm fluid, truncal fluid and body weight. Both regimes also resulted in lymphatic territory softening and improvements in subjective symptoms. It is of interest that although the majority of parameters increased at 1 month follow up, none returned to the baseline value. This may indicate that there are ongoing benefits of massage (whether it be manual lymphatic drainage or mechanised massage via LPG), but is more likely to be related to the fact that the majority of the women in this trial were fitted with the new sleeve at the end of the trial (therefore it fitted the newly reduced arm) and wore this for most of the time during the 1 month period. These women also received general lymphoedema education during the trial period (as it gave them the opportunity to ask questions and clarify issues) and were constantly reminded of important issues such as skincare. This emphasizes the need for regular input from a therapist and/or allied health professional during all treatment regimes.

Recommendations for improvement of outcomes

Change in protocol

It is clear that a better outcome for the LPG treated patients can be obtained with a slight change in the treatment protocol, namely an increased attention to the clearance of fluids from the root of the extremity. It is estimated that this could achieve a further 5-10% reduction and would perhaps take no more than 5 minutes.

Further follow-up

In view of the fact that the one month follow-up has showed a maintenance of treatment effect both from the subjective and objective aspects, it would be worth while in any future study to have a longer follow up period which encompasses measurement monthly for say 6 months. Of course there may be many confounders in this time but it would be scientifically and practically worth while to determine the longevity of treatment effect.

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Recommendations for further research

Fatty (mid stage of lymphoedema) investigation

A relatively good correlation was observed between the levels of fat in the person generally and in the affected area, and the effectiveness of treatment. It may be that this aspect of LPG treatment on the fatty stage of lymphoedema could be further investigated as the target group in this trial were mainly of the fluid rich variety

Impact of LPG on fibrotically indurated tissues due to surgery or radiotherapy

There seemed some good outcomes for the reduction of fibrotic induration when it occurred (although in the trial we did not specifically select for patients who had induration as a consequence of the surgery, radiotherapy or the lymphoedema progression). There may be some considerable merit and worth in investigating the impact of LPG on cases with fibrotic induration as a specific entry criteria.

Impact on primary and secondary leg lymphoedemas

The good outcomes on secondary arm lymphoedemas beg the question as to whether similar outcomes might be obtained on the notoriously difficult to treat primary and secondary lymphoedemas of the legs. These are difficult to treat due to the fact that in the first instance (primary Lymphoedemas) there are too few lymphatic vessels and if the LPG treatment reduces lymph load then they may experience a good outcome, and in the second instance (secondary leg lymphoedemas) they are compounded often by significant vascular problems, which would also strongly benefit if the LPG treatment was to influence vascular outflow or clearance via it.

Impact on Lipoedemas

Other significant areas of problems in terms of a high incidence and prevalence in the population are lipoedemas. This metabolically and genetically determined predisposition to deposit large amounts of fats subcutaneously in the tissues of the legs occurs in between 10-15% of women. It is progressive and to date there are non effective treatments. In view of the findings from this trial on similar fatty type tissues of lymphoedema it would seem not unreasonable to expect that LPG treatment would have a beneficial effect on this very unfortunate group of women.

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Publishing and presentation proposals

The outcomes from this study will be published in a range of international journals such as Lymphology and Lymphatic Biology and Research.

The outcomes from this study will be presented at a range of international congresses, the first of which will be the (b)(4) [redacted]

(b)(4) [redacted]

Further presentations will occur as the opportunity arises.

Financial Statement

(b)(4) [redacted]

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1. References

1. Weissleder H & Schuchhardt C. Lymphedema Diagnosis and Therapy – 2nd Edition, 1997. Kagerer Kommunikation, Germany: pg 166

2. Berlin E, Gjores J, Ivarsson et al. Postmastectomy lymphoedema. Treatment and a five-year follow-up study. Int Angiol, 1999; 18(4): 294-8

3. Erickson V, Pearson M, Ganz P et al. Arm edema in breast cancer patients. J Nat Cancer Inst, 2001; 93(2): 96-111

4. Bates D, Levick J, Mortimer P. Starling pressures in the human arm and their alteration in post mastectomy oedema. J Physiol, 1994; 477(Pt 2): 355-363

5. Browning C. Lymphoedema: Prevelance, risk factors and management: A review of research. NHMRC National Breast Cancer Centre, 1997.

6. Petlund C. Prevalence and incidence of chronic lymphoedema in a Western Europe country. In Nishi M, Uchino S & Yabuki S (Eds) Progress in Lymphology XII, 1990: 391-394

7. Vignes S, Champagne A, Poisson O: [Management of lymphedema: experience of the Cognacq-Jay Hospital]. [French] [Abstract] Revue de Medecine Interne, 2002; 23(Suppl): 414-20.

8. Kriederman B, Myloyde T, Bernas M, et al. Limb volume reduction after physical treatment by compression and/or massage in a rodent model of peripheral lymphedema. Lymphology 2002; 35:23-7.

9. Piller NB, Harris R. Where does the fluid go? Objective measurement of fluid movement around the body using perometry and bio-impedance in two case studies of chronic primary and secondary lymphoedema. In: Proceedings of the 4th Australasian Lymphology Association Conference, 2001, Adelaide, 2001:85-91.

10. Williams AF, Vadgama A, Franks A, et al. A randomized controlled crossover study of manual lymphatic drainage therapy in women with breast cancer-related lymphoedema. Euro J Cancer Care, 2002; 11:254-61.

11. Johansson K, Lie E, Ekdahl C, et al. A randomized study comparing manual lymph drainage with sequential pneumatic compression for treatment of postoperative arm lymphedema. Lymphology, 1998; 31:56-64.

12. Franzeck UK, Spiegel I, Fischer M, et al. Combined physical therapy for lymphedema evaluated by fluorescence microlymphography and lymph capillary pressure measurements. J Vasc Res, 1997; 34:306-11.

13. Földi E, Sauerwald A, Hennig B. Effect of complex decongestive physiotherapy on gene expression for the inflammatory response in peripheral lymphedema. Lymphology, 2000; 33:19-23.

14. Bartolo M & Allegra C. Microlymphatic system and LPG technique. Proceedings of the 14th World Congress of the 'Union Internationale de Phlebologie" Sep 2001, Rome.

15. Leduc A, Bourgeois P, Leduc O. LPG systems and lymphatic activity. Proceedings of the XV International Congress of Lymphology, Sep 1995, Sao Paulo.

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16. Campisi C, Boccardo F, Azevedo WF, Gomes CS, Couto EM, Napoli E, Zilli A, Maccio A. LPG system in the treatment of peripheral lymphoedema: Clinical preliminary results and perspectives. Euro J Lymphology, 2001; 9(34):78

17. Guillot B. Prospective study of the use of LPG technique in the treatment of cutaneous fibrosis induced by radiotherapy. XXII Congress National de Medecine Esthetique, 2001, Rome.

18. Leduc O, Klien P, Rasquin C et al. Reliability of a volume measuring device (Volumeter®) for human limbs. Eur J Lymphol, 1992; 3:53-56.

19. Stanton AW, Northfield JW, Holroyd B, et al. Validation of an optoelectronic limb volumeter (perometer). Lymphology, 1997; 30:77–97.

20. Clodius L, Deak I, Piller N. A new instrument for the evaluation of tissue tonometry in lymphedema. Lymphology, 1976; 9:1–5.

21. Ward L, Byrne N, Rutter K et al Reliability of multiple frequency bioelectrical impedance analysis: an inter-machine comparison. Am J Human Biol, 1997; 9:63-72

22. Cornish B, Chapman M, Hirst C et al. Early diagnosis of lymphedema using multifrequency bioimpedance. Lymphology, 2001; 34(1): 2-11

23. Moseley A, Piller N & Carati C. Combined opto-electronic perometry and bioimpedance to measure objectively the effectiveness of a new treatment intervention for chronic secondary leg lymphoedema. Lymphology, 2002; 35: 136-143

24. Lee JW. Jones PS. Mineyama Y. Zhang XE. Cultural differences in responses to a Likert scale. Research Nursing & Health, Aug 2002; 25(4):295-306

25. Swedborg I. Effects of treatment with an elastic sleeve and intermittent pneumatic compression in post-mastectomy patients with lymphoedema of the arm. Scand J Rehab Med, 1984; 16:35-41.

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APPENDIX I

Copies of the (b)(4) y reports and the pre and post treatment scans of the women (n = 6) who underwent this procedure.

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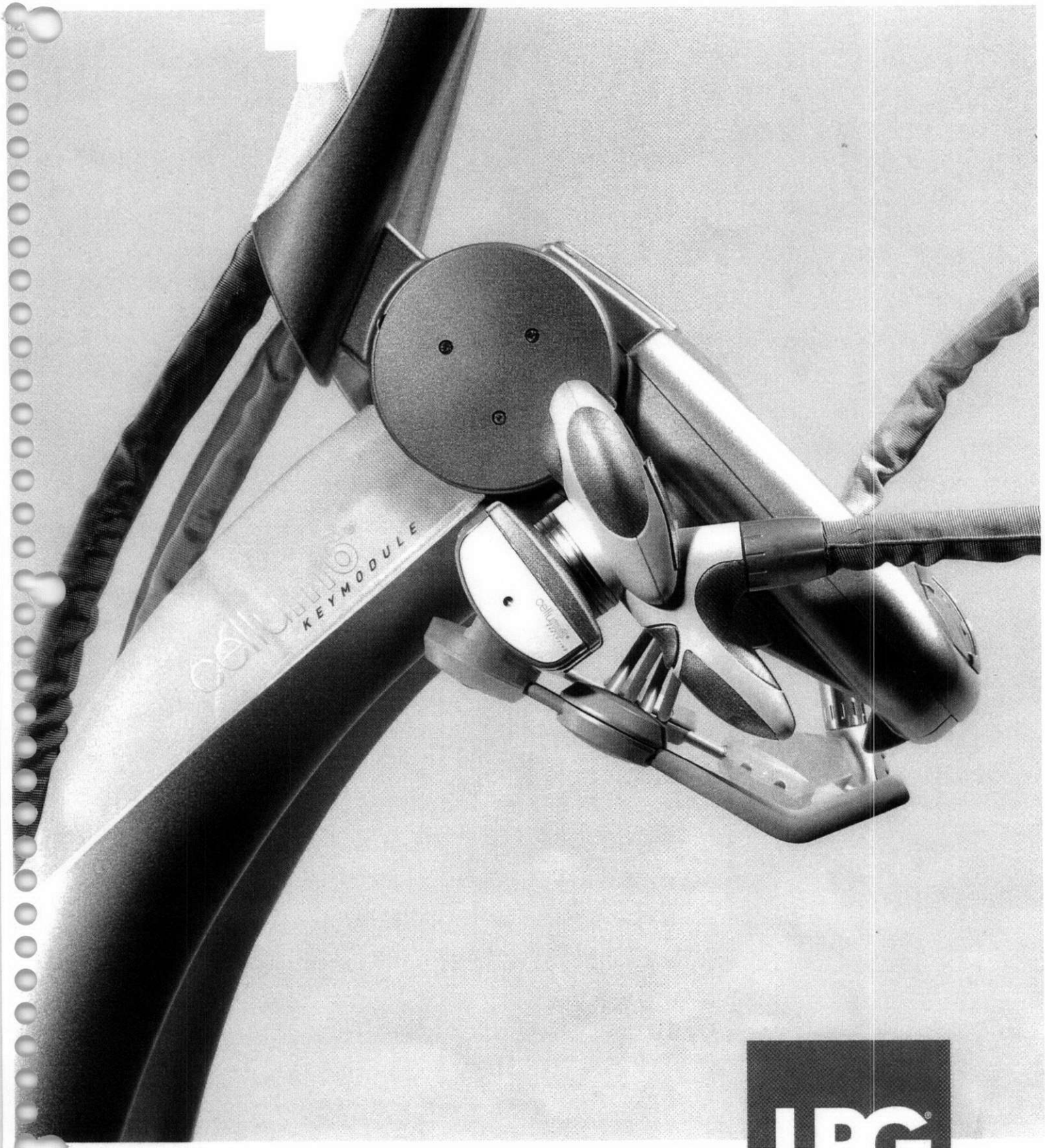

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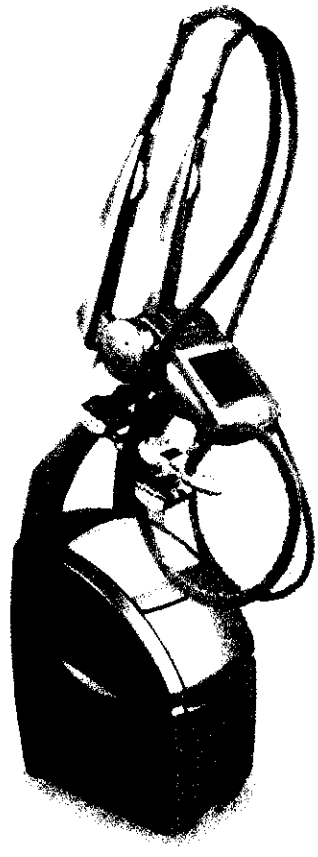

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- A set of auxiliary heads
- A set of micro-nozzles/micro-heads
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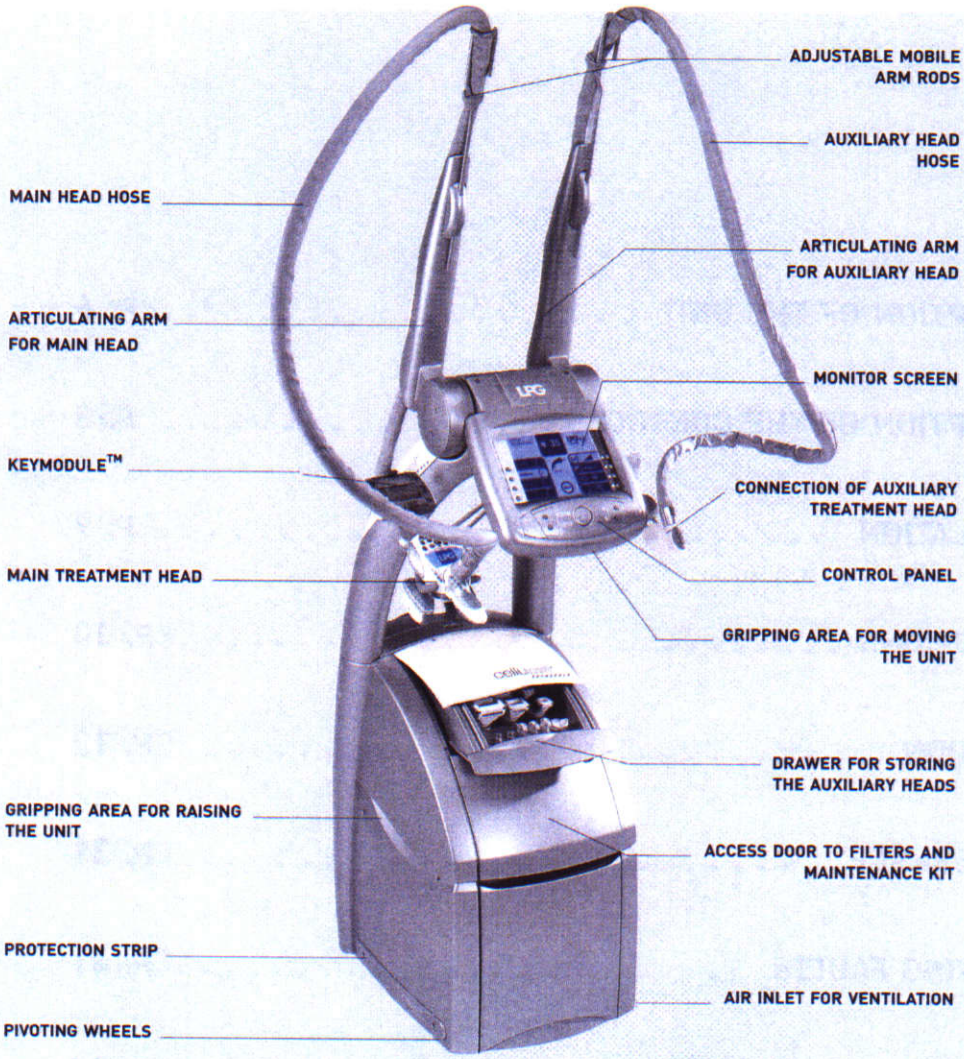
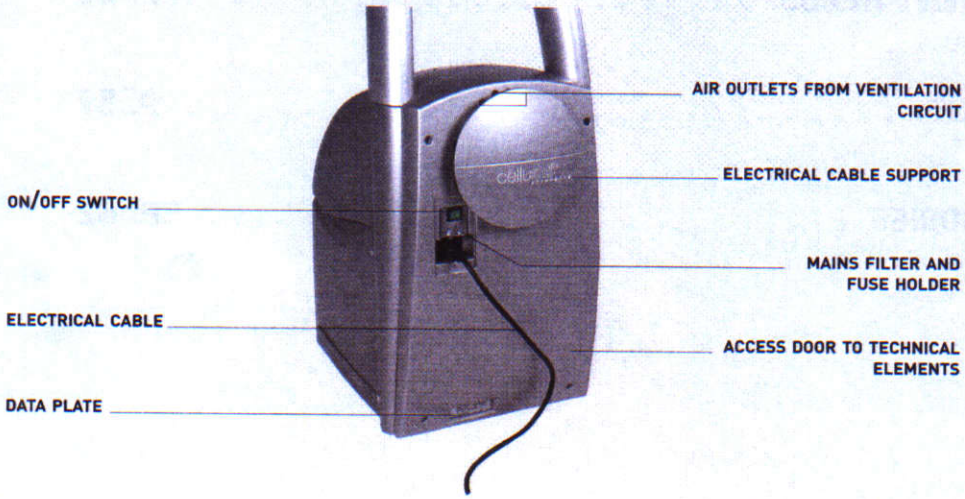
Cellu M6® Keymodule *i*



BEFORE USE MAKE SURE THAT THE SUPPLY CABLE IS COMPLETELY UNWOUND



The unit can only operate if it is connected to the mains by its supply cable and provided the on switch has been actuated and the green voltage light is on. When the unit is switched on, the pump starts to run automatically for about ten seconds for priming.

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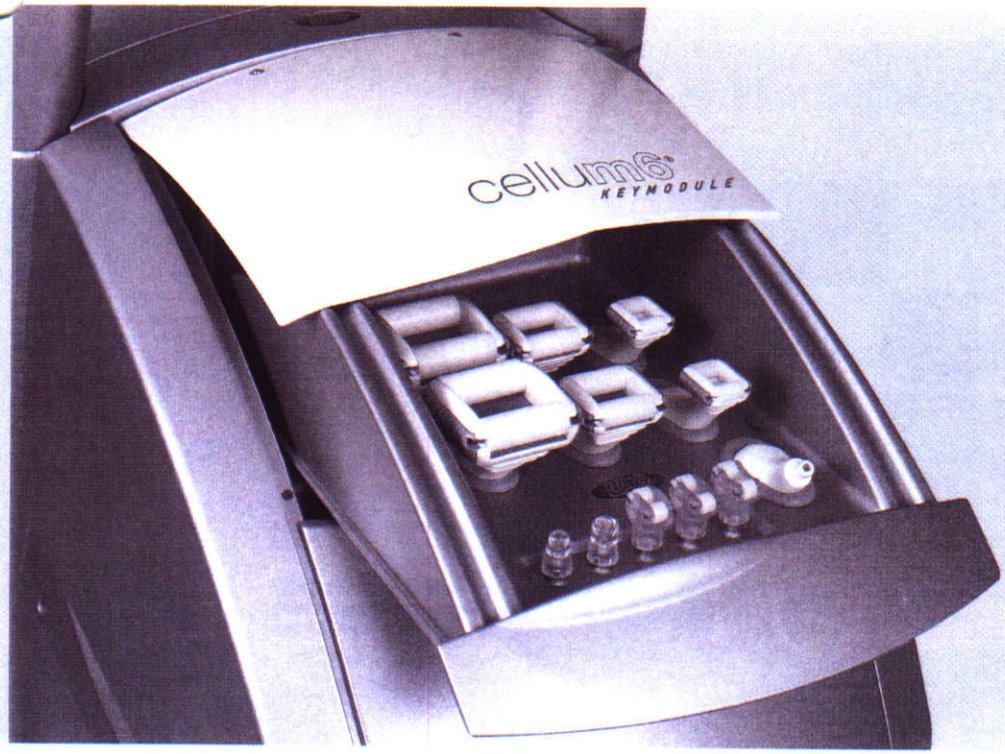
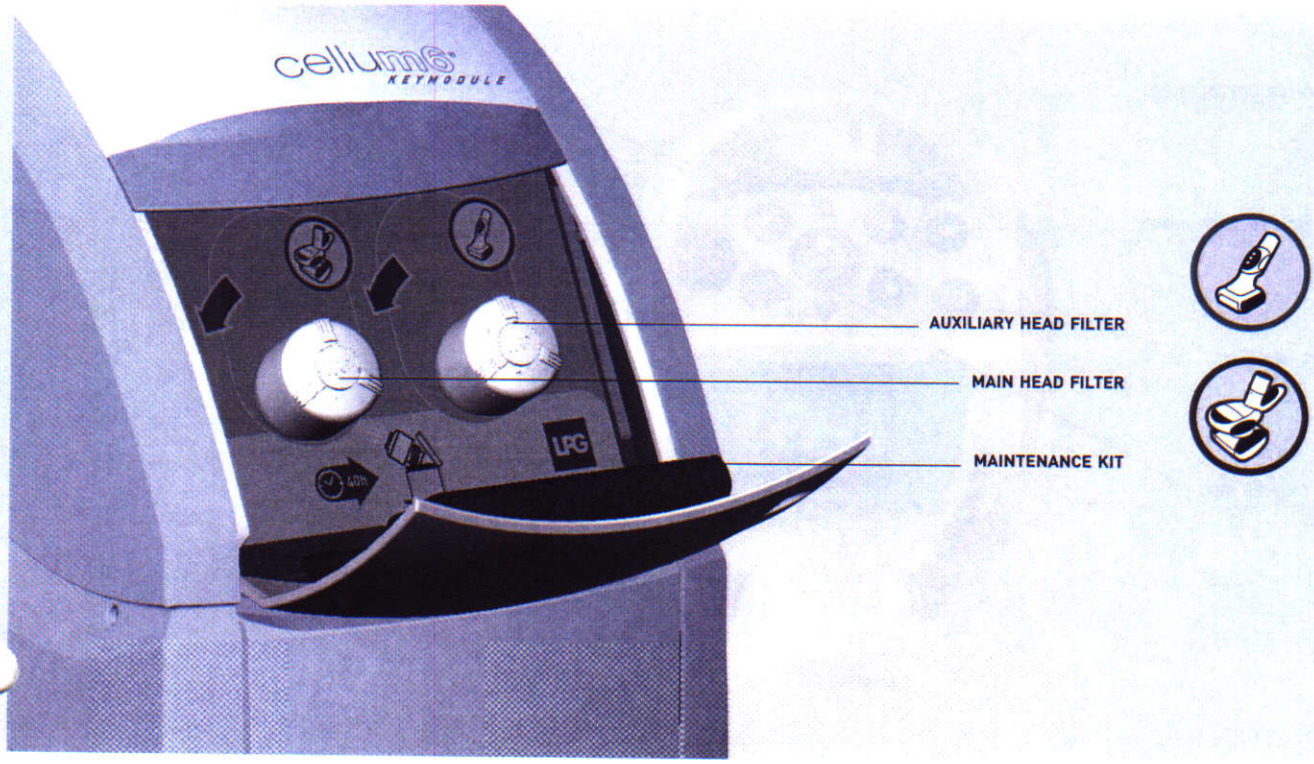
Drawer for storing the series 600 auxiliary heads



Access to the filters



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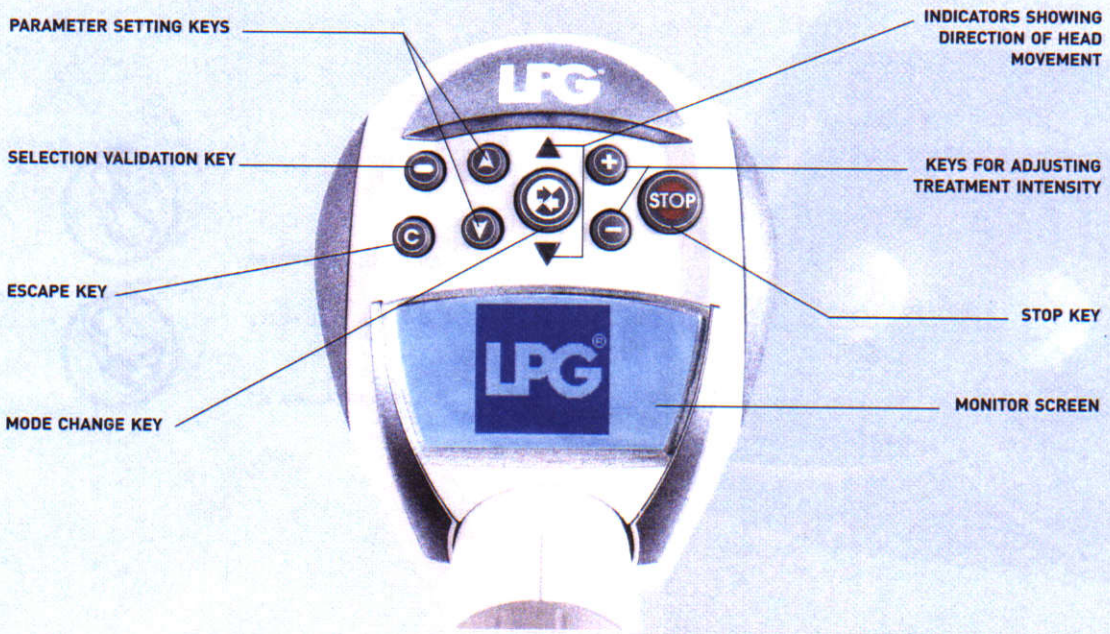
Control panel

Main head



904

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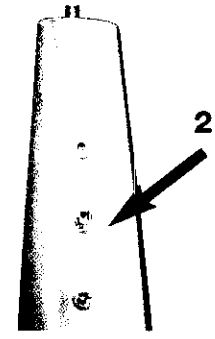
Adjusting the articulating arm rods

It is possible to personalize the position of the 2 articulating arm rods (depending on size and working position of the operator) so as to obtain even greater freedom of movement.

- Remove the hose from its housing on the articulating arm rod by pulling on the self-grip collar (**1**)
- Loosen the locking screws using the large hexagonal spanner (**2**)
- Adjust the rod to the length required position (**3**)
  (recommended length L=10 to 20 mm)
- Retighten the screw (**2**)
- Repeat the same operation for the second arm



Fully unwind the electrical cable from its support, to ensure good ventilation of the unit.

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Precautions

- Check that the supply voltage of the unit indicated on the data plate complies with the mains voltage.
- The unit must be connected to a grounded outlet in accordance with current electrical standards.
- Never use the unit on a dusty, uneven floor, or in a moist atmosphere.
- Check that the inlet to the ventilation circuit is always unobstructed.
- Avoid operating the unit in a room where the ambient temperature exceeds 40°C.
- Fully unwind the electrical cable from its support to ensure good ventilation of the unit.
- Switch the unit off if it is not going to be used for a long period.
- Do not allow solid debris or liquid to be sucked into the unit, as these could cause damage.
- Never use the auxiliary adapter as a treatment head or allow it to come into direct contact with the skin.
- Do not use the main head to carry out treatment of the scalp.
- Only use the treatment heads supplied with your unit or recommended by LPG.
- Only use LPG One treatment garments.
- Never use the unit for purposes other than those recommended by LPG One.
- LPG One will not be liable for any inappropriate use of the equipment.
- With respect to treated tissue, some parameters may cause pain or tissue lesions. The operator must be particularly attentive to the sensations felt by the person undergoing treatment when :
  - the intensity is greater than 4 in continuous or sequential mode (for frequencies less than 4 Hz).
  - the system has changed to reverse mode (rollers rotating in opposite direction).
- The operator must ensure that the parameters (intensity, sequentiality, differential, ...) are always adapted to the cutaneous tissue being treated.

Where the unit has not been used for a long time, it is possible that marks may form on the ground where the wheels are. This phenomenon is the result of a chemical reaction between the components of some floorings and those of the wheels of the Cellu M6® Kevmodule i.

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Contra-indications

- Do not treat open wounds, the eyes, intra-cavity areas, mucous membranes, the genitals and breasts.
- In the event of pregnancy, do not treat the lumbar-abdominal region. Consult with the doctor with regard to this treatment.
- Do not treat a patient with an infectious disease, a growing tumour, phlebitis etc....
- Consult with the doctor where the subject has a case history of tumours or is in remission.
- Do not treat any swollen or inflammed areas without seeking medical advice and without training in the LPG® technique in this particular area.
- Do not treat a patient suffering from inexplicable and persistent pain without seeking medical advice and without training in the LPG® technique in this particular area.
- Do not treat a patient following invasive medical treatment, without seeking the medical advice of the doctor or surgeon who performed this operation and without training in the LPG® technique in this particular area.

As this list is not exhaustive, always seek out medical advice in the event of doubt.

This unit contains programs to help the operator obtain the best anticipated results for each case undergoing treatment. Under no circumstances may these programs be construed as a guarantee of successful treatment, which varies, depending on the morphology, physiology and eating behavior of each patient.

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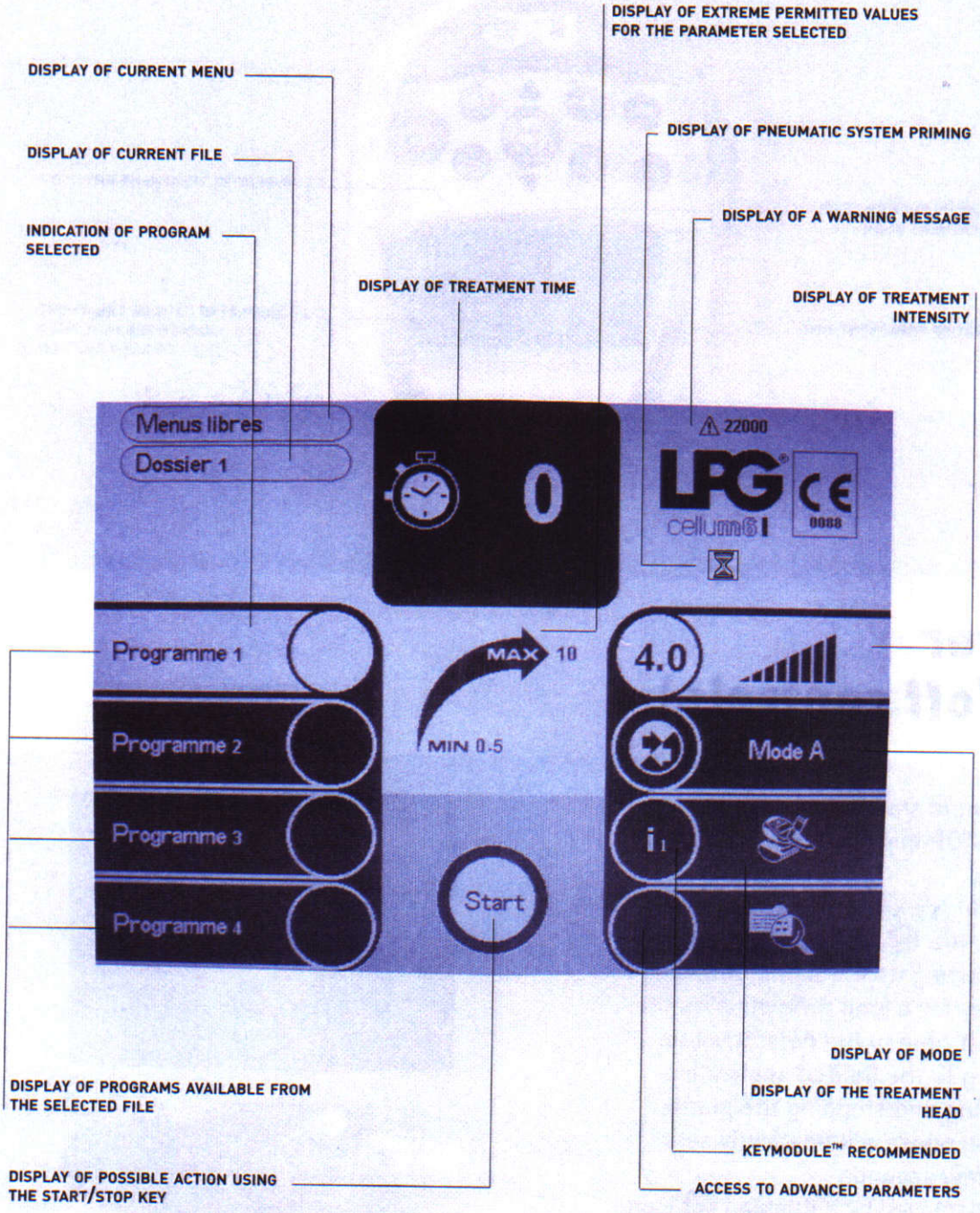
Monitor screen



The parameter selected is a reverse video.

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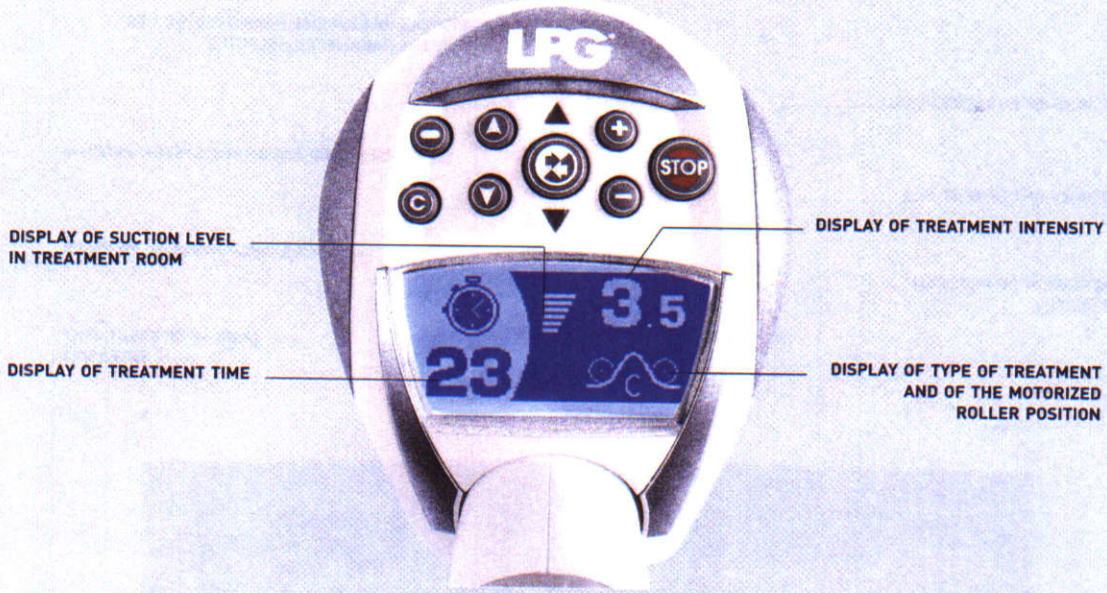
Main head screen



Power (on/off controls)

Treatment is started by pressing the START/STOP key once the icon is displayed.
Treatment is stopped by pressing the same key once the icon is displayed.
When starting up the pump, pressing the VALID key for a long time initiates the treatment time to the default value, according to the field of application.
On starting and stopping the pump, a priming phase automatically sets in for a few seconds.
This is displayed by a flashing icon or by simultaneous audible beeps. The user can proceed with no action during this period.

The unit can only be started when it is switched on. If the equipment is not used, it will automatically go to standby mode after 3 minutes. Press any key on the control panel to reactivate the unit.

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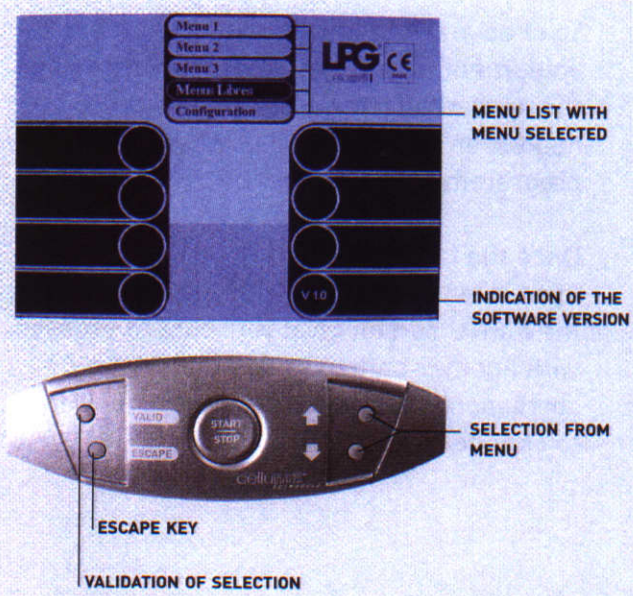
Menu screen

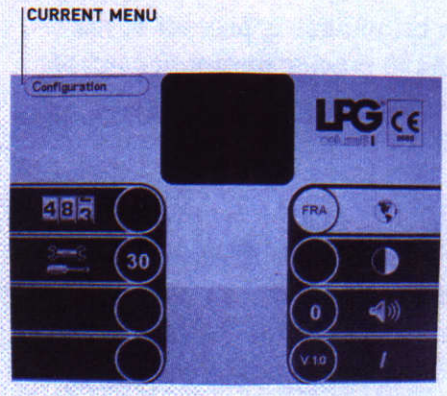
Use the navigation keys to select the required menu and reverse contrast, then confirm your choice by pressing the VALID key.

Use the ESCAPE key in the event of error or to exit from a menu.



Configuration screen

The CONFIGURATION menu will allow you to select the language of use, adjust the contrast, select and adjust the keyboard beep and to consult the TIME METER and other maintenance functions.



A menu is selected when it is in reverse video.

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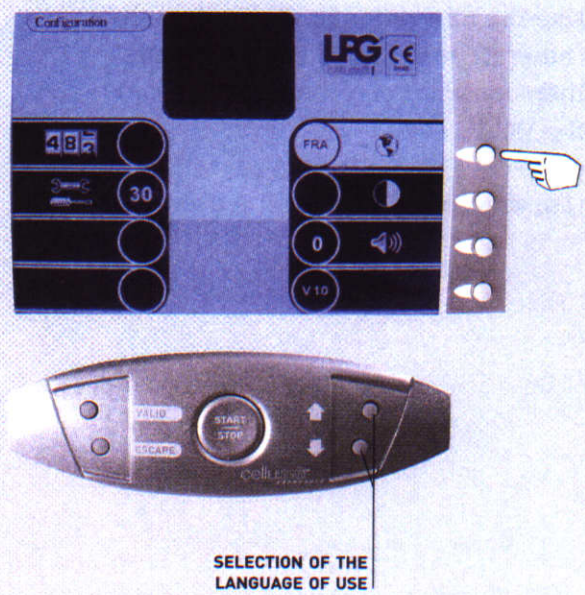
Language selection

To choose the language of use for your equipment, select the icon by pressing the appropriate key and then use the nagivation keys to scroll down the various programmed languages.

Once the language of use has been decided upon, press the ESCAPE key to return to the MENU screen or, if you want to proceed with another setting, press the key corresponding to the parameter you wish to change.



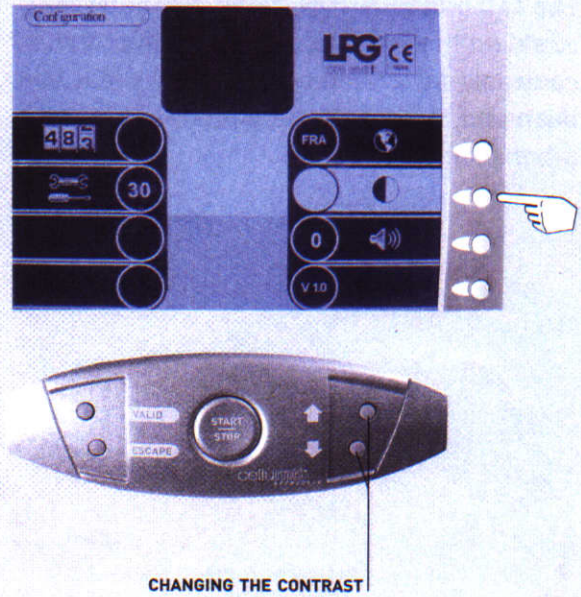
SELECTION OF THE LANGUAGE OF USE

Adjusting the screen contrast

The screen brightness is pre-set at the factory so as to provide optimum contrast for an ambient temperature of 22°C. However, this parameter may be changed.

To adjust the screen contrast from the control panel, select the icon by pressing the appropriate key and then use the navigation keys to change the contrast.

Once the contrast has been adjusted, press the ESCAPE key to return to the MENU screen or, if you want to proceed with another adjustment, press the key corresponding to the parameter you want to change.



CHANGING THE CONTRAST

Sudden changes in temperature will affect the screen contrast. In such cases, wait for the brightness to stabilize before proceeding with any adjustment.

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Selection/adjustment of the keyboard beep and control panel

Each time one of the keys of the control panel of your Cellu M6® Keymodule *i* is pressed, a beep will sound. The volume and pitch can be adjusted.

Adjusting the keyboard beep volume:

This adjustment is made via the CONFIGURATION screen. Select the icon by pressing the appropriate key and by using the navigation keys to adjust the keyboard beep volume:

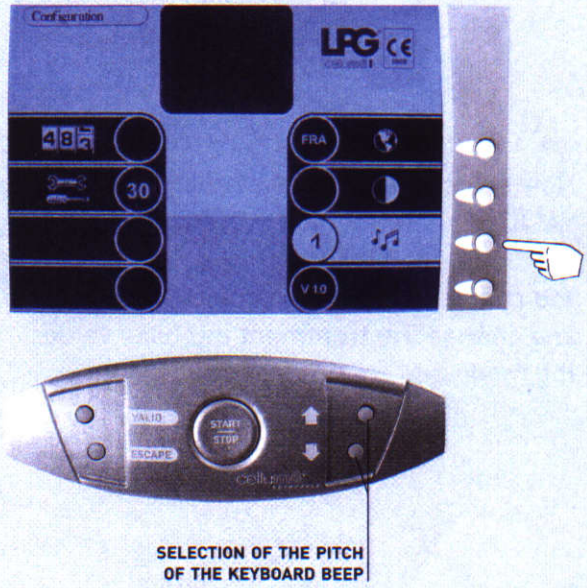
- 0: silent
- 1: weak
- 2: average
- 3: loud

ADJUSTING THE KEYBOARD BEEP VOLUME

Selecting the keyboard beep pitch:

This selection is made via the CONFIGURATION screen. Select the icon by pressing the appropriate key and by using the navigation keys to change the pitch of the keyboard beep:

- 1: a high pitch
- 2: medium pitch
- 3: low pitch



SELECTION OF THE PITCH OF THE KEYBOARD BEEP

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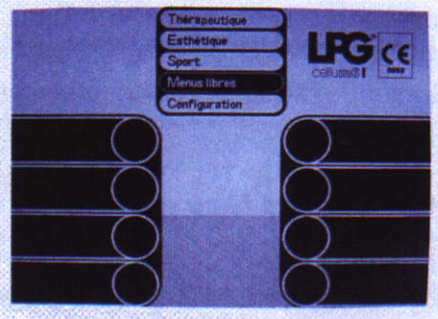
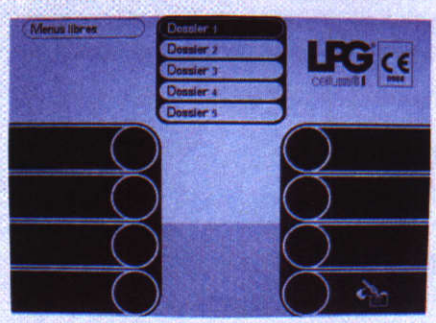
Selecting a program

When you are at the root menu, you can select from the areas of aesthetics, therapeutics or sport.

At any time during program selection, you can return to the previous menu by pressing ESCAPE.

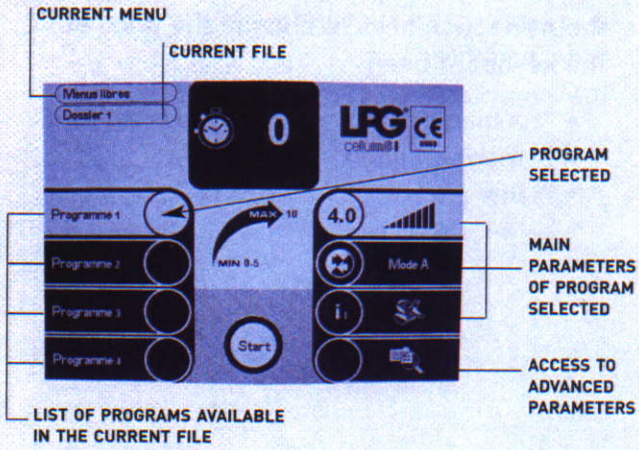
Select the appropriate area and then press VALID. You will now access the FILES.





Now select the appropriate FILE by pressing VALID. You now get to PROGRAM MENU.

You can now select the program you require and change the treatment intensity values, the mode and treatment head.



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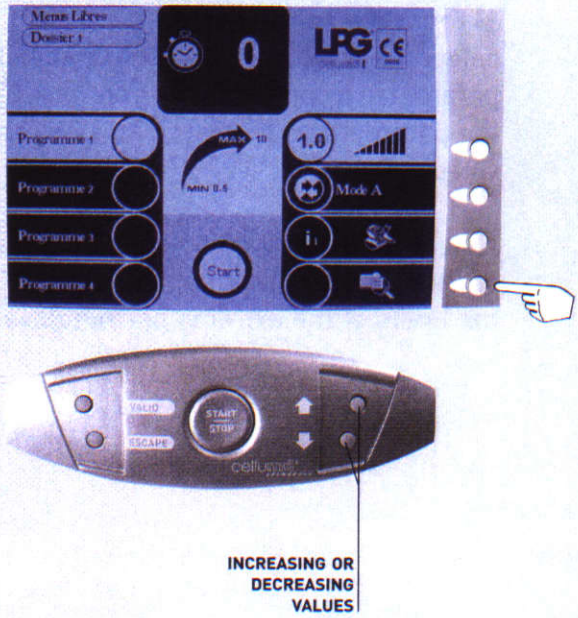
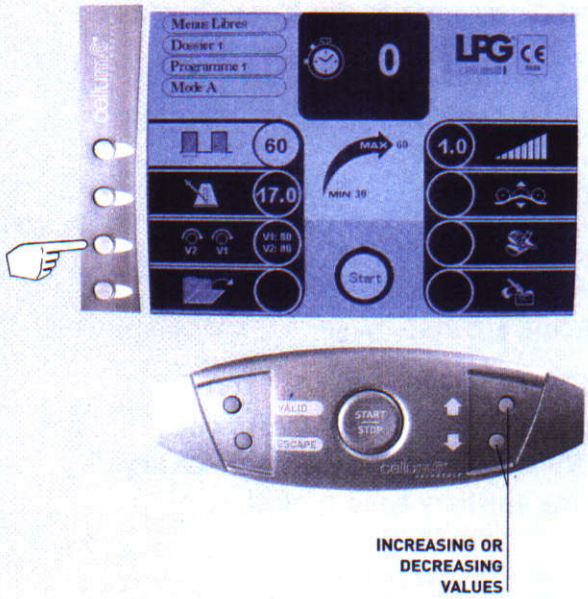
Selecting a program

Once you are in the program, you can gain access to the advanced parameters to see the pre-programmed parameter values by clicking on the icon. Increase or decrease the values using the arrows. The screen will tell you if you are in continuous or sequential mode via the icon.



You can also have access to the roller parameters (differential with respect to direction and speed) in order to amend the other parameters in the same way.

Press Start/Stop to start the treatment.



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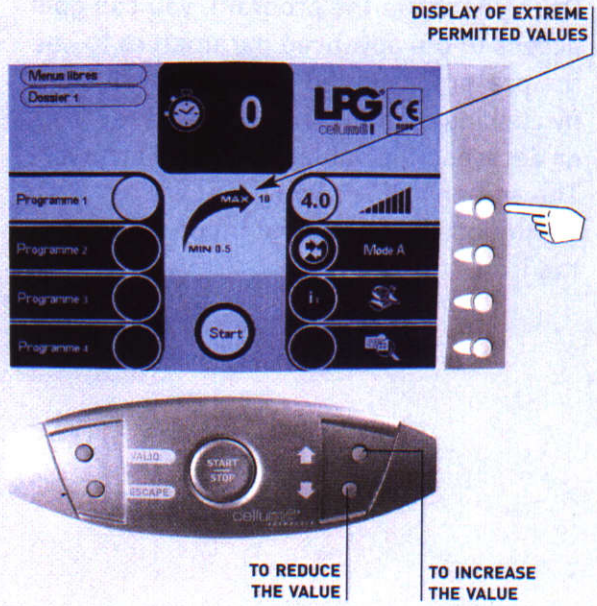
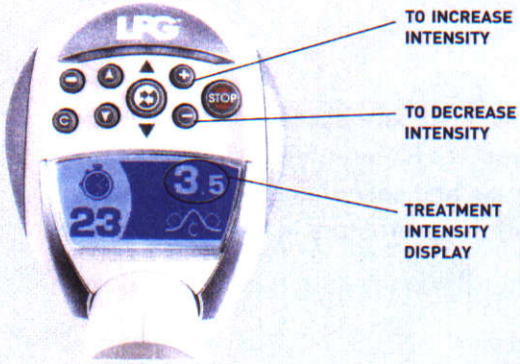
Adjusting the treatment intensity

1) From the control panel,
select the treatment INTENSITY adjustment parameter by pressing the appropriate key; the parameter is displayed as a reverse video.

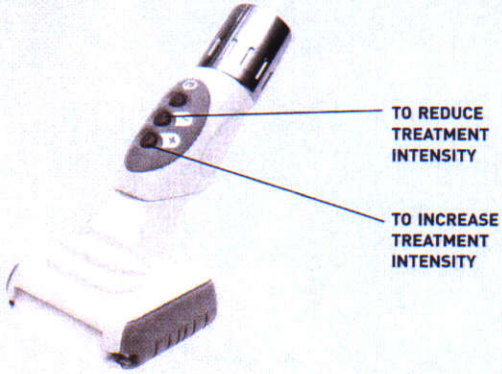
Now use the navigation keys to increase or decrease the treatment INTENSITY within the limits of the extreme permitted values.



2) From the main head,
set or adjust the required treatment INTENSITY by pressing the ⊕ or ⊖ keys.



3) From the auxiliary head,
set or adjust the required treatment INTENSITY by pressing the ⊕ or ⊖ keys from the auxiliary head control.



The treatment intensity selected is continuously checked by an electronic vacuum sensor. However, too high a treatment intensity or a badly adjusted treatment intensity may lead to pain and traumatize the cutaneous tissue, thereby encouraging the onset of bruising.

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Selecting continuous or sequential treatment

ONLY FROM A FREE MENU

You can select the type of treatment (CONTINUOUS or SEQUENTIAL) you require from all the programs in the FREE MENU.

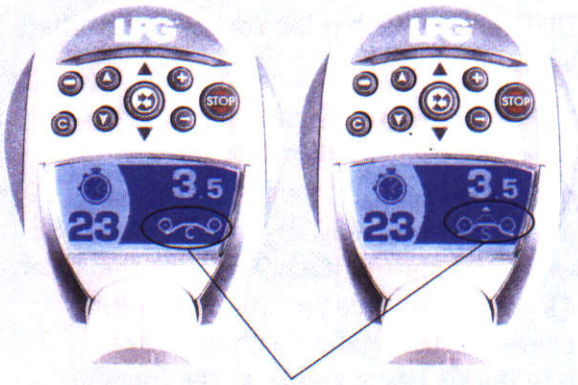
CONTINUOUS TYPE TREATMENT

To do this, go to the ADVANCED PARAMETERS screen of the FREE PROGRAM you selected and successively press the key, corresponding to the type of treatment.

SEQUENTIAL TYPE TREATMENT

At all times, the type of treatment you programmed will be displayed on the screen of the main head.

When you use a PARAMETERIZED PROGRAM, the type of treatment is defined by the program and cannot be changed; however, the screen of the main head will inform you of the type of treatment.



DISPLAY OF TYPE OF TREATMENT

If you work with continuous suction, the sequence-forming parameters (cycle and frequency ratio) will not be accessible.

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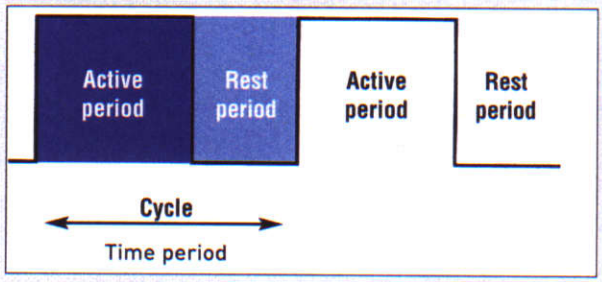
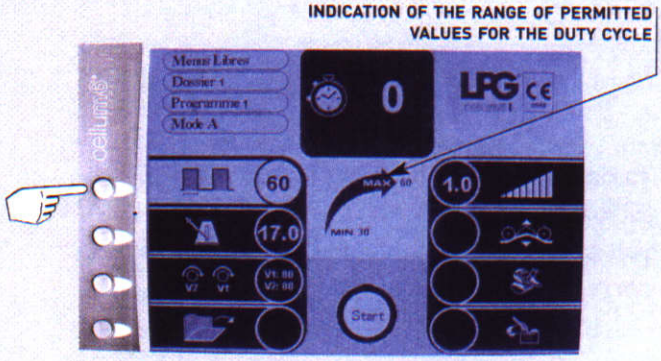
Setting the duty cycle

FOR SEQUENTIAL TYPE TREATMENT ONLY

The sequential mode can be compared with the throbbing of a tissular seizure; this throbbing is characterized by two parameters – frequency and the duty cycle. The frequency corresponds to the number of beats over a given period of time (cycle). The duty cycle corresponds to a time of activity over a given period of time (cycle). The sequentiality can therefore be shown as follows:
When setting the frequency, the cycle time is increased or decreased. When setting the duty cycle, the phase of activity over one cycle is increased or decreased.



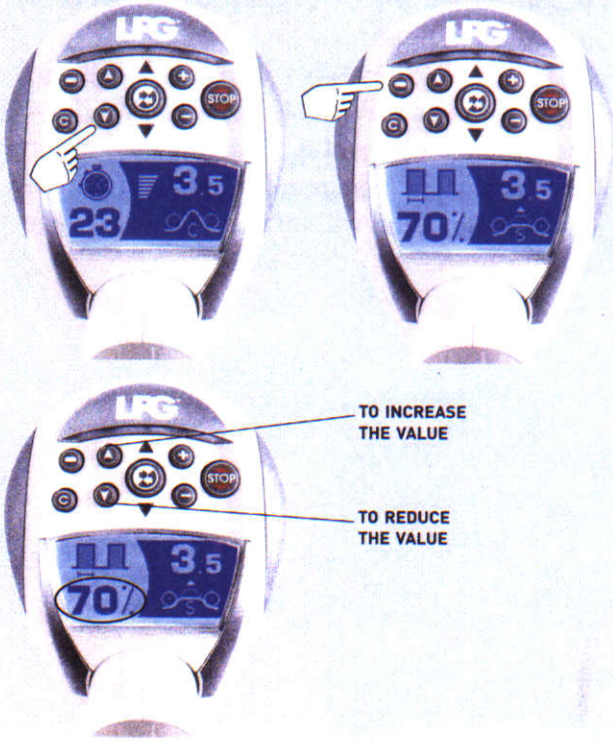


1) From the control panel,

to proceed with setting the DUTY CYCLE, first go into ADVANCED PARAMETERS of the program selected. To do this, press the KEY corresponding to ADVANCED PARAMETERS. Now select the DUTY CYCLE parameter by pressing the corresponding key.
Then use the nagivation keys to adjust the DUTY CYCLE within the range of permitted values.

2) From the main head,

press a ▼ key to display the value of the DUTY CYCLE parameter. Validate by pressing the ⊖ key, and the DUTY CYCLE value will start to flash. Now use the ▲ or ▼ keys to set this parameter to your convenience. Validate with the ⊖ key. Use the C key to return to the monitor screen.



! *Certain value combinations between the duty cycle and the frequency are invalid. This is to prevent improper treatment configurations.*

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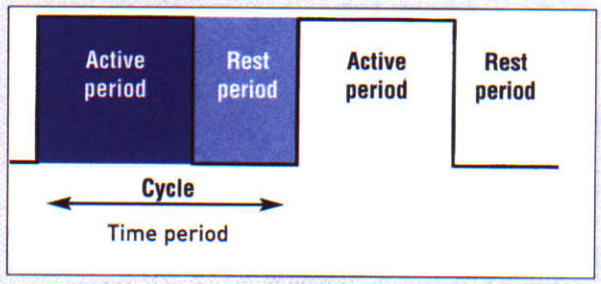
Setting the frequency

FOR SEQUENTIAL TYPE TREATMENT ONLY

The sequential mode can be compared with the throbbing of a tissular seizure; this throbbing is characterized by two parameters – frequency and the duty cycle. The frequency corresponds to the number of beats over a given period of time (cycle). The duty cycle corresponds to a time of activity over a given period of time (cycle).
The sequentiality can therefore be shown as follows:

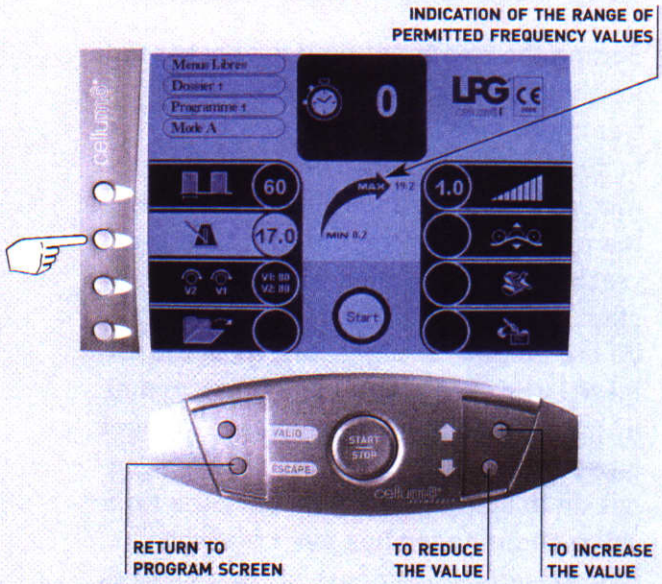
- when setting the frequency, the cycle time is increased or decreased
- when setting the duty cycle, the phase of activity over one cycle is increased or decreased.



1) From the control panel,
to proceed with setting the FREQUENCY, first go into ADVANCED PARAMETERS of the program selected. To do this, press the KEY corresponding to ADVANCED PARAMETERS.

Now select the FREQUENCY parameter by pressing on the corresponding key.

Then use the nagivation keys to adjust the FREQUENCY within the range of permitted values.



Certain value combinations between the duty cycle and the frequency are impossible. This is to prevent absurd treatment configurations.

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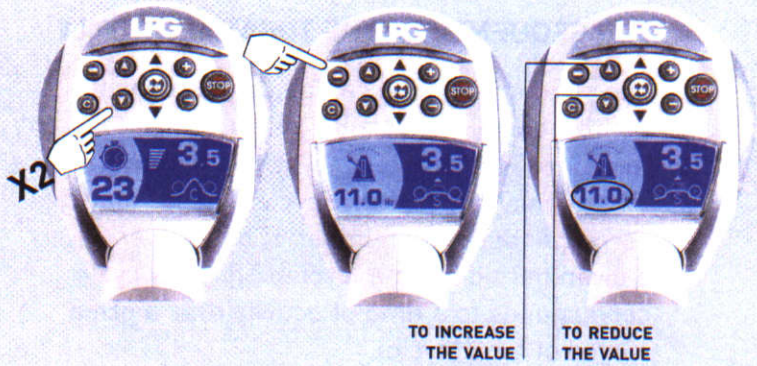
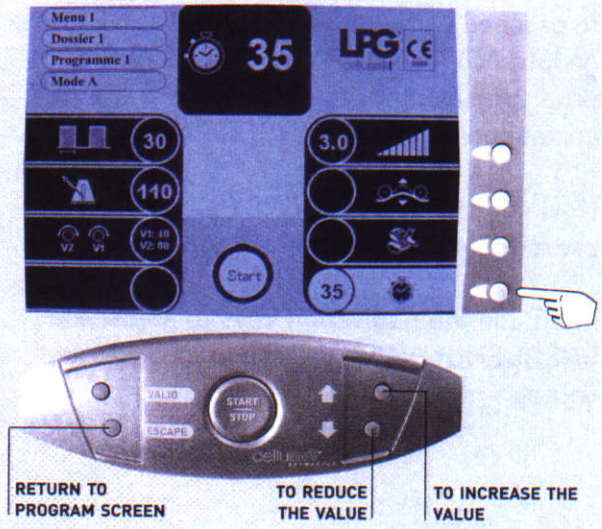
Setting the frequency

2) From the main head,
press a key twice in succession to display the value of the FREQUENCY parameter.
Validate by pressing the key , and the FREQUENCY value will start to flash. Now use the and keys to set this parameter to your convenience.
Validate with the key.
Use the key to return to the monitor screen.



Setting the treatment time

Setting the treatment time is only possible for those programs already offering a treatment time.
In such cases, time starts to decrease, minute by minute and at all times shows the remaining treatment time; once the time reaches 0, the machine will automatically stop.
Where no time is suggested, as in the FREE MENU, the time starts to increase minute by minute and at all times shows the time lapsed since the start of the session; you decide to stop the machine once the time you recommended has been reached.
It is consequently impossible and useless to proceed with any modification to this parameter.
In order to set the treatment TIME, first go the ADVANCED PARAMETERS of the program selected. To do this, press the key corresponding to the ADVANCED PARAMETERS.



Select the treatment TIME by pressing the appropriate key and use the navigation keys to increase or decrease the treatment TIME from 0 to 99 minutes.
A short press corresponds to one minute.
A long press corresponds to ten minutes.

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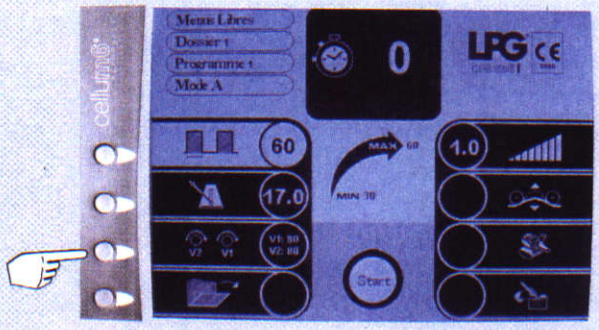
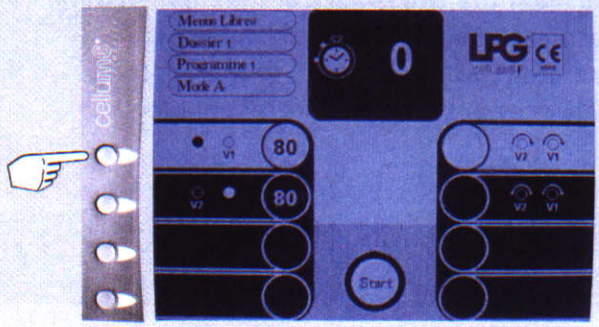
Setting the speed and direction of rotation of the rollers of the main head

The ROLLER SPEED AND DIRECTION OF ROTATION of the main head can be adjusted independently for each of the two rollers.
To proceed with adjusting these parameters, go to ADVANCED PARAMETERS. To do this, press the key corresponding to ADVANCED PARAMETERS.

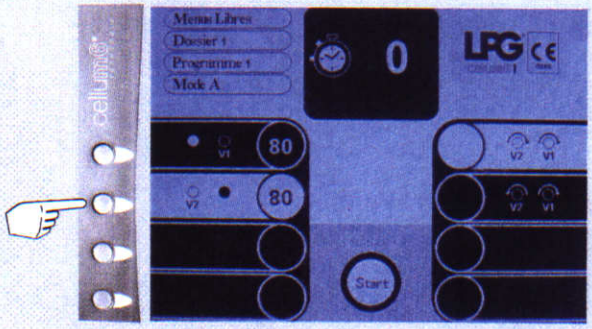


Then select the ROLLER SPEED AND DIRECTION OF ROTATION parameter by pressing the corresponding key.



Select the parameter for adjusting the front roller V1 (in relation to the direction of head movement), by pressing the corresponding key.
Set the speed of rotation of roller V1 from 0 to 100% by using the navigation keys.
The settings go in 10s.

Select the parameter for adjusting the rear roller V2 (in relation to the direction of head movement), by pressing the corresponding key.
Set the speed of rotation of roller V2 from 0 to 100% by using the navigation keys.
The settings go in 10s.



Warning: Setting the roller speed is only possible if the main head is selected.

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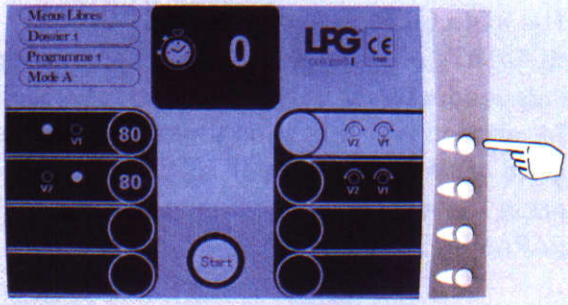
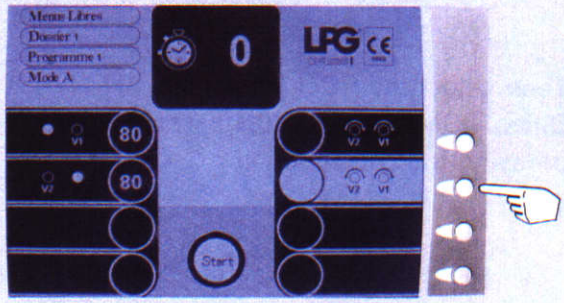
Setting the speed and direction of rotation of the rollers of the main head

If you want the two rollers of the main head to turn in the same direction, select parameter V1 and V2 to run in the same direction by pressing the corresponding key.



If you want the two rollers of the main head to turn in the opposite direction, select parameter V1 and V2 to run in the opposite direction by pressing the corresponding key.



Selecting the treatment mode

For some programs, the Cellu M6® Keymodule ***i*** offers you the option to select from two treatment modes, which entails different settings of certain parameters, for the same program.

1) From the control panel,
Successively press the selection key corresponding to the mode, so that you can change from one mode to the other.

Ensure that the parameters are always adapted to the cutaneous tissue undergoing treatment.

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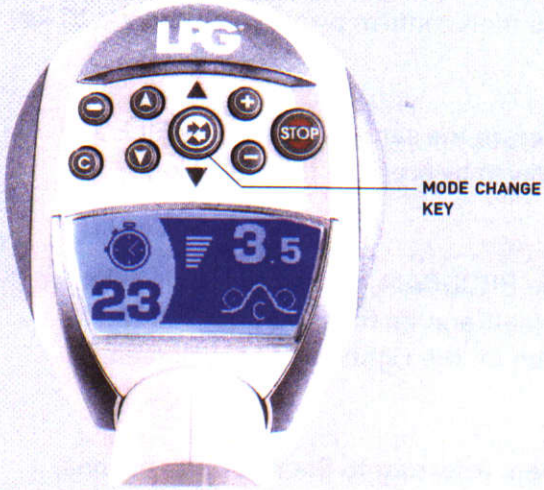
Selecting the treatment mode

2) From the main head, use the central key to go from one mode to the other.



Selecting the type of treatment head

The choice governing the type of head is based on the treatment to be carried out and the type of area being treated.

Select the type of head required by successively pressing the appropriate selection key.

Direct selection by pressing a key of the selected head when suction is not efficient.

Comment: when the auxiliary head type is selected, it is not possible to access *"setting the roller speed and direction of rotation"* for the main head.

SELECTING THE MAIN HEAD

SELECTING THE AUXILIARY HEAD

! *Never proceed with this setting when the treatment head is in contact with the cutaneous tissue.*

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Programming a free menu

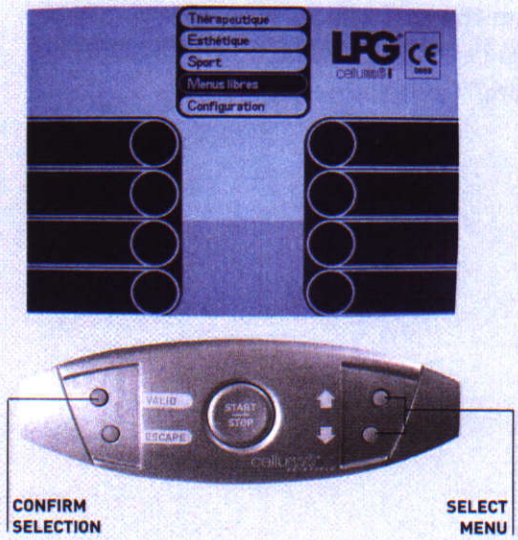
Select a MENU by using the navigation keys and then confirm by pressing the VALID key.

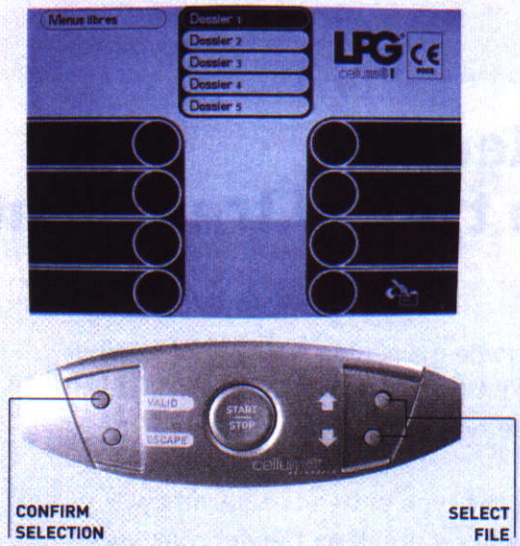
Then, in the same way, select a FILE and confirm by pressing the VALID key.

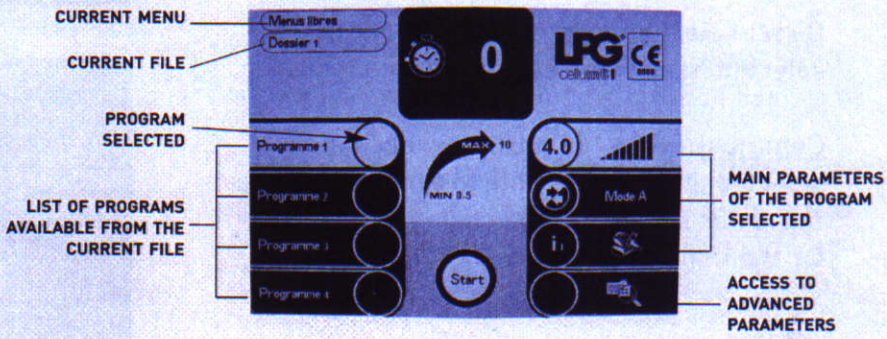
The PROGRAM, at the top left, is selected by default and its main parameters can be seen on the right side of the screen.

Then, referring to the relevant sections, set the different parameters of the selected PROGRAM :

- Treatment intensity
- Duty cycle (for sequential type treatment)
- Frequency (for sequential type treatment)
- Motorized roller speed and direction of rotation (for treatment with the main head)







Each program contains adjustments specific to a treatment, originating from our research and assessment center. However, the parameters that characterize these programs may be modified at any time during treatment by the operator. Once the unit is shut down or the program window comes on, all these settings will

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Creating a free program based on a parameterized program

This function allows you to create a FREE PROGRAM on the basis of a PARAMETERIZED PROGRAM.
From the ADVANCED PARAMETERS screen of a FREE PROGRAM, select the icon by pressing the relevant key.

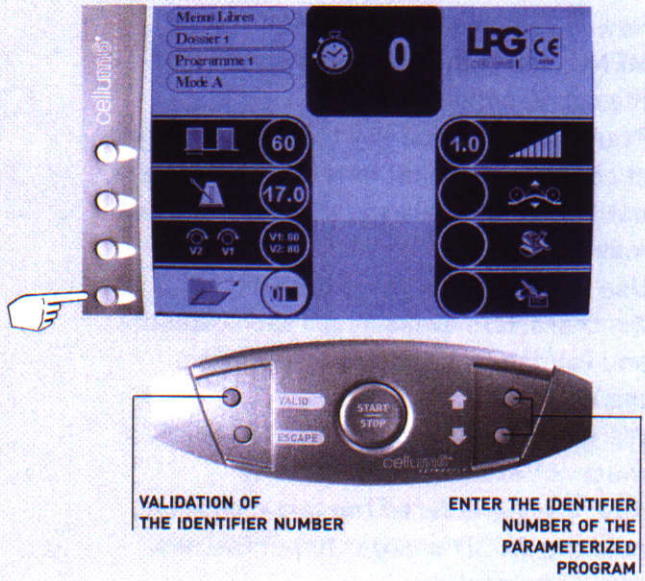
Now go to the PROGRAM LIST in order to identify the program number to recall the parameters.

Use the navigation keys to enter the number you identified and then validate. The parameters of your FREE PROGRAM are now copied to the PARAMETERIZED PROGRAM you selected. Now finalize your FREE PROGRAM by adapting the various treatment parameters you want to carry out.

Make sure that the parameters of your program are adapted to the cutaneous tissue undergoing treatment.

Programming and the use of a free menu is at the operator's option and is his responsibility alone.

Refer to the precautions and contra-indications on pages 10 and 11.



The adjustments made to the free program parameters are automatically stored and can be reused at a later stage.

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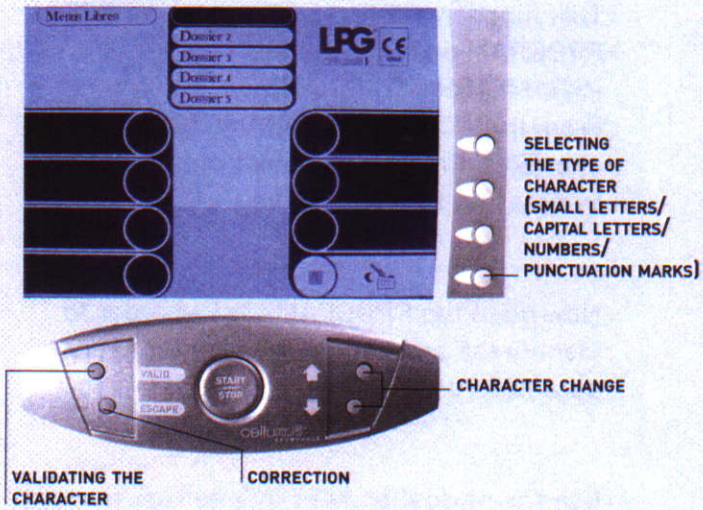
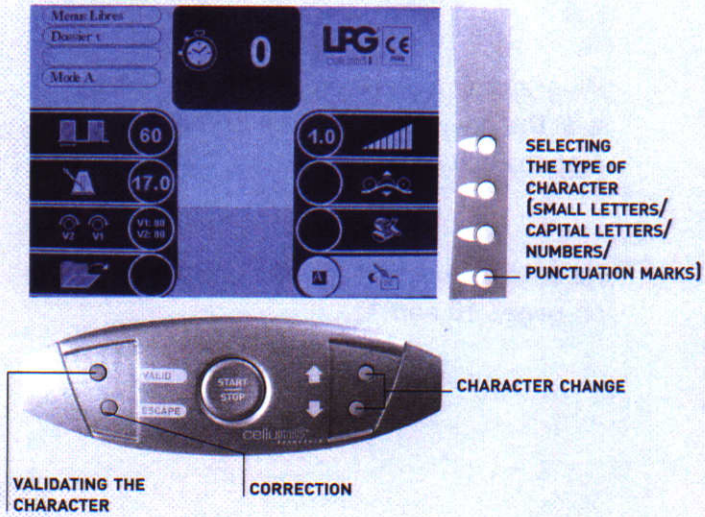
Personalization of file names from the free menu

Having selected a FILE from the FREE MENU, select the icon by pressing the corresponding key.
Press the selection key to choose the type of character (capital letters, small letters, number or punctuation marks) which will make up the new name of your FILE.
Use the navigation keys to scroll the characters available for each category and validate your choice by pressing the VALID key.
Warning: The name you give to your FILE must not exceed 16 characters.
After having entered the last character, hold the VALID in order to put the new name into service.



Personalization of program names from the free menu

After selecting a PROGRAM from the FREE MENU, select the icon by pressing the relevant key.
Press the select key to choose the type of character (capital letters, small letters, numbers or punctuation marks) which will make up the new name of your PROGRAM.
Use the navigation keys to scroll the characters available for each category and validate your choice by pressing the VALID key.
Warning: The name you give to your PROGRAM must not exceed 16 characters.
After having entered the last character, hold the VALID in order to put the new name into service.



This function is only possible in free menu

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MAINTENANCE FILE . . . . . .P. 40

ALL THE MAINTENANCE OPERATIONS DESCRIBED IN THIS SECTION MUST BE CARRIED OUT WITH THE UNIT SWITCHED OFF AND THE POWER CABLE DISCONNECTED.

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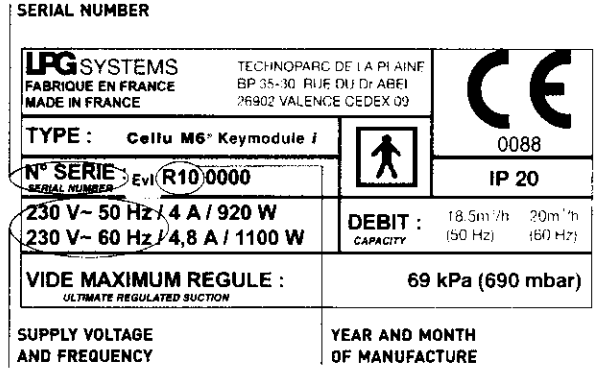
Identification rating plate

Your unit is identified by a serial number shown on the rating plate.
The rating plate also shows the permitted supply voltage for the unit.

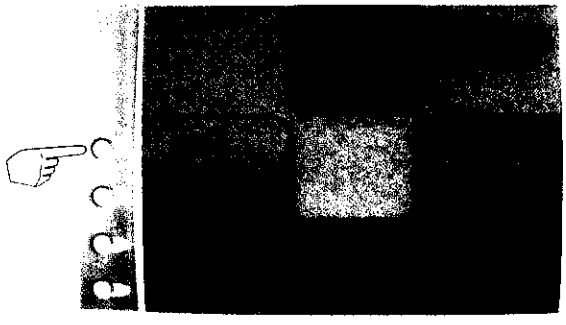
When you contact LPG One Customer Service because of a technical problem, please indicate the serial number of your Cellu M6® Keymodule *i*.
The letter indicates the year of manufacture:
R = 2001, S = 2002, T = 2003, U = 2004...
while the two figures indicate the month of production :
01 = January, 02 = February, 03 = March...



Time meters

Your unit comprises several TIME METERS that total the operating hours of the various units for periodic maintenance purposes.
These meters can be seen at control panel level, from the CONFIGURATION screen and MAIN HEAD screen.
Access the TIME METERS by pressing the key relating to the icon.

FROM THE CONTROL PANEL



The identification rating plate is located on the bottom, behind the unit.

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Time meters

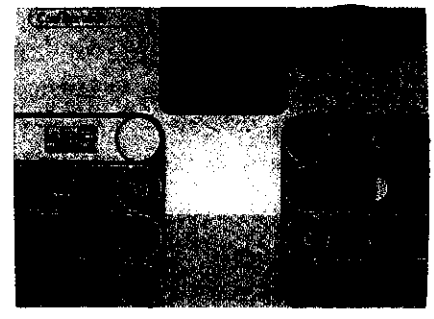
CHM: Machine Time Meter that totals the number of hours your machine has been operating.

CHTP: Main Head filter Time Meter totals the number of hours the main head has been operating.

CHTA: Auxiliary Head filter Time Meter totals the number of hours the auxiliary head has been operating.

CUT: Main Head Unit Meter totals the number of hours the main head has been operating.

CUS: Keymodule™ Unit Meter totals the number of hours the Keymodule™ connected to the main head has been operating.



To display the TIME METERS of the main head, go to the MAINTENANCE MENU of the main head by pressing the key twice in succession .

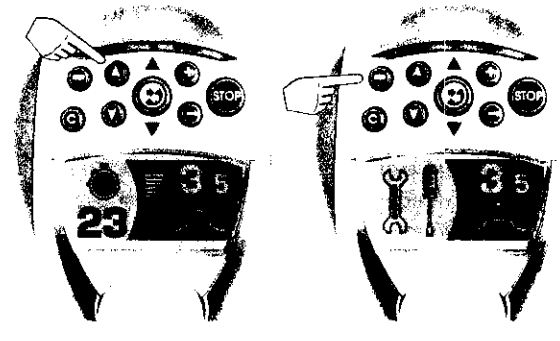
From the MAINTENANCE MENU, one press on the key will display the TIME METERS of the main head.

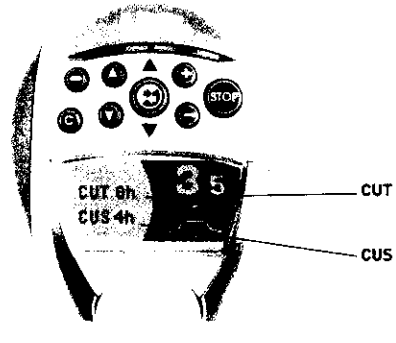
CUT: Main Head Unit Meter totals the number of hours the body of the main head has been operating.

CUS: Keymodule™ Unit Meter totals the number of hours the Keymodule™ of the main head has been operating.

Press the key twice in succession to return to the monitor screen.

FROM THE MAIN HEAD





For further information, please see pages 34 and 35 (Replacing filter cartridges).

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Cleaning the unit

We recommend that you clean your unit as often as possible, not only for reasons of hygiene and aesthetics but also because cleaning the unit will help keep it in a good state of repair and extend its life.

Using a vacuum cleaner with fine nozzle, clean the following sections:

- The inside of the access drawer to the auxiliary heads, (having already removed all the auxiliary heads),
- The inside of the access door to the filters.

Using a moist sponge, clean the following sections:

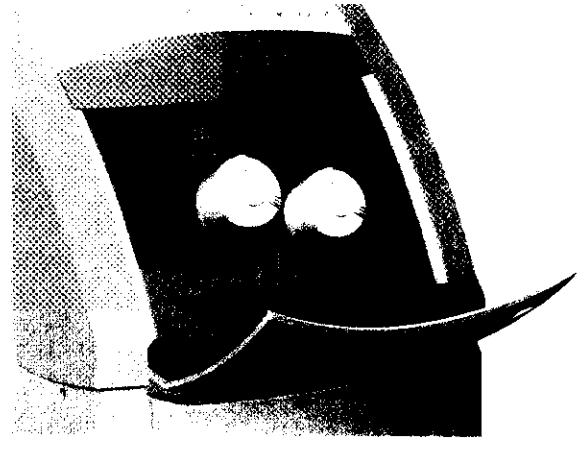
- All the external hoods,
- Hoses,
- The power cable.

Using a cloth soaked with a little domestic cleaning product not containing alcohol, clean the following sections:

- Monitor screen and control panel,
- The inside of the access drawer to the auxiliary heads,
- The inside of the access door to the filters.

Replacing filter cartridges

Your unit accommodates 2 filters. One is for filtering the circuit of the main head while the other filters the circuit of the auxiliary heads. The filter cartridge guarantees the efficiency of your unit and extends its useful life. Remember to change the cartridge every forty hours.



Do not use aggressive products, such as acetone, trichloroethylene or alcohol at 90°, or abrasive sponges.

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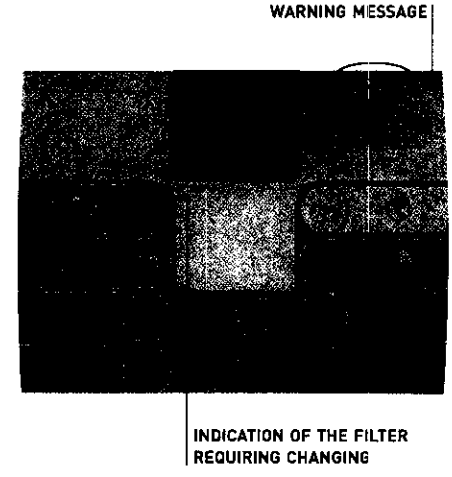
Replacing filter cartridges

Replacement of filter cartridges:
If a filter change request occurs, a warning message is displayed at the top right of the CONTROL screen of the control panel and an icon showing the filter that requires changing appears in the CONFIGURATION screen. This happens each time the pump shuts down until the filter change has been acknowledged.



1 = Main head filter (warning message number: 22000)

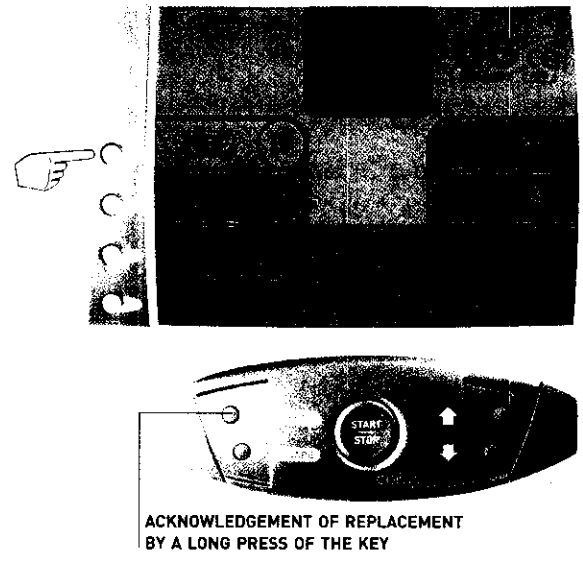
2 = Auxiliary head filter (warning message number: 22001)

Open the filter access hood. Unscrew the filter cartridge and replace with a new one.

Once the cartridge is in place, validate the operation by selecting the icon representing the filter you have just changed, by pressing the appropriate key and hold the VALID.

To confirm replacement, the icon depicting the filter disappears.

Remember to purchase new cartridge filters from LPG One Customer Service, so that you always have a spare on hand.



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Never use your unit without LPG® filter cartridges.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Replacing fuses

Your unit is protected against short-circuits by 2 ceramic 6.3 mm x 32 mm time-delay fuses.

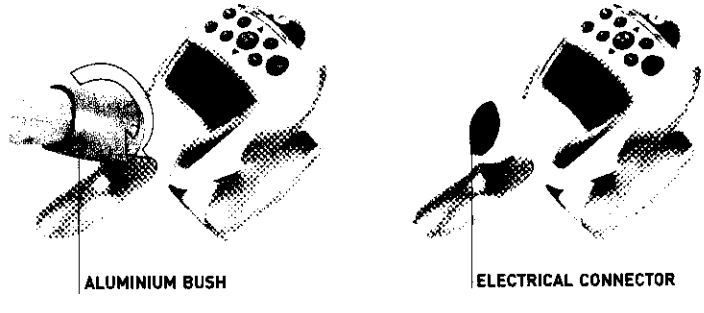
Fuse replacement:

- Disconnect the supply cable from the mains.
- Loosen one of the 2 fuse holders.
- Remove the fuse.
- Repeat the same operation for the second fuse holder.
- Replace with the fuses supplied in the maintenance kit.

Remember to purchase new fuses from LPG One Customer Service, so that you always have a spare on hand.

Instructions for disconnecting the treatment heads

Because of its rapid-fit twist connection, the main treatment head can easily be disconnected from its hose by loosening the aluminium connection bush.



To connect the head, take hold of the hose and proceed with its electrical connection and then screw tight by tightening the aluminium bush.

If fuses with the incorrect rating are used, this could result in damage to the entire electrical system. See page 43 concerning the identification of fuse ratings to be used

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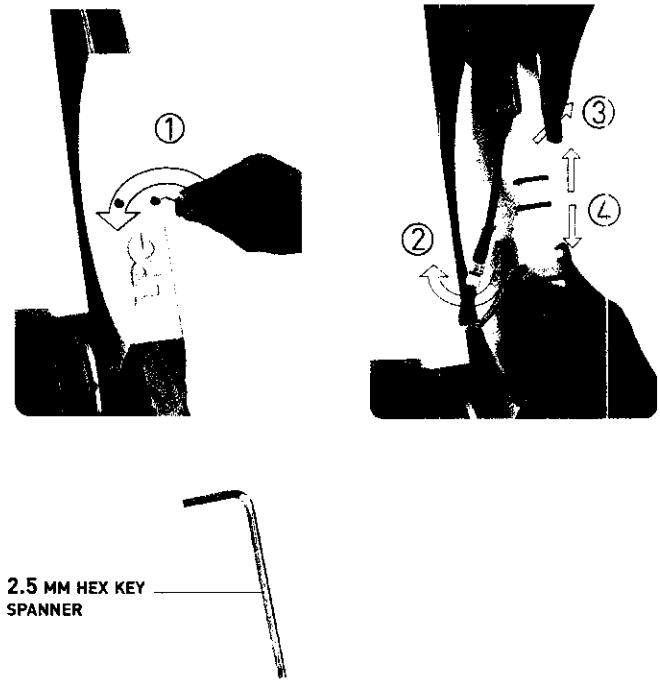
Instructions for disconnecting the treatment heads

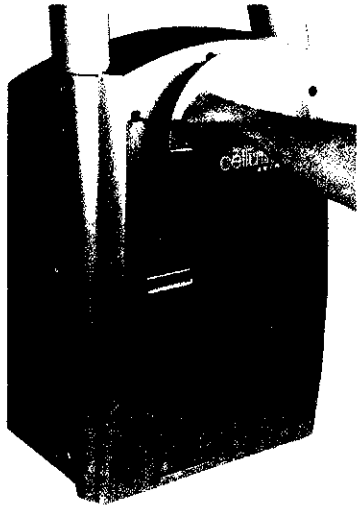
Disconnecting the treatment heads and hoses is quick and easy.

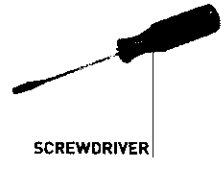
1 : Loosen the two screws and remove the rear screen located on the mobile arm, using the small, hex key.
2 : Loosen and disconnect the electric connection.
3 : Remove the plastic connection from its housing.
4 : Disconnect the plastic connection.

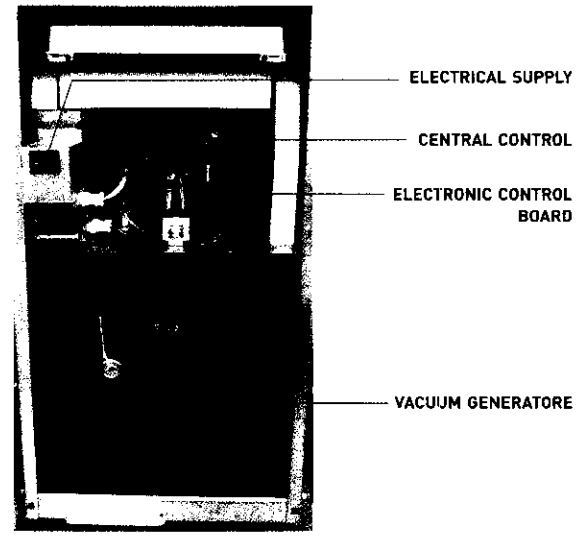


Access to the technical items

Disconnect the supply cable. Open the rear door to gain access to the technical elements using a screwdriver. Only loosen the 4 fixing screws a quarter turn.







Connection system identical for the two circuits.

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Replacing the filters of the vacuum generator

The vacuum generator has two filter cartridges:

- One paper cartridge at the inlet, on the left side
- One metal cartridge on the discharge side, on the right side

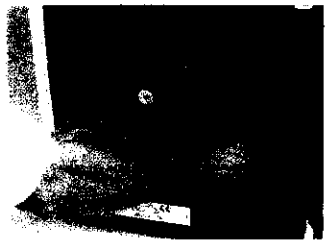
These two cartridges must be replaced after every 1000 hours of operation.
If a filter change request occurs, a warning message is displayed at the top right of the CONTROL screen of the control panel and an icon showing the pump filters that require changing appears in the CONFIGURATION screen. This happens each time the pump shuts down until the filter change has been acknowledged.

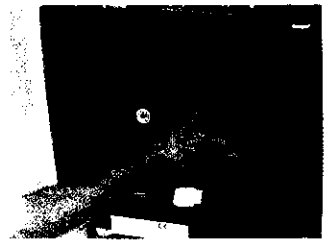
= Vacuum pump filter (warning message number: 22002)

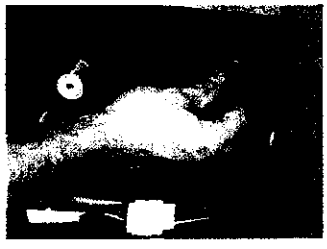
No special tool is required for this operation.

1 : Open the rear door to gain access to the technical elements
2 : Loosen the two knurled nuts of the vacuum generator hood
3 : Unscrew the cover
4 : Unscrew the central knurled nut
5 : Remove the cartridge from the spring
6 : Replace with a new cartridge
7 : Repeat the same operation for the second cartridge
8 : Once the new filters are in place, validate the operation by selecting the icon representing the filters you have just changed, by pressing the appropriate key and hold the VALID.

To confirm replacement, the icon depicting the filters disappears.


②


③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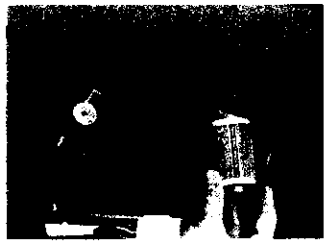
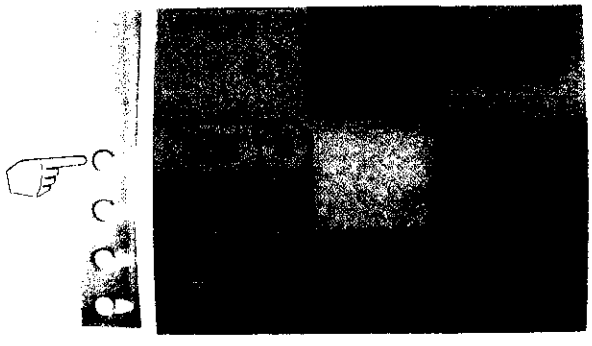

⑤


⑧

ACKNOWLEDGE REPLACEMENT BY PRESSING THE KEY FOR A LONG TIME

It is important to replace the filter cartridges one after the other, so that the correct cartridge is replaced in its housing. The Cellu M6® must be switched off before proceeding with a filter cartridge change. The unit must also be

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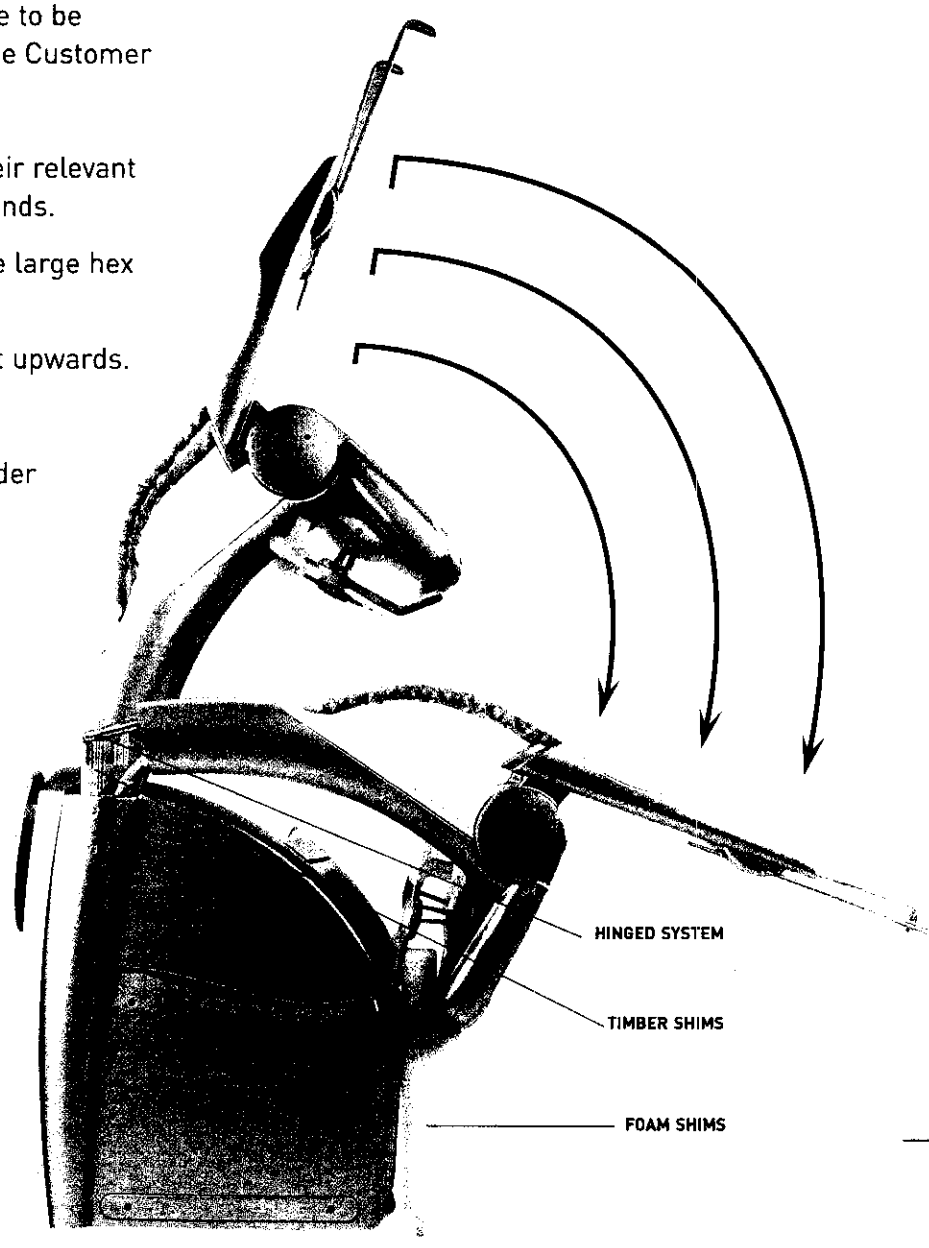
Transport/Storage

In the event of having to relocate the unit by professionals, it is essential to pack the unit in its original packaging.
Where the unit is only being moved a short distance or when stored for a short while in the folded position, it is essential to insert the two shims provided for this purpose

If you require any information on the packaging, shims and procedure to be adopted, please contact LPG One Customer Service.

- Fix the treatment heads to their relevant support using large rubber bands.
- Loosen the 4 screws using the large hex key.
- Pull the top section of the unit upwards.
- Bend while holding the unit.
- Insert the various shims in order to protect the hoods.



LPG® will not be liable for damage caused by transport or storage in the folded position, if the shims provided for this purpose, are not in place.

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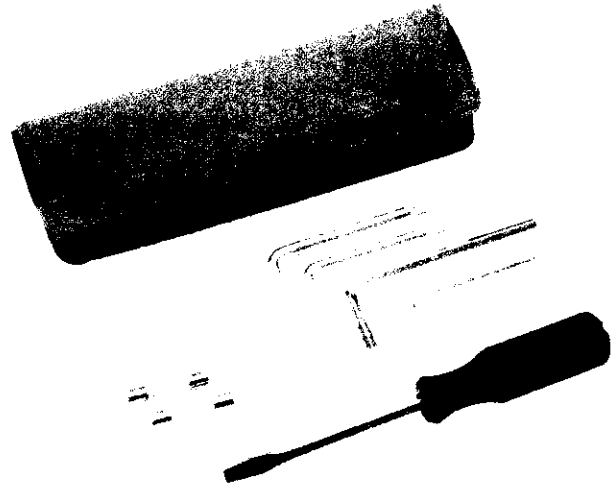
Maintenance kit

The tools supplied with the equipment in the tool box are sufficient to carry out the maintenance operations defined in this guide.



Contents of the maintenance kit:

- 4 hole covers
- 2 spare fuses
- 2 hex key (model No. 2.5 and 5)
- 1 torx T10 key
- 1 torx T30 key
- 1 screwdriver

Maintenance file

Replacement of the filter cartridge for the main head circuit . . . . . .40 hours
Replacement of the filter cartridge for the auxiliary head circuit . . . . . .40 hours
Overhaul of the main head . . . . . .approx. every 1000 hours
Replacement of the vacuum generator filters . . . . . .1000 hours

DATE	NUMBER OF HOURS	OPERATIONS CARRIED OUT

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A little problem! What should I do ?

If your unit is not working properly, proceed with the following checks before calling Customer Service of LPG One:

- Is the unit properly connected to a main plug?
- Is the main plug live?
- Is the ON switch lit up?
- Are the fuses of the unit in good order?
- Are the filter cartridges clean and properly in place?
- Are the hoses free?
- Are the hoses properly connected to the mobile arms of the balancer?
- Are the sealing valves of the main head in their proper place, clean and moving?
- Is the Keymodule™ of the main head correctly fitted?
- When switching on, the main head screen is blocked in the MAINTENANCE MENU. This means that there is a compatibility problem with the electronic boards of the T70 and Cellu M6® Keymodule *i*. Please contact Customer Service of LPG One.

Once these checks have been carried out and if the malfunction persists, please contact Customer Service of LPG One, or the nearest authorized dealer,indicating the model of your unit, its serial number and operating time in hours (see pages 32 and 33 re access to the time meters).

Customer Service of LPG One:

Tel. (888) 730 0144
Fax (888) 571 0040

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General characteristics

Dimensions: Length x width x height .....60 x 46 x 210 cm
Net weight .....90 kg
Maximum set pression .....69 kPa (690 mbar)
Fuses .....Time-delay
.....Dimensions 6,3 x 32 mm
Cooling .....By way of mechanical ventilation incorporated in the pump
Protection index .....IP 20
Electrical protection class 1

Unit fitted with patented treatment heads.

The Cellu M6® Keymodule *i* is marked CE 0088 as a medical device by virtue of Annex V of regulation 93/42/EEC (standards 60601-1-1 and 60601-1-2)

Electrical properties

230V - 50Hz

Supply voltage .....230 V AC
Frequency .....50 Hz
Intensity consumed .....4 A
Power consumed .....920 Watts
Pump output .....18,5 m^3/h
Ceramic fuses T8A

230V - 60Hz

Supply voltage .....230 V AC
Frequency .....60 Hz
Intensity consumed .....4,8 A
Power consumed .....1100 Watts
Pump output .....20 m^3/h
Ceramic fuses T8A

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Electrical properties

115V - 60Hz

Supply voltage	115 V AC
Frequency	60 Hz
Intensity consumed	8,7 A
Power consumed	1000 Watts
Pump output	20 m^3/h
Ceramic fuses	T16A

127V - 60Hz

Supply voltage	127 V AC
Frequency	60 Hz
Intensity consumed	10 A
Power consumed	1200 Watts
Pump output	20 m^3/h
Ceramic fuses	T12,5A

100V – 50/60Hz

Supply voltage	100 V AC
Frequency	50/60 Hz
Intensity consumed	12,5 A
Power consumed	1250 VA (50Hz)/1250 W (60 Hz)
Pump output	18,5 m^3/h at 50Hz
	20 m^3/h at 60Hz
Ceramic fuses	T20A

Please consult LPG One Customer Service center regarding other voltages.

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TREATMENT HEAD

cellum6i KEYMODULE

Registered trademark

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9 DESCRIPTION OF KEYMODULE™ . . . . . .P. 47

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9 DESCRIPTION OF AUXILIARY HEADS . . . . . .P. 51

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9 MAINTENANCE . . . . . .P. 54

The manufacturer reserves the right to amend the product technical specifications without prior notice. Any reproduction, even in part, is prohibited. All the illustrations of this treatment head supplement are non-binding.

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Main head T70

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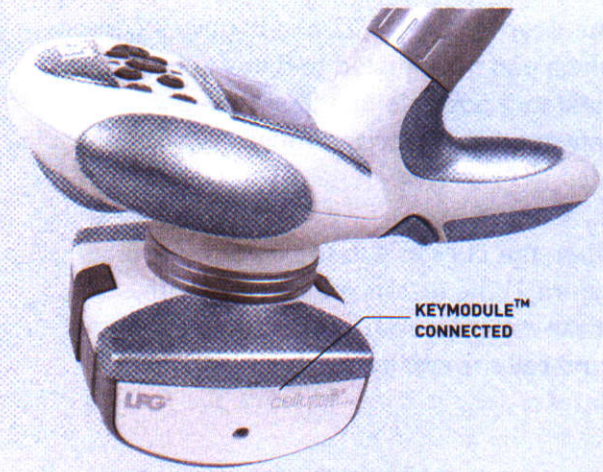
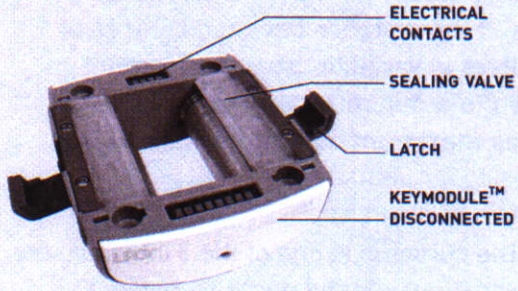
Keymodule™

The Keymodule™ is the bottom interchangeable section of the T70 main head. It comprises the motorised rollers and sealing valves.

You have three Keymodule™ the characteristics of which differ from the motorized rollers in several points:

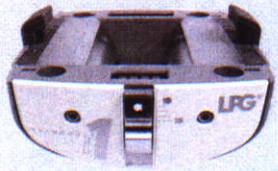
- Diameter and texture of the rollers
- Rigidity of return springs





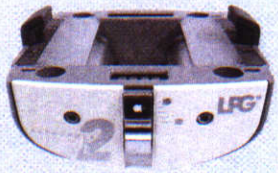
Keymodule™ i1:
This is recommended for the programs in the AESTHETICS menu.
It is characterized by the following points:

- Roller diameter: 26 mm
- Hard springs
- Roller spacer stop (28 to 10 mm) to select the treatment depth



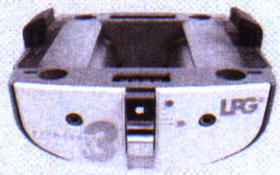
Keymodule™ i2:
This is recommended for the programs in the THERAPEUTICS and SPORT menus.
It is characterized by the following points:

- Roller diameter: 24 mm
- Extra-soft springs
- Roller spacer stop (30 to 12 mm) to select the treatment depth



Keymodule™ i3:
This is recommended for the programs in the Sihouette, RELEASE and RELAXATION menus.
It is characterized by the following points:

- Roller diameter : 28 mm
- Moderate springs
- Roller spacer stop (26 to 8 mm) to select the treatment depth



Movement and direction of rotation are visually displayed by LEDs for the three Keymodule™.

Before running your unit for the first time, ensure that a Keymodule™ was properly connected to the T70, because otherwise the screen will display an error message.

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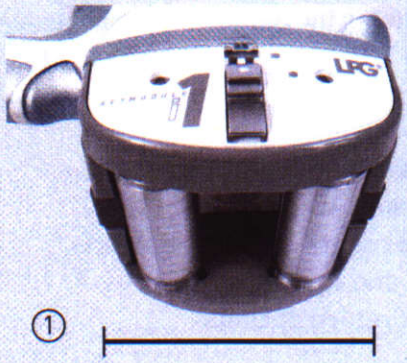
Setting the cursor of keymodule™ i1, i2 et i3

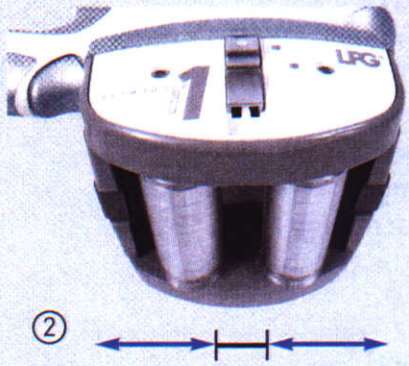
The Keymodule™ i1, i2 and i3 have a cursor, which can be adjusted to 5 positions, thereby making it possible to adjust the spacing between the motorized rollers.

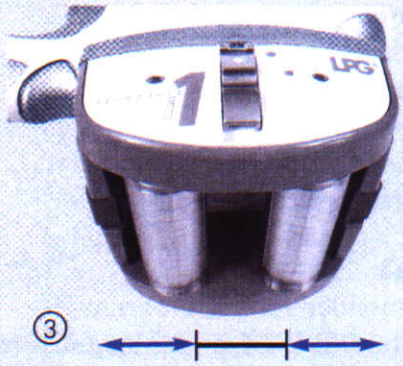
When the cursor is in the bottom position (figure 1) the distance between centres of the rollers is maximum and fixed, there is no roller mobility.

When the cursor is in the top position (figure 2) the distance between centres of the rollers is variable, from a maximum position to a minimum position, which ensures maximum mobility of the rollers.

When the cursor is in one of the 3 intermediate positions (figure 3) the distance between centres of the rollers, as well as their mobility, are variable.







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Functions incorporated in the main head

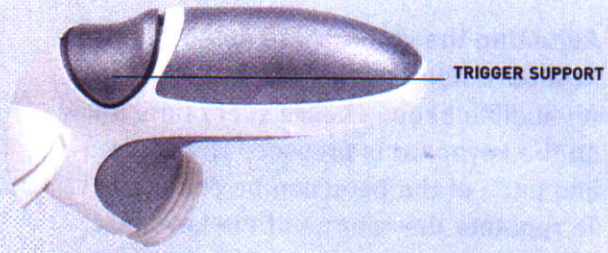
Apart from setting the treatment intensity, duty cycle, frequency or method of treatment, the main head also incorporates the start/stop and reverse functions and displays the direction of movement, as well as adjusting the volume and selecting the keyboard beep pitch.

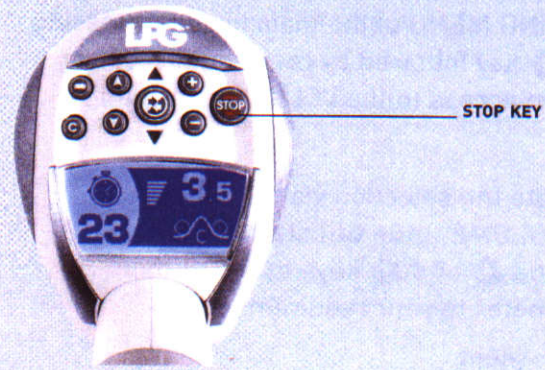
START/STOP function:
Once the pump has been switched on by the START button on the control panel keyboard, treatment start and stop are controlled by the main head.
To start treatment, press the trigger.
To stop treatment, press the STOP key.

Indication of the direction of head movement (where the rollers move in the same direction):
Each time the trigger is pressed, this reverses the direction of head movement. The direction of movement of the main head is indicated throughout treatment by flashing lights.

Reverse mode and LEDs:
When you are in reverse mode (the rollers are turning in the opposite direction), the flashing LEDs become specific:

- In wound/wound mode (where the 2 rollers wind the fold), the 2 diodes are lit and flashing
- In unwound/unwound mode (where the 2 rollers unwind the fold), the 2 diodes are lit and continuous.





These functions are only possible provided the main treatment head has been selected.

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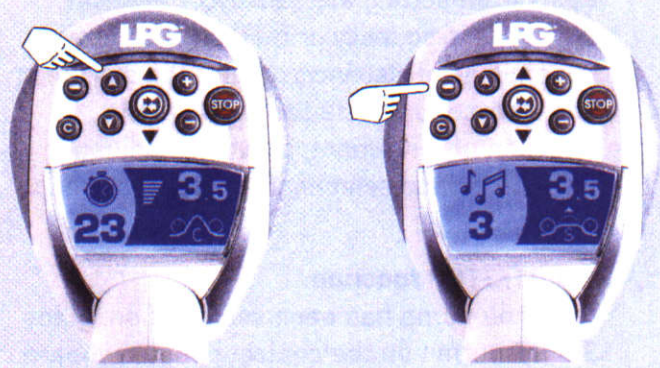
Functions incorporated in the main head

Adjusting the volume and selecting the keyboard beep pitch:
An audible beep is heard every time a key on the keyboard is pressed. The volume and pitch of the beep can be changed.
To regulate the volume of the keyboard beep (quiet, soft, average or loud), go to the RING MENU of the main head by pressing the ▼ key followed by pressing the ⊖ key to gain access to the VOLUME parameter.

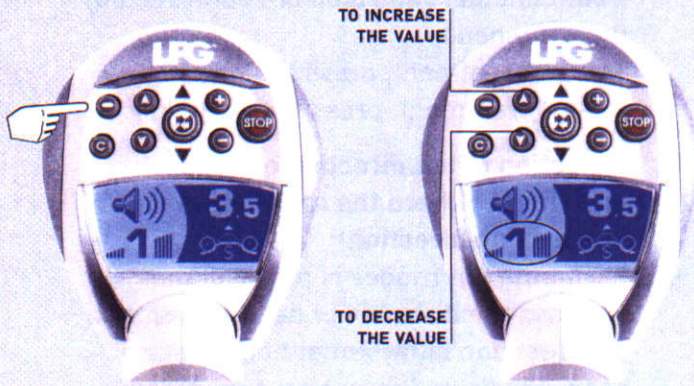


Validate the selection via the ⊖ key the VOLUME value will start to flash.
Use the ▲ and ▼ keys to adjust this parameter to your requirements.

- 0: silent
- 1: soft
- 2: average
- 3: loud

Validate by pressing the ⊖ key.

Use the ⊙ key to return to the monitor screen.



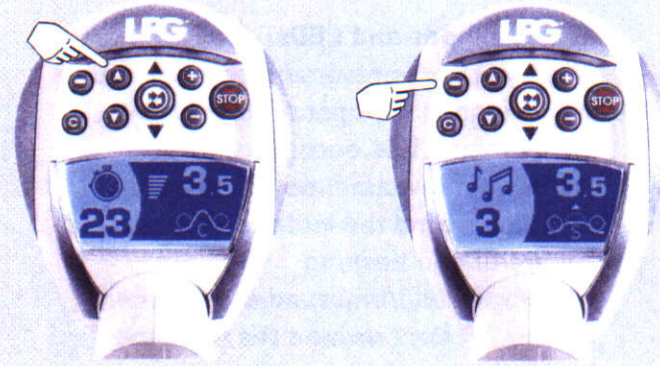
To regulate the pitch of the keyboard beep (low, medium or high) from the VOLUME parameter, press the ▼ key to gain access to the TONE parameter. Validate by pressing the ⊖ key and the TONE value will start to flash.

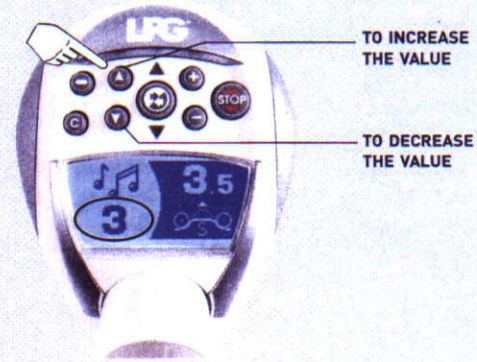
Use the ▲ and ▼ keys to adjust this parameter to your requirements.

- 1: high pitch
- 2: medium pitch
- 3: low pitch

Validate by pressing the ⊖ key.

Use the ⊙ key to return to the RING MENU and then to the monitor screen.





These functions are only possible provided the main head has been selected.

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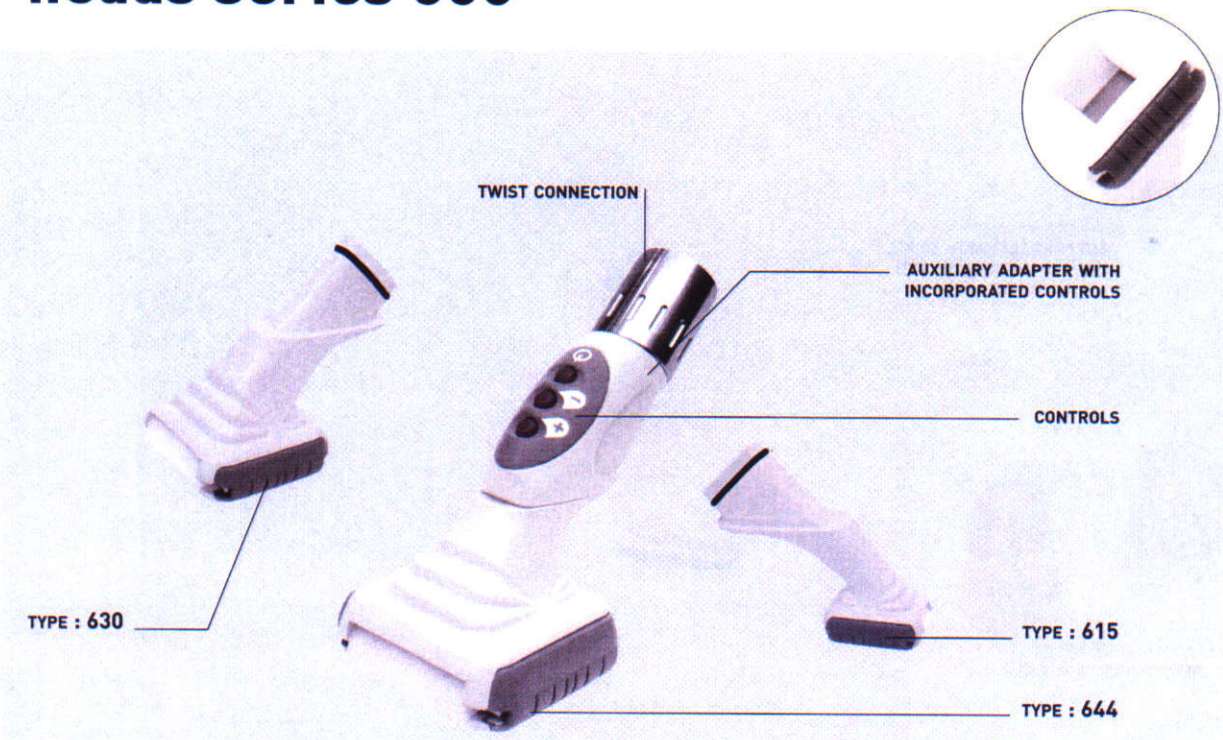
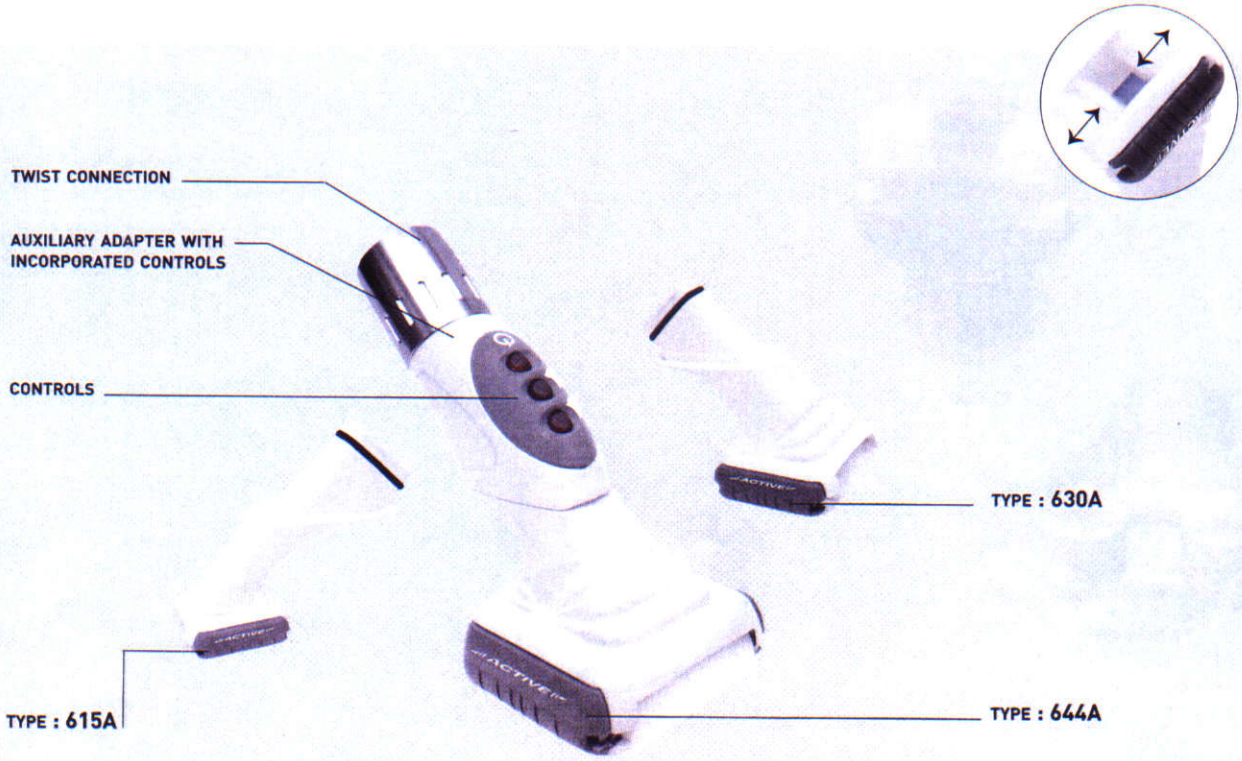
Auxiliary heads series 600



Auxiliary heads series 600 – active



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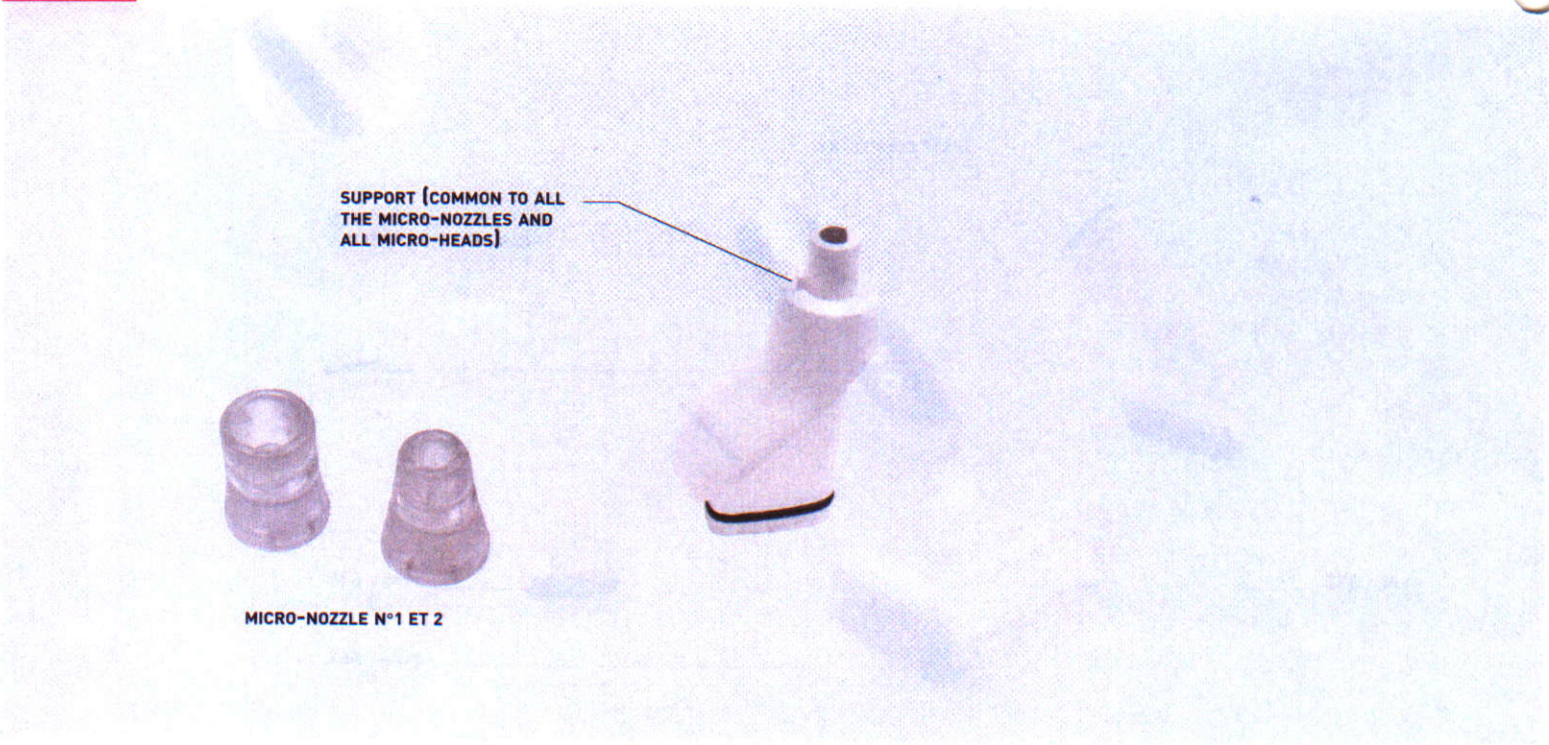
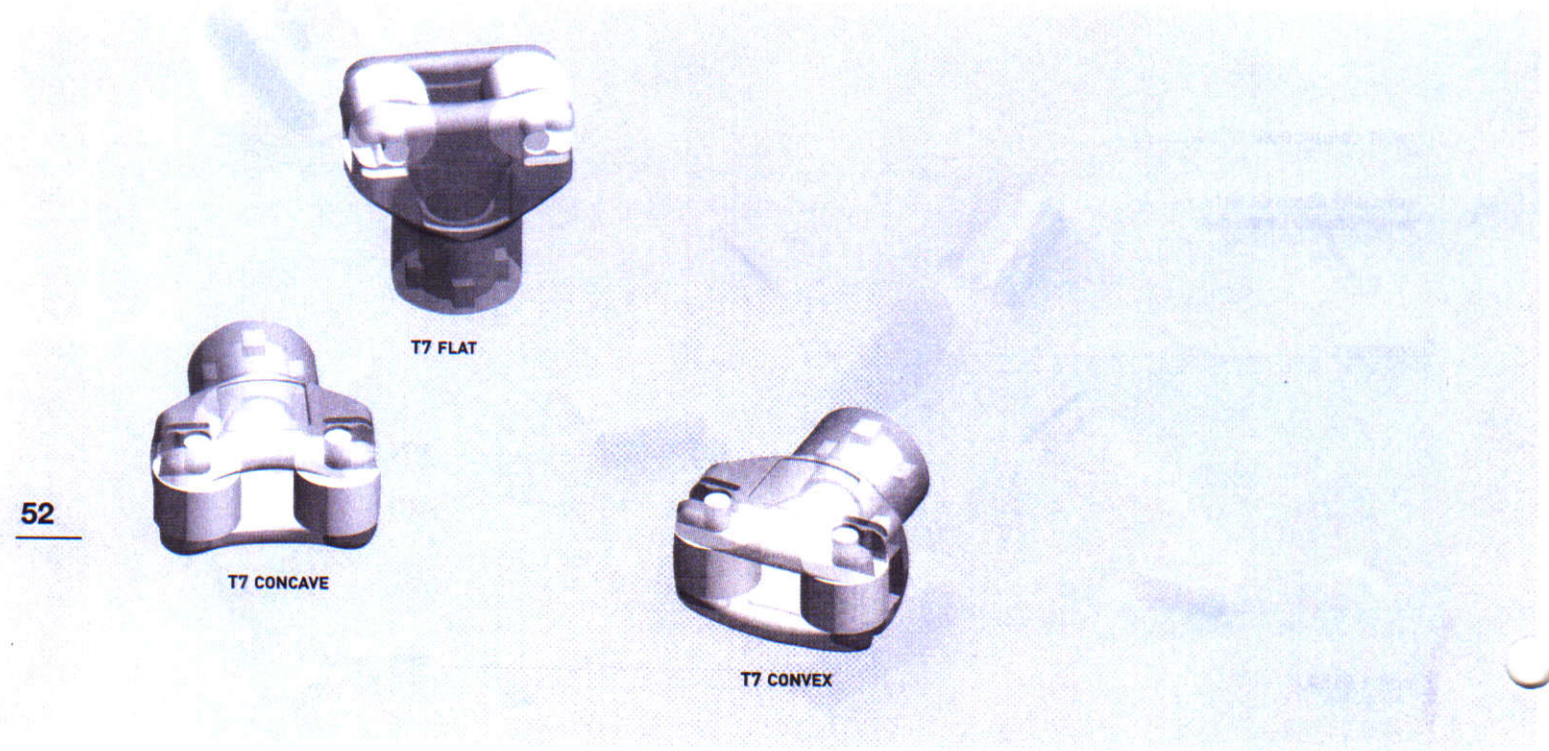
Micro-nozzles series 600



Micro-heads series 600



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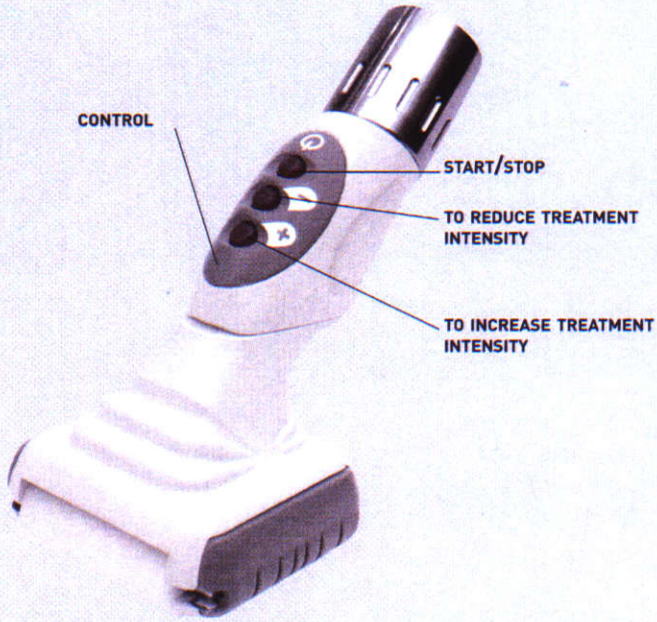
Functions incorporated in the auxiliary adapter

Because the control is incorporated in the auxiliary head connection, you can start or stop your treatment by operating the START/STOP switch and adjust the treatment intensity using the +/- keys without having to go to the control panel of your unit.



These functions are only possible provided the auxiliary treatment head has been selected.

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CLEANING THE AUXILIARY HEADS
MICRO-HEADS AND MICRO-NOZZLES . . . . . .P. 57

OVERHAUL OF THE KEYMODULE™ . . . . . .P. 58

All the maintenance operations described in this section must be carried out with the unit switched off and the supply cable disconnected.

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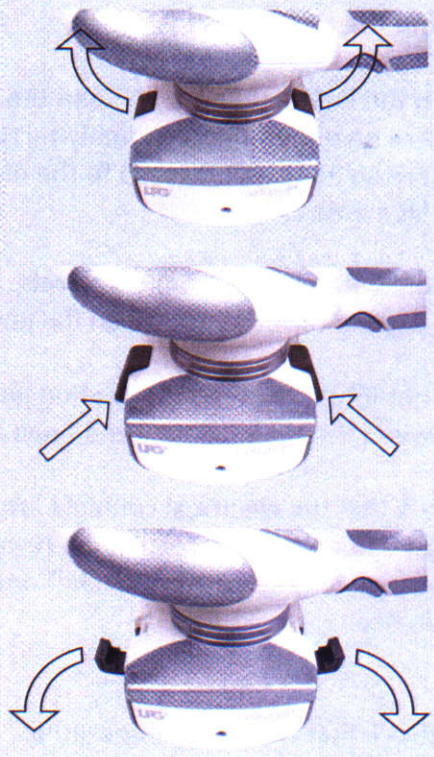
Cleaning the main head

For hygiene reasons, the treatment heads must be cleaned after each use, using antiseptic wipes with a bactericidal and fungicidal solution.

Special attention must be paid to those parts coming into contact with the patient.



Cleaning the tightness valves:

1) Release the Keymodule™ as shown on the photos

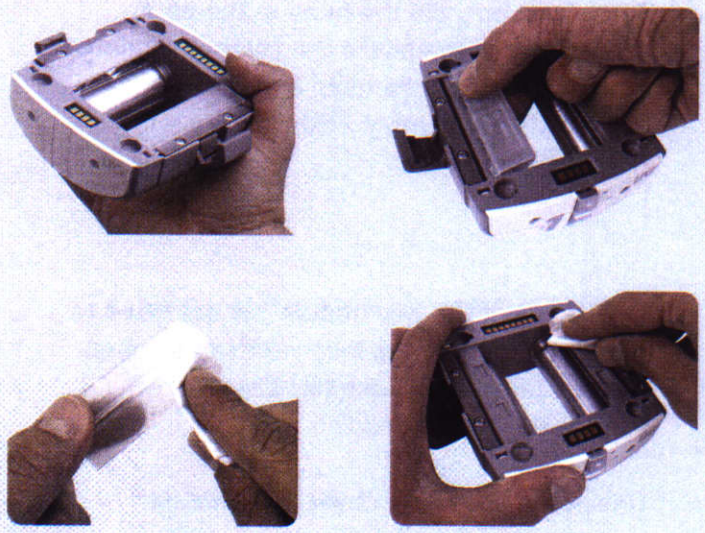
2) Make sure that the cursor is in the top position (see page 48)

3) Bring the roller to the center

4) Remove the corresponding sealing valve by handling it as shown on the photo. Repeat this operation for the other valve.

5) Then clean the valves and their location

Replace the valves after:
100 hours' operation



Do not use aggressive products, such as acetone, trichloroethylene or alcohol at 90°, or abrasive sponges.

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Cleaning the main head

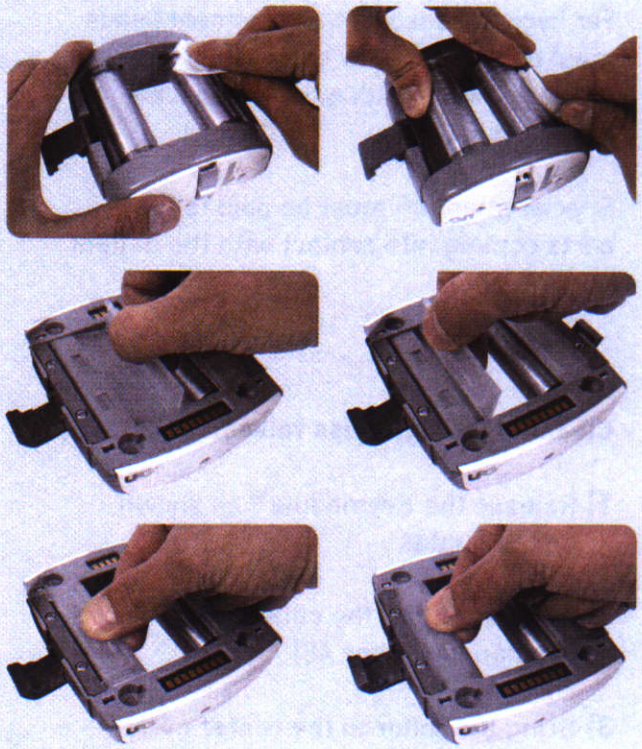
Cleaning the Keymodule™:

1) Turn the Keymodule™ and clean the rollers on either side. Manually turn the rollers so as to gain access to the entire surface area.

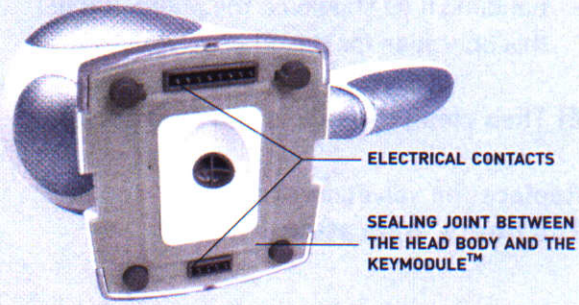
2) Turn the Keymodule™ again and refit the sealing valves as shown on the photos.

3) Do not forget to clean the sealing joint between the Keymodule™ and head body.

4) Check that the electrical contacts are clean and dry and proceed in the reverse sequence to refit the Keymodule™ onto the main head.



Now check that the head is operating correctly.
To do this, operate the head in the palm of your hands to ensure the correct sealing of the treatment chamber and visually inspect the movement of the valves and that of the rollers.



WARNING: if the Keymodule™ is not fitted to the main head, if it is incorrectly positioned or even faulty, the main head screen will display the icon alongside:

Check the assembly of the Keymodule™.

Do not use aggressive products, such as acetone, trichloroethylene or alcohol at 90°, or abrasive sponges.

9S2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cleaning the auxiliary heads micro-heads and micro-nozzles

For hygiene reasons, the treatment heads must be cleaned after each use, using wipes containing an antiseptic, bactericidal and fungicidal solution.

Cleaning the auxiliary heads:

- Disconnect the auxiliary head of the adapter for cleaning purposes.
- Remove the two head rollers to proceed with quick and efficient cleaning as shown on the photograph. For micro-heads, use the micro-head tool supplied.
- Clean the rollers and the treatment chamber.
- Refit the rollers and check that they rotate freely.
- For cleaning the micro-nozzles, use cotton swabs containing the same solution.

Do not use aggressive products, such as acetone, trichloroethylene or alcohol at 90°, or abrasive sponges.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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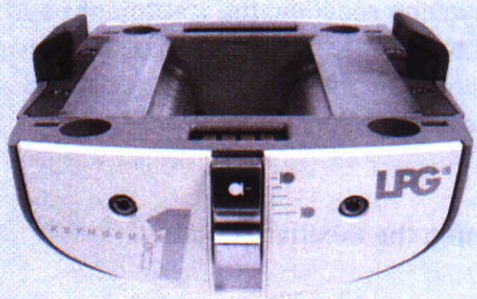
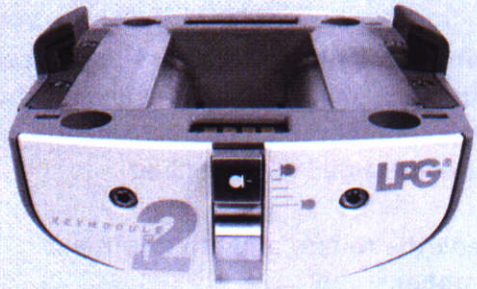
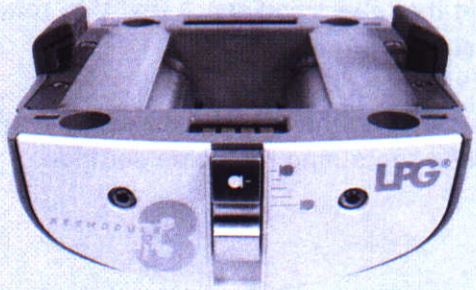
Overhaul of the keymodule™

The Keymodule™ is a high-technology unit comprising numerous mobile micro-mechanical parts. The unit must be returned to our Technical Support Center if certain wear items require replacing.

The head may start to lose some of its characteristics at around 1000 hours of operation.







954

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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General warranty conditions

You have just purchased an LPG unit. Purchasing this unit implies full legal acceptance of the present general conditions by the purchaser / professional operator. If the unit has been sold by an approved agent of LPG One, the operator must refer to the general guarantee conditions of his supplier, which will not, under any circumstances, have the effect of increasing the manufacturer's commitment under the present warranty. This warranty can only be implemented and is only valid provided the guarantee slip has been duly filled in and returned to LPG One within 15 days following delivery, irrespective of the country in question. All warranty slips that are only partially filled in will be rejected.

LPG One guarantees this unit againt all manufacturing flaws or defects in the raw materials. The present warranty is valid for a period of one year with the first operator, without this exceeding 2000 hours of operation from the date of invoice. During this period, we undertake to exchange or repair, free of charge, any part acknowledged by ourselves as being faulty, without this necessarily entailing a complete replacement of the unit. Shipping costs and return forwarding costs of the unit or spares to/from our After Sales department, are not covered by this warranty.

Any replacements or repairs under the warranty, whether these cause an immobilization of the unit or not, will not have the effect of extending the period of cover, under any circumstances. The replaced parts become the property of LPG One. No compensation will be awarded for inconvenience enjoyment.

The purchaser is duty-bound to give us the necessary time and means to proceed with any repairs and replacement deliveries of spares. Failure to comply will absolve us from our obligation under the warranty.
It is expressly agreed that the company accepts no liability in the event of use exceeding the level of professional qualification of the operator or where the unit is used incorrectly.
The courts located within the jurisdiction of the registered office of LPG One are alone competent in the event of disputes, despite any other clause, which may specify a different jurisdiction featuring on the commercial invoices of the contracting parties.

The warranty is also excluded in cases of:

- Damage that occurred during transport. This unit is forwarded at the risk and peril of the recipient. It is up to the latter to check that it is in a perfect state prior to delivery;
- Non-observation of the installation rules and the LPG One operator's manual, failure to carry out maintenance of the unit and to clean the filter cartridges, connecting the unit to a faulty electric line or one which does not have an earth connection, or to a power supply whose voltage is different to the one indicated on the unit;
- Resale of the unit (except in the case of exemption and only with the express agreement of LPG One;
- Modification, fitting accessories or dismantling the unit;

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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General warranty conditions

- Any intervention work not scheduled in the LPG One operator's manual and which was carried out on the unit by the operator or third party not approved by LPG One;
- Using inappropriate consumables or parts not supplied by LPG One;
- Blocage of the unit as a result of the aspiration of a foreign object or through the use of consumables other than those recommended and/or supplied by LPG One;
- Wear to all parts of the unit as a result of normal use;
- The unit being dropped, in the event of impact, lightning, fire, force majeure, water damage and natural disasters.

Under no circumstances will this warranty give rise to any form of damages or compensation.

Limitation and exoneration of liability

Non-compliance with the general guarantee conditions during the term of the warranty and following expiry of the latter, may lead to LPG One being exonerated of any liability in the event of damage attributed to the products supplied.

LPG One will not be held liable with respect to equipment/material losses or physical accidents (i), following installation that does not comply with the statutory or regulatory provisions of the country where the unit is to be used or (ii) which could jeopardize a Cellu M6® Keymodule *i* unit, which was the subject of intervention work not scheduled in the LPG One operator's manual and/or carried out by the operator or a third party not authorized by LPG One.

LPG One will be absolved of its liability in the event of use exceeding the level of professional competence/qualification of the operator or resulting from the incorrect use of the unit.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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To be filled in by the manufacturer

LPG ONE, inc - Executive Office
701 Brickell Avenue
Miami
FL. 33131
Tel.:(305) 379 8800
Fax:(305) 375 0903

Type of unit: Cellu M6® Keymodule *i*

To be completed and returned to LPG One

Name: .....

Adress: .....

Country: .....

Tel.: .....

Type of establishment: .....

Profession: .....

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Type of unit: **Cellu M6® Keymodule *i***
Serial number: .....
Date: .....

To validate the warranty, detach this slip and return to the address below within 15 days following use of the unit:

LPG ONE, inc
7060 S.R. 84 Suite 1

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Endermo™ Results

As a high-tech referential and diagnostic tool, Endermo™ Results provides the practitioner with the objectivation of areas to undergo treatment or to be taken into account and then rationalizes the results.

Endermo™ Results allows each subject to be positioned in a few seconds, under strictly reproducible and comparable conditions, thereby allowing a true comparison to be made before and after treatment. Use of the numeric camera* makes storage and the use of photographs easier and maintains confidentiality.

Endermo™ Results is the logical and inevitable complement to the LPG One technique.

* *Endermo™ Results is available either with or without a camera (digital or reflex).*

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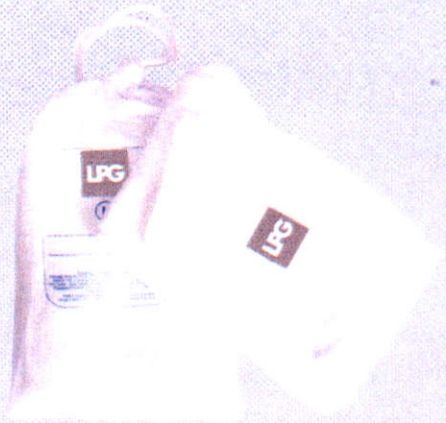
Endermo™ wear

LPG® recommends that patients should wear the "Endermo™ wear" during the treatment sessions. In fact, apart from the advantages of using this bodywear, (resistance, hygiene, respect of intimacy, working facility of the practitioner), these quality garments, which are not abrasive on account of the materials used, minimise wear to the Keymodule™.



They are available in different sizes:
-average (up to size 42 or 1m70)
-large (above size 42 or 1m70)
man size (single size).

The Endermo™ wear treatment garments are available from:

Customer Service, LPG One

Tel. (888) 730 0144
Fax (888) 571 0040

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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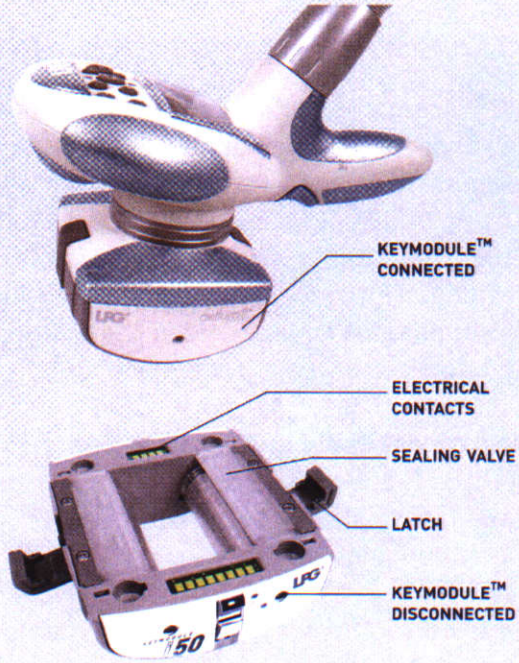
Description unit

The Keymodule *i* 50 is adaptable to the main head of the Cellu M6 Keymodule *i* T70. It consists of two motorised rollers and airtight valves.

It is characterized by the following points:

- Roller diameter: 26 mm
- Soft springs
- Roller spacer stop (28 to 10 mm) to select the treatment depth.



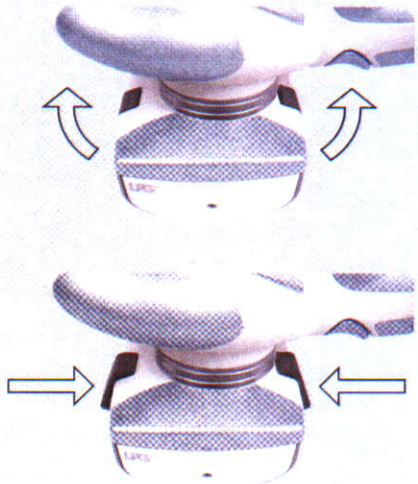
Installation

The Keymodule *i* 50 is designed to be compatible with the main head T70.

Attach the Keymodule to the main head as shown in the photos opposite.

To remove the Keymodule release the latches.

For Cellu M6 Keymodule i up to and including version 3.0, the picograph is displayed on the screen.



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Precautions

- The Keymodule *i* 50 must only be used with the main head T70 of the Cellu M6 Keymodule *i* machine.
- Do not use the Keymodule *i* 50 to treat the scalp.
- LPG Systems absolves itself from all responsibility in the case of any inappropriate use.
- All the usage precautions of the Cellu M6 Keymodule *i* also apply to the Keymodule *i* 50. Please refer to the operator's manual.

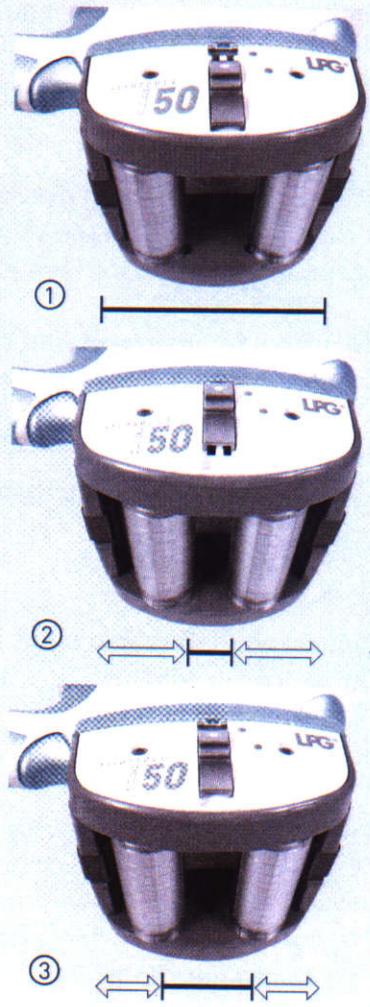
Adjustment of the cursor of the Keymodule™ *i* 50

The Keymodule *i* 50 has a cursor which can be set in 5 different positions to adjust the distance between the motorised rollers.

When the cursor is in the bottom position (figure 1) the distance between the rollers is maximum and fixed, there is no roller mobility.

When the cursor is in the top position (figure 2) the distance between the rollers is variable, from a maximum position to a minimum position, which ensures maximum mobility of the rollers.

When the cursor is in one of the 3 intermediate positions (figure 3) the distance between the rollers, as well as their mobility, are variable.



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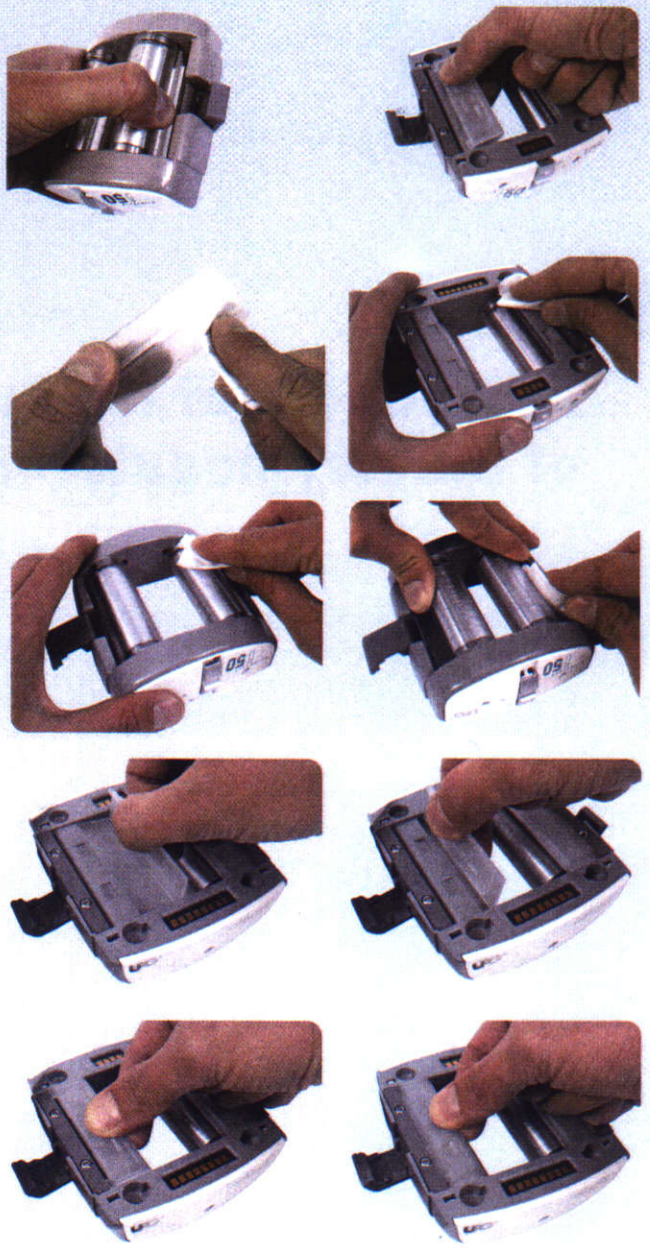
Maintenance

In order to guarantee optimum hygiene as well as the performance of your machine it is important to clean your Keymodule *i* 50 after each treatment session.



Cleaning the Keymodule™

- After removing the Keymodule ensure that the cursor is in the highest position.
- Bring the roller to the center.
- Remove the corresponding sealing valve by handling it as shown on the photo. Repeat this operation for the other valve.
- Then clean the valves and their chambers.
- Replace the valves after: 100 hours' operation.
- Turn the Keymodule and clean the rollers on either side. Manually turn the rollers so as to clean to the entire surface area.
- Turn the Keymodule again and refit the sealing valves as shown on the photos.
- Do not forget to clean the sealing joint between the Keymodule and the main head.
- Make sure that the electrical contacts are clean and dry, then reattach the Keymodule to the main head.

Overhaul of the Keymodule™ *i* 50

- The Keymodule is a high-technology unit comprising of numerous mobile micro-mechanical parts. The unit must be returned to our Technical Support Center if certain parts require replacing.
- The head may start to lose some of its characteristics at around 1000 hours of operation.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Notes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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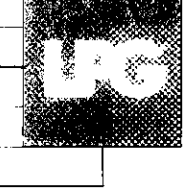
LPG ONE, INC - Executive Office
701 Brickell Avenue • Miami • FL 33131
Tel (305) 379 8800 Fax (305) 375 0903 Tel (800) 229 3911 • fax (800) 573 0063
Training and Technical Center
7060 State Road 84 • Davie • FL 33317
Tel (954) 476 7199 - Fax (954) 476 9295 Tel (888) 730 0144 • Fax (888) 571 0040 - www.lpgone.net



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SHEPARD MEDICAL PRODUCTS

The Compression Specialists

SPORTMED

Dealer Price List

SHEPARD'S SPORTMED™ PUMP is an easy-to-use intermittent compression system that does it all!! Designed for sports professionals, it will operate from a wall outlet or 12 volt rechargeable battery. The system is compact and lightweight. It can operate several sleeves concurrently. Cold and compression on an injury reduce pain and swelling. All air and electrical connectors are quick-connect types. The sleeves may be filled, chilled and held ready for instant use. The user can adjust sleeve pressure and compression time ON-and-OFF intervals.

ITEM NO.	ITEM DESCRIPTION	DEALER PRICE
301	SYSTEM Connects to 12 Volt DC. Rechargeable from 120 Volt outlet. (Includes 314, 341, 342, 353, 362)	(b)(4) [redacted]
314	PUMP (12 Volts DC)	
322	Connector, Two Sleeve	
332-1	Sleeve, Arm	
332-3	Sequential Arm Sleeve	
333-1	Sleeve, Knee Length Boot	
333-3	Sequential Knee Boot	
334	Sleeve, Ankle Length Boot	
335-1	Leg Sleeve, Full	
335-3	Sequential Leg Sleeve	
336-1	Leg Sleeve, Extra Large	
336-3	Sequential Leg Sleeve—Extra Large	
337	Thigh Wrap	
341	Bag, Carrying	
342	Container, Fill/Drain—1 Gal.	
342-3	Container, Fill/Drain—2.5 Gal.	
342-4	Container, Fill/Drain—5 Gal.	
353	Battery (12 Volts DC)	
362	Charger, Battery (120 Volts AC)	
371	Cable, Car Lighter (12 Volts DC)	
P-40	Chiller, 12 Volt/Heater	
AC-10	120 Volt Adapter	
400 NEW	Pressure Gauge—in Line Plug	

*SPORTMED Sleeves will operate on any compression pump.

PRICES: F.O.B. MELROSE PARK, IL. *WARRANTY: 1 YEAR PARTS AND LABOR*

2000 N. Hawthorne St. Melrose Park, Illinois 60160 708-865-2121 Telex - 289470 Fax - 708-865-0124

BEST COPY AVAILABLE H2965

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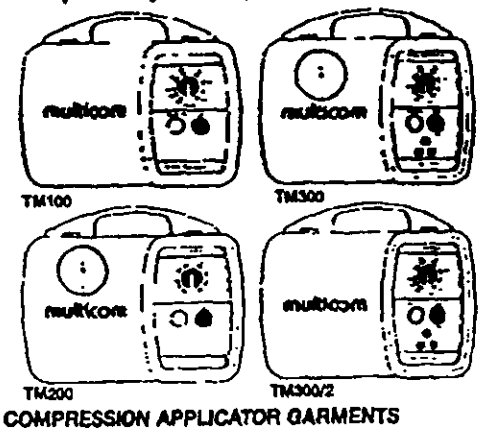
The Multicom intermittent and sequential compression systems are for use by the patient and the medical profession in the treatment of many conditions, such as: Primary lymphoedema, post mastectomy oedema, leg ulcers, oedema following trauma and sports injuries, post immobilisation oedema, prophylaxis of deep vein thrombosis, venous insufficiencies due to muscle inactivity, as in paralysis, multiple sclerosis.

CONTRAINDICATIONS

Acute pulmonary oedema, acute thrombophlebitis, acute congestive cardiac failure, acute infections.

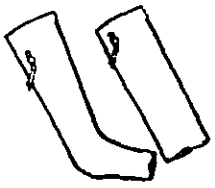


MULTICOM POWER UNITS

Construction:	All plastic
Size:	235 X 168 X 119mm
Weight: Model TM100	2.20kgs
TM200	2.43kgs
TM300	2.43kgs
TM300/2	2.23kgs
Electricity Supply:	220/250V 50Hz Other voltages available
Electricity Consumption:	8 watts
Fuse Rating:	160mA
Insulation:	Double insulated (no earth required)
Variable Pressure Control:	40-120mmHg
Cycle Time:	5 minutes

COMPRESSION APPLICATOR GARMENTS

Manufactured from polyurethane coated nylon with zip fastener on leg applicators. Fitted with quick release air valves.



INTERMITTENT

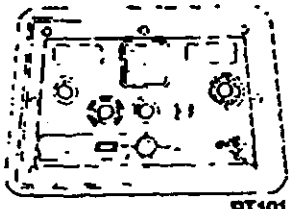
Ref: TM10	Calf applicator
Ref: TM20S	Complete leg applicator
Ref: TM20M	Complete leg applicator
Ref: TM20L	Complete leg applicator
Ref: TM30	Forearm applicator
Ref: TM40	Complete arm applicator

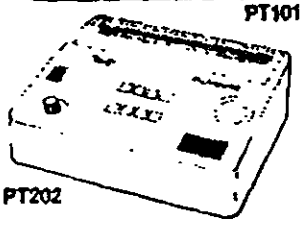
SEQUENTIAL

Ref: TM60S	Complete leg applicator
Ref: TM60M	Complete leg applicator
Ref: TM60L	Complete leg applicator
Ref: TM70	Complete arm applicator
Ref: TM70L	Complete arm applicator

Other sizes can be made to suit individual needs.
Garment expanders are also available for some garments. Contact us for details.

PT101 & PT202 PRESSURE THERAPY UNITS


PT101


PT202

SPECIFICATIONS	Cat.Ref. PT101	Cat. Ref. PT202
Dimensions:	43 x 26 x 31cms	35 x 35 x 20cms in case with garment
Weight:	11.20kgs	7.5kgs
Electricity Supply:	200/250V 50Hz	230/250V 50Hz
Electricity Consumption:	52 watts	26 watts
Full Load Current:	600 mA	260 mA
Fuse Rating:	5 Amp	3 Amp
PCB Fused:	1 Amp 250v	1 Amp 250v
Sphygmomanometer:	0-300mmHg	0-300mmHg
Therapy Time:	Continuous or Timed 5-55 minutes	30, 60, 120 minutes or continuous
Pressure Control:	0-130mmHg	0-150mmHg
Compression Cycle Time:	(s) 30-120 seconds	1 to 10 chambers, 30, 70, 110 seconds
	(i) 8-30 seconds	–
Deflation Time:	(i) Auto – 2 minutes	–
Mode Selector:	Sequential Compression Intermittent Compression	Sequential only –
Neon Indicators:	Green – Power On/Off Switch Orange – Sequential Compression Red – Intermittent Compression	Green – Power On/Off Switch –

COMPRESSION APPLICATOR GARMENTS

Polyurethane coated nylon with zip fastener on leg applicators.

INTERMITTENT

Ref: PT10	Calf applicator
Ref: PT20S	Complete leg applicator
Ref: PT20M	Complete leg applicator
Ref: PT20L	Complete leg applicator
Ref: PT30	Forearm applicator
Ref: PT40	Complete arm applicator

SEQUENTIAL

Ref. PT60	Leg applicator (ten chamber)
Ref. PT70	Arm applicator (ten chamber)

PROTECTIVE SLEEVING

We recommend that all compression garments are used with an inner protective sleeving. This provides extra patient comfort and helps to keep the garment clean. Available in 10 metre rolls or packs of five one metre lengths.
Ref: PS010 Protective sleeving (10 Metre roll) Ref: PS005 Protective sleeving (5 x 1 Metre lengths).

TREATMENT TROLLEY

A treatment trolley is available for the PT101 AND PT202. Contact us for details.

REFERENCES

Hills N.H., Pflug J.J., Jayasingh K., Scardman L., Calman J.S. Prevention of Deep Vein Thrombosis by Intermittent Pneumatic Compression of Calf. B.M.J. 1972 1:131-5
Arfanby F., Boardman L., Pflug J.J., Calman J.S. Effects of external pneumatic intermittent compression on fibrinolysis in man. Lancet 1973 1412-4
McNally T.J., Martin I.J., Orr J.D. Intermittent compression for lymphoedema of arm. Clinical Oncology 1976, 2:239-42
Malone D.G., Wright M.T.M., Simandl E. The stripping of varicose veins: a clinical trial of intermittent compression dressings. Br. J. Surg. 1979 66:53-5.
Nicolaides A.N., Fernandes e Fernandes J., Pellicciari R. Intermittent sequential pneumatic compression of the legs in the prevention of venous stasis and postoperative deep venous thrombosis. Surgery 1980, 87:99-76.
Hazanka E.Z., Wright D.E. Chronic leg ulcers: The effect of pneumatic intermittent compression. The Practitioner 1981; 225:189-92
Zelenovic A., Dietrich A., Rees R. The Sequential pneumatic compression device in surgery for lymphoedema in PG units. Journal of Cardiovascular Surgery 1983; 24:122-5

Whilst correct at time of going to press, we reserve the right to alter and improve the specification of any product without prior notification.
Always seek professional medical advice before using any of these products.

TALLEY Premier Way, Abbey Park Industrial Estate, Romsey, Hants. SO51 9AQ
Telephone: 0794 830866 Fax: 0794 830702 Telex: 477956 Talley G

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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foi

KR10020 A

Shepard Medical Products 510(k): Cryopress Sport Pump, Camp Multi-Temp Sport Pump

This document was provided by: **FOI Services, Inc**
11 Firstfield Road
Gaithersburg MD 20878-1704 USA
Phone: 301-975-9400
Fax: 301-975-0702
Email: infofoi@foiservices.com

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IMAGE

CDRH Document Imaging System

User: *VEJ: Johnson, V. Elaine (OSM/DID)*
Note: *FOI REDACTED*

Folder: *K912004*
Pages: *Entire Folder (1 document, 61 pages)*

Pages Printed: *61*

Date Requested: *Fri Jul 28 12:43:04 2000*
Date Printed: *Fri Jul 28 12:43:59 2000*
Printer: *OK4IMG01*

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

JUL 25 1991

Mr. Howard M. Holstein
Hogan and Hartson
Representing Shepard Medical Products, Inc.
Columbia Square
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109

Re: K912004
Shepard Cryopress Sport Pump
Camp Multi-Temp Sport Pump
Regulatory Class: II
Dated: July 15, 1991
Received: July 15, 1991

Dear Mr. Holstein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Carl A. Larson

Carl A. Larson, Ph.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

ate

From REVIEWER(S) - NAME(S) Tracey Clark

Subject 510(k) NOTIFICATION K912004

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

✓ (A) Is substantially equivalent to marketed devices.

____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

____ (C) Requires more data.

____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:
Subs. Equiv. to K 901022 Damor's Sport-Med, Powered Inflatable Tube Massager

☒ - Statement
This 510(k) contains a 510(k) statement that safety and effectiveness information will be made available

The submitter requests under 21 CFR §807.95:

____ No Confidentiality

____ Confidentiality for 90 days

✓ Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

IRP 89 II

Additional Product Code(s) w/Panel (optional):

REVIEW: [signature] for MB REDB REDB
(BRANCH CHIEF) (DATE)

FINAL REVIEW: Carl A. Larson 6/3/91
(DIVISION DIRECTOR) (DATE)

OK M. Shulman 9/1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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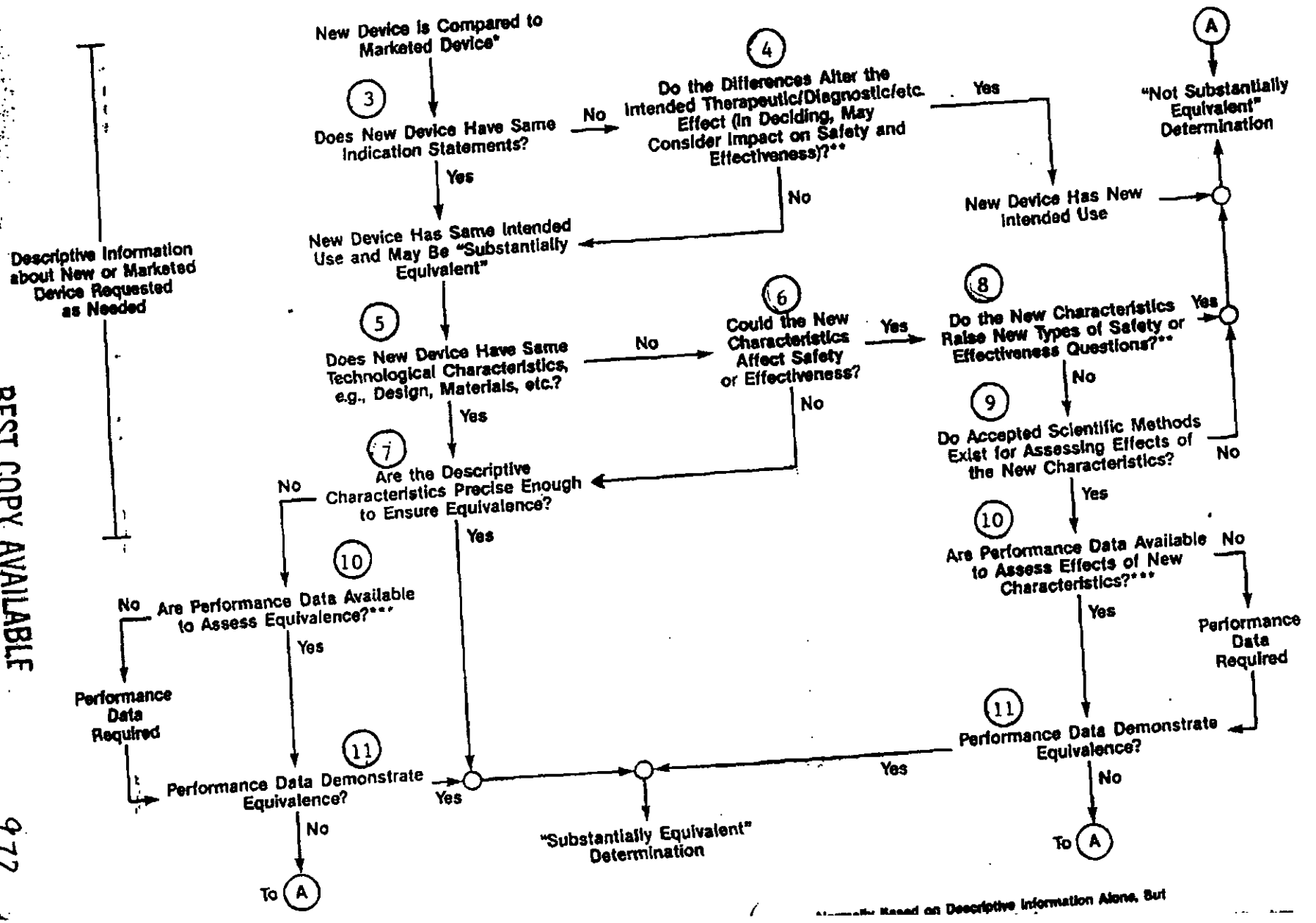
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



BEST COPY AVAILABLE

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K 912004 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: Tracey Clark DIVISION/BRANCH: DGRD/REDB

TRADE NAME: Sports Pump COMMON NAME: Inflatable Tube Massag

PRODUCT TO WHICH COMPARED: K901022 Sport-Med
(510(k) NUMBER IF KNOWN)

	YES	NO	
1. IS PRODUCT A DEVICE?	✓		- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	✓		- IF NO STOP
3. SAME INDICATION STATEMENT?	✓		- IF YES GO TO
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP
5. SAME TECHNOLOGICAL CHARACTERISTICS?	✓		- IF YES GO TO
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	✓		- IF NO GO TO 1 - IF YES STOP
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP
9. ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP
10. PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST
11. DATA DEMONSTRATE EQUIVALENCE?			

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: Reduction of pain and swelling of limbs by application of intermittent compression

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the dev for home use or prescription use? Does the device contain drug or biologica product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY: Same device as Damor's Sport-Med, with same labeling and usage. The only changes are company and product names.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. EXPLAIN WHY NOT A DEVICE: _____

2. EXPLAIN WHY NOT SUBJECT TO 510(k): _____

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION: _____

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE _____

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS: _____

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS: _____

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7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH:

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED:

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED:

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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H-179

HOGAN & HARTSON

COLUMBIA SQUARE
555 THIRTEENTH STREET NW
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202/637-5600

BRUSSELS, BELGIUM
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BALTIMORE, MARYLAND
BETHESDA, MARYLAND
McLEAN, VIRGINIA

HOWARD M. HOLSTEIN
PARTNER
DIRECT DIAL 202/637-5813

July 15, 1991

Document Mail Center (HFZ-401)
Office of Device Evaluation
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

BY HAND

Re: Premarket Notification for Shepard Medical Products, Inc.'s Powered Inflatable Tube Massager

Dear Sir or Madam:

Shepard Medical Products, Inc. ("Shepard"), by its attorneys, hereby submits this additional information for its premarket notification 510(k) submission for its powered inflatable tube massager device. As indicated in Shepard's 510(k) submission, the device will be marketed by Shepard under the name Cryopress Sports Pump and by Camp International, Inc. ("Camp") under the name Multi-Temp Sports Pump ("Sports Pump").

The purpose of this letter is to amend Shepard's July 3, 1991 submission of additional information regarding the above named device. That submission is amended to state that Shepard will make available any information respecting safety and effectiveness of this device upon the request of any person.

Please direct any further questions you may have concerning this submission or requests for additional information to Rady A. Johnson, Esq., Hogan & Hartson, at 202-637-6435.

Sincerely,

Howard M. Holstein

cc: Christopher A. Wright, Shepard, Inc.
Rady A. Johnson, Esq.

JUL 1991 RECEIVED

0705W

977

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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HOGAN & HARTSON

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BETHESDA, MARYLAND
McLEAN, VIRGINIA

HOWARD M. HOLSTEIN
PARTNER
DIRECT DIAL 202/637-5513

July 15, 1991

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Please direct any further questions you may have concerning this submission or requests for additional information to Rady A. Johnson, Esq., Hogan & Hartson, at 202-637-6435.

Sincerely,

Howard M. Holstein

cc: Christopher A. Wright, Shepard, Inc.
Rady A. Johnson, Esq.

0705W

FAX: 202/637-5910 TELEX: 248370(RCA), 892757(WU) CABLE: HOGANDER WASHINGTON

978

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BETHESDA, MARYLAND
McLEAN, VIRGINIA

HOWARD M. HOLSTEIN
PARTNER
DIRECT DIAL 202/637-5813

July 3, 1991

Document Mail Center (HFZ-401)
Office of Device Evaluation
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

BY HAND

Re: Premarket Notification for Shepard Medical Products, Inc.'s Powered Inflatable Tube Massager

Dear Sir or Madam:

Shepard Medical Products, Inc. ("Shepard"), by its attorneys, hereby submits this additional information for its premarket notification 510(k) submission for its powered inflatable tube massager device. As indicated in Shepard's 510(k) submission, the device will be marketed by Shepard under the name Cryopress Sports Pump and by Camp International, Inc. ("Camp") under the name Multi-Temp Sports Pump ("Sports Pump").

The purpose of this letter is to inform you that Shepard will make available an adequate summary of any information respecting safety and effectiveness of this device upon the request of any person, in lieu of submitting this summary to FDA at the present time.

Please direct any further questions you may have concerning this submission or requests for additional information to Rady A. Johnson, Esq., Hogan & Hartson, at 202-637-6435.

Sincerely,

Howard M Holstein

Howard M. Holstein

cc: Christopher A. Wright, Shepard, Inc.
Rady A. Johnson, Esq.

3818w

FAX: 202/637-5910 TELEX: 248370(RCA), 892757(WU) CABLE: HOGANDER WASHINGTON

979

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

MAY 8, 1991

SHEPARD MEDICAL PRODUCTS, INC.
ATTN: HOWARD M. HOLSTEIN
C/O HOGAN & HARTSON
555 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20004

510(k) Number: K912004
Received: 05-06-91
Product: SHEPARD CRYOPRESS/CAMP MULTI-TEMP SPORT PUM

We have received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

In addition, the SMDA requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination is based, or (2) state that such information will be made available to interested persons upon request. Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information that supports a finding of substantial equivalence. The information could be descriptive information about the new and predicate device, or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

FDA acknowledges that the law provides the 510(k) submitter a choice of providing the agency either a summary of safety and effectiveness information or stating that the information will be made available to the public. FDA encourages manufacturers to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting summaries of the information to the agency, until FDA promulgates a regulation on the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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content and format of summaries. Since the law requires that FDA must make the summary (referred to in (1), above) publicly available within 30 days of making an equivalence determination, we advise you that we must disregard any request for extended confidentiality for those 510(k)s containing this summary. Requests for extended confidentiality will be adhered to, per 21CFR 807.95, if you include the statement in (2) above.

Additionally, this legislation also requires any person who asserts that a device is substantially equivalent to a class III device to: (1) certify that they have conducted a reasonable search of all information known, or otherwise available, about the generic type of device; and (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description. The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this certification and description (with citations) in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K912004

HOGAN & HARTSON

COLUMBIA SQUARE
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BRUSSELS, BELGIUM
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BALTIMORE, MARYLAND
BETHESDA, MARYLAND
McLEAN, VIRGINIA

HOWARD M. HOLSTEIN
PARTNER
DIRECT DIAL (202) 637-5613

May 6, 1990

Document Mail Center (HFZ-401)
Office of Device Evaluation
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

Re: Premarket Notification for Shepard Medical Products, Inc.'s Powered Inflatable Tube Massager

Dear Sir or Madam:

Shepard Medical Products, Inc. ("Shepard"), by its attorneys, hereby submits this premarket notification 510(k) submission for its powered inflatable tube massager device which will be marketed by Shepard under the name Cryopress Sports Pump and by Camp International, Inc. ("Camp") under the name Multi-Temp Sports Pump ("Sports Pump"). The Shepard Sports Pump is the identical product as the Sport-Med device that was previously marketed by Damor America, Inc. ("Damor"), and which obtained premarket clearance through premarket notification 510(k) (K901022). (See Attachment 1). Damor transferred this product to Shepard. There are no modifications to the device that affect safety and effectiveness. However, because the product will no longer be marketed by Damor under the name Sport-Med, this 510(k) is submitted in order to obtain specific 510(k)s clearance in Shepard's name and for the new trade name under which the Sport Pump will be marketed.

As requested by FDA regulations and 21 C.F.R. § 807.81, Shepard is submitting this 510(k) premarket notification at least 90 days prior to the time when it plans to market the device as relabeled. The following information is required in accordance with FDA regulations at 21 C.F.R. § 807.81.

FAX: 202/637-5910 TELEX: 248370(RCA) 892757(WU) CABLE: HOGANDER WASHINGTON

982

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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I. Name of the device:

Classification name: Powered Inflatable Tube Massager

Trade name: Shepard Cryopress Sport Pump
Camp Multi-Temp Sport Pump

II. Establishment Registration Numner:

Shepard Medical Products
2000 North Hawthorne Street
Melrose Park, Illinois 60160

Shepard is the specification developer for the Sport Pump, which is produced for Shepard by a contract manufacturer. Shepard has submitted an establishment registration form to FDA but has not yet received a registration number.

III. Class of the device:

Powered inflatable tube massagers have been classified into class II, per 21 C.F.R. § 890.5650. These devices are reviewed by the General Hospital and Personal Use Devices Branch.

IV. Performance standards:

No performance standards have been developed under Section 514 of the FDC Act for powered inflatable tube massagers.

V. Proposed labels and labeling:

The labels and labeling for the Sport Pump as it will be distributed by Camp appears as Attachment 2 to this submission. This includes the labels that appear on the front and back of the compression pump and the draft user instructions for the use of the device. Except for the name change, identical labeling will be used when distributed by Shepard as the Cryopress Sport Pump. These claims are identical to those made by Damor in its 510(k).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The following claims will be made for the device:

1. For acute care of arm and leg swelling.

2. For treatment of chronic edema.

3. For treatment of lymphadema, including post traumatic, and rheumatic edema and chronic venous insufficiency and venous stasis ulcers

References supporting the use of the device for the claims listed above, as well as for the use of the device in the treatment of sports injuries are shown in Attachment 3.

Use of the device will be contraindicated for:

1. Acute deep vein thrombosis (known or suspected), pulmonary embolism, or thrombophlebitis.

2. Congestive heart failure or other conditions where increased venous and lymphatic return are undesirable.

3. In cases of severe peripheral arterial disease or arterial insufficiency ulcers.

4. Lymphatic obstruction.

5. Active infection in a limb, including erysipelas, lymphangitis, cellulitis.

These contraindications are identical to those in Damor's 510(k).

VI. Substantial equivalence:

The Shepard Sport Pump is identical to the Damor Sport Med which received premarket clearance through premarket notification section 510(k), and is currently marketed (K901022). Indeed, the Shepard Sport Pump and the Damor Sport Med are the same product. The only difference between the two is the company and product name. Because

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Damor no longer exists, and the Sport Pump is now manufactured and marketed by Shepard, this 510(k) premarket notification is submitted to reflect the change in company and product names under which it will be marketed: (1) Shepard Cryopress Sport Pump; and (2) Camp Multi-Temp Sport Pump. The product will continue to be marketed for identical indications under the new trade names as those for which it is presently marketed. A copy of the 510(k) premarket notification submitted for the Damor Sport-Med is provided in Attachment 1.

The Sport Pump device consists of two components: a compression pump and a cryogenic sleeve. One sleeve is specifically designed for use with the Sport Pump compression pump, while other sleeves are available for use with other manufacturers' sequential compression pumps.

The Sport Pump cryogenic sleeve is a triple wall sheath designed to encase an arm or leg. It consists of an interior and an exterior bladder, each of which can be filled with air or fluid. The interior bladder is divided into longitudinally segmented interior cells. One or more of the interior cells may be filled with a therapeutic solution, i.e. cold or hot fluid or gel, allowing the therapist to control the administration of cryogenic therapy to the acute care site rather than to the entire extremity. The exterior bladder is manufactured in two styles, allowing it to accommodate to either single cell intermittent compression pumps or sequential pumps.

The Sport Pump is a portable 12 volt DC intermittent compression pump. It is compact and lightweight, so that it can be used in any setting conveniently. The pump is battery operated and can operate six hours before recharging.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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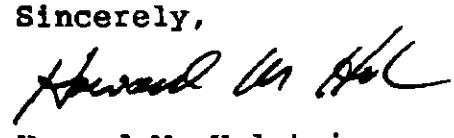
VII. Confidentiality

Shepard has maintained the existence of this submission as confidential commercial information and has not disclosed it to anyone except its employees, consultants, and law firms. Accordingly, Shepard requests that FDA not disclose the existence of this submission until such time as final action is taken upon it. In addition, Shepard requests extended confidentiality for the contents of the submission beyond the period of FDA review, as certain information contained in the submission may represent confidential commercial information.

Please direct any questions concerning this submission or requests for additional information to Rady A. Johnson, Hogan & Hartson at 202-637-6453.

Sincerely,



Howard M. Holstein

Enclosures

3892J

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1

ANDREWS OF PRODUCTS CAPITOL HEIGHTS, MD

987

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

MARCH 6, 1990

DAMOR AMERICA, INC. C/O HOGAN & HARTS
ATTN: HOWARD M HOLSTEIN
COLUMBIA SQUARE
555 THIRTEENTH STREET NW
WASHINGTON, DC, 20004

D.C. Number : K901022
Received : 03-05-90
90th Day : 06-03-90
Product : POWERED INFLATABLE TUBE MASSAGER, SPORT-MED

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act for the above referenced device has been received and assigned an unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

988

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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HOGAN & HARTSON

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HOWARD M. HOLSTEIN
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6701 ROCKLEDGE DRIVE
BETHESDA, MARYLAND 20817
301/493-0030

111 SOUTH CALVERT STREET
BALTIMORE, MARYLAND 21202
301/659-2700

8300 GREENSBORO DRIVE
McLEAN, VIRGINIA 22102
703/848-2800

March 5, 1990

BY HAND

Document Mail Center (HFZ-401)
Office of Device Evaluation
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

RE: Premarket Notification for Damor America, Inc.'s Powered Inflatable Tube Massager, Sport-Med

Dear Sir or Madam:

Damor America, Inc., ("Damor"), by its attorneys, is submitting the information required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and implementing regulations at 21 C.F.R. §§ 807.81 et seq. (1989), for its powered inflatable tube massager, Sport-Med. The following information is submitted at least 90 days prior to the time that Damor intends to introduce its device for commercial distribution.

Name of the device:

Classification name: Powered Inflatable Tube Massager

Trade name: Sport-Med

Establishment Registration Number:

Damor America, Inc.
2000 North Hawthorne Street
Melrose Park, Illinois 60160

Damor is the specification developer for the Sport-Med device. The company has submitted an establishment

CABLE: "HOGANDER WASHINGTON" • TELEX: 248870 (RCA), 892757 (WU) • FACSIMILE: 202/637-5910 • EASYLINK: 62776734

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registration form to FDA, but has not yet received a registration number. A contract manufacturer produces the device for Damor.

Class of the device:

Powered inflatable tube massagers have been classified into class II, per 21 C.F.R. § 890.5650. These devices are reviewed by the General Hospital and Personal Use Devices Branch.

Performance standards:

No performance standards have been developed under Section 514 of the FDC Act for powered inflatable tube massagers.

Proposed labels and labeling:

The labels and labeling for the Damor Sport-Med appear as Attachment 1 to this submission. This includes the labels that appear on the front and back of the compression pump and the draft user instructions for the use of the device.

The following claims will be made for the device:

1. For acute care of arm and leg swelling.

2. For treatment of chronic edema.

3. For treatment of lymphadema, including post traumatic, and rheumatic edema and chronic venous insufficiency and venous stasis ulcers

References supporting the use of the device for the claims listed above, as well as for the use of the device in the treatment of sports injuries are shown in Attachment 2.

Use of the device will be contraindicated for:

1. Acute deep vein thrombosis (known or suspected), pulmonary embolism, or thrombophlebitis.

2. Congestive heart failure or other conditions where increased venous and lymphatic return are undesirable.

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3. In cases of severe peripheral arterial disease or arterial insufficiency ulcers.

4. Lymphatic obstruction.

5. Active infection in a limb, including erysipelas, lymphangitis, cellulitis.

Substantial equivalence:

The Damor Sport-Med is substantially equivalent to the following devices:

Name of device	Manufacturer	510(k) number
PresSsion	Chattanooga Corp.	K832920
Flowtron AC 200/2	Huntleigh	K874688
Ventipress	Ventipress OY	K893950
Hydropulse	Amrex-Zefron	K834507
I.C.E. Box	LHS Industries	K821920

The Sport-Med is also substantially equivalent to the following devices, for which 510(k) numbers are not available:

Wright Linear Pump
BioCompression Systems' Sequential Circulator
Jobst Cryo/Temp Therapy Systems

A chart comparing the features of these devices to the Sport-Med appears as Attachment 3. Attachment 4 contains advertising and other informational materials on substantially equivalent devices.

The Sport-Med device consists of two components: a compression pump and a cryogenic sleeve. One sleeve is specifically designed for use with the Sport-Med compression pump, while other sleeves are available for use with other manufacturers' sequential compression pumps.

The Sport-Med cryogenic sleeve is a triple wall sheath designed to encase an arm or leg. It consists of an interior and an exterior bladder, each of which can be filled with air or fluid. The interior bladder is divided into longitudinally segmented interior cells. One or more of the interior cells may be filled with a therapeutic solution, i.e. cold or hot fluid or gel,

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allowing the therapist to control the administration of cryogenic therapy to the acute care site rather than to the entire extremity. The exterior bladder is manufactured in two styles, allowing it to accommodate to either single cell intermittent compression pumps or sequential pumps.

The Sport-Med pump is a portable 12 volt DC intermittent compression pump. It is compact and lightweight, so that it can be used in any setting conveniently. The pump is battery operated and can operate for twenty to thirty hours before recharging. See the chart in Attachment 3 for additional pump specifications.

Confidentiality

Damor has maintained the existence of this submission as confidential commercial information and has not disclosed it to anyone except its employees, consultants, and law firms. Accordingly, Damor requests that FDA not disclose the existence of this submission until such time as final action is taken upon it. In addition, Damor requests extended confidentiality for the contents of the submission beyond the period of FDA review, as certain information contained in the submission may represent confidential commercial information.

Please direct any questions concerning this submission or requests for additional information to Patricia B. Shrader, Hogan & Hartson at 202-637-8696.

Sincerely,

Howard M. Holstein

Howard M. Holstein

Enclosures

cc: Christopher H. Wright, Damor
Patricia B. Shrader

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Attachment 3

Comparison of the Damor Sport-Med and Substantially Equivalent Devices

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Comparison of the Damor Sport-Med
and Substantially Equivalent Devices

Device	Mfr.	Therapy Session Timer	Sequential	Sequential Cell Inflation Time Programmable	Sequential Cell Inflate Pressure Programmable	Rest Time Deflation Programmable	Single Cell Inflation Time Programmable	Single Cell Inflation Pressure Programmable	Pressure Indication Dial
Sport-Med	Damor	NO	NO			YES 15-175 sec.	YES 15-220 sec.	YES 0-185 mmHg	NO
WLP	Wright	YES 0 to 12 hrs.	YES 3 cells	YES Individual	YES Individual	YES			YES 0-160 mmHg
Sequential Circulator	Bio Compression	NO	YES 6 cells	NO 2 speeds	YES Only Overall Uniform Pressure	YES YES			YES YES 0 to 250 mmHg Overall
Lymphapress		NO	YES 10 Cells	NO 1 speed Preset Factory	YES Only Overall Uniform Pressure	NO Preset Factory			YES
Hemaflo I		NO	YES	NO Preset	YES	NO Preset			YES
Flowpress	Huntleigh	NO	YES	NO Preset 2 min.	YES 30 to 100 mmHg	NO Preset 1 min.			Optional

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Device	Mfr.	Therapy Session Timer	Sequential	Sequential Cell Inflation Time Programmable	Sequential Cell Inflate Pressure Programmable	Rest Time Deflation Programmable	Single Cell Inflation Time Programmable	Single Cell Inflation Pressure Programmable	Pressure Indication Dial
Flowtron	Huntleigh	NO	NO			NO Preset 90 sec. off	NO Preset 90 sec. on	YES 20-90 mmHg	Optional
Hemaflo II		NO	NO			NO Preset	NO Preset	YES 30-120 mmHg	YES
Presssion	Chattanooga	NO	NO			YES 3-240 sec.	YES 3-240 sec.	YES 30-120 mmHg	NO
Cryo-Temp Super	Jobst	NO	NO			YES 0-180 sec. off	0-60 sec.	0-120 mmHg	YES
Cryo-Temp Mini	Jobst	NO	NO			NO Present 130 Sec.	NO Present 90 Sec. On	0-90 mmHg	YES

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ANDREWS OFF PRODUCTS CAPITOL HEIGHTS, MD

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CAMP®

Multi Temp™
COMPRESSION THERAPY

INSTRUCTIONS:

Multi-Temp applies intermittent compression with either hot or cold temperatures to the injured limbs for reduction of swelling and pain.

The Multi-Temp Portable Compression System can operate one or more sleeves at the same time.

CONTENTS:

The Multi-Temp Compression System includes:

- Pump Model #6900
- 12 Volt Battery Model #6901
- Battery Charger #6902
- Pump Carrying Bag Model #6903
- Tubing Model #6904
- Collapsible Fill Container Model #6905

One or more of the following garments may be used with the Multi-Temp System:

- Arm Sleeve Model #6908
- Boot Model #6909
  - Small #6909-02
  - Large #6909-04
- Leg Sleeve Model #6910
  - Standard #6910-03
  - X-Large #6910-05

The following accessories are available:

- Tandem Hook-up Model #6906
- Fill Container 2-1/2 gallon Model #6907
- Cigarette Lighter Adaptor Model #6911
- Koolatron Cooler #P40 Model #6912
- Koolatron 110/12 Volt Adaptor Model #6913
- Pressure Gauge Model #6915

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PRECAUTIONS:

1. Federal law requires a physician to control use of this product.

2. Never adjust sleeve pressure or timing intervals to uncomfortable values.

3. Use a stockinette and check skin every few minutes.

4. Do not use extreme temperatures without continuous monitoring.

5. Keep electrical components dry.

TO FILL SLEEVE/BOOTS:

1. Pour one gallon of alcohol-water mixture, such as windshield washer fluid into collapsible container.

2. Connect the collapsible container to the sleeve and transfer the fluid into the sleeve/boot. Repeat step #1 if more fluid is needed in the sleeve.

3. Before disconnecting the fill container, squeeze all remaining air out of the sleeve and back into the container. Be sure to hold the sleeve so the connector is uppermost and squeeze until liquid starts to exit. Fluids will not leak from the sleeve once it is disconnected.

4. Refrigerate the sleeve for later use.

FOR USE:

1. The alcohol-water mixture should be refrigerated in either the container or in the garments prior to use.

2. For comfort, place a stockinette on the limb before positioning the garment.

3. Connect the air hose to the pump.

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onnect the red and black electrical connectors on the pump and battery pack.

NOTE: To avoid damage to the pump; Do not cross the color coded fittings.

5. Turn the switch to ON. The LED light indicates current to the pump has been established.

6. The dials on the end of the pump represent inflation and deflation time intervals. Adjust intervals to comfort and tolerance.

7. Garment pressure is controlled by the dial on the far right on the end of the pump. The numbers on the pressure control represent actual inflation pressures in the garment. Garment pressures are adjustable from zero to over 100 mm Hg.

GARMENTS:

1. Sleeves contain two bladders. The bladder nearest the skin can be filled with liquid or air. The fittings are a quick disconnect that blocks flow when uncoupled. The outer bladder is for air only and vents freely when disconnected.

   NOTE: These sleeves are available in segmented design for sequential pumps such as HEMAFLO.

2. To empty sleeve, connect pump to the garment. Plug in the collapsible bottle to fill connector, turn on the pump. Inflation of the sleeve forces the fluid to exit the garment.

3. The Multi-Temp Pump may be used to operate several sleeves at the same time. Simply attach the "Y" connectors (Model #6906) to the pump.

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CLEANING INFORMATION:

1. Garments are hand washable in mild detergent such as Tru Kleen ®, followed by a complete rinse. Pat dry with cloth.

2. Do not wring, machine wash or machine dry garments.

3. Do not dry clean sleeves.

4. The carrying case may be machine washed and dried.

5. Clean the pump with a soft damp cloth. Do not immerse.

WARRANTY:

In case of malfunction, return to seller or manufacturer for repair. Do not remove cover. Any user tampering will void warranty. See warranty card for instructions.

Camp International, Inc.
World Headquaters
Jackson, Michigan, U.S.A. 49204-0089

Write or call for more information:
1-800/492-1088
FAX 517-789-3299

Q-2502C3/90

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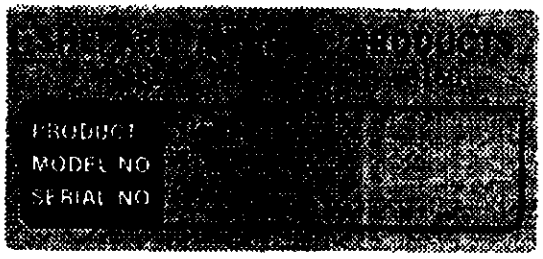

Multi Temp™
COMPRESSION THERAPY

- ☐ **Model 6900** Multi-Temp Pump
- ☐ **Model 6901** Battery
- ☐ **Model 6902** Battery Charger
- ☐ **Model 6903** Bag
- ☐ **Model 6904** Tubing
- ☐ **Model 6905** Fill Container (collapsible)

Camp International, Inc.
Jackson, MI 49204-0089 U.S.A.
1-800/492-1088

CAMP®

Multi Temp™
COMPRESSION THERAPY

- ☐ **Model 6908** Arm Sleeve
- ☐ **Model 6909-02** Boot - Small
- ☐ **Model 6909-04** Boot - Large
- ☐ **Model 6910-03** Leg Sleeve - Standard
- ☐ **Model 6910-05** Leg Sleeve - X-Large

Camp International, Inc.
Jackson, MI 49204-0089 U.S.A.
1-800/492-1088

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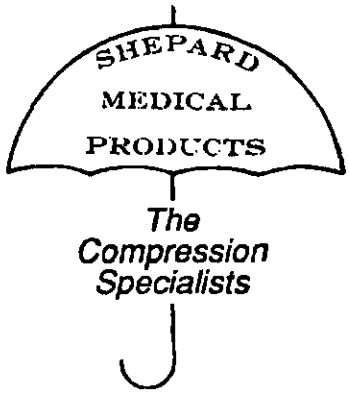

SPORTMED

Dealer Price List

SHEPARD'S SPORTMEDTM PUMP is an easy-to-use intermittent compression system that does it all!! Designed for sports professionals, it will operate from a wall outlet or 12 volt rechargeable battery. The system is compact and lightweight. It can operate several sleeves concurrently. Cold and compression on an injury reduce pain and swelling. All air and electrical connectors are quick-connect types. The sleeves may be filled, chilled and held ready for instant use. The user can adjust sleeve pressure and compression time ON-and-OFF intervals.

ITEM NO.	ITEM DESCRIPTION	DEALER PRICE
301	SYSTEM Connects to 12 Volt DC. Rechargeable from 120 Volt outlet. (Includes 314, 341, 342, 353, 362)	(b)(4) [redacted]
314	PUMP (12 Volts DC)	
322	Connector, Two Sleeve	
332-1	Sleeve, Arm	
332-3	Sequential Arm Sleeve	
333-1	Sleeve, Knee Length Boot	
333-3	Sequential Knee Boot	
334	Sleeve, Ankle Length Boot	
335-1	Leg Sleeve, Full	
335-3	Sequential Leg Sleeve	
336-1	Leg Sleeve, Extra Large	
336-3	Sequential Leg Sleeve—Extra Large	
337	Thigh Wrap	
341	Bag, Carrying	
342	Container, Fill/Drain—1 Gal.	
342-3	Container, Fill/Drain—2.5 Gal.	
342-4	Container, Fill/Drain—5 Gal.	
353	Battery (12 Volts DC)	
362	Charger, Battery (120 Volts AC)	
371	Cable, Car Lighter (12 Volts DC)	
P-40	Chiller, 12 Volt/Heater	
AC-10	120 Volt Adapter	
400 NEW	Pressure Gauge—In Line Plug	

***SPORTMED Sleeves will operate on any compression pump.**

PRICES: F.O.B. MELROSE PARK, IL. *WARRANTY: 1 YEAR PARTS AND LABOR*

2000 N. Hawthorne St. Melrose Park, Illinois 60160 708-865-2121 Telex - 289470 Fax - 708-865-0124 1002

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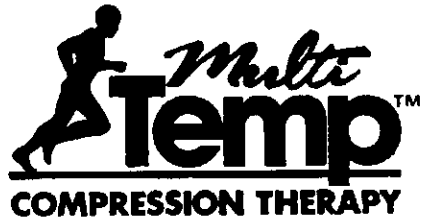

- ☐ **Model 6911**
  Cigarette Lighter Adaptor
- ☐ **Model 6913**
  Koolatron 110V/12 Volt Adaptor
- ☐ **Model 6912**
  Koolatron Cooler P40

Camp International, Inc.
Jackson, MI 49204-0089 U.S.A.
1-800/492-1088

1003

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SHEPARD MEDICAL PRODUCTS

The Compression Specialists

SPORTMED

Dealer Price List

SHEPARD'S SPORTMEDTM PUMP is an easy-to-use intermittent compression system that does it all!! Designed for sports professionals, it will operate from a wall outlet or 12 volt rechargeable battery. The system is compact and lightweight. It can operate several sleeves concurrently. Cold and compression on an injury reduce pain and swelling. All air and electrical connectors are quick-connect types. The sleeves may be filled, chilled and held ready for instant use. The user can adjust sleeve pressure and compression time ON-and-OFF intervals.

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332-3	Sequential Arm Sleeve	
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333-3	Sequential Knee Boot	
334	Sleeve, Ankle Length Boot	
335-1	Leg Sleeve, Full	
335-3	Sequential Leg Sleeve	
336-1	Leg Sleeve, Extra Large	
336-3	Sequential Leg Sleeve—Extra Large	
337	Thigh Wrap	
341	Bag, Carrying	
342	Container, Fill/Drain—1 Gal.	
342-3	Container, Fill/Drain—2.5 Gal.	
342-4	Container, Fill/Drain—5 Gal.	
353	Battery (12 Volts DC)	
362	Charger, Battery (120 Volts AC)	
371	Cable, Car Lighter (12 Volts DC)	
P-40	Chiller, 12 Volt/Heater	
AC-10	120 Volt Adapter	
400 NEW	Pressure Gauge—in Line Plug	

***SPORTMED Sleeves will operate on any compression pump.**

PRICES: F.O.B. MELROSE PARK, IL. *WARRANTY: 1 YEAR PARTS AND LABOR*

2000 N. Hawthorne St. Melrose Park, Illinois 60160 708-865-2121 Telex - 289470 Fax - 708-865-0124 1004

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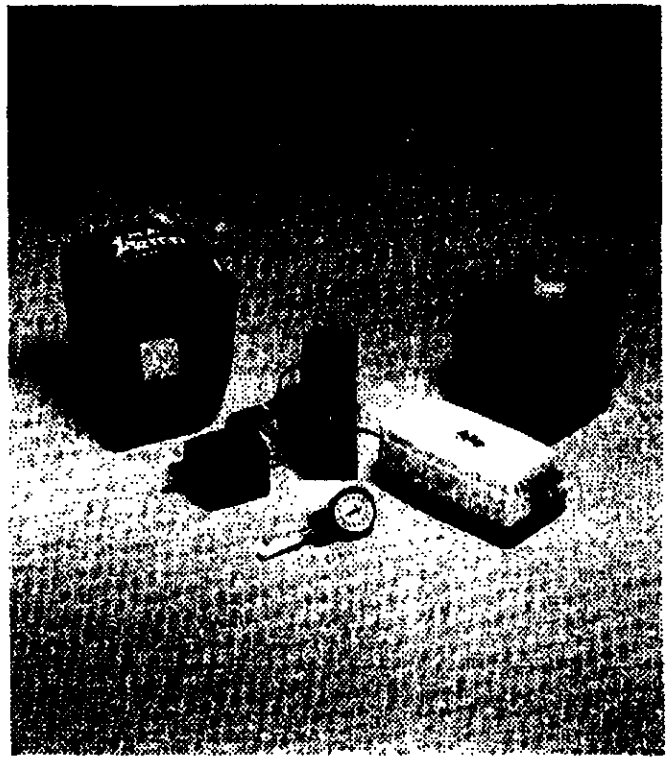
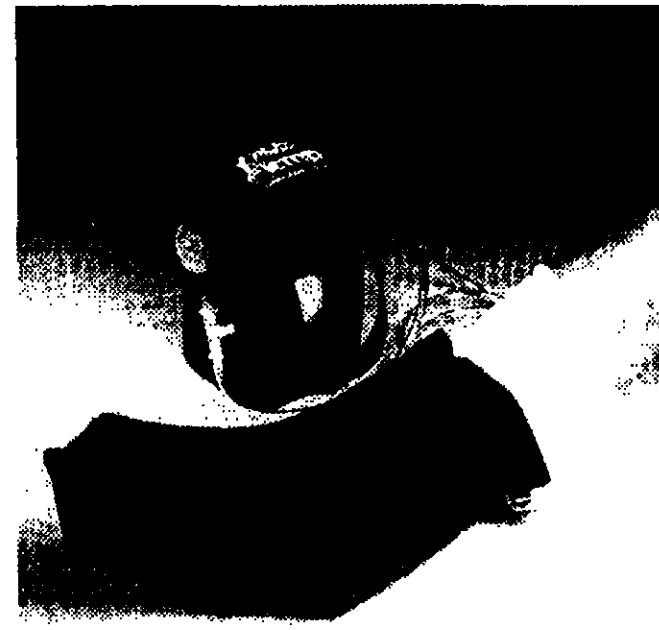
Intermittent Compression





6915 MULTI-TEMP™ Portable Compression System *

Consists Of:

MODEL	DESCRIPTION
6900	Multi-Temp Pump
6901	Rechargeable Battery
6902	Battery Charger
6903	Cordura Carrying Case
6904	Tubing
6905	Collapsible Fill Container
6916	Mm Hg Pressure Gauge

Features

Compact, portable, immediate on-site treatment for sprains and edema of the leg and arm.

Continued care may be extended wherever patients need it; home, vehicle, hotel, training room or sidelines.

Ideal for sports medicine applications.

Hot or cold treatment temperature.

One Year warranty on pumps and 6 months on garments.

Gelcel rechargeable battery.

Cordura carrying case.

*Note: Garments are sold separately.

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CT-A5.1/5M10/90

Camp International, Inc.
P.O. Box 89
Jackson, Michigan 49204
1-800-492-1088

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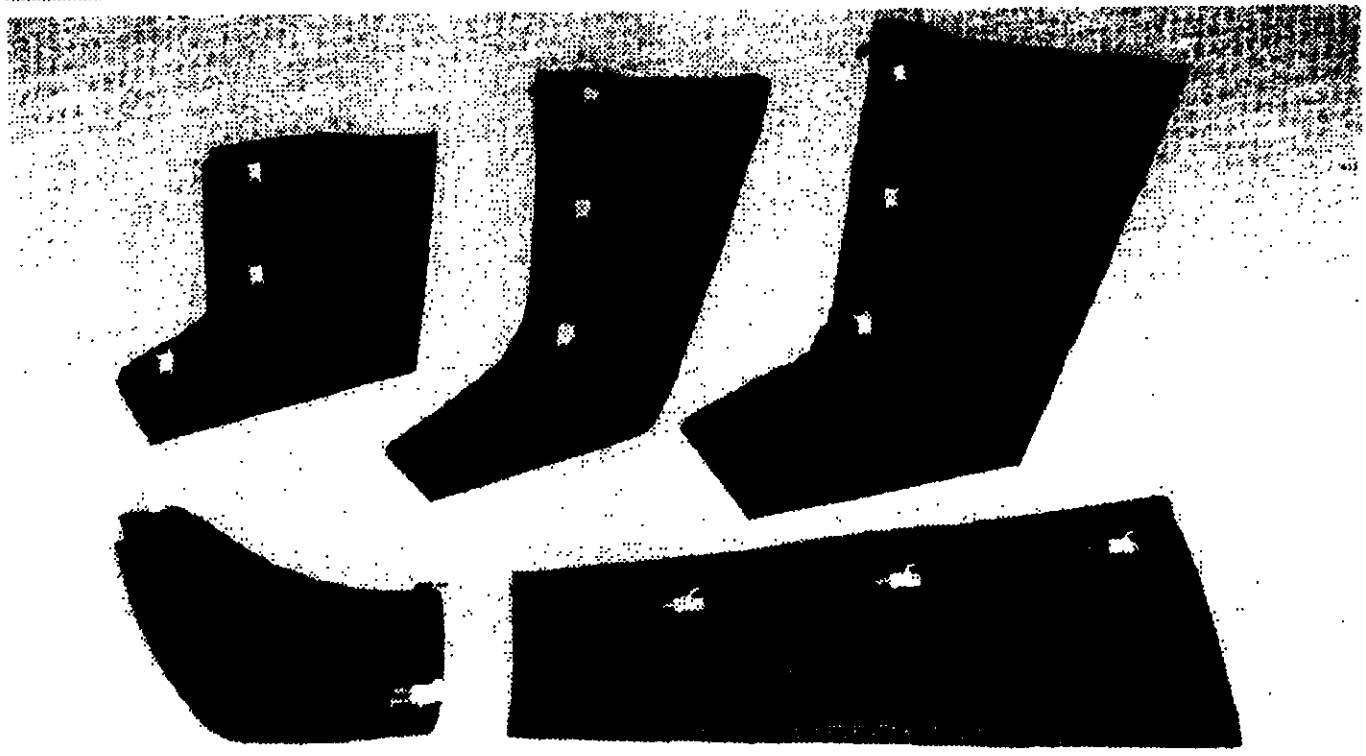
PNEUMATIC

Intermittent Compression

Multi Temp™
COMPRESSION THERAPY



6908 Arm Sleeve, 6909 Boot, 6910 Leg Sleeve

GARMENT	MODEL	LENGTH	CIRCUMFERENCE	
Arm Sleeve	6908	29" (74 cm)	28" (71 cm)	Upper
			18" (46 cm)	Lower
Boot Small	6909-02	13" (33 cm)	18" (46 cm)	Top
			18" (46 cm)	Toe
Boot Large	6909-04	13" (33 cm)	25" (64 cm)	Top
			22" (57 cm)	Toe
Leg Sleeve Standard	6910-03	32" (81 cm)	28" (71 cm)	Top
			14" (35.5 cm)	Ankle
Leg Sleeve X-Large	6910-05	37" (94 cm)	36" (91 cm)	Top
			24" (61 cm)	Ankle

Features

Polypropylene coated nylon for longer lasting wear.
Open toe-zippered garments.
Double welded seams for longevity.
Fluid filled bladder for hot-cold temperature.
Easily cleaned with a mild detergent such as Camp Tru Kleen ®.
Garments have three fluid cells for even distribution.

WARNING: This system should be used only under medical supervision with treatment authorized by a physician or a prescription.

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Camp International, Inc.
P.O. Box 89
Jackson, Michigan 49204
1-800-492-1088

CAMP®

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ANDREWS OF PRODUCTS CAPITOL HEIGHTS, MD

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THE CRYOPRESS COMPRESSION SYSTEM

"A PROTOCOL FOR TREATMENT"

By

David G. Kleinmeyer, PT, AT, C/R

Ice, compression and elevation have been used effectively in decreasing swelling and pain in soft tissue injuries. Clinical evidence shows, when cryogenics and compression are applied immediately, the patient recovery rate is substantially shorter. This is due to the PREVENTION of Hematoma and Hypoxic injury to soft tissue.

In the past, an ice pack applied by an elastic wrap was the treatment of choice. Conforming the cold to the injured area and consistency of the compression applied are drawbacks of this application. Fortunately, today there is a modality that can control this problem of conformity and consistency. The Shepard Medical **CRYOPRESS** and Camp's **MULTITEMP** Sports Pumps were designed with this in mind.

These Sports Pumps utilize a compression sleeve filled with windshield washer fluid that won't freeze until it is -30°. The sleeve is constructed of 10 mil, 200 denier urethane coated nylon. The fluid is added to the sleeve through a special fill container provided with the pump. The sleeve is then attached to a hose that also attaches to the pump system. The system is portable and runs off a battery pack that is fully rechargeable. When not in use, the sleeve can be stored filled with fluid, in either a refrigerator or freezer.

The sleeve utilizes the chilled fluid to provide even and consistent application of cold. The compression is generated by the pump. It provides even, consistent application of cold and intermittent compression. This aids in the conformity of the cold application. The fluid conforms to the injured area, whereas with the application of ice, there might be some uneven pressure.

The compression sleeve can be utilized on all soft tissue injuries. There are sleeves designed for both upper and lower extremities.

This product is currently being used by many universities, colleges, high schools and most notably, the **CHICAGO BEARS**. I, personally, have been utilizing the Shepard Medical **CRYOPRESS** Sports Pump for three years. To date, it has provided my injured athletes with the best treatment available for soft tissue injuries. The **CRYOPRESS** has made my job easier by returning healthy athletes to the playing field faster, keeping us a leader in the sports medicine field.

The following is the protocol I follow when treating a soft tissue injury.

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"PROTOCOL FOR TREATMENT"

1) Check the athlete's skin integrity. Also check for signs of possible hemorrhage or fracture.

2) Measure area to be treated for swelling. These measurements will be compared with measurements taken after treatment.

3) Take athlete's blood pressure. If possible, it should be taken on the extremity to be treated. The blood pressure is necessary in determining how much pressure should be applied during treatment.

4) Position the athlete comfortably with the extremity to be treated elevated. Elevation will aid in venous return to the circulatory system.

5) Apply stockinette to extremity, keeping fingers or toes exposed. The digits are left exposed to check for possible circulatory problems, cold burns or frostbite. Be sure the stockinette is smooth as wrinkles may cause irritation.

6) Apply the sleeve to the extremity.

7) Attach the tube to the sleeve and then to the pump.

8) Time Settings: The "Rest Time/Pump Time" knobs can be adjusted from 0 to 2.5 minutes. Set "Pump Time" at 3 to 4 times the "Rest Time", ie. 120/30. Turn the "Rest Time" knob to 30 seconds. Turn the "Pump Time" knob to 120 seconds.

9) Initial Sleeve Inflation: Use pump at maximum setting to inflate sleeve. Do not allow the pressure to build.

10) Pressure Settings: Place finger over pressure gauge outlet with pump on. Set operating pressure. Reconnect hose to appliance.

11) Do not exceed the athlete's diastolic blood pressure. If the compression does exceed the diastolic pressure, possible hypoxic injury could occur to the soft tissues in the injured area.

12) The athlete should not feel any pain, tingling, numbness or a pulse during the treatment.

13) Pump compression pressure applied should not exceed 40-60 mm Hg for the upper extremity and 60-100 mm Hg for the lower extremity.

14) The pressure is adjusted to coincide with the athlete's diastolic blood pressure.

15) Pressure applied and released should be determined by the athlete's tolerance and comfort. Do not use a pressure setting which causes pain or discomfort.

16) During the exhaust cycle, the patient should be encouraged to exercise his/her fingers or toes. This will aid circulation and decrease chances of cold injury.

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17) The treatment time should be 20-30 minutes each hour. This should be repeated at least 2 to 3 times during the day. If time permits, additional treatments can be initiated.

18) In between treatments, active movement should be attempted if tolerable. This will also assist circulation and improve active range of motion.

19) Remeasure the treated area after treatment to determine decrease in swelling.

BIBLIOGRAPHY

"The American Journal of Sports Medicine", volume 10, no. 5. Authored by John E. Hocutt, Jr., M.D. and others. "CRYOTHERAPY IN ANKLE SPRAINS", 1982.

"The Physician and Sports Medicine", volume 13, no. 6. Authored by Gary B. Wilkerson, ATC. "EXTERNAL COMPRESSION FOR CONTROLLING TRAUMATIC EDEMA", 1985.

"The Journal of Orthopaedic and Sports Physical Therapy", volume 4, no. 1. Authored by Lt. William S. Quillen, MSC, USN. "INITIAL MANAGEMENT OF ACUTE SPRAINS WITH RAPID PULSED PNEUMATIC COMPRESSION AND COLD", 1982.

"The Physician and Sports Medicine", volume 7, no. 6. Authored by Lan Barnes. "CRYOTHERAPY - PUTTING INJURY ON ICE", 1979.

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External Compression for Controlling Traumatic Edema

Gary B. Wilkerson, ATC

In brief: External compression is widely advocated for treating acute sports injuries. However, the rationale for using it is seldom discussed. Maintaining joint function and reducing pain and secondary hypoxic tissue death lead to more rapid and complete recovery of edema associated with sprains and strains. Poorly managed edema may contribute to the development of restricted range of motion, muscle atrophy, reduced ligament tensile strength, and joint laxity—all of which predispose an athlete to reinjury. The mechanism of action of external compression in controlling edema may be explained on the basis of its effect on capillary filtration and lymphatic drainage.

Ice, compression, and elevation are now widely recognized as the standard care for acute musculoskeletal injuries.[1-8] Of these measures, compression seems to be the most effective deterrent to swelling.[9] Applying external compression inhibits seepage of fluid into underlying tissue spaces and disperses excess fluid.[4,5,10-12] Recent studies suggest that ice has a limited effect on swelling and may actually cause it to increase as a result of cold-induced ischemic damage to blood vessels.[6,13,14] Regardless of whether ice causes increased swelling, its use is still indicated for acute trauma to control inflammation, pain, and

continued

Mr. Wilkerson is head athletic trainer at Centre College in Danville, Kentucky.

◀ *The accumulation of fluid associated with sports injuries delays recovery and may predispose athletes to reinjury.*

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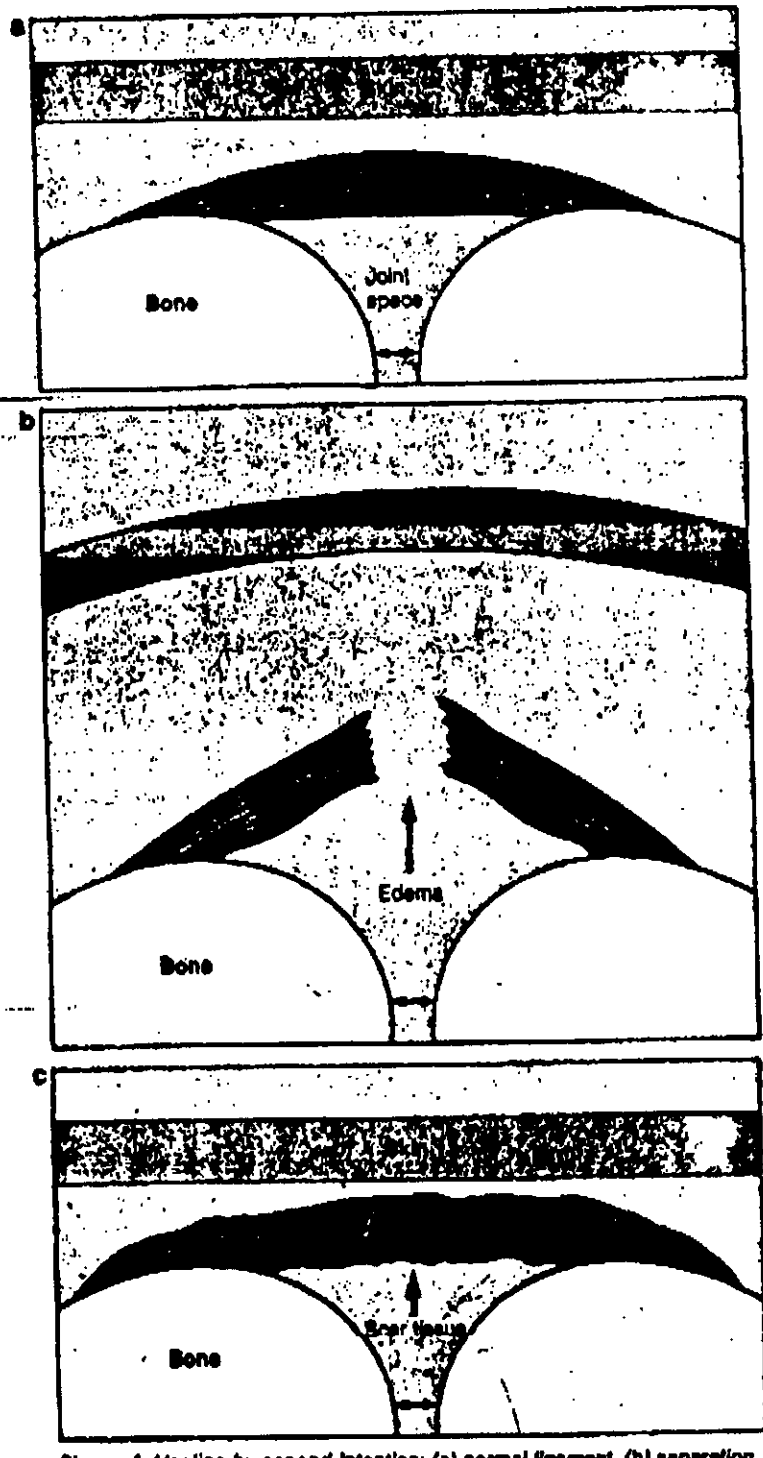

Figure 4. Healing by second intention: (a) normal ligament, (b) separation of torn tissue ends, (c) ligament lengthened by scar tissue.

Effects of Edema

The accumulation of fluid around an injury site compounds the extent of tissue damage, delays healing, and may result in some degree of chronic disability. Congestion of the interstitium inhibits the delivery of oxygen and nutrients to the cells that survived the traumatic incident. Oxygen deprivation causes secondary hypoxic tissue death that adds to the necrotic debris caused by the original trauma and further increases the osmolarity of the interstitial fluid. Thus, fluid accumulation causes the total amount of tissue damage to be greater than that caused directly by trauma.[4,15]

Fluid accumulation beneath damaged ligaments may cause separation of torn tissue ends.[13] Such separation may prevent healing by first intention, which requires good apposition of the torn tissue edges for direct union. Indirect union of the torn edges can be achieved through fibrosis (ie, healing by second intention), by which the gap is filled and bridged with scar tissue. Tensile strength is reduced when ligament fibers are separated by scar tissue, and chronic instability may result because the healed ligament may be longer than normal[2,27-29] (figure 4).

Pain associated with traumatic injuries is caused by damage to nerve fibers, hypoxia, and pressure on free nerve endings.[4,20,25,26] As fluid accumulates, pressure on free nerve endings initiates the pain-spasm-pain cycle.[13] The body responds to increased pain by increasing muscle spasm, which increases pain, and so on. A vicious cycle of escalating pain and muscle spasm often results.

Excessive edema and its associated pain restrict active movement of a joint through a normal range of motion. Lack of use results in muscle atrophy and fluid stasis. Stagnation of edema leads to coagulation, which inhibits its removal. Fibrinogen, present in the exudate that passes through the capillary walls, is deposited in the interstitium as an insoluble mesh of interlacing filaments (ie, fibrin). As necrotic debris and platelets become trapped in the web-like mesh, the edema thickens to the point that fluid barely flows through the tissues. Eventually, the injury site is isolated from the circulating fluids of the body by a wall of necrotic debris. Many months may be required for its complete resorption.[4,10,20,25,30] The ease with which the tissues can develop severe edema is increased as the tissue spaces gradually become stretched by persistent edema.[16] Soft tissues in the region of long-lasting edema become indurated and thickened.[31] There is also a tendency toward the development of adhesions and joint contractures[32] (figure 5).

Healing cannot begin until enough of the necrotic barrier has been broken down by proteolytic enzymes and phagocytosis to permit

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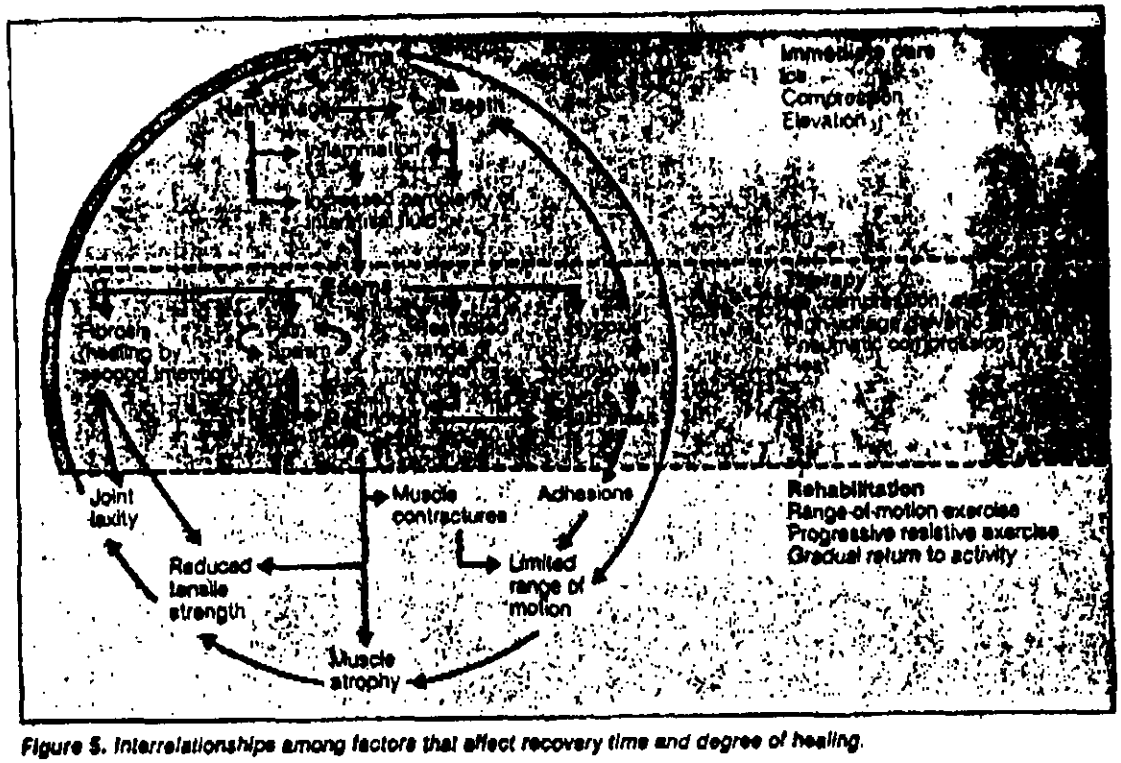

Figure 5. Interrelationships among factors that affect recovery time and degree of healing.

growth of new tissue.[4,26] Proliferation of new capillaries into the damaged area results in the delivery of oxygen and nutrients to fibroblasts that begin to synthesize new collagen. Thus, recovery time is determined by the size of the original necrotic mass and the speed with which the body mobilizes the debris.[1]

Control of Edema

The complications caused by fluid accumulation may be minimized by the early application and continuous use of external compression. By increasing the hydrostatic pressure of the interstitial fluid, external compression counteracts the forces that cause fluid to move out of the capillaries after tissue damage occurs (primarily increased osmolarity of interstitial fluid).[4,9] Fluid is forced toward areas where hydrostatic pressure is lower, in either the capillaries, lymph vessels, or tissue spaces away from the injury site (figure 6).

Elevation of the affected extremity lowers the hydrostatic pressure exerted by the blood against the capillary walls by counteracting the force produced by the heart with the force of gravity.[19] Elevation also decreases interstitial osmolarity by facilitating lymphatic drainage.

Drainage of protein-containing fluid from the interstitium is the primary function of the lymphatic system. Fluid may be reabsorbed by the capillaries to some extent, but there is no other route besides the lymphatic vessels through which free proteins can be removed from the interstitium. The flow of lymph is normally very slow, since there is no pumping force like that provided by the heart in the cardiovascular system. Any factor that tends to increase interstitial hydrostatic pressure increases the rate of lymph flow. The presence

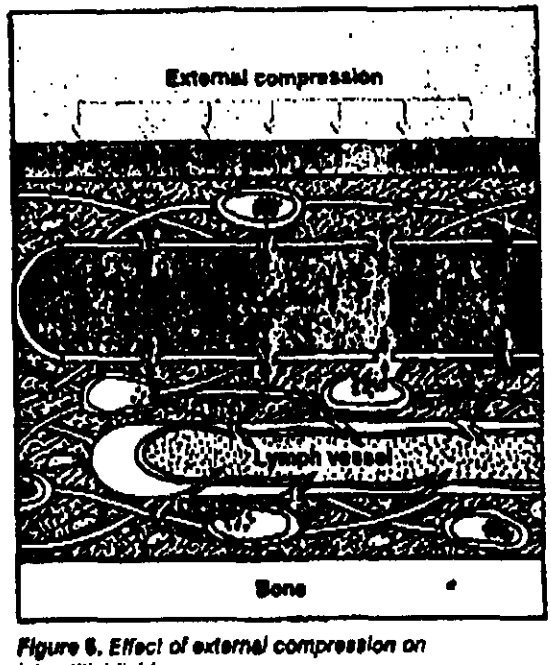

Figure 6. Effect of external compression on interstitial fluid.

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of one-way valves ensures that fluid moves in only one direction whenever a lymph vessel is compressed. Lymph flow is sustained primarily by the milking action of muscle contractions.[5,22,33] Active exercise increases lymph flow by as much as 5 to 15 times normal.[16] This lymph-flow mechanism provides the rationale for the widespread use of high-voltage galvanic muscle stimulation and intermittent pneumatic compression for mobilizing edema.[12,34-36]

Summary

The accumulation of fluid associated with sports injuries has the effect of delaying recovery and may predispose an athlete to reinjury if poorly managed. Edema may be controlled (or at least decreased) by applying external compression, which counteracts forces tending to move fluid out of the capillaries and into the tissue spaces. Control of edema brings about more rapid and complete healing by (1) reducing the extent of secondary hypoxic tissue damage, (2) facilitating healing by first intention through better apposition of torn tissue edges, (3) inhibiting development of a necrotic debris barrier around the injury site, (4) reducing pain and associated muscle spasm, and (5) maintaining joint mobility and function.

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References

1. Barnes L: Cryotherapy—putting injury on ice. Phys Sportsmed 1979;7(June):130-136
2. Cox JS, Brand RL: Evaluation and treatment of lateral ankle sprains. Phys Sportsmed 1977;5(June):51-55
3. Hocutt JE Jr, Jaffe R, Rylander CR, et al: Cryotherapy in ankle sprains. Am J Sports Med 1982; 10 (September-October):316-319
4. Knight KL: Cryotherapy in sports medicine, in Scriber K, Burke EJ (eds): Relevant Topics in Athletic Training. Ithaca, NY, Mouvement Publications, 1978, pp 52-59
5. Kolb P, Denegan C: Traumatic edema and the lymphatic system. Athletic Training 1983;18(4):339-341
6. McMaster WC, Liddle S: Cryotherapy influence on posttraumatic limb edema. Clin Orthop 1980; 150 (July-August):283-287
7. Snedeker J, Recine V, MacCartee C: Cryotherapy and the athletic injury. Athletic J 1974;55:16-18
8. Weiker GG: Ankle injuries in the athlete. Primary Care 1984;11(January):101-108
9. Matsen FA, Krugmire RB: The effect of externally applied pressure on postfracture swelling. J Bone Joint Surg 1974;56(December):1586-1591
10. O'Donoghue DH: Treatment of Injuries to Athletes, ed 3. Philadelphia, WB Saunders Co, 1976, pp 48-50
11. Quillen WS, Rouillier LH: Initial management of acute ankle sprains with rapid pulsed pneumatic compression and cold. J Orthop Sports Phys Ther 1982;4(1):39-43
12. Starkey JA: Treatment of ankle sprains by simultaneous use of intermittent compression and ice packs. Am J Sports Med 1976;4(July-August):142-144
13. Farry PJ, Prentice NG, Hunter AC, et al: Ice treatment of injured ligaments: an experimental model. NZ Med J 1980;91(January):12-14
14. Matsen FA, Questad K, Matsen AL: The effect of local cooling on post-fracture swelling. Clin Orthop 1975;109:201-206
15. Spiker J: Implications of tissue healing to treatment, in Bell GW (ed): Professional Preparation in Athletic Training. Champaign IL, Human Kinetics Publishers, 1982, pp 107-110
16. Guyton AC: Textbook of Medical Physiology, ed 6. Philadelphia, WB Saunders Co, 1981, pp 70, 358-380
17. Anthony CP, Thibodeau GA: Textbook of Anatomy and Physiology, ed 11. Philadelphia, WB Saunders Co, 1983, pp 50-54, 675-676
18. Hargens AR: Tissue Fluid Pressure and Composition. Baltimore, Williams and Wilkins Co, 1981, pp 2-18
19. Moyer JG, Fuchs M: Edema Mechanisms and Management, ed 1. Philadelphia, WB Saunders Co, 1960, pp 3-14
20. Carpenter PL: Microbiology, ed 3. Philadelphia, WB Saunders Co, 1972, p 332
21. Taber's Cyclopedic Medical Dictionary, ed 14. Philadelphia, FA Davis Co, 1982
22. Tortora GJ, Anagnostakos NP: Principles of Anatomy and Physiology, ed 3. New York City, Harper and Row Publishers, 1981, pp 98-100, 524, 529
23. Arrigoni-Martelli E: Inflammation and Anti-inflammatories. New York City, Spectrum Publications Inc, 1975, pp 89-92, 153-156
24. Katona G, Blengio JR: Inflammation and Anti-inflammatory Therapy. New York City, Spectrum Publications Inc, 1975, pp 89-92, 153-156
25. Klafs CE, Arnheim DD: Modern Principles of Athletic Training, ed 5. St. Louis, CV Mosby Co, 1981, pp 211-214
26. Roy S, Irvin R: Sports Medicine, ed 1. Englewood Cliffs, NJ, Prentice-Hall, 1983, pp 125-127
27. Freeman MA: Treatment of ruptures of the lateral ligament of the ankle. J Bone Joint Surg 1965; 47(November-December):661-668
28. Clayton ML, Miles JS, Abdulla M: Experimental investigations of ligaments healing. Clin Orthop 1968; 61:146-153
29. Saunders EA: Ligamentous injuries of the ankle. Am Fam Phys 1980;22(August):132-138
30. Frobisher M: Fundamentals of Microbiology, ed 8. Philadelphia, WB Saunders Co, 1968, p 308
31. Wakim KG, Martin GM, Kruser FH: Influence of centripetal rhythmic compression on localized edema of an extremity. Arch Phys Med Rehabil 1955;36:98-103
32. Salter RB: Textbook of Disorders and Injuries of the Musculoskeletal System. Baltimore, Williams and Wilkins Co, 1970, p 24
33. Elkins EC: Effect of various procedures on the flow of lymph. Arch Phys Med Rehabil 1953;34:31-39
34. Brown S: Ankle edema and galvanic muscle stimulation. Phys Sportsmed 1981;9(November):137
35. Lamboni P, Harris B: Use of ice, airsplints, and high voltage galvanic stimulation in effusion reduction. Athletic Training 1983;18(January):23
36. Wilkerson J: Contrast baths and pressure treatment for ankle sprains. Phys Sportsmed 1979;7(April):143

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Initial Management of Acute Ankle Sprains with Rapid Pulsed Pneumatic Compression and Cold

Lt. WILLIAM S. QUILLEN, MSC, USN,* Ens. LEON H. ROUILLIER, MSC, USN*

Sports medicine practioners must be prepared to aggressively treat musculoskeletal trauma with both therapeutically sound and time efficient regimens. Thorough early treatment is essential for prevention of further trauma, for an expedient recovery, and for the earliest possible return to activity. The present study sought to evaluate the efficacy of rapid pulsed pneumatic compression along with cold in the amelioration of the acute symptoms associated with lateral ankle ligament sprains. Active range of motion and volumetric measures of ankle edema were made before and after 20-minute compression treatments on a series of 19 acute grade I lateral ankle ligament sprains. The number of treatments required before initiation of rehabilitation exercise ranged from one to eight with a mean of three. Rapid pulsed pneumatic compression along with cold is a safe and therapeutically sound method of controlling pain, loss of motion, and edema associated with this common injury.

Injuries to the lateral ligaments of the ankle comprise approximately 85% of all ankle injuries.[3] The "turned ankle" is such a common occurrence that it has been identified as being the cause of the second greatest number of days lost from work because of injury.[1] With the rapid growth of recreational and leisure time athletic participation, the incidence of sprained ankles is most certainly on the rise. The sports medicine practitioner must be prepared to vigorously treat this injury entity with a therapeutically sound and time efficient regimen. Aggressive early treatment and appropriate rehabilitation are essential in the prevention of chronic instability and residual disability.

P-R-I-C-E summarizes the current, conventional management protocol for these ligament injuries: P for protection, R for rest, I for cryotherapy (ice), C for compression, and E for elevation. By controlling the cardinal symptoms of acute inflammation (pain, edema, and increased tissue metabolism) that lead to loss of function and prolonged disability, the practitioner seeks the most effective means of treatment to allow his patient an expedient recovery. The question then that confronts the clinician is: what method or modality is physiologically sound, cost effective, and safely and easily administered to the patient?

While the concept of intermittent compression and cold in the treatment of acute ankle sprains is not new,[5] the present study sought to evaluate the efficacy of a new form of rapid pulsed pneumatic compression (Thera-Nu; Thera Corp., Orlando, FL). With rapidly alternating compressions, there is sufficient pressure to assist in venous and lymphatic return yet not impair general circulation.

Pneumatic compression is a safe, noninvasive form of treatment. During inflation, excess fluid from interstitial spaces is forced to vascular and lymphatic compartments, where it is perfused by blood passing from superficial to deep veins. During deflation normal arterial flow returns to the skin and superficial tissues. Improved circulation and decreased interstitial fluids result in a reduction of pain, increased active range of motion, and potentially, more rapid healing. The

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BASELINE EVALUATION FLOW SHEET

NO. _____

ACUTE ANKLE EDEMA STUDY

NAME _____ CLASS _____ COMPANY _____

SS# _____ AGE _____ SEX _____

DX: 1° ____ 2° ____ I ____ E ____ LEFT ____ RIGHT _____

DOI: _____ TOI: _____

DATE/TIME OF FIRST TREATMENT: _____

VOLUMETER:

Treatment	Uninvolved	Involved	%	DF AROM
1 Pre		_____		
1 Post	_____	_____	_____	_____
2 Pre		_____	_____	_____
2 Post		_____	_____	_____
3 Pre		_____	_____	_____
3 Post		_____	_____	_____
4 Pre		_____	_____	_____
4 Post		_____	_____	_____

Fig. 1. *Baseline evaluation flow sheet. Dx: diagnosis, I: inversion, E: eversion, DOI: date of injury, TOI: time of injury, DF AROM: dorsiflexion active range of motion.*

Fig. 2. *Volumetric displacement of the foot/ankle was measured via a bucket tank with runoff collected in a graduated cylinder.*

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Fig. 3. *Elasticized stockinet is applied over the affected foot/ankle.*

Fig. 4. *A "cryoglove" is molded around the traumatized anterolateral ankle joint.*

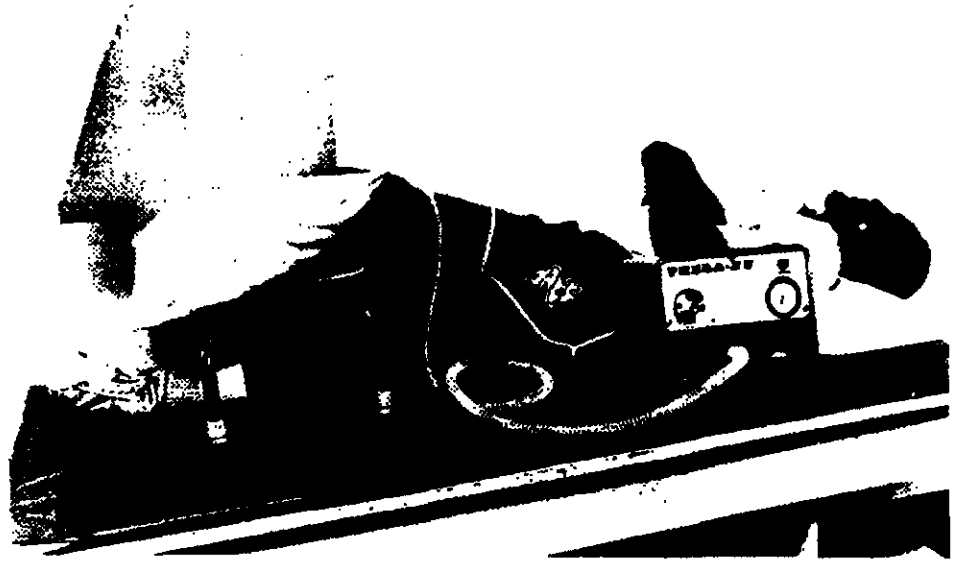

Fig. 5. *The Thera-Nu rapid pulsed pneumatic compression device with foot/ankle boot is inflated to 70–90 mm Hg as tolerated and treatment proceeds for 5 minutes. The "cryoglove" is removed after 5 minutes and then compression is continued for an additional 15 minutes.*

simultaneous application of cold reduces the metabolic demands of the tissues while this pumping action occurs.

Patients who had sustained grade I inversion ankle ligament sprains were referred to the Physical Therapy Branch, Orthopaedic/Sports Medicine Service, United States Naval Academy, for treatment. Nineteen patients were included in this initial study, of which 14 (74%) were evaluated and treated within 24 hours of injury. Two (10%) were treated within 48 hours and the remaining three (16%) within 72 hours of injury.

Upon entering the treatment protocol, a baseline evaluation flow sheet (Fig. 1) was completed on the injured ankle consisting of active range of motion, stability, and volumetric displacement measures. These same data were collected before and after each treatment session.

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Figs 6, 7, and 8 When the symptoms have subsided, the patient is begun on isokinetic rehabilitation, surgical taping exercises for the peroneal evertors, and a functional progression of walking, jogging, running, and agility drills

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TABLE 1
Summary of results of treatment

Number of subjects	19
Mean volume of normal foot/ankle of subjects (ml)	2025
Mean volume of injured foot/ankle pretreatment (ml)	2107
Mean volume change post-treatment sessions (ml)	
1	−72.89
2	−16.31
3	+10.45*
4	−46.14
5	−25.00
6	−29.98
Mean number of treatments required before initiation of rehabilitation exercise	3
Range of treatments	1–8

* "Rebound phenomenon" observed post-treatment.

The volumetric displacement of the foot/ankle was measured via a lucite tank with runoff collected in a graduated cylinder (Fig. 2). Utilizing Archimedes principle, edema changes as a function of displacement could be objectively measured.

The basic treatment regimen consisted of: *1)* applying elasticized stockinet over the affected foot/ankle (Fig. 3); *2)* molding a "cryoglove"† around the traumatized anterolateral ankle joint (Fig. 4); *3)* utilizing the Thera-Nu rapid pulsed pneumatic compression device with foot/ankle boot for 5 minutes at 70–90 mm Hg as tolerated by patient (Fig. 5); *4)* at the completion of 5 minutes of combined treatment, removing the "cryoglove" and continuing compression for an additional 15 minutes; *5)* at the termination of treatment, supporting the patient's ankle with a soft cast, strapping, or thermoplastic ankle stirrup dependent upon residual symptoms as per our standard ankle protocols[2,4]; and *6)* encouraging progressive partial weight-bearing ambulation with crutches to tolerance.

Patients were continued on this acute treatment protocol until volumetric changes stabilized, dorsiflexion acute range of motion approached normal limits, and there was minimal to no pain upon weight bearing. At that time, patients were begun on isokinetic rehabilitation (Fig. 6), surgical tubing for peroneal evertors (Fig. 7), and a functional progression of walking, jogging, running, and agility (Fig. 8), with ultimate weaning from tape or stirrup support.

The first 19 patients treated with this regimen were selected for inclusion in this report. Table I summarizes the mean foot/ankle volumes pre- and post-treatments and by treatment sessions. The number of treatments required to relieve the acute symptoms associated with lateral ankle ligament sprains before the initiation of rehabilitation ranged from one to eight with a mean of three. It should be noted that during treatment session 3 a "rebound phenomenon" was observed in several patients with a mean increased post-treatment volume reported for the sample group. Closer examination revealed that those patients had inadvertantly dangled their feet before post-treatment measurements. This reinforces the necessity for the *immediate* application of external support post-treatment to maintain edema reduction gains.

The use of a rapid pulsed pneumatic compression device in the acute management of lateral ankle ligament injuries is a safe and therapeutically sound method of controlling pain and edema associated with this injury, which often delays the implementation of appropriate rehabilitation exercise. Physical therapists and other sports medicine practitioners must be prepared to initiate care for musculoskeletal trauma at the earliest possible time in order to minimize residual disability and time lost from activity.

The authors would like to acknowledge the assistance of HM2 L. Underwood, HM2 M. Ragon, HM3 K. Regan, and HM3 L. Hepp in the clinical data collection phase of this study.

The authors would like to acknowledge the fine photographic illustrations provided by the United States Naval Academy Photographic Lab.

† The "cryoglove" was developed by one of the authors (L. H. R.) as a readily available flexible form of cold.

REFERENCES

1. Choi J: Acute conditions incidence and associated disability. Vital Health Stat [10] 120:10, 1978
2. Cox JS, Brand RL: Evaluation and treatment of lateral ankle sprains. Phys Sportsmed 5:51–55, 1977
3. O'Donoghue DH: Treatment of ankle injuries. Northwest Med 57:1277–1286, 1958
4. Quillen WS. An alternate management protocol for lateral ankle sprains. J. Orthop Sports Phys Ther 2:187–190, 1981
5. Starkey JA. Use of intermittent compression and cold in the treatment of ankle sprains. Am J Sports Med 4:142–144, 1976

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Cryotherapy—Putting Injury on Ice

Lan Barnes

Cheap, simple, safe, and effective, ice therapy after soft-tissue injury can cut weeks off of recovery time—but almost nobody uses it.

In the 1961 winter issue of *Athletic Training*, the Journal of the National Athletic Trainers Association, a trainer named Don Bennett published an article on the use of cold water to control hemorrhage and swelling in athletic injuries.[1] Cold, by that time, was a well-established modality in the treatment of nonsports-related conditions such as vasticity, and European sportsmedicine specialists had experimented extensively with cold. Nevertheless, Bennett's paper marked one of the first, if not the very first, mentions of cold therapy for athletic injuries in the American literature.

In the nearly 20 years since then, the use of cold as a first-aid and rehabilitative modality has been discussed, investigated, proved, refined, validated, and rediscussed. Cold—or more specifically, ice—works. But according to Robert J. Moore, PhD, ATC, RPT, head athletic trainer and professor of physical education at San Diego University, California, cryotherapy is seldom understood or applied correctly.

"People often use ice therapy in off-the-wall ways—as they do all physical therapy modalities—without looking at the literature," Dr. Moore told THE PHYSICIAN AND SPORTSMEDICINE. "The interest is out there. I started to give talks on ice therapy a while back, and now I get asked to give em all the time. But at the grass roots, the high school team physicians and coaches, most people don't understand the goals or application of the technique."

Lan Barnes is features editor of THE PHYSICIAN AND SPORTSMEDICINE.

ICE vs Ice

Some misunderstanding is inevitable. First of all, cryotherapy (sometimes called cryokinetics) is often confused with using ice as a first-aid modality in treating acute injury.[2] The issue isn't simplified by the common use of the mnemonic ICE—Ice/Immobility, Compression, Elevation—which usually is administered in the form of ice packs left in place for 20- to 60-minute periods over the first 24 to 48 hours posttrauma. It's effective. Hematoma formation is controlled and secondary hypoxic injury to the soft tissue is prevented.

Rehabilitative cryotherapy, on the other hand, begins on the first or second postinjury day, depending on the severity of the injury. The technique is relatively simple, and all variations lead to the same conclusion. After 6 to 12 minutes of chilling through ice massage, ice towels, or iced whirlpools, the athlete takes advantage of the partial anesthesia afforded by hypothermia to put himself through active range-of-motion exercises until pain returns. When pain comes back, the athlete goes through further cycles of ice and exercise.

"The distinction between ice for first aid and ice for rehabilitation is a meaningful and important one," says James L. Green, MD, a general surgeon in Jacksonville, Illinois, and team physician for the Jacksonville high school. A cryotherapy advocate, Dr. Green says that ice therapy can save days or weeks of rehabilitation

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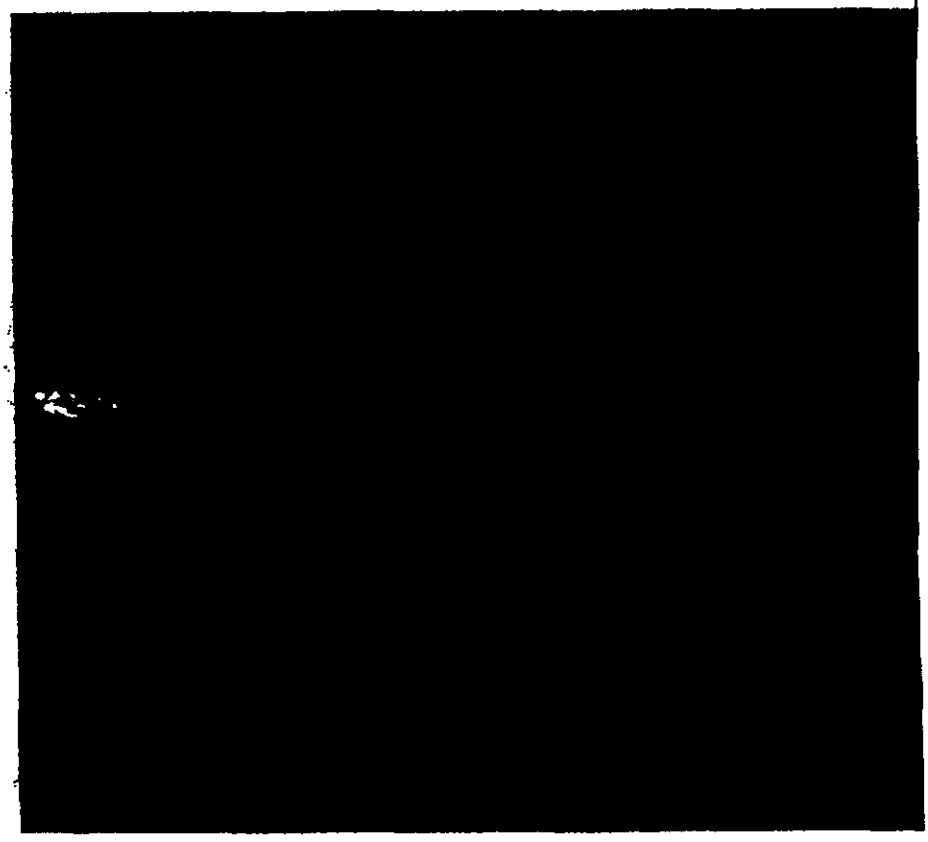
time, but that it's been a struggle to get his colleagues to accept it.

"I had to put a sign up in the emergency room telling the ER staff to use ice first," he says. "Then if a youngster with a sprained ankle didn't happen to see me the next day, he'd be referred to his private physician and would be likely to show up later on crutches with an elastic bandage. If they used heat, then we were worse off than the day of the injury."



An Old Technique

Dr. Green's frustration is understandable considering how long cryotherapy has been around. As early as 1964 Hayden[3] and then Grant[4] published the results of their trials of ice massage for painful musculoskeletal conditions. While neither was concerned with athletic injuries—both series were conducted on servicemen—they were able, respectively, to return 97% and over 80% of their patients to duty the same day, after ice massage with exercise. Although there was no breakdown by type of musculoskeletal complaint, the percentage of success and the sheer numbers (7,000 successive patients for Grant and 1,000 for Hayden) indicated that they were on to something.

Subsequent research has shown that physiologic responses to ice massage, while complex, are all of some benefit to the injured athlete. At the injured-tissue level, the most important responses are (1) initial vasoconstriction, (2) later deep-tissue vasodilation, (3) reduction in muscle tone and spasm, and (4) limited thermal anesthesia.

Vasoconstriction. During the first 9 to 16 minutes of cold application, the affected area undergoes a reduction in blood flow through both reflexive vasoconstriction and increased blood viscosity. Local edema is reduced and hematoma formation is controlled in the acute phase of injury. Less inflammation is seen, although it's not clear if the inflammatory response itself is affected.[5]

Vasodilation. If cold application is continued, a sudden deep-tissue vasodilation of four to six minutes will occur. This circulatory rush, which is seen as a thermoregulatory defense against thermal insult, can raise the local temperature six-fold. Vasoconstriction is then reestablished, followed by vasodilation in a 15- to 30-minute cycle termed the "hunting response."[6]

Muscle spasm. One of the original uses of cold was to reduce spasticity,[7] and this application extends into sportsmedicine both for relaxing acute muscle cramps and as preparation for rehabilitation. Investigators have found that the action potential firing decreases in frequency when a muscle is cooled, and that deep tendon reflexes diminish on cooling.[2]

Limited anesthesia. Perhaps the most important effect of cold in cryotherapy is the simplest. Five to ten minutes of ice packs or massage will reduce pain in a pulled or strained muscle or ligament to a level that permits active exercise through an increased range of motion. Often it's difficult to convince athletes—and physicians—that ice numbs pain. Heat feels good immediately. When ice is applied, the athlete successively feels intense cold, burning, and aching before thermal anesthesia takes effect. Nevertheless, Benson and Copp[8] not only demonstrated that cold was superior to heat in raising the pain threshold in normal subjects' shoulders, but showed that after 30 minutes the heat-treated shoulders were more sensitive to pain than the control shoulders, while the cold-treated shoulders still retained some anesthetic effect.

Exercise Is the Key

Cumulatively these effects of ice therapy add up to less time lost by the athlete. "Recovery time," says

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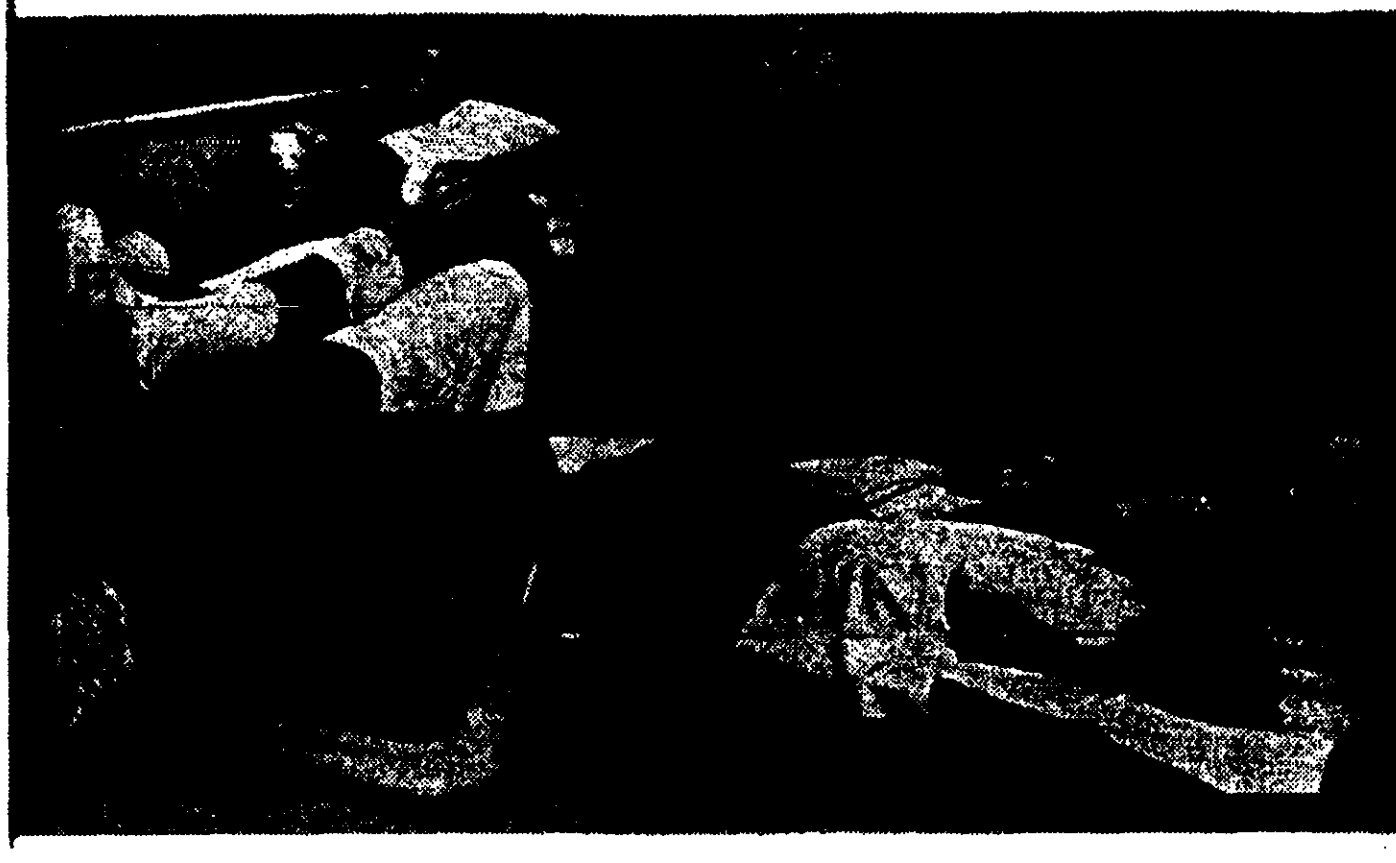

Wayne Rasmussen, ATC, RPT, director of rehabilitation at the Sports Medicine Clinic in Seattle, "is determined by the size of the original hematoma and the speed with which the body mobilizes the debris. Ice limits the initial damage, and ice and exercise help move the debris out."

Both Rasmussen and Dr. Moore emphasize that exercise is the key to cryotherapy. "We don't ice people just to have them sit around," Rasmussen says. "It's ice *and* exercise: the secret is to increase the circulation, to pump it up."

According to Dr. Moore, the guidelines for proper exercises for cryotherapy are similar to those used in other rehabilitative techniques: motion should be voluntary and active; maximal resistance that allows pain-free movement through the range of motion should be applied; painful motion should be avoided; rotatory components of joints and muscle groups should be stressed; spiral and diagonal exercises should be included; and the injured area should be relaxed before exercising.[5]

Case Reports

The response to cryotherapy can be so dramatic than an athlete who might have been lost for a season through more conventional, passive therapy, can be returned to play within one or two weeks. Three cases cited by Dr. Moore[4] are illustrative:

Case 1. A basketball player suffered a first-degree ankle sprain during practice. Ice packs for first aid were applied to the ankle overnight. Ice therapy and exercise were used once the following day and twice the next day. The second day after the injury, the player participated for 40 minutes in an intercollegiate basketball game with his ankle taped. After one week of daily treatment, the player was able to participate with only a cloth ankle wrap for protection

Case 2. A football player suffered a complete dislocation of the radioulnahumeral complex. The dislocation was reduced by the closed method and the player's involved arm was placed in a sling. The attending physician felt that the sling would be required for at least five weeks and that the athlete would not be able to participate in football for the remainder of the season. Two days after the injury, ice therapy (immersion technique) was instituted under the direction of the team physician, in addition to rehabilitative exercise. Full, pain-free range of motion was achieved on the fourth day. On the fifth day the athlete was able to perform two chin-ups and five push-ups without pain. Nine days after the injury the attending physician allowed the player to resume full participation in football. The athlete remained on a rehabilitation program for the rest of the season but was able to play as a regular team member without reinjury.

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ice *continued*

Case 3. A football player received a shoulder separation (acromioclavicular sprain). X-ray examination showed this to be a severe third-degree type of injury. After standard first aid procedures, ice therapy and exercise were initiated on the second day after the injury. Eight days after the initial treatment the player was allowed to return to full participation. He did not suffer reinjury and, in fact, distinguished himself by outstanding play in three games.

Contraindications

Usually any treatment that offers such marked therapeutic successes is so effective that it carries with it a rash of contraindications. Cryotherapy is not an exception, although problems aren't common. McMaster's list[1] is inclusive and bears repeating:

Patients with rheumatoid conditions, he writes, may respond to cold with increased pain and joint stiffness. In Raynaud's phenomenon cold can cause excessive arterial spasm leading to ischemic necrosis with the potential for amputation or excessive skin loss. Cold allergy manifested by giant hives and joint pain can occur. Patients with rheumatic disease may also respond with cryoglobulinemia. Paroxysmal cold hemoglobinuria can cause renal dysfunction, and systemic elevation in blood pressure in response to cold challenge has been recorded. Finally, anesthetic skin in a paralyzed or comatose patient is in jeopardy with ice therapy.

These cold-specific contraindications are relatively rare, and probably occur in athletes less frequently than in the general population. Contraindications aside, there's one caveat for cryotherapy that is athlete-specific: an injured athlete should never be returned to intense physical activity under the anesthetic effect of ice therapy.

This precaution goes beyond the usual dictum not to have an athlete play on a numbed limb. When an acutely injured ligament or tendon is chilled, the physical characteristics of its collagen are altered. It becomes less extensible and tends to contract, a phenomenon that benefits the injury during elevation and compression, but which threatens more serious injury if stress is continued.

"Cryotherapy is probably the safest of modalities," Dr. Moore says, "but there must be a thorough evaluation of the injury, including x-ray if there's any question, followed by 24 to 48 hours of ice, compression, and elevation before the active range-of-motion exercises begin."

Safe, Simple, Cheap

The safety, simplicity, and economy of cryotherapy are points that Dr. Moore and other ice advocates keep returning to. Hayden and Grant froze cylindrical ice cubes in cleaned juice cans, and had the patient hold the ice in a hand towel to rub it on the affected area. Shaved ice in a towel

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pack or immersion in a bucket of ice water were also used by cold therapy pioneers.

Since those simpler days, sporting goods manufacturers have provided physicians and trainers with frozen gel packs, chemical (endothermic) ice envelopes, refrigerant-inflated bladders, and ethyl chloride spray. A high school trainer whose budget only leaves room for a cooler of ice cubes might feel inferior.

He needn't. McMaster and coworkers[9] evaluated each of those cooling methods (except ethyl chloride, a special case favored for quick pain relief) for deep temperature changes over 60 minutes in the thighs of anesthetized dogs. Ice won, with frozen gel running a respectable second. The only real technologic advance since Grant and Hayden, Dr. Moore says, is that "we now freeze our ice in Styrofoam cups instead of freezing it in juice cans."

The simplicity of application hasn't changed much either. Although Lowdon and Moore[10] have demonstrated that intramuscular cooling with ice is a function of time of application, skinfold thickness, and limb circumference, for the purpose of cryotherapy, athletes can administer cold to themselves until their exercises are pain free. "We want to get them involved in their own therapy for the psychologic benefit," Rasmussen says. "Even after a serious injury, if they put themselves through a good workout, they can say to themselves, 'I'm going to make it.'"

Hard to Go Wrong

Cold therapy lends itself to self-administration, Dr. Moore says, "because it's hard to go wrong with it. If there's been a proper evaluation of the injury and a day or two of elevation and compression, then cold and exercise can't possibly hurt.

"Basically we haven't found any contraindications in athletes," he told SPORTSMEDICINE. "In less than 1% of patients there's a little bit of histamine welling, but it's no big thing. Some people are concerned about using cold in peripheral vascular diseases, but not many athletes have those conditions, and I'd be more worried about using heat in those cases anyway."

When do you go to heat? "We don't," says Dr. Moore. "Heat's a mistake," says Dr. Green. "Never," says Rasmussen.

"That's the fallacy of heat," Rasmussen continues. "Many people, consciously or unconsciously, have a time-frame for getting from ice to heat. They think in terms of three days of ice and then heat, when it should be one day of ice, compression, and elevation and then ice therapy."

continued

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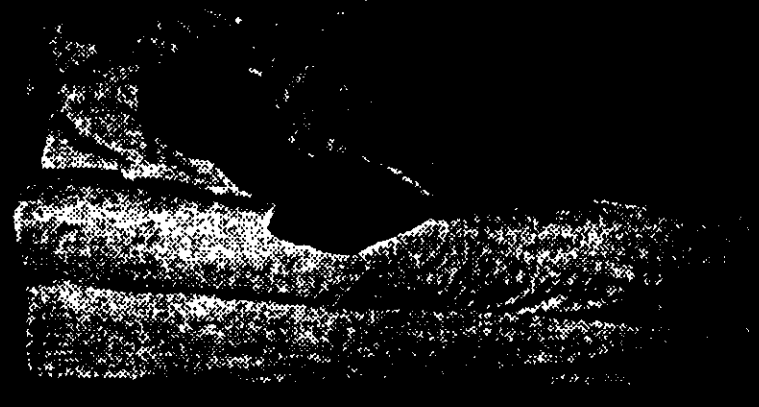

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Brief Summary

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PRECAUTIONS

Thrombocytopenic purpura may follow the administration of quinine in highly sensitive patients. Recovery will follow withdrawal of the medication.

Cinchona alkaloids, including quinine, have the potential to depress the hepatic enzyme system that synthesizes the vitamin K-dependent factors. The resulting hypoprothrombinemic effect may enhance the action of warfarin and other oral anticoagulants.

ADVERSE REACTIONS

Aminophylline may produce intestinal cramps in some instances, and quinine may produce symptoms of cinchonism, such as tinnitus, dizziness, and gastrointestinal disturbance. If ringing in the ears, deafness, skin rash, or visual disturbances occur, the drug should be discontinued.

DOSAGE AND ADMINISTRATION

1 tablet upon retiring. When necessary, 1 additional tablet may be taken following the evening meal.

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Rasmussen says his opposition to heat grew out of his own studies as well as clinical experience. "We did water-displacement measurements on injured extremities to quantitate swelling," he says. "Heat *always* increased the swelling. It increases the circulation, but only in the surface area. We feel that a deep circulation response coupled with exercise is the best way to clear out the debris of injury."

Slow Acceptance

But ice therapy doesn't seem to be gaining acceptance, Rasmussen says. "Except for Bob Moore, Jim Green, myself, and a couple of others, I don't know of anyone who won't use heat," he says. "At the high school level, which is where the injuries happen, too many youngsters just get a few minutes of ice, and then go straight to a hot whirlpool. We've found that the ones who keep ice on longest—up to 30 hours—do best."

For Dr. Green, who views sportsmedicine from the perspective of a grass-roots high school team physician, the ice situation is improving, if only through his own efforts. "I don't think any physician around here puts heat on injuries anymore. In the six years I've been here, people have gone from 24 to 72 hours of ice after injury. At least a 48-hour improvement over six years is some progress."■

References

1. Bennett D: Water at 67° to 69° Fahrenheit to control hemorrhage and swelling encountered in athletic injuries. JNATA, winter 1961, pp 12-14
2. Moore RJ: Uses of cold therapy in the rehabilitation of athletes, recent advances. Read before the 19th American Medical Association National Conference on the Medical Aspects of Sports, San Francisco, June 18, 1977
3. Hayden CA: Cryokinetics in an early treatment program. Am J Phys Ther 44:990-993, 1964
4. Grant AE: Massage with ice (cryokinetics) in the treatment of painful conditions of the musculoskeletal system. Arch Phys Med 45:233-238, 1964
5. McMaster WC: A literary review on ice therapy in injuries. Am J Sports Med 5:124-126, 1977
6. Wise DD: Ice and the athlete. Read at a meeting at the University of Western Ontario, London, Canada, April 1973
7. Mead S, Knott M: Topical cryotherapy use for the relief of pain and spasticity. Calif Med 105:179-181, 1966
8. Benson TB, Copp EP: The effects of therapeutic forms of heat and ice on the pain threshold of the normal shoulder. Rheumatol and Rehab 13: 101-104, 1974
9. Moore RJ, Nicolette RL, Behnke RS: The therapeutic use of cold (cryotherapy) in the care of athletic injuries. JNATA 2:6-13, summer 1967
10. McMaster WC, Liddle S, Waugh TR: Laboratory evaluation of various cold therapy modalities. Am J Sports Med 6:291-294, 1978
11. Lowdon BJ, Moore RJ: Temperature changes in muscle during cold therapy and following sustained contraction. Australian J Sports Med, May/June/July 1977, pp 9-12

Suggested Reading

1. Downey JA: Physiological effects of heat and cold. Am J Phys Ther 44:713-717, 1964
2. Juvenal JP: Cryokinetics: a new concept in the treatment of injuries. Scholastic Coach, May 1966, pp 40-42
3. Knight K: The effects of hypothermia on inflammation and swelling. JNATA 11:7-10, March 1976
4. Lowdon BJ, Moore RJ: Determinants and nature of intramuscular temperature changes during cold therapy. Am J Phys Med 54:223-233, 1975
5. McMaster WC: When to use ice for injuries. Consultant, April 1977, pp 83-85
6. Waylonis GW: The physiologic effects of ice massage. Arch Phys Med Rehab 48:37-42, 1967

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Cryotherapy in ankle sprains

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ABSTRACT

This study assesses recovery from ankle sprains. Thirty-seven final participants were categorized according to the severity of their injury and the use of cryotherapy (15 minutes, one to three times per day) versus heat therapy (15 minutes, one to three times per day) for a minimum of three days. Therapy commenced either less than one hour, from one to 36 hours, or greater than 36 hours after the traumatic event. Sprains were graded into five categories based on the severity of the injury, but only two categories, subject to conservative treatment, are considered in this study.

The study showed that cryotherapy started within 36 hours after the injury was statistically more effective than heat therapy for complete and rapid recovery. Patients in a group with Grade four sprains (unable to bear weight because of pain) reached full activity in 13.2 days compared to 30.4 days in a group using cryotherapy initiated 36 hours after injury or to 33.3 days in a group using heat therapy.

Therefore, early use of cryotherapy, continued with adhesive compression, is an effective treatment of ankle sprains yielding earlier complete recovery than late cryotherapy or heat therapy.

The effectiveness of some therapeutics practiced in medicine today has not been documented in the literature. This appears to be true for the ankle sprain, defined as an overstress to the ankle causing some degree of damage to the ligamentous fibers of their attachments. This common injury is treated with a variety of medical and nonmedical therapeutics.[1, 3, 4, 6, 8, 9, 14, 16]

For many years athletic trainers have been using cryotherapy rather than heat treatment on many different acute injuries including sprains. No controlled study, up to this time, has been published showing that such therapy was more effective than heat therapy in bringing about a rapid recovery from sprains according to a medline search, 1966 to 1981. Though this study is limited, it demonstrates that an early start of cryotherapy is very effective in bringing about a faster rehabilitation than heat in an outpatient population.

MATERIALS AND METHODS

Fifty-three participants were initially entered in the study. These were people treated at two locations between September 4, 1979, and November 15, 1980. Each patient's injury was classified as a Grade three or four ankle sprain. Fractures were excluded by radiographic examination.

Sprains were graded as follows:

Grade	Description
1	The patient has mild pain, is able to run and jump without significant pain during the examination, and there is no more than slight discomfort to palpation.
2	The patient is able to walk, climb stairs, and jump with only mild to moderate discomfort.
3	The patient is able to stand only without pain; climbing stairs and walking are greatly limited because of pain.
4	The patient is unable to stand or bear weight because of pain.
5	There is complete or a near complete tear of ligaments requiring surgery.

The above classification was chosen to improve consistency in clinical grading of the severity of sprains among different examiners. Dividing nonsurgical ankle injuries into four clinical categories as opposed to two anatomical divisions proved to be of value clinically and prognostically.

Thirty-seven people completed the study. These included men and women ranging in age from 15 to 46 and one 8-year-old boy (mean age, 25). Sixteen patients were excluded because of inadequate follow-up or because adhesive tape wrapping was used without cryotherapy.

Cryotherapy in this study is defined as either use of an ice whirlpool between 40 to 50°F for 12 to 20 minutes one to three times per day, or application of an ice pack on the injured area for 15 to 20 minutes, one to three times per day. The injured ankles were then wrapped with adhesive bandage.

Heat therapy involved soaks in a warm bath or application

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of a heating pad for approximately 15 minutes, one to three times per day, for a minimum of three days. The injured ankle was also wrapped in an Ace (Becton-Dickinson, Rutherford, NJ) bandage.

Patients were instructed in the use of heat or cryotherapy and adhesive wrapping or Ace bandages were applied. Participants in the study were not consistently encouraged to attempt early ambulation or passive exercise if tolerated.

The following three treatment methods were applied:

Day 0, treatment was started and adhesive or Ace wrapping was applied within one hour of the injury. One mode of therapy was continued for at least three days.

Day 1, treatment was started and adhesive or Ace wrapping was applied between 1 to 36 hours after injury. The chosen treatment was continued at least three days.

Day 2, treatment and adhesive or Ace wrapping was not used for at least 36 hours (usually 48 hours) after the injury.

Patients were then asked to indicate when (after how many days) they were able to perform the following tasks without pain—walking, climbing stairs, and running and jumping. The results were tabulated for each patient and cumulative results for each treatment modality (i.e., cryotherapy versus heat) were recorded.

RESULTS

Uniformly it was found that cryotherapy treatment begun on Day 0 or Day 1 resulted in more rapid resumption of full activity (as assessed by the patient) than cryotherapy begun on Day 2 or heat therapy begun on Day 0, Day 1, or Day 2. This held true for Class three and four sprains.

Patients with Grade three sprains treated on Day 0 or 1 with cryotherapy were able to run and jump without pain in six days whereas those beginning cryotherapy on Day 2 required 11.0 days before they were able to run and jump without pain. Patients using heat therapy begun Day 0 or 1 could not run and jump without pain until 14.8 days after injury (Tables 1 and 2).

In a similar pattern, patients with Grade four sprains treated with cryotherapy begun on Day 0 or 1 returned to full activity (run and jump without pain) in 13.2 days after the injury whereas patients beginning cryotherapy on Day 2 were fully active 30.4 days after the injury. Those patients

TABLE 1
Ankle sprains—Class 3 (18)

Treatment schedule	Walk without pain[a]	Climb stairs without pain[a]	Run and jump without pain[a]
Cryotherapy 0–1[a] (10)[b]	2.6	3.7	6.0
Heat therapy 0–1 (4)	7.8	9.0	14.8
Cryotherapy 2 (4)	5.2	6.8	11.0

[a] Day number of initiation therapy.
[b] No. of patients.

TABLE 3
Ankle sprains—Class 4 (19)

Treatment schedule	Stand without pain[a]	Walk without pain[a]	Climb stairs without pain[a]	Run and jump without pain[a]
Cryotherapy 0–1[a] (11)[b]	2.7	4.2	5.7	13.2
Heat therapy 0–1 (3)	5.7	9.7	9.7	33.3
Cryotherapy 2 (5)	6.2	12.0	13.6	30.4

[a] Day number of initiation of therapy.
[b] No. of patients.

TABLE 2
Ankle sprains—Class 3 (18)

Treatment schedule	Able to walk without pain[a]	Able to climb stairs without pain[a]	Able to run and walk without pain[a]	Initials and age (years)
Cryotherapy 0–1[a]	1	1	3	JS 19
	2	2	4	SN 28
	2	7	7	TH 23
	1	2	4	MS 21
	3	3	8	CB 19
	3	5	8	JW 42
	3	5	5	RB 46
	2	2	4	SA 20
	5	6	9	PF 25
	4	4	8	CS 37
Heat 0–1	5	7	10	JD 15
0–1	13	13	19	MH 15
0–1	8	10	21	MW 41
0–1	5	6	9	PF 25
Cryotherapy 2	4	4	10	WM 36
2	5	6	6	BW
2	7	12	18	TJ 20
2	5	5	10	BM 18

[a] No. of days.
[b] No. of days.

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TABLE 4
Ankle sprains—Class 4 (19)

Treatment schedule	Able to stand without pain*	Able to walk without pain*	Able to climb stairs without pain*	Able to run and jump without pain*	Initials and age (years)
Cryotherapy 0–1*	1	1	4	10	RF 20
	4	4	5	21	PP 19
	3	3	4	14	BH 38
	4	6	6	6	RA 2
	2	3	4	15	EB [illegible]
	3	3	6	21	BL [illegible]
	2	4	6	10	JD [illegible]
	3	4	7	17	MW 19
	4	6	6	14	DG 19
	3	5	8	10	JC 24
	1	7	7	7	KM 20
Heat 0–1	3	5	5	42	KM 17
	7	10	10	30	MD 46
	7	14	14	28	RG 8
Cryotherapy 2	5	10	12	40	FS 21
	10	16	20	37	JK 36
	3	8	8	27	RW 19
	10	21	21	30	WP 32
	3	5	7	18	BJ 18

* No. of days.

using heat therapy on Day 0 or 1 needed 33.3 days before returning to full activity (Tables 3 and 4).

Early cryotherapy allowed patients to return to full activ- on the average about 15 days sooner compared to late herapy or early heat therapy.

All statistics were significant to a 0.05 confidence level by the Scheffé method.

DISCUSSION

Ankle sprains are one of the more common injuries encountered by the primary care physician. Once a fracture has been ruled out by x-ray films and/or physical examination, the physician is expected to advise the patient on a therapeutic regime which will lead to healing and resumption of usual activity in the shortest possible time.

The immediate application of cryotherapy is accepted by most practitioners as the initial treatment of choice.[1, 3, 4, 6, 8, 9, 14, 16] It is obvious that prompt application of ice to an ankle sprain helps control hemorrhage and edema formation. A much debated topic is how long should cryotherapy be continued and when (if ever) should heat treatments be used.

The use of cryotherapy is based on known physiology. Cold causes a vasoconstriction which decreases blood flow and therefore hemorrhage to the traumatized area. The lowering of tissue temperature decreases the metabolism and chemical actions of cells and thus diminishes O_2 and nutrient needs in the affected area. The decreased flow through damaged vessels also limits edema; there is less histamine release and therefore less capillary breakdown would normally be present after injury. There is better phatic drainage from the injured area because of the lower pressure on the extravascular fluid.[1, 8, 15]

Heat on the other hand, increases blood flow and the cellular metabolic rate and increases inflammatory response and edema. It also increases the possibility of a hematoma becoming infected, promotes abnormal ossification, and worsens pain (especially 30 minutes after application is discontinued).[2, 3, 8, 9, 15] This does not refute the temporary soothing effect of applied heat. Heat may prevent adhesion formation and promote reabsorption of hematomas. However, it is not as effective in the overall time required for recovery as is cryotherapy, as demonstrated by this study.

Compression, generated by an adhesive bandage, was part of the prescribed treatment. This prevents swelling and immobilizes the injured area which prevents further injury and promotes healing.[1, 4, 8, 15]

Application of cryotherapy produces three and possibly a fourth stage of sensation.[1, 7, 8, 11, 15, 16] First, a cold feeling is noted for one to three minutes. This is followed by the second stage of a burning or aching sensation occurring two to seven minutes after cold application. Five to 12 minutes after the start of cryotherapy, Stage 3 is noted with local numbness or anesthesia (decreased conductivity of regional nerve fibers). Thus the pain and reflex impulses are inhibited and the pain-spasm cycle is interrupted. Reflex deep tissue vasodilation without an increase in metabolism is sometimes demonstrable after 12 to 15 minutes of intense cryotherapy, constituting the fourth and last stage. Thus, the rationale for a minimum of 15 minutes of cold application per treatment is obvious.[1, 8–12, 15, 16]

Cryotherapy includes application of ice, immobilization, compression of the injured area, and limb elevation. Passive exercise in all directions should be performed only with minimal discomfort under the anesthetic effect of cryotherapy (Stage 3) and stopped when pain recurs. This is an important component of the therapeutic regime. One must be aware that an injury can be extended if the patient performs unreasonable activity while under the effects of Stage 3 cryotherapy. Early activity is beneficial because injury debris is cleared, muscle atrophy is prevented, fewer

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adhesions occur, and earlier complete rehabilitation is achieved.[1,3,4,8,15]

Cryotherapy is absolutely contraindicated in patients with cold allergy (may produce hives and joint pain) and Raynaud's phenomenon (causes arterial spasm leading to possible ischemic necrosis). Relative contraindications include some rheumatoid conditions (increases pain and joint stiffness), paroxysmal cold hemaglobinuria with renal dysfunction and secondary hypertension, and coma.[5,6,15]

Application of ice is relatively safe, simple, and inexpensive, but the ice should not be held immobile in one area for any length of time or frostbite may result.

Ice therapy should provide deep penetration to gain full benefit, consequently local freezing sprays are not indicated because of lack of cold penetration. Ice packs, ice massage, ice water whirlpool, and iced wet towels are of most benefit. An average reduction of 8 to 11°C per hour may be detected in the muscle with the above four methods of cryotherapy.[12]

More expensive methods such as chemical reaction devices or inflatable splints with refrigerant gas are commercially available but are generally less effective in producing cold penetration and may cause other complications, including skin burns and neuropathy. The inflatable splints do provide effective compression, but a minimum of cryotherapy.[6,12,15]

Stage 2 cryotherapy is uncomfortable. Patients often prefer the temporary soothing feeling of moist heat until they experience the comfort and benefit of Stage 3 and 4 cryotherapy. Therefore, it is important for the physician or therapist to explain the four stages of sensation in cryotherapy along with the anticipated benefit of treatment. If patients are encouraged to endure the mild discomfort of Stage 2 cryotherapy, they are more likely to continue with the prescribed treatment and avoid moist heat applications. The patient's reward will be more rapid recovery.

ACKNOWLEDGMENTS

The authors wish to thank Sally Brown, MS; William Funk, MD; Keith Handling RPT, ATC; Lois Impagliazzo, RPT, ATC; Nancy Janeway, MS, ATC; and Gary M. Owens, MD for their participation in obtaining and evaluating patients for this study.

Statistical analyses were performed by Steve Camper, MS Candidate, University of Delaware, Newark, Delaware.

REFERENCES

1. Barnes L. Cryotherapy—putting injury on ice. *Physician Sportsmed 7* 130–136, 1979
2. Benson TB, Copp EP: The effect of therapeutic forms of heat and ice on the pain threshold of the normal shoulder. *Rheumatol Rehabil 13*. 101–104, 1974
3. Capello WN: The sprained ankle. *Hosp Med 17*: 46E–46T, 1981
4. Cox JS, Brand RL: Evaluation and treatment of lateral ankle sprains. *Physician Sportsmed 5*: 51–55, 1977
5. Drez D, Faust DC, Evans JP: Cryotherapy and nerve palsy. *Am J Sports Med 9*: 256–257, 1981
6. Floriani LP. Ankle injury mechanism and treatment guides. *Physician Sportsmed 4*: 72–78, 1976
7. Guyton AC: *Textbook of Medical Physiology* 6th Edition WB Saunders, Philadelphia, 1981, p 354
8. Hocutt, Jr, JE: Cryotherapy. *Am Fam Physician 23*: 141–144, 1981
9. Kalenak A et al: Athletic injuries: Heat vs cold. *Am Fam Physician 12*: 131–135, 1975
10. Kalenak A et al: Treating thigh contusions with ice. *Physician Sportsmed 3*: 65–67, 1975
11. Knight KL, Londeree BR: Comparison of blood flow in the ankle of uninjured subjects during therapeutic applications of heat, cold, and exercise. *Med Sci Sports 12*: 76–80, 1980
12. McMaster WC, Liddle S, Waugh TR: Laboratory evaluation of various cold therapy modalities. *Am J Sports Med 6*: 291–294, 1978
13. Oliver RA, Johnson DJ: The effect of cold water baths on post-treatment leg strength. *Physician Sportsmed 4*: 87–89, 1976
14. Porcelli AV et al: Assessing and treating the injured ankle. *Patient Care 15*: 108–145, 1981
15. Snedeker J, Recine V, MacCartee C: Cryotherapy and the athletic injury. *Athletic J 55*: 16–18; 55: 10, 1974
16. Waylonis GW: The physiologic effects of ice massage. *Arch Phys Med Rehabil 48*: 37–42, 1967

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KR23870

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Progressive Medical Technology 510(k): Multipulse Seguential Compression Unit

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

FEB 11 1992

KR23870

Mr. Jack S. Van Dyke
Vice President
Progressive Medical Technology, Inc.
Representing Tailey Group Limited
815 Terminal Road
Lansing, Michigan 48906

Re: K914774
Multipulse Seguential Compression Unit
Regulatory Class: II
Dated: October 15, 1991
Received: January 9, 1992

Dear Mr. Van Dyke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. This decision is based on the information contained in your January 9, 1992 letter to the FDA, and that the beneficial claims for your device such as:

1. "Accelerated Wound Healing"

2. "Effects of External Pressure On Flexion Contractures"

3. "Speedy" Reduction of Swelling

4. "Reduction of Swelling with Ease and Speed"

5. "Treatment of Ulcers," and Leg Ulcers

have been deleted from labeling and promotional material. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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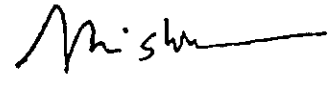
publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device.

Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



for Philip J. Phillips
Interim Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

2

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From — REVIEWER(S) - NAME(S) Elmar Einhorn

Subject — 510(k) NOTIFICATION K914774 FB

To — THE RECORD

It is my recommendation that the subject 510(k) Notification:

✓ (A) Is substantially equivalent to marketed devices.

____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

____ (C) Requires more data. ~~telephone 1/23/92~~

____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.) ~~interim memo that the claims [illegible]~~

~~Additional Comments: Data not yet deleted.~~

Is this device subject to Postmarket Surveillance? Yes ☐ No ☑

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☑ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

Massager, inflatable tube

The submitter requests under 21 CFR 807.95:*

✓ No Confidentiality

____ Confidentiality for 90 days

____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class: 89 IRP Class II

Additional Product Code(~~s~~) w/Panel (optional):

REVIEW: [signature] (BRANCH CHIEF) — RED B (BRANCH CODE) — 2/6/92 (DATE)

FINAL REVIEW: [signature] (DIVISION DIRECTOR) — 2/11/92 (DATE)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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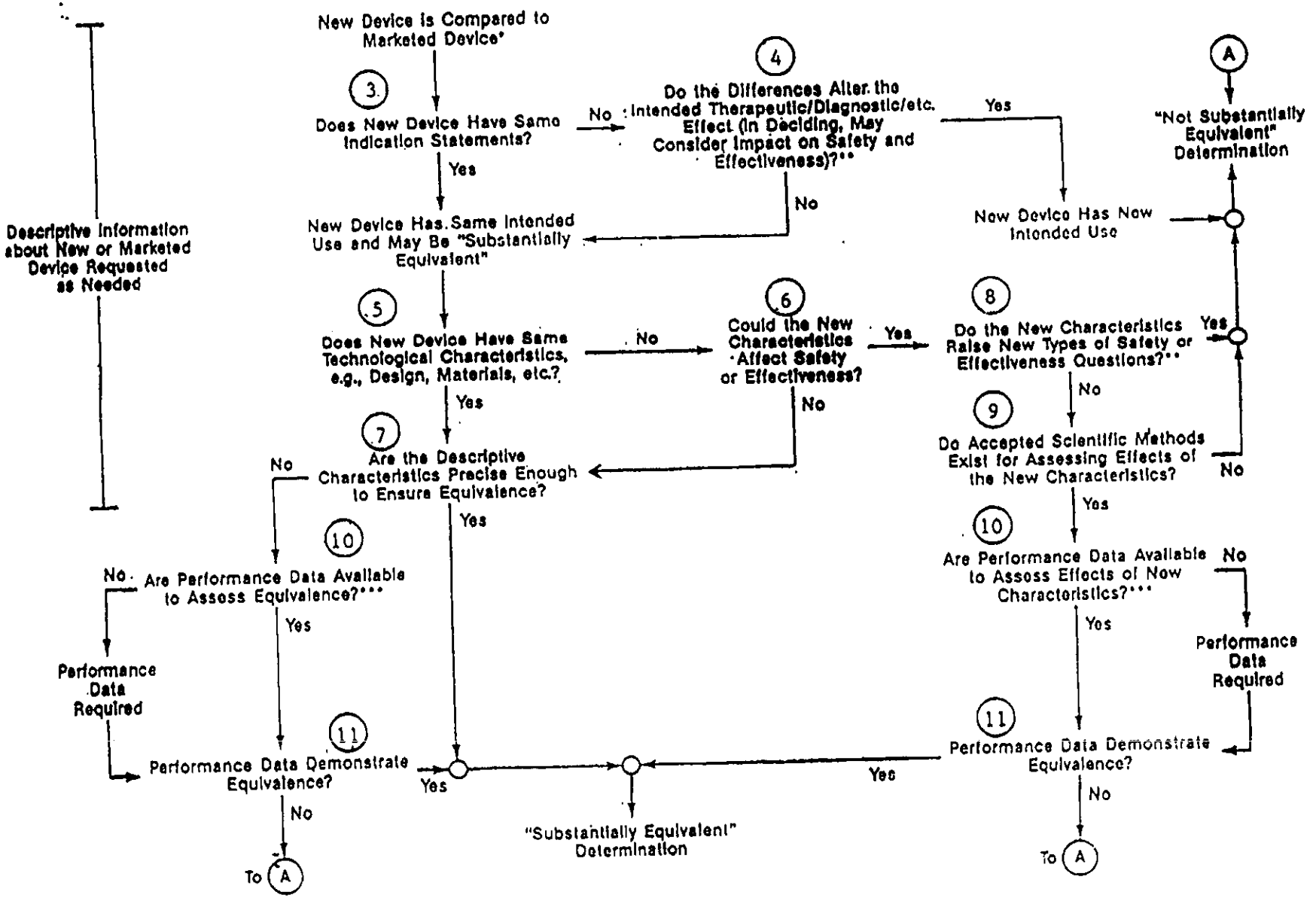
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests

** This Decision is Normally Based on Descriptive Information Alone, But

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

JANUARY 16, 1992

TALLEY GROUP, LTD.
ATTN: JACK VAN DYKE
C/O PROGRESSIVE MEDICAL TECH
815 TERMINAL ROAD
LANSING, MI 48906

510(k) Number: K914774
Received: 01-15-92
Product: MULTIPULSE SEQUENTIAL COMPRESSION UNIT

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K 914774 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: E. Einberg DIVISION/BRANCH: DGRD

TRADE NAME: Multipulse Segmented Compression Unit COMMON NAME: Massager, inflatable tube

PRODUCT TO WHICH COMPARED: K 893950
(510(k) NUMBER IF KNOWN)

	YES	(NO)	
1. IS PRODUCT A DEVICE?	✓		- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	✓		- IF NO STOP
3. SAME INDICATION STATEMENT?	✓		- IF YES GO TO 5
(4.) DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?			- IF YES STOP - NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?	✓		- IF YES GO TO 7
(6.) COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?			- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	✓		- IF NO GO TO 10 - IF YES STOP - SE
(8.) NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?			- IF YES STOP - NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?			- IF NO STOP - NE
10. PERFORMANCE DATA AVAILABLE?			- IF NO REQUEST DAT.
(11.) DATA DEMONSTRATE EQUIVALENCE?			

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: To relieve minor muscle aches and pains and to increase circulation by inflatable pressure cuff.

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY: Same technological characteristics as in prostate device

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. EXPLAIN WHY NOT A DEVICE:_____

2. EXPLAIN WHY NOT SUBJECT TO 510(k):_____

3. HOW DOES THE NEW INDICATION DIFFER FROM THE PREDICATE DEVICE'S INDICATION:_____

4. EXPLAIN WHY THERE IS OR IS NOT A NEW EFFECT OR SAFETY OR EFFECTIVENESS ISSUE:_____

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:_____

6. EXPLAIN HOW NEW CHARACTERISTICS COULD OR COULD NOT AFFECT SAFETY OR EFFECTIVENESS:_____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7. EXPLAIN HOW DESCRIPTIVE CHARACTERISTICS ARE NOT PRECISE ENOUGH:

8. EXPLAIN NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:

9. EXPLAIN WHY EXISTING SCIENTIFIC METHODS CAN NOT BE USED:

10. EXPLAIN WHAT PERFORMANCE DATA IS NEEDED:

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATES THAT THE DEVICE IS OR IS NOT SUBSTANTIALLY EQUIVALENT:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PROGRESSIVE
Medical Technology, Inc.

K914774 /B

January 9, 1992

RECEIVED
15 JAN 92 14 49
FDA/CDRH/OCE/DRC

Food and Drug Administration
Document Control Center HFZ-401
Center for Devices and
Radiological Health
5600 Fishers Lane
Rockville, MD 20857

ATTN: Investigator Einberg

RE: File #K914774

Dear Mr. Einberg:

Enclosed is additional information on the Talley PT202 Sequential Compression Therapy System.

1. Information on the safety and effectiveness of the Talley PT202 will be made available to interested persons upon request.

2. The PT202 power unit has no exposed metal parts. It is double insulated and, thus, has no ground leakage.

3. Enclosed is a revised draft of the PT202 brochure.

Very truly yours,

Jack S. Van Dyke
Vice President

Enclosure

fda3.ein

Progressive Medical Technology, Inc. • 815 Terminal Road, Lansing, MI 48906
(517) 321-6089 • FAX (517) 321-7075

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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THE MULTICOM SYSTEM IN ACTION

The Talley Multicom arm and leg garments come in a range of sizes and are manufactured in a hard-wearing, washable material. All garments have quick release air valves.

Multicom pumps are small and unobtrusive and can be left free-standing on any flat surface near the patient. Treatment is comfortable and requires no specific concentration from the patient, who can watch television or read during treatment.

All Multicom pumps are economical to run and use less power than an ordinary light bulb. The retail cost of a pump and its garment is competitively priced, and supported by a comprehensive after-sales service.

SEQUENTIAL COMPRESSION UNITS

The sequencing action ensures that there is always at least one chamber of the garment inflated to prevent back-flow of fluid.

There are three types of garments available for sequential treatment; the three chamber garment, the five chamber garment, and the very advanced ten chamber garment. All are available in leg or arm shape.

The sequential mode is unique in its operation and, as an advanced clinical unit, has no equal. Only three of the ten chambers are inflated at any one time, which creates a painless wavelike action. This allows the therapist to apply greater pressures over a smaller area to increase the rate of edema reduction.

The Therapy Time Control regulates the treatment time for sequential modes and, by selecting the desired treatment time, it will automatically count down and switch off. In cases where longer treatment is required, such as overnight, there is a continuous override facility.

The Compression Cycle Time controls the amount of inflation time in one cycle. In sequential mode, there is a range of 30-120 seconds. These control units are also adaptable to bilateral applications.

THE PRINCIPLE PATIENT BENEFITS

The most noticeable benefits of the Talley Multicom compression system are on the lymphatic system; the venous networks; and in the prevention of deep vein thrombosis. The overall benefit is the reduction of swelling, which leads to increased joint comfort and greater freedom of movement of the limb.

The Talley PT202 is the latest advancement in sequential compression therapy system.

It employs a compact pump unit featuring power indicator, on/off switch, adjustable pressure control, pressure readout gauge, and multiport garment attachment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The ten chamber garments feature a washable nylon covering and porous inner liner. This porous liner provides air flow to the skin to reduce perspiration and maceration.

The system operates on the unique sequential wave principle which releases the pressure on the tissue behind the wave of compression moving up the limb.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PROGRESSIVE
Medical Technology, Inc.

January 24, 1992

31 JAN 92 12 04

Food and Drug Administration
Document Control Center HFZ-401
Center for Devices and Radiological Health
5600 Fishers Lane
Rockville, MD 20857

ATTN: Investigator Einberg

RE: 510 (k) NUMBER K914774
PRODUCT: TALLEY MULTIPULSE SEQUENTIAL COMPRESSION UNIT

Dear Mr. Einberg,

For your information, the following wording will be deleted from any promotional brochures and literature on the Talley Multipulse Sequential Compession Unit.

"Accelerated Wound Healing"

"Beneficial Effects of External Pressure On Flexion Contractures"

"Speedy" Reduction of Swelling

"Reduction of Swelling with Ease and Speed"

"Treatment of Ulcers"

"Leg Ulcers"

Please contact me in the event you need further information regarding this file.

Thank you very much,

Jack S. Van Dyke
Vice-President

fda7.ein

Progressive Medical Technology, Inc. • 815 Terminal Road, Lansing, MI 48906
(517) 321-6089 • FAX (517) 321-7075

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

JANUARY 9, 1992

TALLEY GROUP, LTD.
ATTN: JACK VAN DYKE
C/O PROGRESSIVE MEDICAL TECH
815 TERMINAL ROAD
LANSING, MI 48906

510(k) Number: K914774
Product: MULTIPULSE SEQUENTIAL COMPRESSION UNIT

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

14 1045

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DO NOT REMOVE THIS ROUTE SLIP!!!!

K-91-4774 1/9/92

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
TALLEY GROUP, LTD. ATTN: JACK VAN DYKE C/O PROGRESSIVE MEDICAL TECH 815 TERMINAL ROAD LANSING, MI 48906	10/15/91	10/23/91	03/09/92
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K914774
	PHONE NO: 517-321-6089		
SHORT NAME: TALLGROU	ESTABLISHMENT NO: 1833587		

TO:
ODE/DMC

CONT. CONF.: ?
STATUS : H
REV PANEL : PM
PAN/PROD CODE(S): PM/ / /

SUBJECT:
MULTIPULSE SEQUENTIAL COMPRESSION UNIT

DECISION:	RQST INFO DATE: 11/21/91	INFO DUE DATE: 12/21/91
DECISION DATE: / /	DATE: 01/08/92	DATE: 02/07/92
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /

SUPPLEMENT: 01 LTR DATE: 911203 LOGIN DATE: 911210

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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VII. SAFETY AND EFFICACY: A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION WILL BE MADE AVAILABLE TO FDA UPON REQUEST.

Your earliest attention and processing of this 510(K) notification would be appreciated.

Very truly yours,

PROGRESSIVE MEDICAL TECHNOLOGY, INC.

Jack Van Dyke
Vice-President

16

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From — REVIEWER(S) - NAME(S) Elmer Einberg

Subject — 510(k) NOTIFICATION K914774/A

To — THE RECORD

It is my recommendation that the subject 510(k) Notification:

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

✓ (C) Requires more data. 1/7/92 by phone

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.) Please see the memo of 1/7/92

Additional Comments:

Is this device subject to Postmarket Surveillance? Yes ☐ No ☑

This 510(k) contains: (check appropriate box(es))

☑ A 510(k) summary of safety and effectiveness, or

☐ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

✓ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

_____

Additional Product Code(s) w/Panel (optional):

_____

REVIEW: _____ (BRANCH CHIEF) BRANCH CODE (DATE)

FINAL REVIEW: _____ (DIVISION DIRECTOR) (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

Revised 11/18/91

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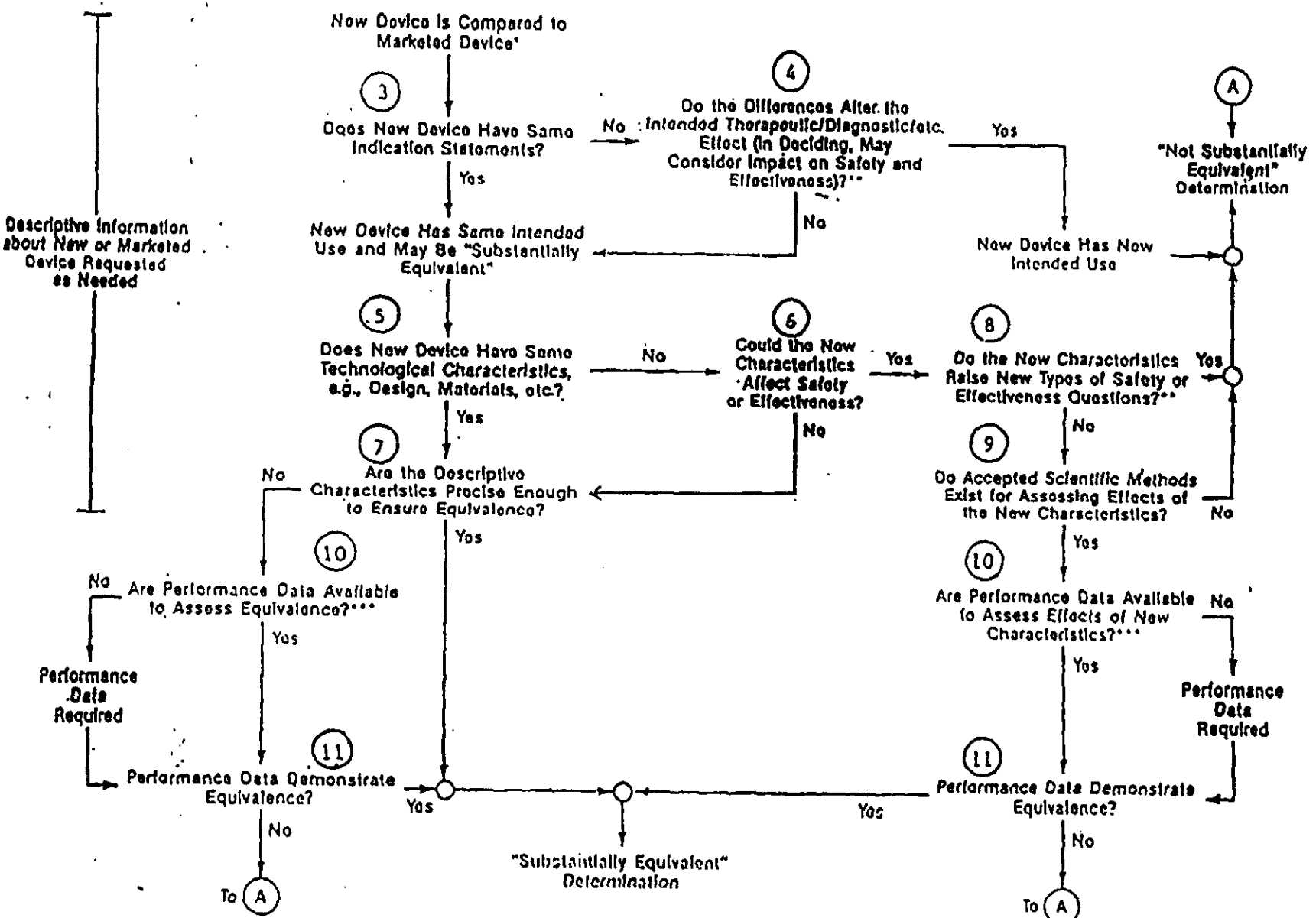
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

510(k) "Substa .ial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information If the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices Is Unclear.

** This Decision Is Normally Based on Descriptive Information Alone, But Limited Testing Information Is Sometimes Required.

*** Data May Be In the 510(k), Other 510(k)s, The Center's Classification Files, or the Literatur

1049

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

MEMORANDUM

TO: Elmar Einberg
FROM: Assistant Medical Review Officer
SUBJECT: Talley Compression Systems, K915637, K915092, K915638, K914774
DATE: 1/2/92

Because all 4 510(k)s are from Progressive Medical Technology, Inc., and are all compression systems with the same types of claims, they are reviewed together in this memo. There are several items that I feel should be substantiated or deleted. They are as follows:

1. " ...in accelerated wound healing; in the beneficial effects of external pressure on flexion contractures, ..." when referring to benefits of the Talley Multicom compression system
2. "speedy" when referring to reduction of swelling
3. " ...reduce swelling with an ease and speed not experienced before."
4. " ...patients with...ulcers respond very well to intermittent compression."
5. " ...for use...in the treatment of...leg ulcers"

All of these items may not be found in every 510(k), but the company should review each submission and make the requested changes where appropriate. It was an observation that these devices may be cardiovascular in nature, given that the predicate devices submitted as substantially equivalent are from the Cardiology Branch (product code JOW). Also, I could not find Venodyne Compression Systems in the files.

Tracey Clark

Tracey L. Clark, D.V.M.

A telephone call was made to Mr. Van Dyke to informed that the claims such as wound healing the beneficial effects of external pressure on flexion contractures the word "speedy" when referring to reduction of swelling, reduction of swelling with ease and speed, treatment of ulcers and leg ulcers must be deleted or clinically substantiated. Mr. Van Dyke will send revised labeling for the device.

Elmer Einberg 1/7/92

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

DECEMBER 11, 1991

TALLEY GROUP, LTD.
ATTN: JACK VAN DYKE
C/O PROGRESSIVE MEDICAL TECH
815 TERMINAL ROAD
LANSING, MI 48906

510(k) Number: K914774
Received: 12-10-91
Product: MULTIPULSE SEQUENTIAL COMPRESSION UNIT

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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1051

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

PROGRESSIVE
Medical Technology, Inc.

K914774/A

FDA-CDRH-ODE

December 3, 1991

DEC 1 0 1991

DOCUMENT MAIL CENTER

Food and Drug Administration
Center for Devices and Radiological
Health Office of Device Evaluation
ATTN: Investigator Einberg
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

RE: 510(K) File # K-914774

Dear Investigator Einberg:

Additional information requested is as follows:

1. Ground leakage from the MULTIPULSE unit? There is none, since unit is double insulated and UL listed as such.

2. Maximum pressure achievable in chambers is 150 mmHg. This compares favorably with competitive units on the market. Most compression therapy is performed at pressures from 40-90 mmHg. The additional higher range allows for treatment of more difficult situations.

3. The MULTIPULSE is similar to the Wright Linear Pump in that it utilizes multiple chambers inflated sequentially distal to proximal. These systems differ from common intermittent compression therapy units which utilize a single inflation chamber.

Several significant advancements in the Talley MULTIPULSE provide features beyond the Wright Linear Pump.

Both units provide compression first to the distal part of the limb and then inflate subsequent chambers to force lymph and venous fluid towards the patient's trunk. However, the Wright Linear Pump uses 3 chambers and the first chamber remains inflated during the entire inflation sequence cycle. This means that the foot or hand tissue is compressed longer than the rest of the limb.

The Talley MULTIPULSE controls 10 individual chambers. This provides more precise application of compression to the limb. Additionally, and most important, is that the entire garment is never inflated all at once. In the MULTIPULSE, as chamber number 3 inflates, the pressure is being vented from chamber 1, releasing the compression on that tissue. Then, when chamber 4

Progressive Medical Technology, Inc. • 815 Terminal Road, Lansing, MI 48906
(517) 321-6089 • FAX (517) 321-7075

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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inflates, chamber 2 deflates. This provides a sequential wave of compression up the limb, a true "milking" action. This produces the directional fluid control as desired, but eliminates the unnecessary tissue compression behind the wave.

Other multiple chamber units are now on the market (Lymphopress, Camp International) utilizing up to 12 chambers. However, they operate like the Wright with constant inflation.

4. To avoid the possibility of a tourniquet effect in the event of a power failure during the compression therapy, the garment has been constructed with a liner of porous nylon. This liner serves two purposes. First, during normal operation, this porous material allows air to seep through to provide air circulation to reduce perspiration on the skin. Secondly, if the pump unit ceases to operate in mid-cycle, the inflated chamber will gradually lose pressure in 1 to 2 minutes, preventing loss of circulation due to the compression.

Very truly yours,

Jack S. Van Dyke
Vice President

fda.3

1053

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

NOVEMBER 21, 1991

TALLEY GROUP, LTD.
ATTN: JACK VAN DYKE
C/O PROGRESSIVE MEDICAL TECH
815 TERMINAL ROAD
LANSING, MI 48906

510(k) Number: K914774
Product: MULTIPULSE SEQUENTIAL COMPRESSION UNIT

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

23

1054

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DO NOT REMOVE THIS ROUTE SLIP!!!!

K-91-4774 11/21/91

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
TALLEY GROUP, LTD. ATTN: JACK VAN DYKE C/O PROGRESSIVE MEDICAL TECH 815 TERMINAL ROAD LANSING, MI 48906	10/15/91	10/23/91	01/21/92
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K914774
SHORT NAME: TALLGROU	PHONE NO: 517-321-6089 ESTABLISHMENT NO: 1833587		

TO:	
ODE/DMC	CONT. CONF.: ? STATUS : H REV PANEL : PM PAN/PROD CODE(S): PM/ / /

SUBJECT:
MULTIPULSE SEQUENTIAL COMPRESSION UNIT

DECISION:	RQST INFO DATE: 11/21/91	INFO DUE DATE: 12/21/91
DECISION DATE: / /	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date

From — REVIEWER(S) - NAME(S) Elmar Eising

Subject — 510(k) NOTIFICATION K914774

To — THE RECORD

It is my recommendation that the subject 510(k) Notification:

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

✓ (C) Requires more data. by phone. 11/18/91

_____ (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.) A telephone call was made to Mr Van Dyk to request the

Additional Comments: 1. Ground leakage current value for all the pumps. 2. What is the maximum cuff pressure. 3. Describe the safety mechanism to prevent the cuff to become a tourniquet. 4. Provide SE comparision with a subst. equivalen device.

This 510(k) contains: (check appropriate box(es))

☐ A 510(k) summary of safety and effectiveness, or

☑ A 510(k) statement that safety and effectiveness information will be made available

☐ The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95:*

✓ No Confidentiality

_____ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/panel and class:

Additional Product Code(s) w/Panel (optional):

REVIEW: _____ (BRANCH CHIEF) | (BRANCH CODE) | (DATE)

FINAL REVIEW: _____ (DIVISION DIRECTOR) (DATE)

*DOES NOT APPLY TO ANY "SE" DECISIONS

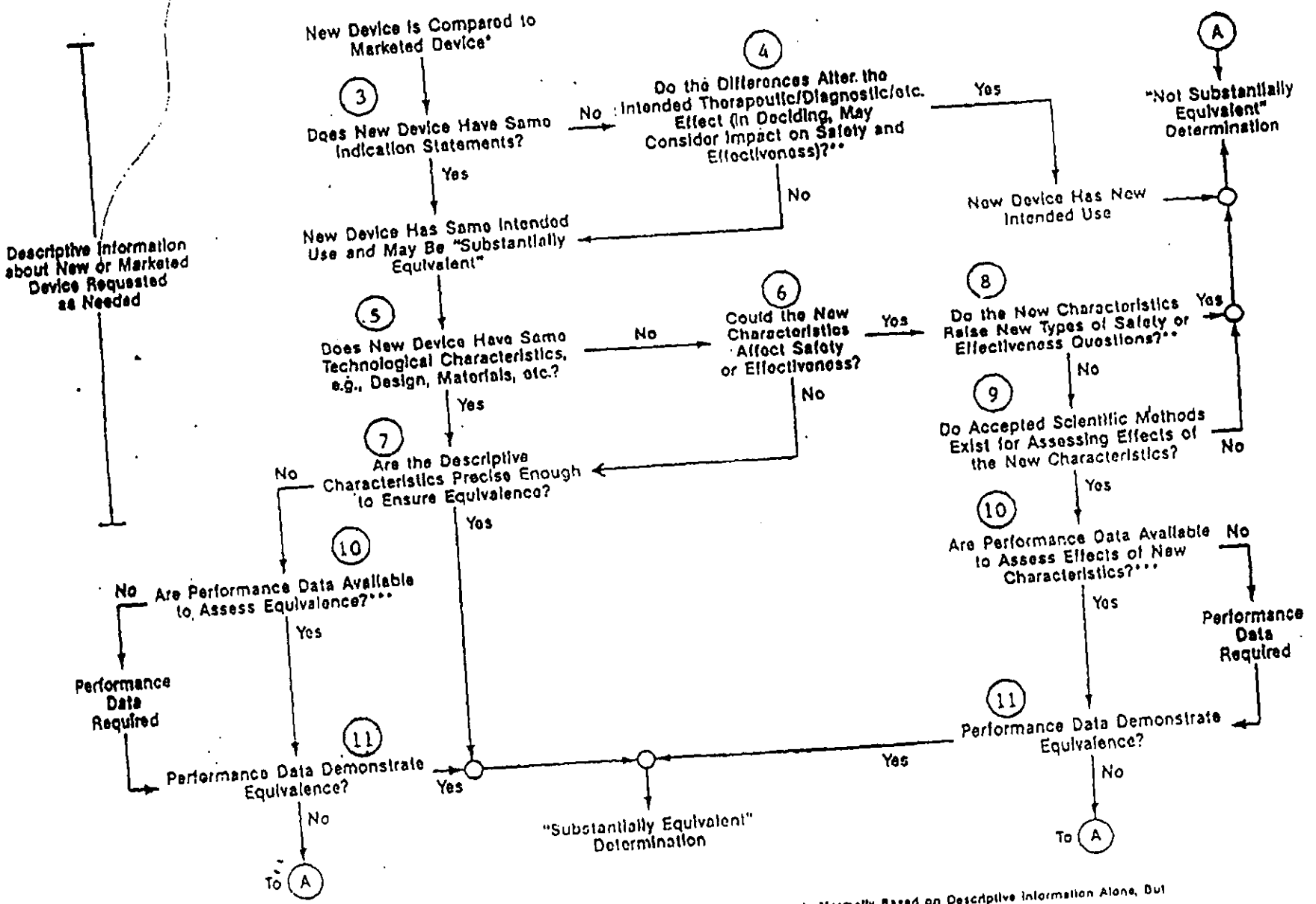
Revised 5/31/91

25 1056

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

OCTOBER 29, 1991

TALLEY GROUP, LTD.
ATTN: JACK VAN DYKE
C/O PROGRESSIVE MEDICAL TECH
815 TERMINAL ROAD
LANSING, MI 48906

510(k) Number: K914774
Received: 10-23-91
Product: MULTIPULSE SEQUENTIAL COMPRESSION UNIT

We have received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required.

The Safe Medical Devices Act of 1990 (SMDA), signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so within 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date, you may want to check with FDA to determine the status of your submission.

In addition, the SMDA requires all persons submitting a premarket notification submission to include either (1) a summary of the safety and effectiveness information in the premarket notification submission upon which an equivalence determination could be based (510(k) summary), OR (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information. We cannot issue a final decision on your 510(k) unless you comply with this requirement.

Although FDA acknowledges that the law provides the 510(k) submitter an alternative, FDA encourages manufacturers to provide a 510(k) statement to FDA and to make their safety and effectiveness information available to the public, excluding confidential manufacturing process information, in lieu of submitting a 510(k) summary to the agency until FDA promulgates a regulation on the content and format of 510(k) summaries. Since the law

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

requires that FDA must make the 510(k) summary, or the source of information referred to in the 510(k) statement, publicly available within 30 days of making a substantial equivalence determination, we advise you that we may no longer honor any request for extended confidentiality under 21 CFR 807.95.

Additionally, the new legislation also requires any person who asserts that a device is substantially equivalent to a class III device to (1) certify that he or she has conducted a reasonable search of all information known, or otherwise available, about the generic type of device, AND (2) provide a summary description of the types of safety and effectiveness problems associated with the type of device and a citation to the literature, or other sources of information, upon which they have based the description (class III summary and certification). The description should be sufficiently comprehensive to demonstrate that an applicant is fully aware of the types of problems to which the device is susceptible. If you have not provided this class III summary and certification in your premarket notification, please provide it as soon as possible. We cannot complete the review of your submission until you do so.

Please note that the SMDA may have additional requirements affecting your device. You will be informed of these requirements as they become effective.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Chief, Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

28 1059

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897, Released 9/15/14

K914774

Premier Way, Abbey Park Industrial Estate,
Romsey, Hants SO51 9AQ. England

Telephone: 0794-830866 (5 lines) Fax: 0794-830702 Telex: 477956 Talley G

TALLEY
GROUP LIMITED

16th October 1991

RECEIVED
23 Oct 91 12 36
DMC

Food and Drug Administration
Center for Devices and Radiological Health
1390 Piccard Drive
Rockville
MD 20850

Dear Sirs

Pursuant to our company appointing [redacted] sole US distributor for the following health care products, please accept this letter as authority for [redacted] to submit Food and Drug Administration 510k documentation on our behalf.

Please copy all documentation to us for record purposes, if possible.

Product Listing:

Sequential Compression Pump PT202, PT60 and PT70

Yours faithfully

R J P Evans
For and on behalf of
Talley Group Ltd

29 1060

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

PROGRESSIVE
Medical Technology, Inc.

K914774

RECEIVED 23 OCT 91 12 36

October 15, 1990

Food & Drug Administration
Document Control Center HFZ-401
Center For Devices And Radiological Health
5600 Fishers Lane
Rockville, MD 20857

ATTENTION: Document Control Clerk

RE: 510(K) NOTIFICATION: PT202 MULTIPULSE SEQUENTIAL COMPRESSION UNIT (10 CHAMBER).
PT60 (10 CHAMBER) SEQUENTIAL COMPRESSION LEG APPLICATOR.
PT70 (10 CHAMBER) SEQUENTIAL COMPRESSION ARM APPLICATOR.

I. CLASSIFICATION NAME: POWERED INFLATABLE TUBE MASSAGER.

COMMON/USUAL NAMES: PNEUMATIC THERAPY, COMPRESSION UNIT, INTERMITTENT PRESSURE SLEEVES, EXTREMITY PUMPS.

PROPRIETARY/TRADE NAME: MULTIPULSE SEQUENTIAL COMPRESSION UNIT.

II. MEDICAL DEVICE ESTABLISHMENT REGISTRATION NUMBERS:

A. SOLE USA IMPORTER: #1833587 PROGRESSIVE MEDICAL TECHNOLOGY, INC.

B. FOREIGN MANUFACTURER: #8010348 TALLEY GROUP, LIMITED.

III. DEVICE CLASSIFICATION: UNDER 21CFR, PART 890 OF THE U.S. FEDERAL REGISTER VOLUME 48, NO. 227 OF NOVEMBER 23, 1983 THE FDA'S FINAL RULE CLASSIFIED POWERED INFLATABLE TUBE MASSAGERS (890.5650) AS CLASS II PHYSICAL MEDICINE DEVICES.

IV. PERFORMANCE STANDARDS: NOT APPLICABLE. THE FDA HAS NOT ESTABLISHED SECTION 514 MANDATORY PERFORMANCE STANDARDS.

V. LABELING AND PROMOTIONAL MATERIAL: ATTACHED IS A COPY OF THE MULTICOM BROCHURE WHICH DESCRIBES THE PT202.

VI. SUBSTANTIAL EQUIVALENCE: THE PRODUCT IS SUBSTANTIALLY EQUIVALENT TO MANY COMPRESSION UNITS MARKETED BY MANY U.S.A. COMPANIES FOR MANY YEARS. ATTACHED IS A COPY OF THE BROCHURE WHICH OF THE CURRENT DEVICES ON THE MARKET, IS MOST CLOSELY EQUIVALENT TO THE PT202 SYSTEM.

Progressive Medical Technology, Inc. • 815 Terminal Road, Lansing, MI 48906
(517) 321-6089 • FAX (517) 321-7075

80 1061

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

VII. SAFETY AND EFFICACY: A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION WILL BE MADE AVAILABLE TO FDA UPON REQUEST.

Your earliest attention and processing of this 510(K) notification would be appreciated.

Very truly yours,

PROGRESSIVE MEDICAL TECHNOLOGY, INC.

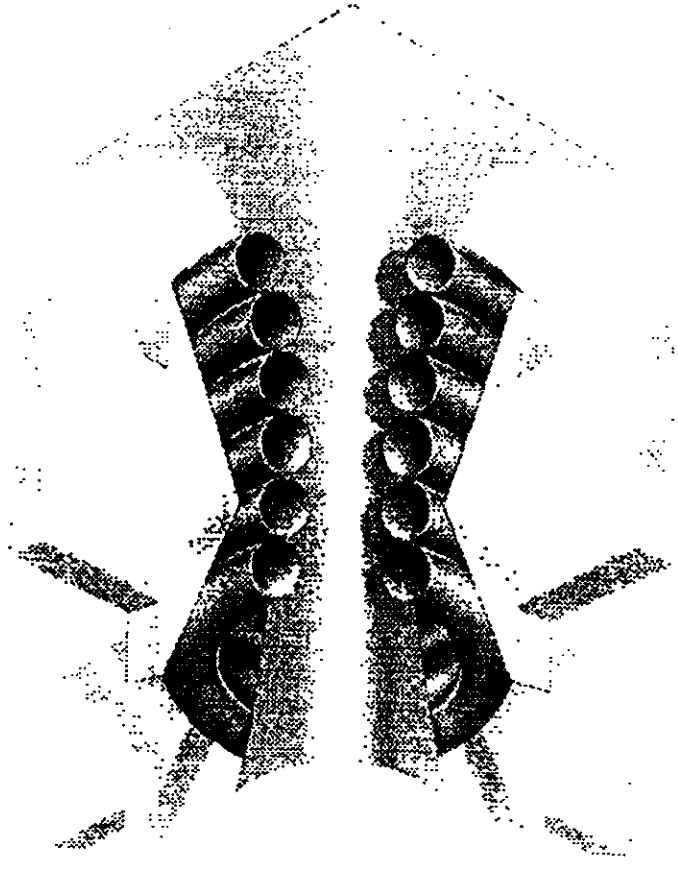
Jack Van Dyke
Vice-President

31

1062

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

multicom



TALLEY

INTERMITTENT & SEQUENTIAL COMPRESSION SYSTEMS

1063

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

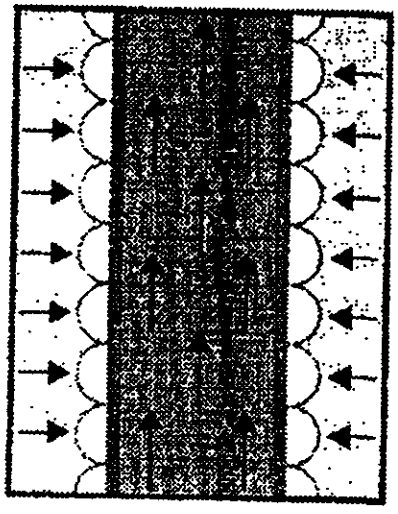
Records processed under FOIA Request 2013-1897, Released 9/15/14

ADVANCED DEVELOPMENTS IN PNEUMATIC COMPRESSION THERAPY FOR THE CARE AND TREATMENT OF OEDEMA, LYMPHOEDEMA AND SIMILAR CONDITIONS

Pneumatic compression therapy has established itself as a most effective, simple and safe method for the control, management and treatment of a range of swollen limb conditions.

Talley Medical are the established innovators and leaders in the field of advanced pneumatic therapy. They have developed the Multicom range of pressure garments and control systems that reduce swelling with an ease and speed not experienced before. Multicom products can be used equally well in the home, hospital or clinic.

THE TREATMENT PRINCIPLE



In both the *Intermittent and Sequential* compression systems the precise air pressure applied in the correctly controlled way, gently stimulates circulation, reduces swelling and can decrease pain.

Most types of swelling will respond to either sequential or intermittent compression. The uses, however, for the versatile Multicom systems are much more widespread, ranging from simple prophylaxis to more protracted and complex therapy applications.

THE PRINCIPLE PATIENT BEN

The most noticeable benefits of the Talley Multicom compression system are on the lymphatic system; the venous networks; in accelerated wound healing; in the beneficial effects of external pressure on flexion contractures, and in the prevention of deep vein thrombosis. The overall benefits are the speedy reduction of swelling and the lowering of pain which in turn lead to increased joint comfort and greater freedom of movement of the limb.

THE SOCIAL AND ECONOMIC ADVANTAGES

The efficiency and flexibility of the Talley Multicom garments and pumps allow treatment to begin and continue at any suitable location.

It is now possible to offer both patient and therapist a practical and sensible regime of treatment that is totally appropriate to individual circumstances.

Treatment can be begun in hospital or clinic on an in-patient basis, progressed to an out-patient situation and used for as long as necessary by the patient in the comfort of their own home.

The economic advantages result from a considerable reduction in prescribed analgesics and the speed at which this type of treatment helps in-patients to be returned to a personal management and home care situation.

multicom

INTERMITTENT & SEQUENTIAL COMPRESSION SYSTEMS

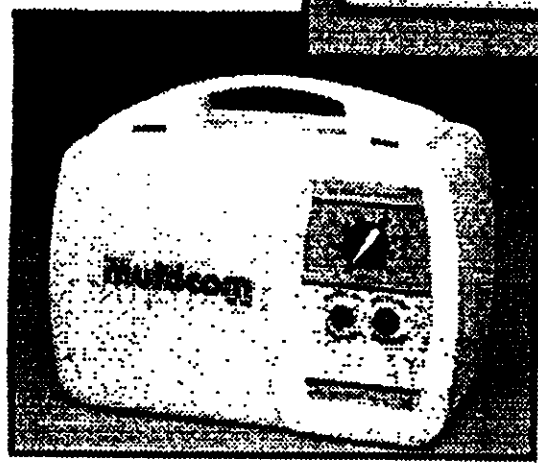
1064

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

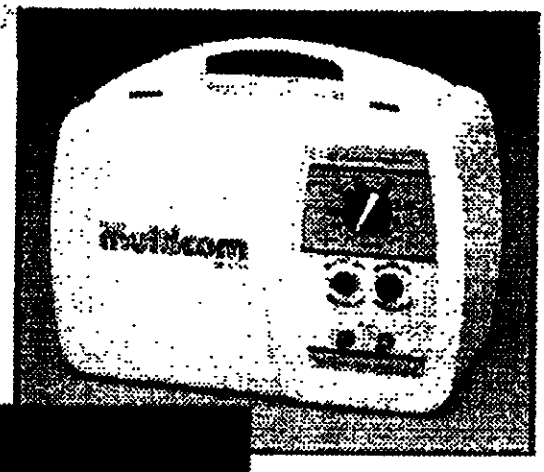
Records processed under FOIA Request 2013-1897, Released 9/15/14

PT101 ▶

TM100 ▼



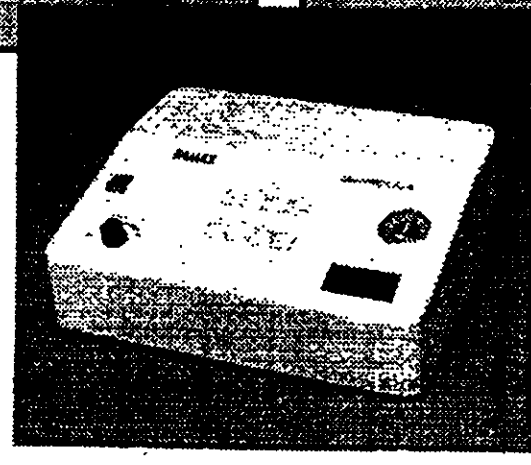
▼ TM300



TM200 ▲

PT202 ▶

▲ TM300/2



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

.AL) MPRESSION UNITS

: of sequential and intermittent compression in one
and therapy time control, and therapists will find that
greater patient/treatment compatibility.
. ne inflation and deflation times controlled
: increased by as much as two minutes to help patients

operation and as an advanced clinical unit has no equal.
me, which creates a painless wavelike action. This allows
area to increase the rate of oedema reduction.
time for both sequential and intermittent modes and
ally count down and switch off. In cases where longer
ntinuous override facility.
. of inflation time in one cycle. In sequential mode, there
intermittent mode. The PT101 has two intermittent
ent of two limbs.

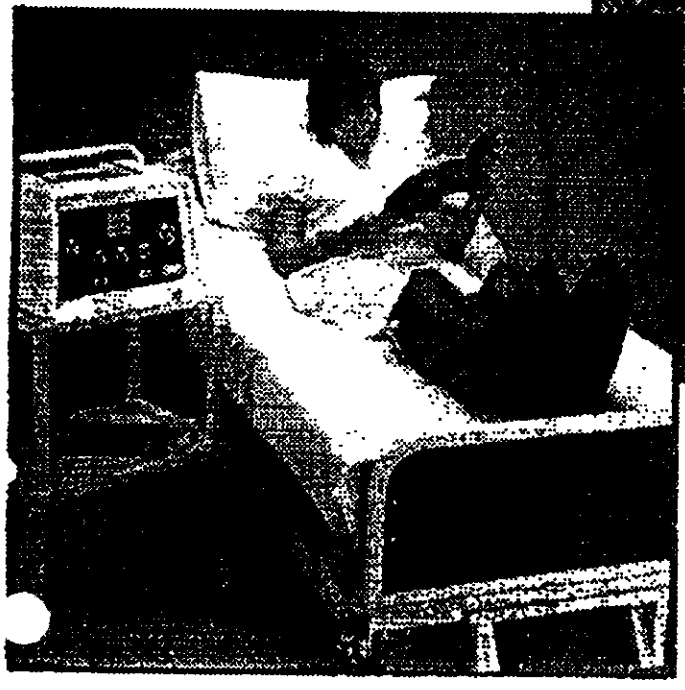
INTERMITTENT COMPRESSION UNITS

The TM 100 and TM 200 intermittent compression pumps are for use with single chamber garments only. In operation they are identical, but differ in that the TM 200 has an external gauge which shows the garment inflation pressure. The TM 100 inflation pressure is indicated on the calibrated fascia panel.

The range of garments available for intermittent treatment include full length arm, forearm, calf, lower leg and full leg garments.

When connected, the whole garment will fill with air during the inflation phase of the pressure cycle. A complete cycle takes two minutes to run and half of this time the garment is inflated and half deflated.

Many patients with either mild, easily controlled swelling or chronic respond very well to intermittent compression.



TALLEY

1066

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-1507, Released 9/15/14

INTERMITTENT AN. S:

The PT101 control unit offers an original to
and. There are special features of compression
the PT101 has a wide range of controls allowe

Only in the Talley Multicom intermittent s
independently. This means that the deflation time
who benefit from a prolonged relaxation cycle

In addition, the sequential mode is unique in
Only three of the ten chambers are inflated at any
the therapist to apply greater pressures over a

The Therapy Time Control regulates the trea
by selecting the desired treatment time, it will auto
treatment is required, such as overnight, there

The Compression Cycle Time controls the
is a range of 30-120 seconds, and 8-30 seconds
garment sockets which allows for simultaneous

MULTICOM SYSTEM IN ACTION

Talley Multicom arm and leg
come in a range of sizes and are
ed in a hard-wearing, washable
al garments have quick release

icom pumps are small and
e and can be left free-standing on
face near the patient. Each unit has
er flex for plugging into any

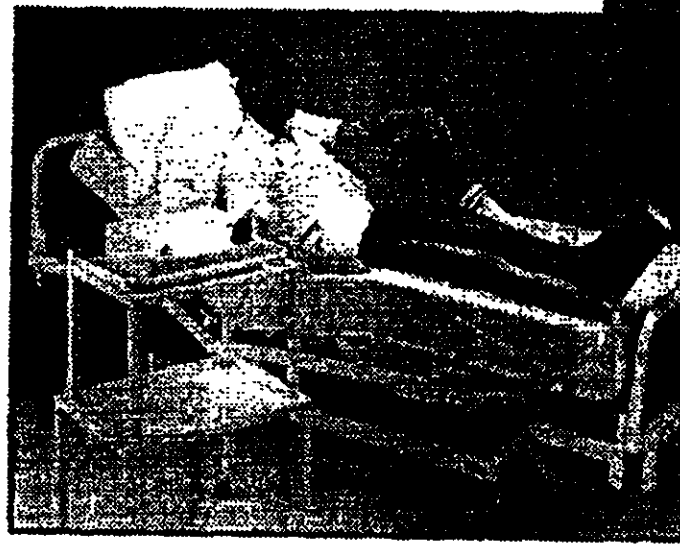
convenient socket. Treatment is comfortable and requires no specific concentration from the patient, who can watch television or read during treatment.

All Multicom pumps are economical to run and use less power than an ordinary light bulb. The retail cost of a pump and its garment is competitively priced, and supported by a comprehensive after sales service.

E ENTIAL RESSION UNITS

sequencing action ensures that
ays at least one chamber of the
flated to prevent back-flow of fluid.
e are two types of garment
f sequential treatment: the three
ment and the very advanced ten
ment. Both are available in leg or

TM300 and the TM300-2 sequential
n pumps work with triple chamber
nd are ideal for
e or hospital.
many patients
ma, only
controllable by
's, the
/ to treat
at home.
ony it may be
p towards total
nce from
ce. These two
actly the same
TM100 range
t as quiet and
. The garments
ed into three
and the tube
s from
pump are
ed to avoid
incorrectly
total cycle time
ates, with the
ng at the extremity, inflating each
ntil all three sections are inflated. All
ns then deflate and, after a short
period, a subsequent cycle begins



THE PT202

The PT202 MULTIPULSE sequential unit is a compact, portable mains power unit that comes complete in its own robust flame retardant and splash-proof carrying case. It works with the advanced ten chamber sequential garment which also fits into the case. The sequential wavelike therapeutic action of this unit is the same as the PT101. With variable pressure, therapy time and compression cycle controls it gives complete flexibility of treatment. The touch sensitive control panel makes setting and adjustment easy and instant.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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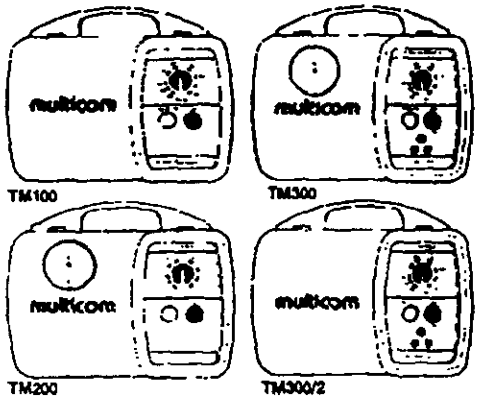
The Multicom intermittent and sequential compression systems are for use by the patient and the medical profession in the treatment of many conditions, such as: Primary lymphoedema, post mastectomy oedema, leg ulcers, oedema following trauma and sports injuries, post immobilisation oedema, prophylaxis of deep vein thrombosis, venous insufficiencies due to muscle inactivity, as in paralysis, multiple sclerosis.

CONTRAINDICATIONS

Acute pulmonary oedema, acute thrombophlebitis, acute congestive cardiac failure, acute infections.

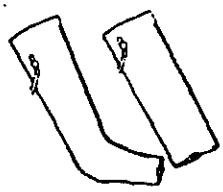


MULTICOM POWER UNITS

Construction:	All plastic
Size:	235 X 168 X 119mm
Weight: Model TM100	2.20kgs
TM200	2.43kgs
TM300	2.43kgs
TM300/2	2.23kgs
Electricity Supply:	220/250V 50Hz Other voltages available
Electricity Consumption:	8 watts
Fuse Rating:	160mA
Insulation:	Double insulated (no earth required)
Variable Pressure Control:	40-120mmHg
Cycle Time:	5 minutes

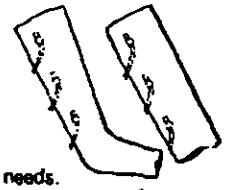
COMPRESSION APPLICATOR GARMENTS

Manufactured from polyurethane coated nylon with zip fastener on leg applicators. Fitted with quick release air valves.



INTERMITTENT

Ref: TM10	Calf applicator
Ref: TM20S	Complete leg applicator
Ref: TM20M	Complete leg applicator
Ref: TM20L	Complete leg applicator
Ref: TM30	Forearm applicator
Ref: TM40	Complete arm applicator

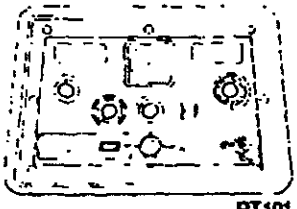


SEQUENTIAL

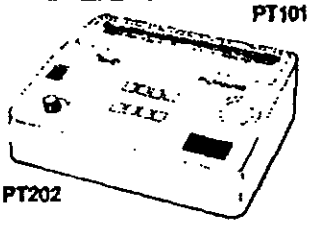
Ref: TM60S	Complete leg applicator
Ref: TM60M	Complete leg applicator
Ref: TM60L	Complete leg applicator
Ref: TM70	Complete arm applicator
Ref: TM70L	Complete arm applicator

Other sizes can be made to suit individual needs.
Garment expanders are also available for some garments. Contact us for details.

PT101 & PT202 PRESSURE THERAPY UNITS



PT101

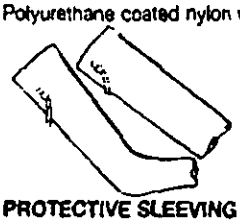


PT202

SPECIFICATIONS	Cat. Ref. PT101	Cat. Ref. PT202
Dimensions:	43 x 26 x 31cms	35 x 35 x 20cms in case with garment
Weight:	11.20kgs	7.5kgs
Electricity Supply:	200/250V 50Hz	230/250V 50Hz
Electricity Consumption:	52 watts	26 watts
Full Load Current:	600 mA	260 mA
Fuse Rating:	5 Amp	3 Amp
PCB Fused:	1 Amp 250v	1 Amp 250v
Sphygmomanometer:	0-300mmHg	0-300mmHg
Therapy Time:	Continuous or Timed 5-55 minutes	30, 60, 120 minutes or continuous
Pressure Control:	0-130mmHg	0-150mmHg
Compression Cycle Time:	(s) 30-120 seconds (i) 8-30 seconds	1 to 10 chambers, 30, 70, 110 seconds –
Deflation Time:	(i) Auto – 2 minutes	–
Mode Selector:	Sequential Compression Intermittent Compression	Sequential only –
Neon Indicators:	Green – Power On/Off Switch Orange – Sequential Compression Red – Intermittent Compression	Green – Power On/Off Switch –

COMPRESSION APPLICATOR GARMENTS

Polyurethane coated nylon with zip fastener on leg applicators.



INTERMITTENT

Ref: PT10	Calf applicator
Ref: PT20S	Complete leg applicator
Ref: PT20M	Complete leg applicator
Ref: PT20L	Complete leg applicator
Ref: PT30	Forearm applicator
Ref: PT40	Complete arm applicator

SEQUENTIAL

Ref. PT60	Leg applicator (ten chamber)
Ref. PT70	Arm applicator (ten chamber)

PROTECTIVE SLEEVING

We recommend that all compression garments are used with an inner protective sleeving. This provides extra patient comfort and helps to keep the garment clean. Available in 10 metre rolls or packs of five one metre lengths.
Ref: PS010 Protective sleeving (10 Metre roll) Ref: PS005 Protective sleeving (6 x 1 Metre lengths).

TREATMENT TROLLEY

A treatment trolley is available for the PT101 AND PT202. Contact us for details.

REFERENCES

Hills N.H., Pflug J.J., Jayasingh K., Boardman L., Calnan J.S. Prevention of Deep Vein Thrombosis by Intermittent Pneumatic Compression of Calf. B.M.J. 1972 1:104-5
Allenby F., Boardman L., Pflug J.J., Calnan J.S. Effects of external pneumatic intermittent compression on fibrinolysis in man. Lancet 1973 1412-4
McNeill T.J., Martin I.J., Orr J.D. Intermittent compression for lymphoedema of arm. Clinical Oncology 1976, 2:239-42
Malone D.G., Wright M.T.M., Schmand E. The stripping of varicose veins: a clinical trial of intermittent compression dressings. Br. J. Surg. 1979 66:53-5.
Nicolaides A.M., Fernandes e Fernandes J., Pollock A.V. Intermittent sequential pneumatic compression of the legs in the prevention of venous stasis and postoperative deep venous thrombosis. Surgery 1980. 87:89-78.
Hazanka E.Z., Wright D.E. Chronic leg ulcers: The effect of pneumatic intermittent compression. The Practitioner 1981: 225:189-92
Zelenovic A., Deutsch A., Reiss R. The Sequential pneumatic compression device in surgery for lymphoedema in the arm. Journal of Cardiovascular Surgery 1983; 24:122-6

Whilst correct at time of going to press, we reserve the right to alter and improve the specification of any product without prior notification. Always seek professional medical advice before using any of these products.

TALLEY Premier Way, Abbey Park Industrial Estate, Romsey, Hants. SO51 9AQ
Telephone: 0794 830866 Fax: 0794 830702 Telex: 477956 Talley G

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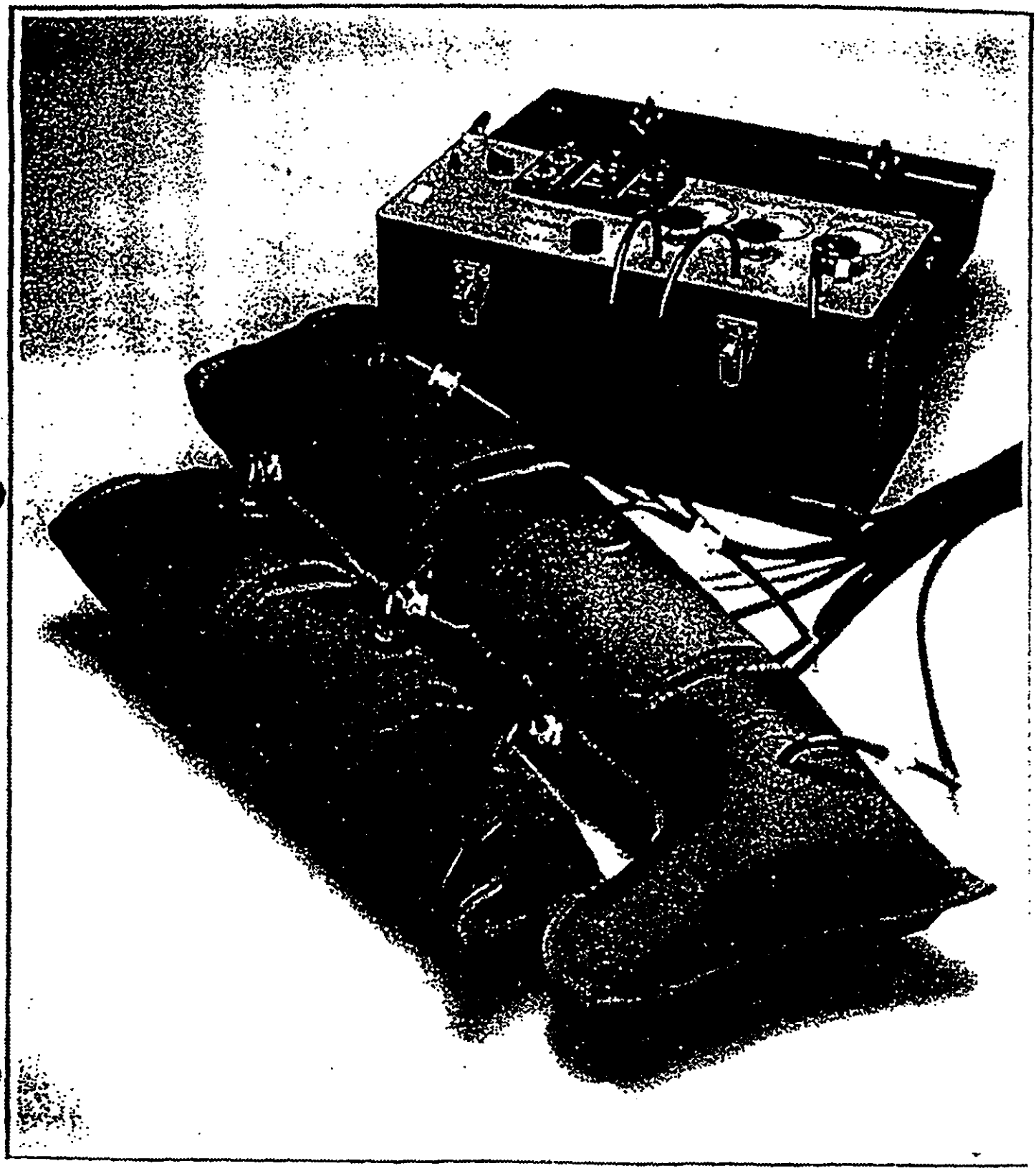
Wright® LINEAR PUMP



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"The Wright Linear Pump is a positive pressure modality for treating lymph accumulation disorders of the extremities by promoting the flow of fluids in a distal to proximal fashion. It is efficacious in multiple disorders that are the result of diminished return of lymphatic fluid. These cases have included post axilla and inguinal node dissections, radiation, congenital lymphedema and childhood onset syndromes such as Park-Weber syndrome.

The Wright Linear Pump features programmable gradient pressure compression through multiple cells. It is this gradient pressure across the limb that has important therapeutic ramifications in the treatment of lymphedema.

It is clear that the disorder is not being cured, but with the combination of the Wright Linear Pump and continued care in managing and containing the limb as it is reduced in size, we can significantly improve the quality of life of a large number of people suffering from chronic lymphedema.

Standards and protocols developed at D.T. Watson Hospital are included in this brochure; we offer these as guides as they do represent our current thinking. We are learning as we continue to work with the Wright Linear Pump gradient pressure system on children and adults of all ages.

I offer Jennifer's story as just one example of many case histories in which the Wright Linear Pump has proven its clinical worth to medicine. As the Wright Linear Pump is a new approach to aid lymph flow deficiencies of the extremities, we are most interested in your results; please share them with us."

M.A. Alexander, M.D.
Medical Director
D.T. Watson Rehabilitation Hospital
Sewickley, PA

Medical terminology in this brochure credited to Dr. M.A. Alexander.

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Wright® LINEAR PUMP

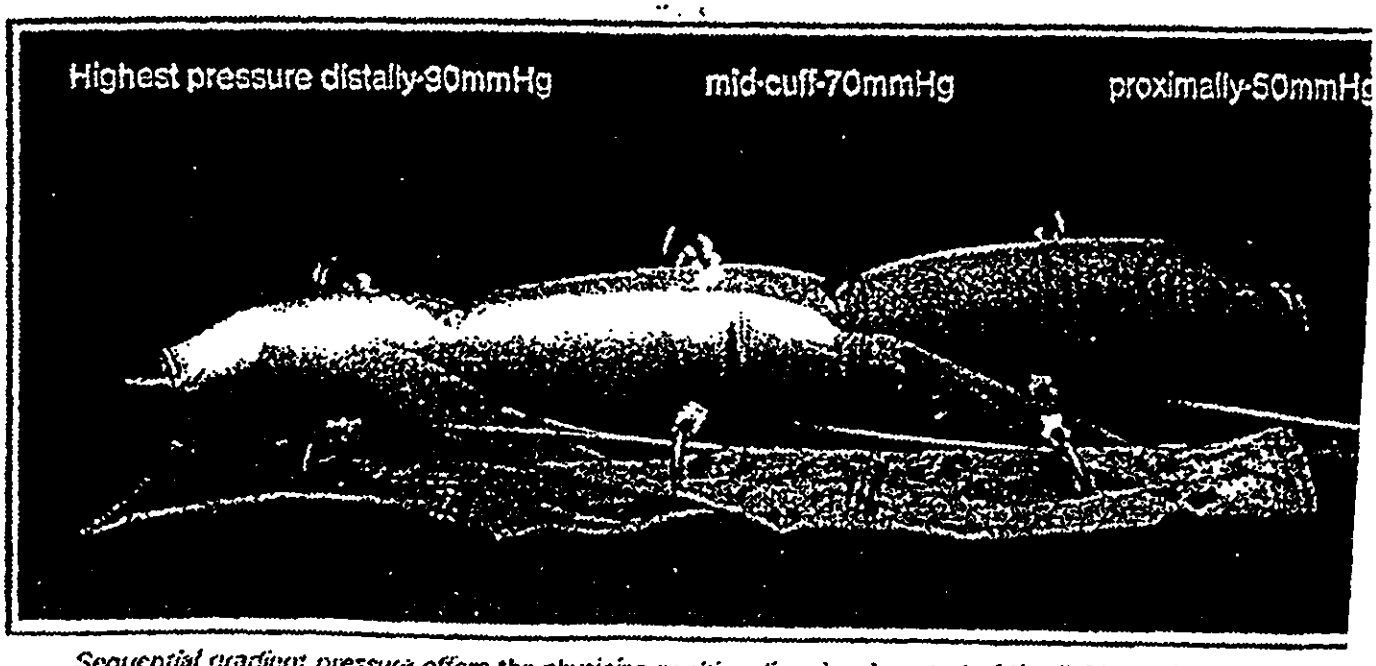
Lymphedema may be congenital or acquired. Congenital types include those isolated lymphedema and those characterized by hemihypertrophy of soft tiss with lymphatic or vascular overgrowth such as Park-Weber syndrome or Klipp Trenaunay-Weber. Acquired lymphedema often follows lymphatic dissections, trauma or radiation. All can result in enlarged, disfigured limbs which are susc tible to superficial and deep infections. There is no cure and limb loss is comm as the body defenses are impaired by the increased accumulation of lymph fl

Single pressure compression systems have been used to treat lymphedema w varied rates of success. These deliver uniform pressure throughout the limb c ing a static pressure system, offering no positive direction to the body fluids. addition, the uniform pressure system has the tendency to pump fluids proxi to distally if there are areas of decreased tissue resistance. With the use of a uniform pressure system there is no way to predictably facilitate lymph return.

The Wright Linear Pump was developed to overcome the disadvantages of st or uniform pressure devices. The advantage of the Wright Linear Pump is its programmable gradient pressure system. Instead of encasing the limb in a sin sheath, the Wright Linear Pump incorporates a three-cell sleeve. The bottom section (cell A) encloses the foot and ankle or hand and wrist, the middle sec (cell B) the calf and knee or forearm and elbow, and the top section (cell C) t thigh or upper arm. A hose that receives air from the pump is connected to t outer wall of each cell. Each pressure and sequence can be prescribed separa

Solid-state electronic timers control the time of sequential pressure cycles an intermittent returns to atmospheric pressure. The highest pressure is delivere the leg or arm by cell A; the pressure of cell B is lower; and of cell C even lo Gradient pressures eliminate the tendency for backflow and promote circulati and the flow of fluids in a proximal direction. At the end of a cycle, all the ce return to atmospheric pressure. Then, after a preset pause, the cycling of seq tial gradient pressure resumes.

EXAMPLE ONLY



Sequential gradient pressure offers the physician positive directional control of the fluids within an extremity.

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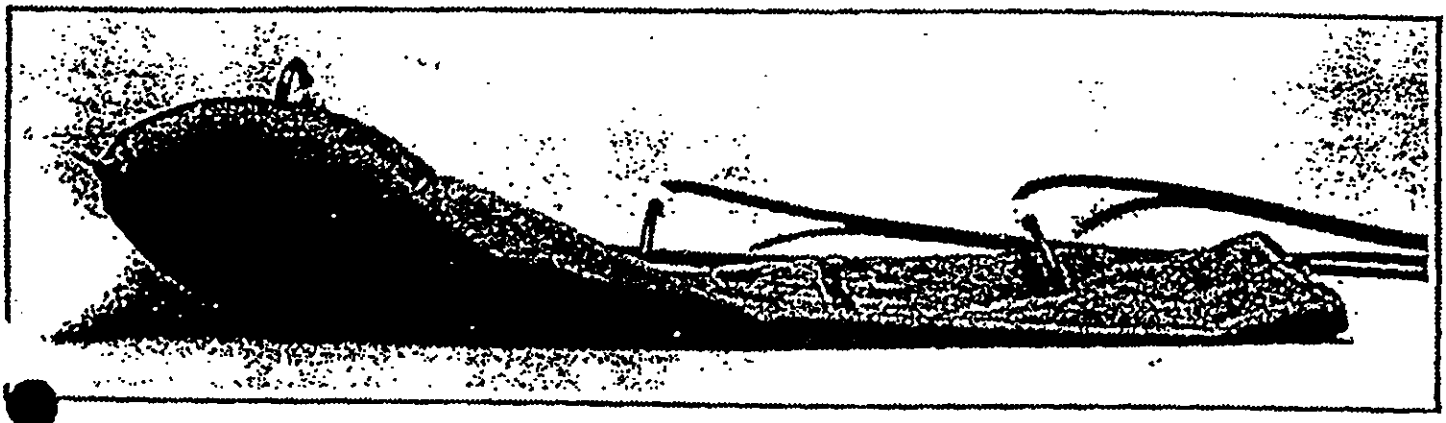
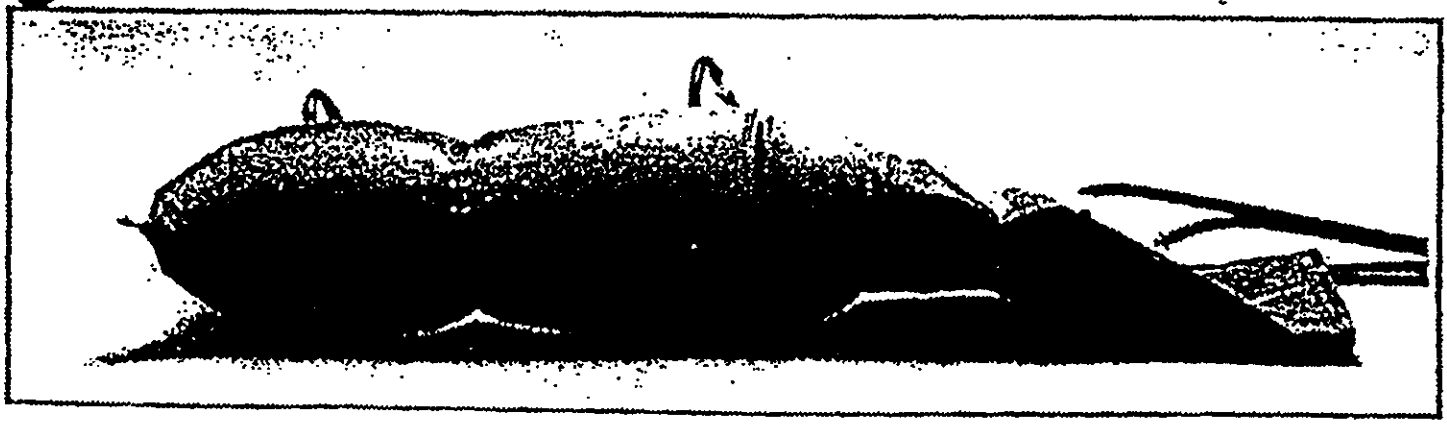
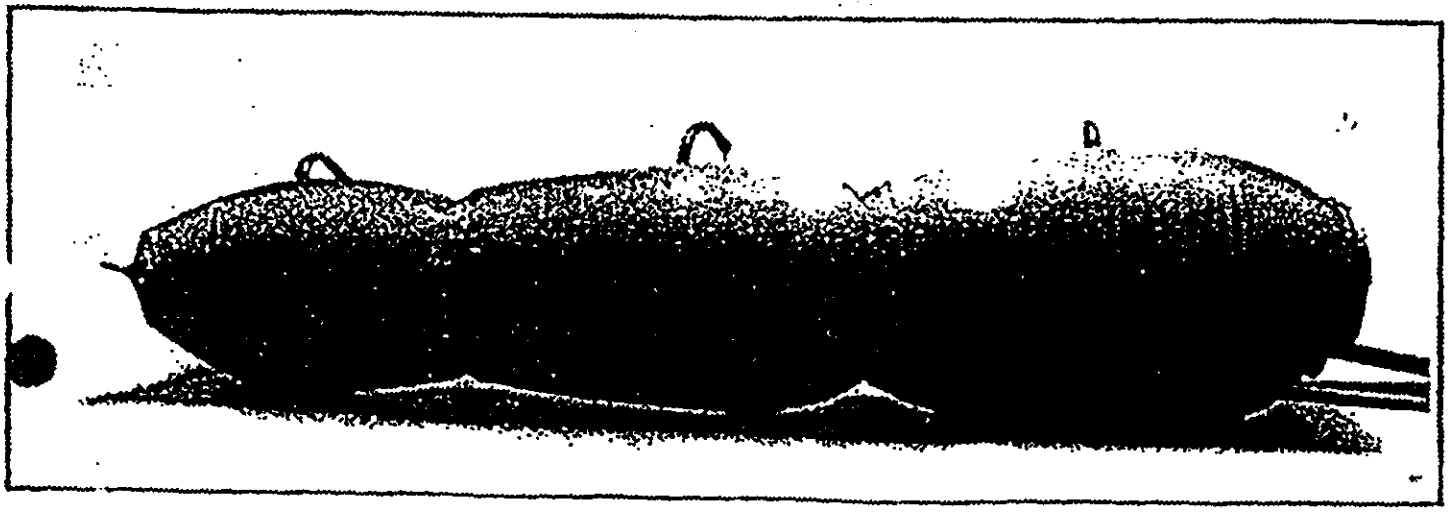
The Wright Linear Pump is a positive pressure modality for treating lymph accumulation disorders d circulation deficiencies of the extremities. It omotes the flow of fluids in a given direction as ired by the physician.







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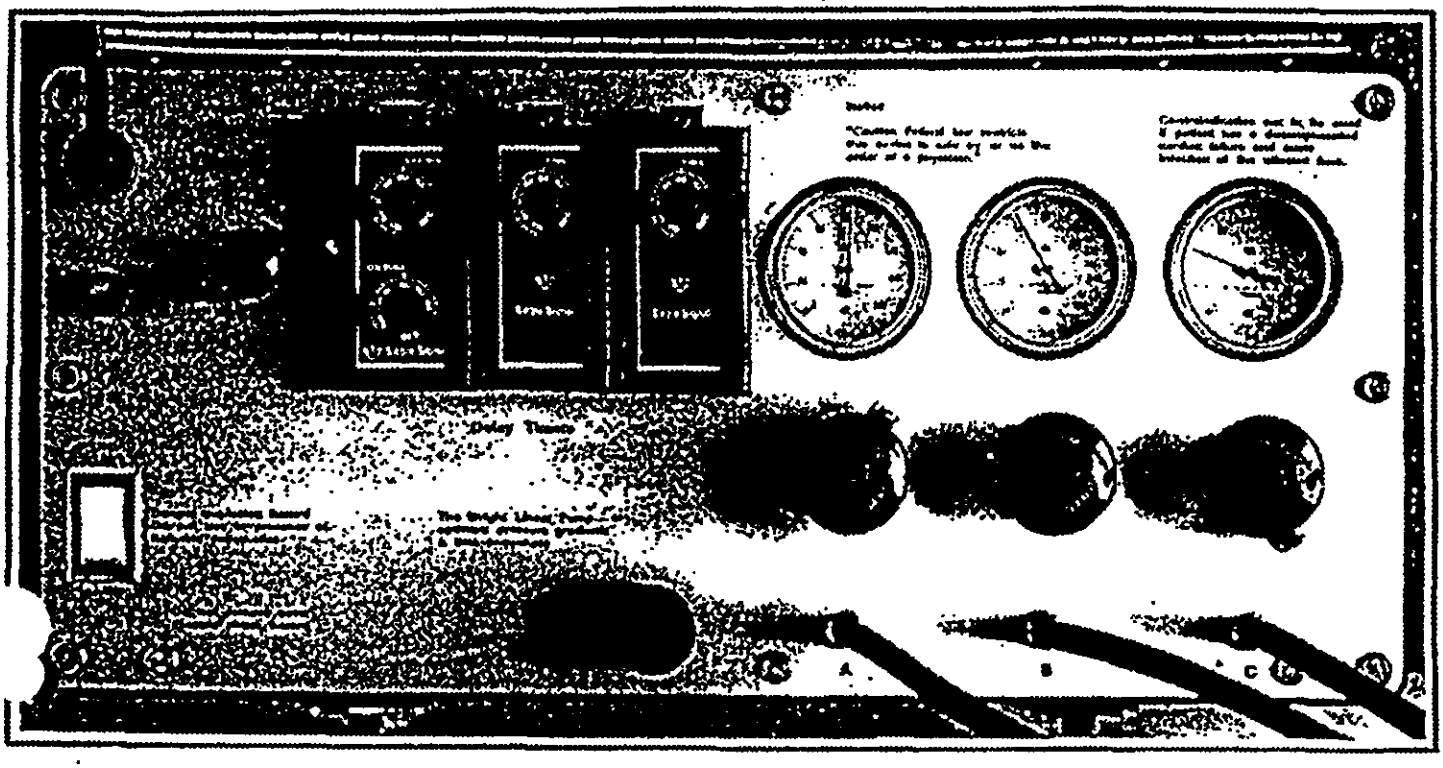
The Wright Linear Pump, a patented medical device, is the only programmable gradient pressure pump available. Continued use can significantly improve the quality of life of a large number of people suffering from chronic lymphedema.



The Wright Linear Pump incorporates a custom-made three cell sleeve for the extremity. The sleeve is open at one end, covering the limb and extending up to the axilla or inguinal region. The sleeve consists of a double wall with an air chamber in-between; a hose to each cell receives air from the Wright Linear Pump at physician prescribed, preset gradient pressures and time sequences. Solid-state electronic timers control the time of sequential pressure cycles and the intermittent returns to atmospheric pressure.

The controls on the panel provide the physician total programmability of gradient pressures for each cell and the flexibility of prescribing the intermittent cycling of "ON" time and "OFF" time (the return to atmospheric pressure) delays. The programmability offers the physician the ability to find what best suits the individual patient's condition. Low pressures with gradient pressure differentials of six or seven mmHg between each cell may be used to advantage. (See Flexibility chart on p. 10 for other illustrations.)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GRAD-LINE (CONFIDENTIAL)

"510 (k) Notification"
Premarket Submission
ATLANT'S

510 (K) Number K 974395

Approved

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GRAD-LINE (CONFIDENTIAL)

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I.	*Instructions for use and operation of ATLANT'S, (The Dynamic Pressure Computer)*	
II.	*ATLANT'S Principle*	
III.	*21 CFR Ch.1 (890. 5650) "Powered inflatable tube massager".*	

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IV. *WRIGHT Linear Pump, (Recommendations for various ulcer treatments).*

V. *Treatment of adult lower extremity Lymphedema with the WRIGHT Linear Pump: Statistical Analysis of a Clinical trial.*

VI. *WRIGHT Linear Pump- Co pression therapy that works in harmony with the natural return circulation.*

VII. *Instructions for use and operation of the Pression® Home and personal units.*

VIII. *Lymphatron® Trio (Calibrated Gradient sequential compression for treatment of Lymphedema and chronic Venous insufficiency).*

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1. Definitions:

- Predicate Device:

A device that was legally marketed in the US prior to May 28, 1976 (preamendment).

- Substantial Equivalence:

This is established with respect to intended use, design, energy used, or delivered. It does not raise new questions of safety and effectiveness and demonstrates that the device is as safe and as effective as the legally marketed device.

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2. Cover Letter: 510(k) Notification

This cover letter provides the information for a Premarket notification (510(k)) submission for the Class II Device, ATLANT'S.

a. **DATE OF APPLICATION:**

November 5. 1997

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3. Premarket Notification Statement (As required by 21 CFR 807.87(j)):

I certify that, in my capacity as Agent for Grad-Line Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted. I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person.

_____
Signature

Walter L. Wasserman
Typed Name

November 5, 1997
Dated

Not Available
*Premarket Notification (510(k)) Number

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From: daniel.maunier@club-internet.fr
Subject: **ATLANT 510K Pages 6-10**
Date: October 17, 2005 3:43:51 AM EDT
To: mvw@mvanwelden.com
5 Attachments, 4.7 MB (Save ▾) (Slideshow)

Dear brother,

Please find enclosed 10 pages of the 510k Submission.

See you soon.

Dan

GRAD-LINE (CONFIDENTIAL)

4. Device Name:

ATLANT'S is a new pressure therapy apparatus which creates a linear and dynamic pressure gradient over the limbs for treatment of Lymphedema and venous edema. The unit offers a range of massaging programs to provide optimal therapeutic benefits for patients.

- Trade Name: ATLANT'S
- Common Name: Inflatable Boot
- Classification Name: Powered inflatable tube Massager (This is a well recognized Medical Device).

a. The device includes a single garment which can be fitted on each limb and comfortably secured, using Velcro type fastenings. Two plastic pipes link the garment to a computer control and ATLANT'S comes with several pre-recorded programs which allow the operator to set the desired optimum pressure, the duration of the action and rest period. Two pressure sensors inside the air chamber allow to set and monitor at all times the true pressure at the lower and upper areas of the limb.

b. Technical Specifications:

- Power requirements: 110V, 0.5 amp, 60 hertz, weight 5.5 kgs.

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- Maximum pressure: 10 to 100 mmHg.
- Working time: 1 to 99 minutes
- The pressure unit can work at room temperature from 10 to 32°C(50 to 90°F).
- The apparatus comes with 1 controller unit, 2 legs and an arm garment, 1 pressure sensor cable, 2 long input and output plastic pipes. 2 short <<Y>> Connectors , Appendix 1.

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c. Intended Use:

This device is a powered, inflatable tube massager intended for medical purposes such as to relieve minor muscle aches and pains and to increase circulation. The front panel includes a visual display which shows at all times the pressure values.

The device provides the three basic programs which are chosen by pushing on the digit switch.

The device provides three actions

- Massage
- Lymphatic node drainage
- Complete drainage

* These programs are based on three different pressure curves. All the three modes can be used at 3 different speeds slow, medium and fast (T1, T2, T3).

5. Registration Number:

This is the establishment registration number if applicable. No number yet

** Please note that registration is not required in order to submit a 510(k), however registration is required within 30 days of marketing this device.*

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6. Classification

This device has been placed under Class II , under section 5.3 of the Federal Food, Drug and Cosmetics (FDFC)Act. This device is subject to 510(k) premarket clearance requirements per 21 CFR 890.5650. See appendix II.

7. Performance Standards:

State if this device meets any mandatory or voluntary standards and identify these standards: The ATLANT's meets most of the standards represented by the WRIGHT Linear Pump (kK number and 510 (k)

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unknown) which is being used in this premarket notification as a substantially equivalent product for performance standards. The ATLANT'S is compared to the WRIGHT Linear Pump - Appendix IV, which is also a device to remove edema and relieve pain associated with leg ulcers. Also a reference paper by Klein et.al. (1998) is included as Appendix V. Equivalency is compared to the WRIGHT Linear Pump, a patented programmable, gradient pressure, sequential, intermittent compression device available, (Appendix VI).

The WRIGHT Linear Pump was developed to overcome the inadequacies of static or uniform pressure devices. This sequential pump's advantage is its programmable "Gradient Pressure System".

In claiming substantiated equivalence , ATLANT'S meets the same standard as the predicate device it is compared to.

8. Labeling:

Proposed labels, labeling and advertisement, instructions, Package Inserts, labeling in software, other labeling/advertisements, promotional materials are included as part of this submission (Appendix I and 2)

The formal label for the product is as follows:

- **Indications:** Chronic venous insufficiency, lymphedema, edema of venous origin, post amputation, wound healing, lymphatic obstruction and contusions.
- **Contraindications:** Non treatable malignant tumors, chronic inflammations, vein thrombosis, congestive heart failure, cancer (in the treated limb), acute pulmonary edema and acute thrombophlebitis.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

- **Warning:** Follow operating instructions to avoid shock hazards.
- **Precautions:** May interfere with the function of pacemakers. Use caution in treating skeletally immature individuals
- **Caution:** This product is limited to the sale, use or under the direction of a licensed health care practitioner by federal law.

THE MATERIALS CONTAINED WITHIN THIS SUBMISSION MARKED AS CONFIDENTIAL MAY NOT BE DISTRIBUTED OUTSIDE THE US GOVERNMENT WITHOUT THE WRITEN CONSENT OF GRAD-LINE

9. Substantial Equivalence Comparison (Clinical study):

Comparison Table : **TABLE 1**

CRITERIA	ATLANT'S	WRIGHT LINEAR PUMP	PRESSION SEQUENTIAL COMPRESSOR	Lymphatron Trio
Indications for use	For treatment of Lymphedema and venous edema	Remove edema, relieve pain associated with leg ulcers	Therapeutic benefits for patients with CVI (Chronic Venous insufficiency) and Lymphedema	calibrated Gradient sequential Compression for treatment of Lymphedema and chronic Venous insufficiency
Target Population	12 clinical patients, treated in France	73 Adult Lymphedema patients · admitted for	NA	NA

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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		48 hr clinical trial		
Performance	Comparison of circumference before and after various prescribed treatment regimens	Comparison of circumference of limb before and after a 48hr treatment period	NA	NA
Conclusions	All patients showed significant reduction in circumference after therapy.	Both sexes experienced an important reduction in leg circumference after therapy	NA	NA

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CRITERIA	ATLANT'S	WRIGHT LINEAR PUMP	PRESSION SEQUENTIAL COMPRESSOR	Lymphatron Trio
Mean Reduction in Swelling: n=4 X	NA	Swollen Limb=97" Normal Limb=16.5"	NA	NA
Weight	5.5 kgs	28.25 lbs	6.3 lbs (2.85 kg)	Model AC350 11 lbs (5kg)
Amp	0.5 amp,	2.5 Amp	0.4 Amp	NA
Voltage	110V, 60 Hz	115V, 60Hz 230V, 50/60Hz	120V, 60Hz	110-120V, AC 60Hz, I W
Length, width, height	NA	10.5/9.5/19.5 "	11/18/15 cm	9.5/12/7 "
Pressure	10-100 mmHg	NA	30-180 mmHg	20-98 mm Hg

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	at room temp. from 10 to 32°C (50 to 90°F).			

10. Appendices

See table of contents.

THE MATERIALS CONTAINED WITHIN THIS SUBMISSION MARKED AS CONFIDENTIAL MAY NOT BE DISTRIBUTED OUTSIDE THE US GOVERNMENT WITHOUT THE WRITEN CONSENT OF GRAD-LINE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Mai A Elkhorada

Subject: 510(k) Number K053225

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☒ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☑ YES	☐ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed (not adequate)

☒ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices NA

☒ The indication for use form not adequate

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

Review: [signature] (Branch Chief) ECDB (Branch Code) 1/13/06 (Date)

Final Review: (Division Director) (Date)

Revised:4/2/03

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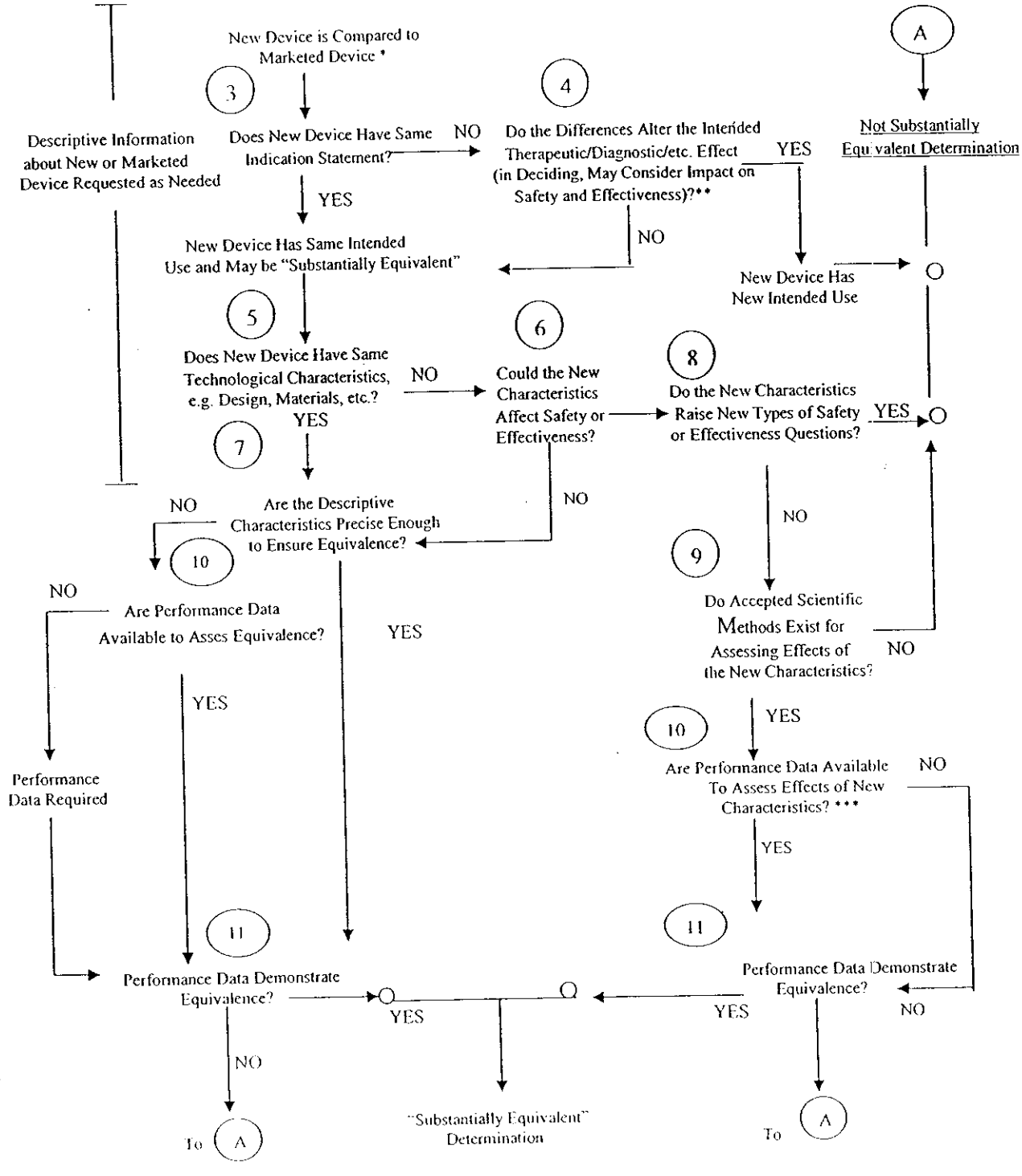
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

MEMORANDUM

DATE January 13, 2006

FROM Director Regulatory Review Officer

SUBJECT K053225 Cellu M6 Keymodule I

TO The Record

Recommendation

Additional information is needed to complete this review.

Background

A similar model of this device was cleared as a massager. Now the sponsor wants clearance as an inflatable tube massager.

Application Contact

Jay Mansour
C/O Mansour Consulting, LLC
1308 Morningside OPark Drive
Alpharetta, Georgia 30022

Telephone 770-777-4146
Fax 678-623-3765

Sponsor
LPG ONE, Inc.
801 Brickell Avenue, Suite 850
Miami, Florida 33131

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

This device is indicated for use for:

Reduction of secondary lymphedema of the arm (SLA) post mastectomy;
Reduction of lymphedematous fibrotic induration;
Improvement of primary and secondary lymphedema;
Prevention of venous stasis and venous insufficiency;
Prevention of deep vein thrombosis (DVT) and
Improvement of lymphatic circulation in the treated area.

This is a prescription device.
It is intended to be used by licensed and trained massage therapists as noted on page S.

The labeling indicates additional uses for fibrosis, stiffness, delayed onset muscle soreness, muscle spasm, muscle aches and pains, appearance of cellulite and circumferential body measurements of cellulite treated areas, relaxation, traumatic edema, spider veins, .

Comments:

At least some states specify that massage therapists are not licensed to treat the medical conditions.

Deficiencies:

Since at least some states do not license massage therapists to treat medical conditions, please revise your prescription statement to specify that Federal law restricts this device to sale by or on the order of a licensed physical therapist or any other practitioner licensed by the law of the State in which he practices to use or order the use of the device.

Your labeling includes indications for use that are not identified in your Statement of Indications for Use, e.g., fibrosis, stiffness, delayed onset muscle soreness, muscle spasm, muscle aches and pains, appearance of cellulite and circumferential body measurements of cellulite treated areas, relaxation, traumatic edema, spider veins. Please resolve any discrepancies and assure that the substantial equivalence section compares your new device to a legally marketed device having the same indications for use. Alternatively, you should justify differences in the indications for use and provide performance data to substantiate substantial equivalence with respect to safety and effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Contraindications

The device should not be used under the following conditions:

- Known sensitivity to the device;
- Skin cancer in the treated area;
- Do not treat over open wounds, infected areas, skin tumors, scars from recent surgery;
- Do not treat patients with infectious progressive illnesses;
- Not recommended for pregnant women;
- Not recommended for anyone under medical care for circulatory conditions without first consulting a physician.

Deficiencies:

Since your device manipulates soft tissues, please amend your labeling to include the following contraindication: *This device should not be used over swollen or inflamed areas of skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.*

Although you contraindicate your device for skin cancer and tumors in the treated area, you have not contraindicated it for other cancerous lesions in the area to be treated. Please amend your contraindications to address this issue or provide data justifying treatment of other cancers in the area to be treated.

Device Description

The device has a console housing a vacuum pump and a regulation system. The main treatment head consists of (b)(4) [redacted] rollers housed in a chamber which produces [redacted] (b)(4) [redacted]. Each roller encloses a miniaturized motor, but this is not discussed in the device description section or in the comparison with the predicate devices. Pressure applied to an (b)(4) [redacted] simultaneously produces suction and rotation of the rollers. The suction pulls a skin fold up between the two rotating rollers in the suction chamber, to massage cutaneous and subcutaneous tissues. The distance between the rollers can be adjusted. The rollers can turn in the same or opposite directions. Each roller can have an independent speed to produce skin folds of different sizes and shapes. There are 10 speeds and 20 different treatment intensities, however, intensity is not defined.

Suction power ranges from 50-500 mmHg, represented by a power scale ranging from 1 to 10. Both (b)(4) [redacted] aspirations are produced. (b)(4) [redacted] aspiration is intended to perform deeper massage and to mobilize more blood flow to the skin's surface while (b)(4) [redacted] aspiration (using a wide variety of duty cycles and frequencies) is intended for more superficial massage and a pumping compression action on the tissues.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The device has software with 55 programs, each program having 2 pre-settings (mode A and mode B).

The labeling mentions three different keymodules: i1, i2, and i3, but these are not discussed in the device description section or the substantial equivalence comparison section.

Deficiencies:

Your labeling indicates that each roller encloses a miniaturized motor and mentions three different keymodules: i1, i2, and i3, but these are not discussed in the device description section or the substantial equivalence comparison section. Please revise these sections to include a precise description of this feature and how it is similar to or different from the legally marketed device to which you claim substantial equivalence. Please amend the device description section to identify all components and accessories with a name and model or part number. Software version should also be identified.

You have not provided any evidence of testing for general safety and general electrical safety to a standard such as IEC 60601-1. Similarly, you have not addressed electromagnetic compatibility or conformance to any other voluntary standards. Please provide evidence of conformance to relevant voluntary standards. Alternatively, please provide and justify alternative test methods and results to address these concerns. In order to allow us to evaluate the safety testing you have performed on your device, any declaration of conformance should include the elements as suggested in the Guidance Document entitled, *Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA" (2001).*

Since your device has software, please identify all indications, intended uses and functions incorporated in the software and provide the information required for a premarket notification application as identified in FDA's *Guidance Document for Software Contained in Medical Devices".*

If your device utilizes off-the-shelf software, please also provide the information identified in FDA's *Guidance for Off-the-Shelf Software Use in Medical Devices.* If not, please specify that it does not utilize off-the-shelf software.

Comparison Devices

K912004 Sportmed Pump (21 CFR 890.5650, Class II, product code ISA)
K914774 Multipulse Sequential Compression Unit
K974395 Atlant's

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The sponsor's comparison does not include specific components or specifications for any of the devices except for reporting of weight, amps, and voltage for some of the devices.

Comments:

It is particularly important to know how much pressure is applied to the tissues and whether this could cause tissue injury, e.g., bruising, swelling, pain, skin disruption. The sponsor provides clarification that the new device is a massager with a suction component that pulls the skin up between two rollers while the rollers compress, stretch and roll on the tissues. The device is rolled across the extremity in various patterns, i.e., it provides pressure to one relatively small area of the extremity at a time. It affects only the cutaneous and subcutaneous tissues. However, the comparison devices consist of inflatable sleeves for the upper and/or lower extremities that provide varying degrees of circumferential pressures to the entire extremity. This significant difference in technology could affect safety and effectiveness. Therefore, clinical performance data is needed to demonstrate substantial equivalence. Comparison of the cleared indications for use of the predicate devices to the new indications has also not been provided.

Deficiency:

Although you provided a brief comparison of your device to three legally marketed inflatable tube massager devices, the comparison is not precise enough to ensure substantial equivalence. Please provide a precise comparison of your new device's indications for use and technological characteristics to those of a legally marketed device. Please compare materials, construction and specifications that are precise enough to ensure substantial equivalence with respect to safety and effectiveness. If you intend to demonstrate substantial equivalence to an inflatable tube massager, then you should provide clinical performance data to substantiate equivalent safety and effectiveness since your device's new technological characteristics could effect safety and effectiveness and acceptable scientific methods exist for assessing the effects of these new characteristics. Please include copies of the investigational plan, informed consent document, case report forms, final study report, statistical results, adverse events and a financial certification or disclosure statement or both in accordance with 21 CFR 807.87(i).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Performance Data

Performance data were not provided.

Comments:

See above deficiency regarding the need for performance data.

CAPT Marie A. Schroeder

CAPT Marie A. Schroeder

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

MEMORANDUM

DATE January 13, 2006

FROM Director Regulatory Review Officer

SUBJECT K053225 Cellu M6 Keymodule I

TO The Record

I faxed the list identifying the additional information (fax attached) needed to:

Jay Mansour
C/O Mansour Consulting, LLC
1308 Morningside OPark Drive
Alpharetta, Georgia 30022

Telephone 770-777-4146
Fax 678-623-3765

Mr. Mansour agreed to provide the information and will cal me if he needs assistance.

CAPT Marie A. Schroeder

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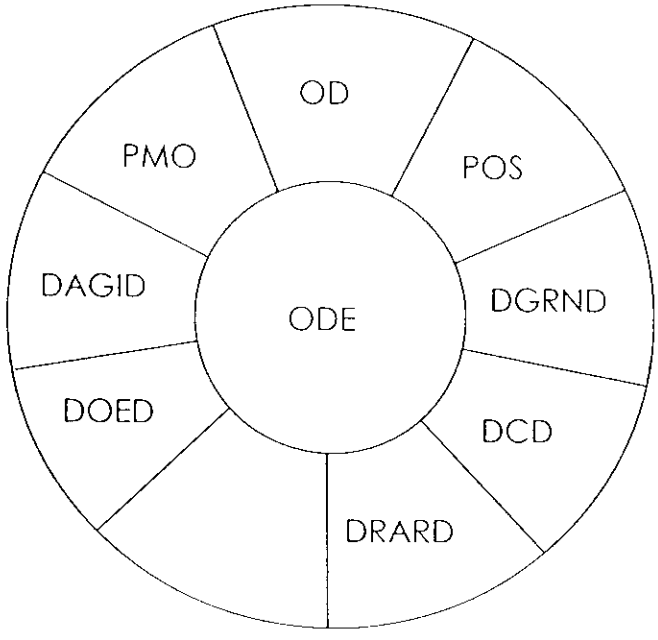
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

FAX



TO:

Name: Jay Mansour
Company: Mansour Consulting LLC
City: Alpharetta State: GA
Phone #: 770-777-4146

FAX #: 678 - 623 - 3765

FROM: Marie A Schroeder
Captain U.S.P.H.S.
Division of General, Restorative and Neurological Devices
9200 Corporate Boulevard, HFZ-410
Rockville, MD 20850
Phone #: (301) 594-1184 or 1296 x 116
Fax #: (301) 594-2358

Date: 1-13-06

Number of Pages (including cover): 3

Comments: Please call me to discuss if you have any questions. Thanks.
Captain Marie A Schroeder

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEDGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on the content of the communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Additional Information Needed for K053225
January 13, 2006

1) Since at least some states do not license massage therapists to treat medical conditions, please revise your prescription statement to specify that Federal law restricts this device to sale by or on the order of a licensed physical therapist or any other practitioner licensed by the law of the State in which he practices to use or order the use of the device.

2) Your labeling includes indications for use that are not identified in your Statement of Indications for Use, e.g., fibrosis, stiffness, delayed onset muscle soreness, muscle spasm, muscle aches and pains, appearance of cellulite and circumferential body measurements of cellulite treated areas, relaxation, traumatic edema, spider veins. Please resolve any discrepancies and assure that the substantial equivalence section compares your new device to a legally marketed device having the same indications for use. Alternatively, you should justify differences in the indications for use and provide performance data to substantiate substantial equivalence with respect to safety and effectiveness.

3) Since your device manipulates soft tissues, please amend your labeling to include the following contraindication: *This device should not be used over swollen or inflamed areas of skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.*

4) Although you contraindicate your device for skin cancer and tumors in the treated area, you have not contraindicated it for other cancerous lesions in the area to be treated. Please amend your contraindications to address this issue or provide data justifying treatment of other cancers in the area to be treated.

5) Your labeling indicates that each roller encloses a miniaturized motor and mentions three different keymodules: i1, i2, and i3, but these are not discussed in the device description section or the substantial equivalence comparison section. Please revise these sections to include a precise description of this feature and how it is similar to or different from the legally marketed device to which you claim substantial equivalence. Please amend the device description section to identify all components and accessories with a name and model or part number. Software version should also be identified.

6) You have not provided any evidence of testing for general safety and general electrical safety to a standard such as IEC 60601-1. Similarly, you have not addressed electromagnetic compatibility or conformance to any other voluntary standards. Please provide evidence of conformance to relevant voluntary standards. Alternatively, please provide and justify alternative test methods and results to address these concerns. In order to allow us to evaluate the safety testing you have performed on your device, any declaration of conformance should include the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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elements as suggested in the Guidance Document entitled, *Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA" (2001).*

7) Since your device has software, please identify all indications, intended uses and functions incorporated in the software and provide the information required for a premarket notification application as identified in FDA's *Guidance Document for Software Contained in Medical Devices".*

8) If your device utilizes off-the-shelf software, please also provide the information identified in FDA's *Guidance for Off-the-Shelf Software Use in Medical Devices.* If not, please specify that it does not utilize off-the-shelf software.

9) Although you provided a brief comparison of your device to three legally marketed inflatable tube massager devices, the comparison is not precise enough to ensure substantial equivalence. Please provide a precise comparison of your new device's indications for use and technological characteristics to those of a legally marketed device. Please compare materials, construction and specifications that are precise enough to ensure substantial equivalence with respect to safety and effectiveness. If you intend to demonstrate substantial equivalence to an inflatable tube massager, then you should provide clinical performance data to substantiate equivalent safety and effectiveness since your device's new technological characteristics could effect safety and effectiveness and acceptable scientific methods exist for assessing the effects of these new characteristics. Please include copies of the investigational plan, informed consent document, case report forms, final study report, statistical results, adverse events and a financial certification or disclosure statement or both in accordance with 21 CFR 807.87(i).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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****
*** TX REPORT ***
****

TRANSMISSION OK

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SUBADDRESS	
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ST. TIME	01/13 04:26
USAGE T	01'36
PGS. SENT	3
RESULT	OK

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?	NA	
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?	✓ ✓	 ✓
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K053225

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		✓ inadequate
Statement of Indications for Use that is on a separate page in the premarket submission.		✓ inadequate
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.		✓
510(k) Summary or 510(k) Statement.		✓
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		✓
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **	NA	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		✓
510(k) Kit Certification ***	NA	

* - May not be applicable for Special 510(k)s.

** Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE **Required Elements for a Declaration of Conformity to a Recognized Standard**, which is posted with the 510(k) boilers on the **H drive.**]		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening ____Yes ✓ No
Reviewer: M Filmoda Additional Info Requested
Concurrence by Review Branch: _____

Date: _____

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 053225

Reviewer: mfchroeder

Division/Branch: DGRND/for REDB

Device Name: Cellulite Keymodule I

Product To Which Compared (510(K) Number If Known): ?

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	?		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

OCTOBER 23, 2006.

From: Reviewer(s) - Name(s) DOLA VEGA, M.D; Ph.D.

Subject: 510(k) Number K053225/S2

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices N/A.

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N/A.

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

21 CFR 890.5660 - ISA - Class II - Therapeutic Massager.

Review: (Branch Chief) RDB (Branch Code) 11/2/06 (Date)

Final Review: (Division Director) 11/6/06 (Date)

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Revised:4/2/03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

JUNE 8, 2006

From: Reviewer(s) - Name(s) DONA. VEGA, M.D., Ph.D.

Subject: 510(k) Number K053225/S1

To: The Record - It is my recommendation that the subject 510(k) Notification:

AI letter

- ☐ Refused to accept.
- ☑ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☑ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☑ YES	☐ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary OR ☐ A 510(k) statement

☐ The required certification and summary for class III devices N/A

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N/A

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 day

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

21 CFR 890.5660 / 890.9 (New intended use/changes in Technology)
ISA - Class II.

Review: (Branch Chief) (Branch Code) FDB (Date) 6/14/06

Final Review: (Division Director) (Date)

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Revised:4/2/03

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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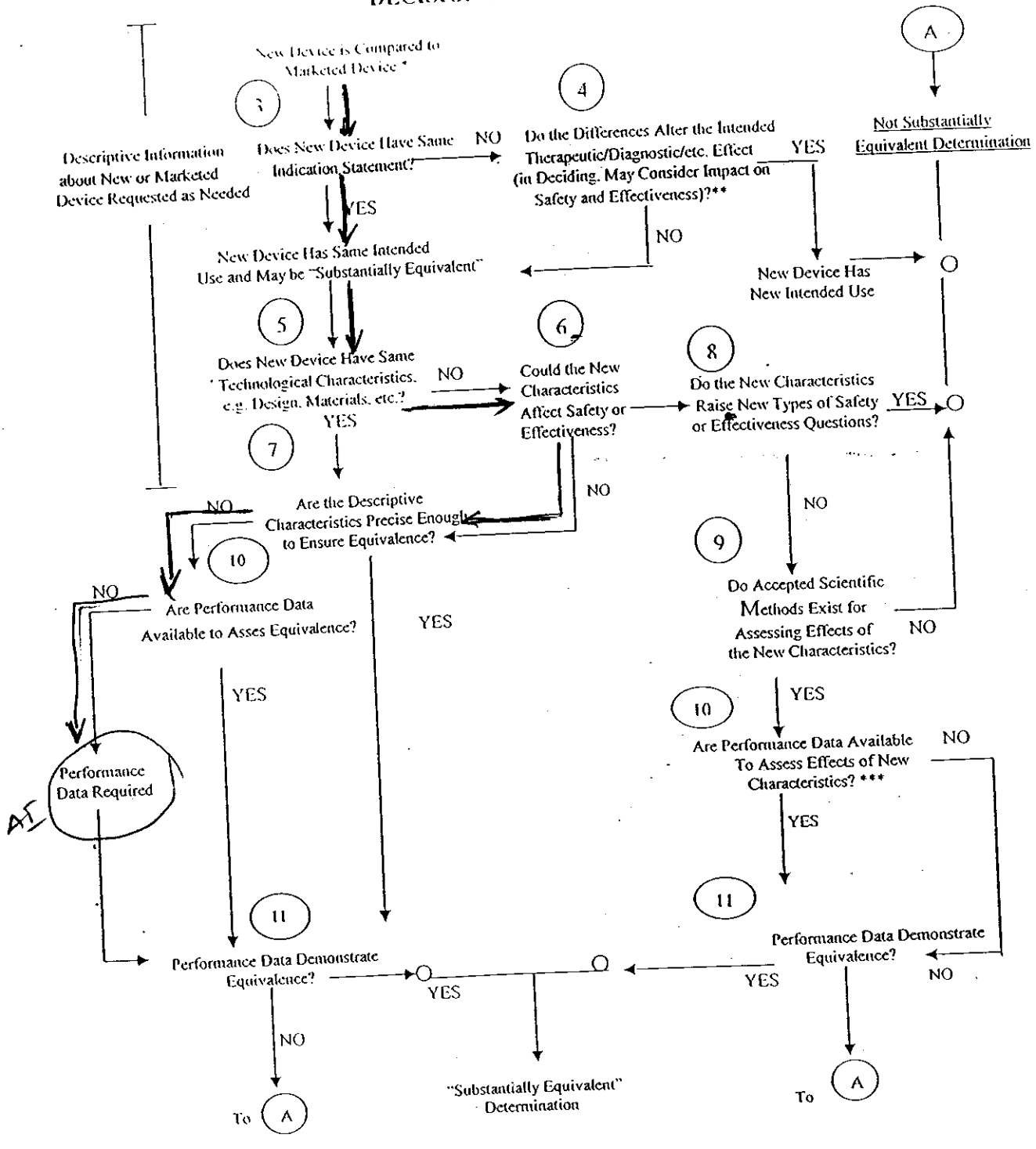
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K053225

Reviewer: DONA. VEGA, M.D. Ph.D.

Division/Branch: DGRND - REDB

Device Name: CRUM M6 KEYMODULE I

Product To Which Compared (510(K) Number If Known): K912004 - K914774 - K974395

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	N/A		If YES = Stop NE
5. Same Technological Characteristics?		✓	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		✓	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		✓	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?	N/A		If YES = Stop NE
9. Accepted Scientific Methods Exist?	N/A		If NO = Stop NE
10. Performance Data Available?		✓	If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?	N/A	
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	
4. If, not, has POS been notified?	N/A	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	N/A	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(K) MEMORANDUM

TO: **K053225**

FROM: Dora Vega, M.D., Ph.D.,
ODE / DGRND
Restorative Devices Branch (HFZ-410)

DATE: June 5, 2006

SUBJ: Cellu M6 Keymodule i Massager

CONTACT: Jay Mansur
C/o Mansur Consulting, LLC
845 Aronson Lake Court
Roswell,
GA 30075
Ph: (770) 777-4146. Fax: (678) 623-3765

Procode: ISA
Class: I
Regulation Number: 21 CFR 890.5560 Physical Medicine
Regulation Name: Physical Medicine

Recommendation: Additional information is requested in order to determine substantial equivalence between the Cellu M6 Keymodule i and the predicates Shepard Medical Sport Pump, K912004; Progressive Medical Multipulse Sequential Compression Unit, K914774; and Grad-Line's Atlant's, K974395.

Reason for this submission: To obtain the clearance of the Cellu M6 Keymodule i, which is proposed to be substantially equivalent to the currently marketed SportMed Pump, K912004, (Sheppard Medical); Multipulse Sequencial Compression Unit, K914774, (Progressive Medical); and Atlant's, K974395, (Grad-Line.)

Reviewer's Comments: The reason of this S001 submission, is to provide response to the FDA's request for AI, fax dated January 13, 2006.
Briefly, the proposed Cellu M6 Keymodule i is a powered inflatable tube massager intended for use for "Reduction of secondary lymphedema of the arm (SLA) post-mastectomy; reduction of

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lymphedematous fibrotic induration; improvement of primary and secondary lymphedema; prevention of venous stasis; prevention of deep venous thrombosis; and improvement of lymphatic circulation in the treated area."
LPG One, Inc., claims that the proposed device is SE to Shepard Medical Sport Pump, K912004; Progressive Medical Multipulse Sequential Compression Unit, K914774; and Grad-Line's Atlant's, K974395.
Overall, the sponsor's provides adequate response to the review concerns issued in fax dated January 13, 2006, but additional information/clarification is believed necessary to determine SE with the predicates. The main concerns raised from the sponsor's response in this submission are related with the apparent discrepancies in device specifications (e.g., maximum power suction),(see listing of deficiencies in this memo.)

REVIEW:

Device Description:

1. **Comparison of the Intended Use/Indications of the Subject Device and Predicate(s)**

Subject Device
The Cellu M6 Keymodule I is intended for the following Indications for Use

- "Reduction of secondary lymphedema of the arm (SLA) post-mastectomy.
- Reduction of lymphedematous *fibrotic induration* (*)
- Improvement of primary and secondary lymphedema
- Prevention of venous stasis
- Prevention of deep venous thrombosis
- Improvement of lymphatic circulation in the treated area."

(*) No supportive scientific data for this IFU is provided. Withdrawal of this IFU is requested in this Supplement, (see section "Deficiencies" in this Memo.)

Predicate device(s)
The IFU for the predicates Shepard Medical Sport Pump, K912004; Progressive Medical Multipulse Sequential Compression Unit, K914774; and Grad-Line's Atlant's, K974395 are:

- Shepard Medical Sport Pump, K912004: "Is indicated for acute care of the arm and leg swelling; treatment of chronic edema; treatment of lymphedema, including post-traumatic and rheumatic edema and chronic venous insufficiency and venous stasis ulcers"

- Progressive Medical Multipulse Sequential Compression Unit, K914774: "Is indicated for primary lymphedema; post-mastectomy edema; leg ulcers; edema following trauma and sport injuries; post-immobilization edema; prophylaxis of deep vein thrombosis; and venous insufficiencies due to muscle inactivity."

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- Grad-Line's Atlant's, K974395: "Is indicated for treatment of chronic venous insufficiency; lymphedema; edema of venous origin; post-amputation; lymphatic obstruction; wound healing; and contusion."

Discussion of whether the intended use/indications are the same.
The proposed Indications for Use except "reduction of lymphedematous fibrotic induration," were found SE to the intended use of the predicates. No SE has been found for the device specific indication for use for "reduction of lymphedematous fibrotic induration," (* above.)

2. **Comparison of the Technological Characteristics (Design, Materials, Sizes, Shapes, etc.) of the Subject Device**
The Cellu M6 Keymodule I is a power suction massager currently conceived as the last version of the LPG – ES1 therapeutic massager exempted from pre-market notification by 21 CFR Section 890.5660. The proposed Cellu M6 Keymodule device has changes in the design, materials, and performance specifications compared to the previously cleared ES1 device. However, these changes not seen to affect the device safety and effectiveness.
The device power suction ranges between 50-500 mmHg and is scaled from level 1 to 10. The device can produce both (b)(4) [redacted] aspiration to produce the massaging action on tissues. The device is comprised of a program console housing the vacuum pump and a regulation system. The device treatment head consists of (b)(4) [redacted] rollers placed inside a chamber, which produces negative pressure above the rollers and positive pressure below the rollers creating a skin fold between the two rollers in the suction chamber mimicking a manual rolling massage technique (i.e. suction skin fold) where roller A folds up the tissues and roller B unfolds them down. The Cellu M6 device has the capability to move the rollers forward, backward, inward, or in the outward direction -independently or together-, which enables the operator to massage the skin in a variety of skin folds shape, depth and thickness (e.g., roll-in, roll-out and roll-up.) Also the variable aspiration setting allows perform a deeper or more superficial massage to tissues. The "Contraindications" for use of the device comprise:
   - ✓ Known sensitivity to the device
   - ✓ Skin cancer in the treated area
   - ✓ Treatment of open wounds, infected areas, skin tumors, and scars from recent surgery
   - ✓ Treatment of patients with progressive infectious illnesses
   - ✓ Pregnant women
   - ✓ Patients under medical circulatory conditions no supervised by a physician.

Predicate Device(s)
Briefly, the technological characteristics of the predicates are as follow:

- Shepard Medical Sport Pump, K912004. Is a powered two –interior and exterior- inflatable bladder massager cleared as Class II device. The interior bladder is longitudinally compartmentalized in cells, and the exterior bladder allows a single cell

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intermittent compression or sequential compression. The device consists in a triple wall sheath designed to wrap/encase the arm or leg. A positive pressure exerted by the liquid or air in the bladders forces the tissue fluids be moved / drained into the underlying lymphatic vessels.

- Progressive Medical Multipulse Sequential Compression Unit, K914774. It consists in a 10 individual inflatable chambers with adjustable pressure control and readout gauge. Three of the 10 chamber are inflated at a time to allow the therapist to adjust the pressure within the range of the patient's comfort. The device has multipulse setting, which consists in the alternative inflation and deflation of the chambers provide sequential wave of compression up the limb (i.e., "milking" action.) It also has a multi-port garment attachment. It is a typical compression device.

- Grad-Line's Atlant's, K974395. It consists in inflatable boots or sleeves massagers which creates a linear and dynamic pressure gradient over the limbs. It has three different pressure curves, which can be operated at three different speeds: slow, medium and fast. The device is made from micro-porous foam encapsulated between two layers of neoprene. When the device is turned-on the air is forced into the distal part of the device and creates a positive pressure, which decreases as air diffuses following a linear gradient of pressure.

Discussion of whether the subject device has a significant change in technological characteristics.

The proposed Cellu M6 Keymodule I is a (b)(4) [redacted] pump that produces a massaging action on tissues. The variable roller settings in the device allow a variety of skin waves, movements and forces that operate between 50 - 500 mm Hg pressure. Contrastingly, the predicates are compression inflatable devices (i.e., boots, sleeves), which exert local increased pressure at the site to mechanically produce movement of the tissue interstitial fluids.

In summary, the main difference in technology between the proposed and the predicate devices is that the predicates' source of mechanical massage is the device air or fluid compression exerted on tissues, while in the Cellu M6 device the vacuum suction between both rollers is the source of the pressure that creates pulsation mechanical forces to the tissues to allow drainage of interstitial fluids.

Note that the LPG – ES1 suction therapeutic massager owned by the sponsor was exempted from pre-market notification by 21 CFR Section 890.5660, Pro-code 89 ISA and 89 IRO, panel Physical Medicine. The proposed Cellu M6 Keymodule device operates also using the *same mode of action –i.e., suction/vacuum pressure.* However the Cellu M6 massager proposes a new intended use (i.e., treatment of lymphedema) as well it has changes in the design, materials, and performance specifications which are subject to 21 CFR 890.9 - Limitations of exemptions from section 890.5660.

In this 510(k) application, all predicates cleared by a 510(k) process operate by "compression" mechanisms instead of "suction" (i.e., negative pressure) as the subject device, which is seen as

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not non-substantial equivalent mode of action, despite that both mechanisms facilitate the mechanical movement of accumulated interstitial tissue fluids (i.e., drainage).

Comparative Data: Safety (in vitro, animal and/or clinical) – Effectiveness Data

Subject Device
LPG One, Inc. states that the material specifications and biocompatibility are the same that those in the LPG Massage Vibrator cleared in K990445.
In addition, the sponsor provides the report of a clinical study on pneumatic compression devices in 10 subjects (original application, Appendix 20) and 45 subjects (original application, Appendix 24), and scientific literature to support the device safety and effectiveness (Attachment 9, 10a, and 15a, S001.)

Predicate Device(s)
The predicate in this application have provided biocompatibility data or showed equivalence for all body-contacting materials for clearance purposes.

A listing of concerns regarding the device safety and effectiveness was issued to the sponsor on January 1, 2006, (original review, fax dated January 1, 2006, Captain Marie Schroeder.)
The current submission, K053225, consists in the LPG's response to the FDA's request for AI, which is discussed below:

Deficiencies

Deficiency #1: Since at least some states do not license massage therapists to treat medical conditions, please revise your prescription statement to specify that Federal law restricts this device to sale by or on the order of a licensed physical therapist or any other practitioner licensed by law of the State in which he/she practices to use or order the use of the device.

Sponsor's response to Def. #1: *"We confirm our acceptance to change our prescription statement to be:*
Caution: Federal law restricts this device to sale by or on the order of a clinician licensed by the Law of the State where she/he practices to use or order the use of the device.
All or our labeling documents have been updated accordingly."

Reviewer's comments/recommendation: - Def. #1: AI
Comments: The response provided is self–explanatory and suffices the FDA's request in this concern. However it is requested the sponsor to include the prescription label in the cover or 1st page of the device labeling.

Deficiency #2: Your labeling includes indications for use that are not identified in your Statement of Indications for Use, e.g., fibrosis, stiffness, delayed onset muscle soreness, muscle spasm, muscle aches and pains, appearance of cellulite and circumferential body measurements of

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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cellulite treated areas, relaxation, traumatic edema, spider veins. Please resolve any discrepancies and assure that the substantial equivalence section compares your new device to a legally marketed device having the same indications for use. Alternatively, you should justify differences in the indications for use and provide performance data to substantiate substantial equivalence with respect to safety and effectiveness.

Sponsor's response to Def. #2: *Briefly, the sponsor states that:*

- *The device labeling documents have been updated to reflect only their specific indications for use as mentioned on page R (Tab 7) or the submission. These changes are: (a) Reduction of secondary lymphedema; (b) Reduction of lymphedematous fibrotic induration; (c) Improvement of primary and secondary lymphedema; (d) Prevention of venous stasis and venous insufficiency; (e) Prevention of deep vein thrombosis (DTV); and (f) Improvement of lymphatic circulation in the treated area.*

Reviewer's comments/recommendation: - Def. #2: AI requested
Comments: The sponsor removed all indications for use identified in concern #2 at the FDA's request with the exemption of "*fibrotic induration*," (b). The FDA requests LPG, One, Inc., the withdrawal of the IFU for reduction of lymphedematous fibrotic induration from the intended use for the device to show substantial equivalence with the IFU in the predicates.

Deficiency #3: Since your device manipulates soft tissues, please amend your labeling to include the following contraindication: This device should not be used over swollen or inflamed areas of skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.

Sponsor's response to Def. #3: *The sponsor states that the product labeling has been updated to include the following contraindication:*

> *"This device should not be used over swollen or inflamed areas of skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician."*

Reviewer's comments/recommendation: - Def. #3: Adequate
Comments: The sponsor's response satisfies the FDA's request for the amendment of the device labeling regarding an additional contraindication.

Deficiency #4: Although you contraindicate your device for skin cancer and tumors in the treated area, you have not contraindicated it for other cancerous lesions in the area to be treated. Please amend your contraindications to address this issue or provide data justifying treatment of other cancers in the area to be treated.

Sponsor's response to Def. #4: *The sponsor states that the product labeling has been updated to include the following contraindication:*

> *"Do not treat patients with active cancer or growing tumor. Consult with the doctor if*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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the patient has had a case history of tumors or is in remission."

Reviewer's comments/recommendation: - Def. #4: Adequate
Comments: The sponsor's response addresses the FDA's concern regarding the use of the device in active cancers and growing tumor including patients with history of tumors or tumors in remission.

Deficiency #5: Your labeling indicates that each roller encloses a miniaturized motor and mentions three different keymodules: i1, i2, and i3, but these are not discussed in the device description section or the substantial equivalence comparison section. Please revise these sections to include a precise description of this feature and how it is similar to or different from legally marketed device to which you claim substantial equivalence. Please amend the device description section to identify all components and accessories with a name and model and part number. Software version should also be identified.

Sponsor's response to Def. #5: The LPG One, Inc. states that:

- *There is only one device called Cellu M6 Keymodule i. The i1, i2, and i3 were different types of heads basically end-attachments to the device conceived for different types of use for some of which are not part of the current submission.*
- *In order to avoid confusion and separate from other IFU not included in the application, the device labeling has been revised to include only the heads applicable for the current IFU.*
- *The LPG One includes a detailed comparison between CelluM6 Keymodule I and its predicate (i.e., earlier version ES1) cleared in K990445, (Attachment 3a, b, c, d, e, and f.)*
- *LPG One includes a list of the components and accessories for Cellu M6 Keymodule i, (Attachment 3 and 4.)*
- *The requested device software information is provided is found adequate, (Attachment 7.)*

Reviewer's comments/recommendation: - Def. #5: Adequate – AI requested.
Comments: LPG provides information that clarifies the technological specifications in the different types of the device heads (i.e., i1, i2, and i3.) Review of this information shows slight differences of the device heads as well as the length (e.g., 24 mm, 26 mm or 28 mm roller width, and 50mm - 70mm roller length, respectively.) LPG also states that "there are three auxiliary heads intended for use for treatment of lymphedema in smaller areas of the body," (Attachment 3a), which more significantly differ from the physical dimensions reported above (e.g., 45 mm x 18 mm; 30mm x 14mm; and 15mm x 10mm.) Also the sponsor states that the labeling of the device has been revised to include the only device heads that are intended for the revised IFU. However there still are apparent discrepancies in the device specifications (e.g., 500 mb, 650 mb and 700 mb maximum negative pressure in the device), which require clarification, (Attachment 3a) in order to determine SE with the predicates. A risk analysis for the device based on the proposed variety of physical dimensions in the device heads and vacuum pressure is requested.)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Deficiency #6: You have not provided any evidence of testing for general safety and general electrical safety to a standard such as IEC 60601-1. Similarly, you have not addressed electromagnetic compatibility or conformance to any other voluntary standards. Please provide evidence of conformance to relevant voluntary standards. Alternatively, please provide and justify alternative test methods and results to address these concerns. In order to allow us to evaluate the safety testing you have performed on your device, any declaration of conformance should include the elements as suggested in the Guidance Document entitled, Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA," 2001.

Sponsor's response to Def. #6: *Briefly, LPG One states that:*

- *"All test applicable to our device and listed as FDA voluntary standards have been successfully tested for.*
- *The results of the tests are in Attachment 5 (IRC 60601-1) and Attachment 6a (Electromagnetic compatibility.)*

Reviewer's comments/recommendation: - Def. #6: Adequate
Comments: The requested testing IEC 60601-1 for general electrical safety and Electromagnetic compatibility are provided in Attachment 5 and 6a-b. The reports include a translation to English and seen adequate.

Deficiency #7: Since your device has software, please identify all indications, intended uses and functions incorporated in the software and provide the information required for a pre-market notification application as identified in FDA's "Guidance Document for Software Contained in Medical Devices."

Sponsor's response to Def. #7: LPG One, Inc., provides additional information regarding the device software in Attachment 7. This information includes:

- The software in the monitor screen (b)(4) [redacted].
- The software in the Pneumatics (b)(4) [redacted]
- The software in the main treatment head, (b)(4) [redacted].
- Software validation, verification and testing (Appendix page 26-88.)

Reviewer's comments/recommendation: - Def. #7: AI requested
Comments: The sponsor reports that the software components tested has used the Stand-alone Cellu M6 Keymodule I with *various* heads attachments. The information provided such as the report for the level of concern for the system, (Attachment 7, page 6-7 is found adequate). However it is unclear the specific device heads tested for the intended use for the device. Additional information that clarifies the device heads tested and their suitability for the intended use for the device is requested.

Deficiency #8: If your device utilizes off-the-shelf software, please also provide the information identified in FDA's Guidance for Off-the-Shelf Software Use in Medical devices. If not, please

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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specify that it does not utilize off-the-shelf software.

Sponsor's response to Def. #8: The sponsor states that (b)(4) [redacted] (b)(4) [redacted]

Reviewer's comments/recommendation: - Def. #8: Adequate
Comments: The sponsor response is self-explanatory and suffices the FDA's request.

Deficiency #9: Although you provided a brief comparison of your device to three legally marketed inflatable tube massager devices, the comparison is not precise enough to ensure substantial equivalence. Please provide a precise comparison of your new device's indications for use and technological characteristics to those of a legally marketed device. Please compare materials, construction and specifications that are precise enough to ensure substantial equivalence to an inflatable tube massager then you should provide clinical performance data to substantiate equivalent safety and effectiveness since your device's new technological characteristics could affect safety and effectiveness and acceptable scientific methods exist for assessing the effects of these characteristics. Please include copies of the investigational plan, informed consent document, case report forms, final study report, statistical results, adverse events and a financial certification or disclosure statement or both in accordance with events and a financial certification or disclosure statement or both in accordance with 21 CFR 807.87(i).

Sponsor's response to Def. #9: LPG One states that:

- The Company introduces the additional Sequential Circulator, Model SC-3008 predicate cleared in K043423.
- The reason to introduce this predicate is that the company has found clinical studies related with the IFU for the proposed Cellu M6 device that support LPG's request.
- Despite that the predicates for Cellu M6 Keymodule are compression devices, the company believes worth mentioning that the use of pneumatic compression devices is currently "controversial for the treatment of lymphedema in the United States."
- LPG One provides comparison of clinical data between Cellu M6 and the predicate Sequential Circulator, Model SC-3008, K043423 to support the SE for the device safety and effectiveness.

Reviewer's comments/recommendation: - Def. #9: AI requested
Comments: The newly introduced predicate Sequential Circulator, Model SC-3008 is an inflatable sleeve which contains chambers that exert pressure at the treatment site. The maximum pressure is 150 mmHg and there is a gradient pressurization –i.e., higher at the distal than the proximal chambers.) The IFU is for the primary or adjunctive treatment of lymphedema. Also the device has been cleared for treatment of venous insufficiency, as well as chronic venous stasis ulcers associated with venous insufficiency as well as general treatment of swelling of the extremities. It is unclear why the sponsor states that the clinical data reported in the predicate Sequential Circulator, Model SC-3008, which differs in its mode of action (i.e., compression device vs. suction device) may serve to support the safety and effectiveness of the Cellu M6 Keymodule I

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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massager. Additional clarification is requested.

Review deficiencies – Supplement 001:

Regarding your response to the FDA's deficiency #1, fax dated January 13, 2006:

1. You confirmed your acceptance to change the device's prescription statement to be: "Caution: Federal law restricts this device to sale by or on the order of a clinician licensed by the Law of the State where she/he practices to use or order the use of the device.
All or our labeling documents have been updated accordingly." However, it was not included in the first page of the device labeling. Please revise your labeling to include the prescription label in the first page of the device labeling.

Regarding your response to the FDA's deficiency #2, fax dated January 13, 2006:

2. Your response dated May 9, 2006 states that the device labeling has been updated to reflect only their specific indications for use as mentioned on page R (Tab 7) or the submission, and that these changes are: (a) Reduction of secondary lymphedema; (b) Reduction of lymphedematous fibrotic induration; (c) Improvement of primary and secondary lymphedema; (d) Prevention of venous stasis and venous insufficiency; (e) Prevention of deep vein thrombosis (DTV); and (f) Improvement of lymphatic circulation in the treated area. The use of your device for *fibrotic induration* is not SE to the IFU for the predicates. Also, section "Selectivity," claims for the device in your response indicates "*deep vein thrombosis as therapeutic use* for the device." Please provide medical scientific rationale and supporting clinical performance data for the use of the device for these IFU and a discussion on why you claim substantial equivalence with the predicates, which contraindicate the use of the device in deep vein thrombosis and thrombophlebitis. Otherwise, please remove these claims for the device labeling.

Regarding your response to the FDA's deficiency #5, fax dated January 13, 2006:

3. Your response, letter May 9, 2006 provides information that clarifies the technological specifications in the different types of the device heads (i.e., i1, i2, and i3.) However you mention that "there are three auxiliary heads intended for use for treatment of lymphedema in smaller areas of the body," (Attachment 3a), which significantly differ (e.g., 45 mm x 18 mm; 30mm x 14mm; and 15mm x 10mm) from the physical dimensions reported for the heads i1, i2, and i3 reported above. In addition, the revised labeling of the device still has some apparent discrepancies in the device specifications (e.g., 500 mb, 650 mb and 700 mb maximum negative pressure in the device, Attachment 3a.) Please provide information that adequately clarifies the physical dimensions in the device heads as well as a discussion about the substantial equivalent performance of the varied dimensions in the device heads, and the vacuum.

Regarding your response to the FDA's deficiency #7, fax dated January 13, 2006:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4. You report that the software components tested has used the Stand-alone Cellu M6 Keymodule I with *various* heads attachments. However it is unclear the specific device heads tested for the intended use for the device. Please provide information that clarifies the device heads tested and a discussion about their suitability for the intended use for the device.

Regarding your response to the FDA's deficiency #9, fax dated January 13, 2006:

5. The newly introduced predicate Sequential Circulator, Model SC-3008 for your device, your letter dated May 9, 2006 is an inflatable –pneumatic- sleeve, which exerts up to 150 mm Hg pressure at the treatment site. Your Cellu M6 Keymodule I differs in the mode of action because operates by suction reaching a maximum vacuum pressure up to 500 mm Hg - 700 mm Hg. Despite of the similar Indications for Use for the treatment of primary or adjunctive treatment of lymphedema, it is unclear why you claim that the clinical data supporting for the predicate Sequential Circulator, Model SC-3008, support the safety and effectiveness performance of your device. Please provide explain your claim for substantial clinical equivalence between your proposed Cellu M6 Keymodule I and the predicate Sequential Circulator, Model SC-3008.

Dora Vega., M.D., Ph.D.
Medical Officer
Division of General, Restorative,
and Neurological Devices
Plastic and Reconstructive Surgery Devices Branch

Date: June 10, 2006.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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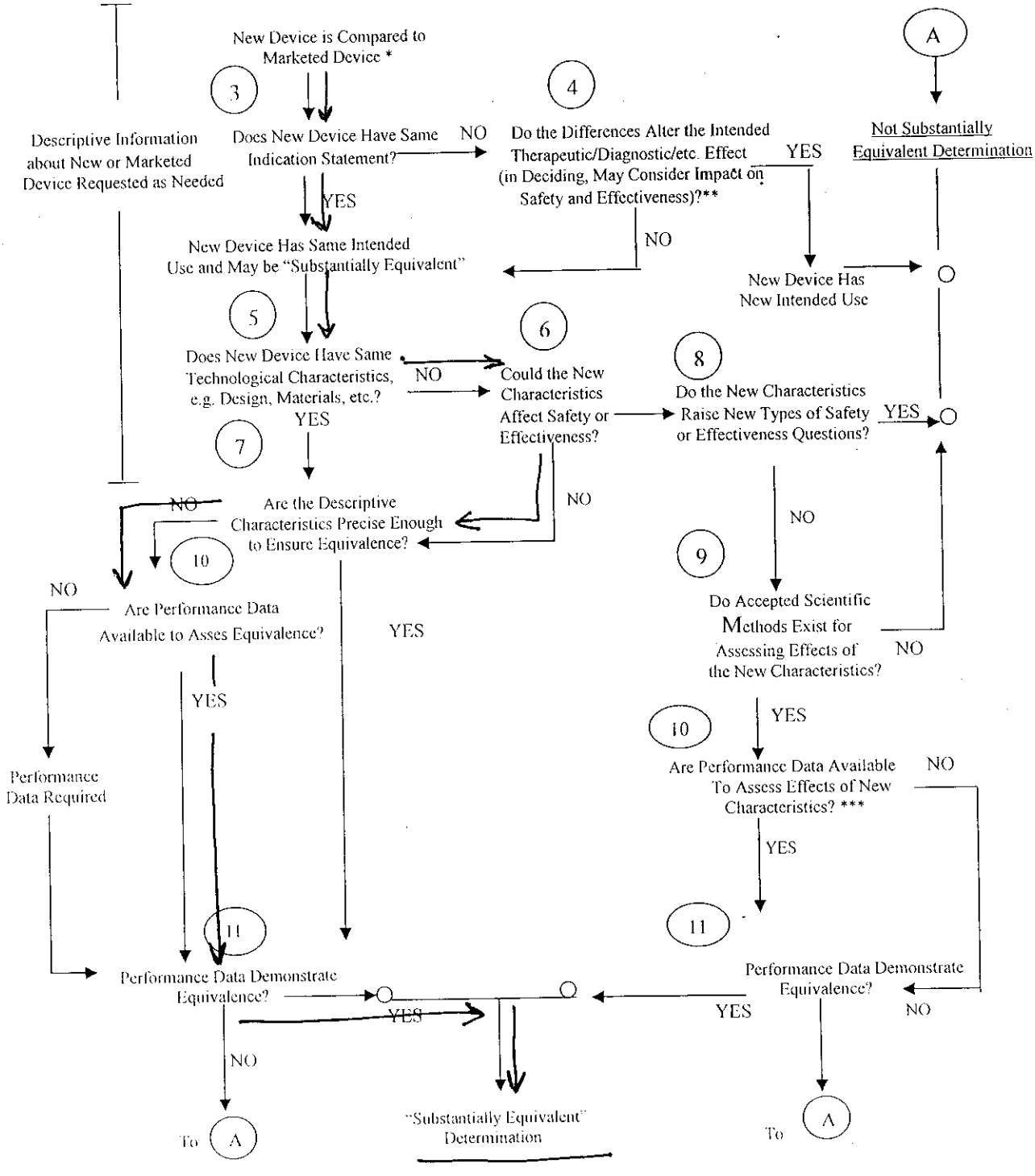
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 053225 / S002

Reviewer: Dona VEGA, M.D., Ph.D.

Division/Branch: DGRND - REDB

Device Name: CELLU MG KEYMODULE i - MASSAGER

Product To Which Compared (510(K) Number If Known): K91 2004 - K 914774 - K97459 and K013061

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	N/A		If YES = Stop NE
5. Same Technological Characteristics?		✓	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?		✓	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	✓		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	✓		If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision: SE.

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. Intended Use: Cellu M6 Keymodule is indicated for:

- Reduction of Secondary Lymphedema of the Arm (SLA) Post Mastectomy
- Improvement of secondary lymphedema
- Improvement of lymphatic circulation in the treated area.

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

Cellu M6 Keymodule I represents the last version of the LPG – ES1 therapeutic massager exempted from pre-market notification by 21 CFR Section 890.5660. The proposed Cellu M6 Keymodule device has slight changes in design, materials, and performance specifications compared to the previously cleared ES1 device. The device power suction ranges between 50-500 mmHg and is scaled from level 1 to 10. At the FDA's request inn this submission, the sponsor limits the device suction power up to level 4, which reaches equivalent power pressure to the predicates (i.e., up to 180 mm Hg compared with 150 mm Hg in the predicates) to generate an equivalent power pressure on tissues to the predicates for the IFU for reduction of secondary lymphedema of the arm post-mastectomy, (see LPG One's response, S002 in the submission.) The device can produce both, (b)(4) [redacted] aspiration to produce the massaging action on tissues. The device comprises a program console that contains the vacuum pump and a regulation system. The device treatment head consists of (b)(4) [redacted] rollers placed inside a chamber that produces negative pressure above the rollers and positive pressure below them creating a skin fold between the two rollers mimicking a manual rolling massage technique (i.e. suction skin fold). The Cellu M6 device has the capability to move the rollers forward, backward, inward, or in the outward direction -independently or together-, which enables the operator to massage the skin in a variety of skin folds shape, depth and thickness.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

Cellu M6 Keymodule I represents the last version of the LPG – ES1 therapeutic massager exempted from pre-market notification by 21 CFR Section 890.5660. It has slight changes in

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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design, materials, and performance specifications compared to the previously cleared ES1 device.
Briefly, Cellu M6 Keymodule I is a (b)(4) [redacted] pump that produces a "tissue wave" massaging action on tissues, and ultimately facilitates circulation of interstitial fluids. For the device specific intended use in the submission, the variable roller settings will operate with vacuum forces up to ~180 mm Hg pressure.
The predicates are compression inflatable devices (i.e., boots, sleeves), which exert local increased pressure at the site to mechanically produce a similar "tissue wave" movement that facilitates circulation / absorption of tissue interstitial fluids.
Therefore, the main difference in technology between the proposed and the predicate devices is that the predicates' source of mechanical massage is the device air or fluid compression exerted on tissues, while in the Cellu M6 device the vacuum suction between both rollers is the source of the mechanic pulsation forces to the tissues to allow drainage of interstitial fluids. But, in both cases, the mode of action of these devices is to increase the local interstitial circulation of fluids but generating equivalent pressure forces in tissues for the same IFU (i.e., reduction of lymphedema.

Note that the previously cleared LPG – ES1 -owned by the sponsor- is also a suction therapeutic massager that was exempted from pre-market notification by 21 CFR Section 890.5660, Pro-code 89 ISA and 89 IRO, Physical Medicine panel. The proposed Cellu M6 Keymodule i device operates also using the *same mode of action –i.e., suction/vacuum pressure.* In this submission, the Cellu M6 massager proposes a new intended use (i.e., treatment of lymphedema), which falls under 21 CFR 890.9 - Limitations of exemptions from section 890.5660.

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?	N/A	
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	
4. If, not, has POS been notified?	N/A	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	N/A	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

May 16, 2006

LPG ONE, INC
C/O MANSOUR CONSULTING, LLC
845 ARONSON LAKE COURT
ROSWELL, GA 30075
ATTN: JAY MANSOUR

510(k) Number: K053225
Product: CELLU M6
KEYMODULE I

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SUPPLEMENT: ORIGINAL COPY

K053225/S1

May 9, 2006

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER HFZ-401

9200 CORPORATE BLVD
ROCKVILLE, MD 20850

K-24.

ATTENTION: CAPTAIN MARIE A. SCHRŒDER
TEL 301-594-1184 OR 301-594-1296 x116. FAX 301-594-2358
DIVISION OF GENERAL, RESTORATIVE AND NEUROLOGICAL DEVICES, HFZ-410

SUBJECT: 510K #K053225 SUPPLEMENT S1

Dear Captain Schrœder,

Our response is sent in two binders: one original, and one copy

VERY IMPORTANT: In order to locate the tab that includes the attachment numbers mentioned throughout this response letter, kindly refer to the table of contents on page 7 of this response letter.

Note that the submission summary[1] is updated and included with this response.

In reference to your fax[2] dated January 13, 2006, our subsequent conference call, as well as to the Document Mail Center letter approving extension of time[3] till May 16, 2006, we respond below, following the same sequence and numbering as per your fax.

For your convenience, please note that a Q&A section has been added on pages 5 and 6 of this response letter.

1- We confirm our acceptance to change our prescription statement[4] to be:

"Caution: Federal law restricts this device to sale by or on the order of a clinician licensed by the Law of the State where he/she practices to use or order the use of the device"

All of our labeling documents[5] have been updated accordingly.

[1] Refer to attachment 2
[2] Refer to attachment 1a
[3] Refer to attachment 1b
[4] Refer to 21 CFR 801.109 (b) (1) and our conference call
[5] Refer to page A4 of attachment 25-1 (brochure), page B1 of attachment 25-2 (directions for use), and page 11 of attachment 25-3 (manual)

Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2- Our labeling documents have been updated to reflect only our specific indications for use as mentioned on page R (Tab 7) of our submission. These are:

(a) Reduction of secondary lymphedema of the arm (SLA) post mastectomy
(b) Reduction of lymphedematous fibrotic induration
(c) Improvement of primary and secondary lymphedema
(d) Prevention of venous stasis and venous insufficiency
(e) Prevention of deep vein thrombosis (DVT)
(f) Improvement of lymphatic circulation in the treated area

3- Our labeling documents have been updated[6] to include the following contraindication:

"This device should not be used over swollen or inflamed areas of skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician"

4- Our labeling documents have been updated to include the following contraindications:

" This device is contraindicated for skin cancer, tumors and other cancerous lesions in the area to be treated".

"Do not treat patients with active cancer or growing tumor. (Consult with the doctor if the patient has had a case history of tumors or is in remission)"

5- There is only one device called CelluM6 Keymodule i. The i1, i2, and i3 were different types of heads used for different types of use and treatments. These heads were basically end-attachments to the device CelluM6 Keymodule i. The device has been originally designed for multiple indications for use, some of which should not have been part of this submission to avoid duplications/confusions. In order to avoid including unnecessary details for all the heads, and more importantly, in order to separate our current medical claims from others, our labeling documents have been revised to include only the heads applicable for our current indications for use. The revised labeling documents do not allow for such misunderstanding now, as there is no more mention of i1, i2 and i3 as before.

As per our conference call, we include a detailed comparison[7] between CelluM6 Keymodule i and its earlier version ES1, despite the fact that ES1 was cleared for different indications for use at that time under 510k #K990445 as located at http://www.fda.gov/cdrh/pdf/k990445.pdf. Our goal is to provide you with a technological comparison, in order to link our current submission to another one being technologically the closest to CelluM6 Keymodule i, subject of this 510k. (More on substantial equivalence under item 9 below).

We also include a list[8] of the components and accessories for CelluM6 Keymodule i.

The software version is discussed along with other software related documentation. Please refer to paragraph 7 below.

[6] Refer to page A6 of attachment 25-1 (brochure), page B7 of attachment 25-2 (directions for use), and page 11 of attachment 25-3 (manual)
[7] Refer to attachments 3a, 3b, 3c/d, 3e, and 3f
[8] Refer to attachment 4

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MANSOUR CONSULTING

6- All tests applicable to our device and listed as FDA voluntary standards have been successfully tested for. The results[9] of such tests are included.

7- Complete details of the software are included[10], all in accordance with the appropriate FDA guidance document.

8- [redacted] (b) (4) [redacted]

9- We now introduce an additional predicate device, being "Model SC-3008 Sequential Circulator", cleared by FDA under 510k #K043423[11], as located at http://www.fda.gov/cdrh/pdf4/k043423.pdf.

The reason for introducing this new predicate device is that **we were able to find the related clinical studies[12] for this new predicate as it relates to our indications for use, for direct clinical linkage and comparison of safety and effectiveness, as per your request.**

Due to the lack of finding another therapeutic massager with the same indications for use claimed in this submission, our predicate devices are compression devices. However, **it is worth mentioning[13] that the use of pneumatic compression devices is now controversial for the treatment of lymphedema in the United States.**

A matrix defining and comparing the different terminologies for the various indications for use of our device with all the predicate devices is provided[14] within this response. This matrix also refers to the directions for use.

A clinical comparison between our device and K043423 is provided[15] within this response, confirming substantial equivalency, in terms of safety and effectiveness.

---

[9] Refer to attachments 5 and 6a/b
[10] Refer to attachment 7
[11] Refer to attachment 8
[12] Refer to attachments 9 and 10a/b
[13] Medifocus Guidebook #OC030 (pages 33 and 41 marked under attachment 11), as well as National Lymphdema Network (NLN)
- **On page 33 of attachment 11**, the following is stated:
"... Currently, there is no general consensus among doctors regarding a uniform, standard treatment of lymphedema... (as) treatment options are individualized to the patient's specific situation and take into account a variety of factors, including the severity of lymphedema..."
- **On page 41 of attachment 11**, the following is stated:
"... At one time, pneumatic compression pumps were a standard treatment for lymphedema in the United States, however, their use today is controversial. While some studies have shown that these devices are effective for the treatment of lymphedema, other studies have found them not to be effective and they may even cause harm to the limb. Some studies have shown that fluid flows right back into the edematous limb with the cessation of treatment.
The absence of clear guidelines and the lack of standardized treatment protocols has contributed to the controversy surrounding the routine use of these devices in the management of lymphedema.
Treatment with pneumatic pumps is not very popular among patients because:
- *It is very expensive*
- *It is very time consuming*
- *It does not help break down fibrotic tissue*

Pneumatic compression is contraindicated if several conditions are present including, ischemia, reduced blood supply to the limb, congestive heart failure, or deep vein thrombosis..."
- **On http://www.lymphnet.org/lymphedemaFAQs/overview.htm webpage of National Lymphedema Network website**, NLN endorses Complex Decongestive Therapy for treatment, and not simply compression devices alone:
"... Depending on the severity of the lymphedema, the recommended treatment plan should be determined using an approach based on the Complex Decongestive Therapy (CDT) methods which consist of: a) manual lymphatic drainage; b) bandaging; c) proper skin care & diet; d) compression garments (sleeves, stockings, devices such as Reid Sleeve, CircAid, Tribute, as well as other alternative approaches); e) remedial exercises; f) self-manual lymphatic drainage & bandaging, if instruction is available; g) continue to follow prophylactic methods at all times..."
[14] Refer to attachment 12
[15] Refer to attachment 13 (part 1: substantial equivalence; part 2: clinical matrix)

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Roswell, GA 30075 USA
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MANSOUR CONSULTING

Note: This comparison includes an additional column incorporating additional information obtained via an additional clinical study that we completed very recently (More on this under paragraph 10 below)

- A technological comparison between our device and all predicate devices is provided[16] within this response.
- An article defining the methods used for manual lymph drainage (MLD) confirming its safety and effectiveness, as well as detailing the measurement techniques is provided[17] within this response. This method is repetitive, and has been used in our clinical studies as well as in one of the predicate clinical study[18] (b) (6) [redacted] MLD is well defined, and the method has not been compromised/altered in any way for any purpose.
- Investigational plan of our clinical study is provided[19] within this response.
- Informed consent document is provided[20] within this response.
- Case report forms are provided[21] within this response.
- Note: Final study report -including statistical results and adverse events- has been provided to you earlier within the original submission under Tab 24 (Appendix 2)
- Financial certification is provided[22] within this response.

10- As part of continual improvement/upgrade to allow for the best use out of our device, an additional clinical study[23] has been recently conducted at the same facility and directed b(b) (6) [redacted] (b) (6) [redacted] who is internationally recognized as a leader in lymphedema clinical studies. Treatment protocol has been upgraded accordingly, as **this new study provides more information that allows faster treatment.**

For this follow up clinical study:

- a summary of the findings is provided[24] within this response.
- final study report is provided[25] within this response including statistical results and adverse events.
- investigational plan is provided[26] within this response.

---

[16] Refer to attachment 14
[17] Refer to attachments 15a (article) and 15b (b)(4) [redacted] r definition)
[18] Refer to attachment 9- MLD was used as part of DLT (Decongestive Lymphatic Therapy)
[19] Refer to attachment 16
[20] Refer to attachment 17
[21] Refer to attachment 18
[22] Refer to attachment 19
[23] Study referred to within the supplement as (b)(4) [redacted] study", or "2006 (b) [redacted] study" to differentiate it from [redacted] (b)(4) [redacted] which is the original study included in original submission (4)
[24] Refer to attachment 20
[25] Refer to attachment 21
[26] Refer to attachment 22

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- informed consent document is provided[27] within this response.
- case report forms are provided[28] within this response (being the same as for the earlier study)
- financial certification is provided[29] within this response.

11- QUESTIONS AND ANSWERS: Q&A

Q: Have you answered all questions and have you submitted all documents necessary to back up your responses.
A: Yes, to the best of our knowledge and ability

Q: Do you consider this supplement to be extensive, documentation-wise?
A: Yes, this supplement includes a lot of information that needs detailed review. We spent a great effort assembling or generating documents in order to reply to your questions in as much details as possible

Q: Have you altered anything in the indications for use within this supplement #1?
A: No. Indications for use remain the same. Additional terminologies shown in original submission file have been cancelled for consistency

Q: Why are you discussing ES1 device?
A: The reason is to provide you with a device cleared by FDA **for us** having VERY similar technological characteristics as our KeyModule i device, as mentioned in our conference call

Q: Why did you add an additional predicate device?
A: The reason is that it is the only device that we could find clinical studies for, which can be linked directly to our device in terms of safety and effectiveness, as mentioned in our conference call

Q: Why did you include a second clinical study conducted on your device?
A: The reason is that –as part of continual improvement- we were able to get better results/data, according to which the directions for use were amended, thus providing the user with better treatment protocols

Q: Several changes occurred on the original submission. Can you summarize those changes for our convenience?
A: Certainly.

- Tab 5 (summary) of original submission is replaced by attachment 2 of supplement
- Cautionary note mentioned at the bottom of Page S of Tab 8 of original submission is superceded by revised cautionary note as mentioned in paragraph 1 mentioned above
- Tab 9 of original submission is deleted to avoid redundancy
- Tab 10 of original submission is replaced by attachment 25-1 of supplement
- Tab 15 of original submission is amended by attachments 13 and 14 of supplement
  (Note: contraindications on page 5.4 of tab 15 of original submission are replaced by page B7 of attachment 25-2 of supplement)

[27] Refer to attachment 23
[28] Refer to attachment 18
[29] Refer to attachment 24

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- Tab 16 of original submission is replaced by attachment 20 of supplement
- Tab 18 of original submission is replaced by attachment 25-2 of supplement
- Pages 8.5 and 8.6 of Tab 19 of original submission are replaced by attachment 21b of supplement
- Tab 25 of original submission is replaced by attachment 25-3 of supplement
- In addition to the above changes, the following attachments are included as part of the supplement, being new documents: attachments 3a, 3b, 3c, 3d, 3e, 3f, 4, 5, 6a, 6b, 7, 8, 9, 10a, 10b, 11, 12, 15a, 15b, 16, 17, 18, 19, 20, 21a, 22, 3 and 24

We hope that you will find this supplement complete, accurate and to your satisfaction. In the meantime, we stand ready to reply promptly to any questions that may arise.

Best Regards,

Jay Mansour, MSQA, BE, RAC, LA
President, Mansour Consulting LLC for LPG One, Inc
845 Aronson Lake Court
Roswell, GA 30075

678-908-8180. Fax 678-623-3765

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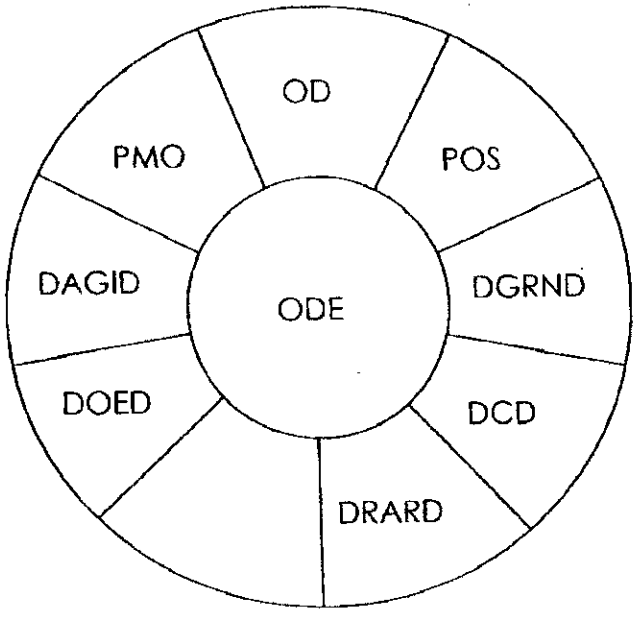
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

ATTACHMENT 1a

FAX



TO:

Name: Jay Mansour
Company: Mansour Consulting LLC
City: Alpharetta State: GA
Phone #: 770-777-4146

FAX #: 678-623-3765

FROM: Marie A. Schroeder
Captain U.S.P.H.S.
Division of General, Restorative and Neurological Devices
9200 Corporate Boulevard, HFZ-410
Rockville, MD 20850
Phone #: (301) 594-1184 or 1296 x 116
Fax #: (301) 594-2358

Date: 1-13-06

Number of Pages (including cover): 3

Comments: Please call me to discuss if you have any questions. Thanks.
Captain Marie A. Schroeder

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEDGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on the content of the communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

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Additional Information Needed for K053225
January 13, 2006

1) Since at least some states do not license massage therapists to treat medical conditions, please revise your prescription statement to specify that Federal law restricts this device to sale by or on the order of a licensed physical therapist or any other practitioner licensed by the law of the State in which he practices to use or order the use of the device.

2) Your labeling includes indications for use that are not identified in your Statement of Indications for Use, e.g., fibrosis, stiffness, delayed onset muscle soreness, muscle spasm, muscle aches and pains, appearance of cellulite and circumferential body measurements of cellulite treated areas, relaxation, traumatic edema, spider veins. Please resolve any discrepancies and assure that the substantial equivalence section compares your new device to a legally marketed device having the same indications for use. Alternatively, you should justify differences in the indications for use and provide performance data to substantiate substantial equivalence with respect to safety and effectiveness.

3) Since your device manipulates soft tissues please amend your labeling to include the following contraindication: *This device should not be used over swollen or inflamed areas of skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.*

4) Although you contraindicate your device for skin cancer and tumors in the treated area, you have not contraindicated it for other cancerous lesions in the area to be treated. Please amend your contraindications to address this issue or provide data justifying treatment of other cancers in the area to be treated.

5) Your labeling indicates that each roller encloses a miniaturized motor and mentions three different keymodules: i1, i2, and i3, but these are not discussed in the device description section or the substantial equivalence comparison section. Please revise these sections to include a precise description of this feature and how it is similar to or different from the legally marketed device to which you claim substantial equivalence. Please amend the device description section to identify all components and accessories with a name and model or part number. Software version should also be identified.

6) You have not provided any evidence of testing for general safety and general electrical safety to a standard such as IEC 60601-1. Similarly, you have not addressed electromagnetic compatibility or conformance to any other voluntary standards. Please provide evidence of conformance to relevant voluntary standards. Alternatively, please provide and justify alternative test methods and results to address these concerns. In order to allow us to evaluate the safety testing you have performed on your device, any declaration of conformance should include the

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elements as suggested in the Guidance Document entitled, *Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA" (2001).*

7) Since your device has software, please identify all indications, intended uses and functions incorporated in the software and provide the information required for a premarket notification application as identified in FDA's *Guidance Document for Software Contained in Medical Devices".*

8) If your device utilizes off-the-shelf software, please also provide the information identified in FDA's *Guidance for Off-the-Shelf Software Use in Medical Devices*. If not, please specify that it does not utilize off-the-shelf software.

9) Although you provided a brief comparison of your device to three legally marketed inflatable tube massager devices, the comparison is not precise enough to ensure substantial equivalence. Please provide a precise comparison of your new device's indications for use and technological characteristics to those of a legally marketed device. Please compare materials, construction and specifications that are precise enough to ensure substantial equivalence with respect to safety and effectiveness. If you intend to demonstrate substantial equivalence to an inflatable tube massager, then you should provide clinical performance data to substantiate equivalent safety and effectiveness since your device's new technological characteristics could effect safety and effectiveness and acceptable scientific methods exist for assessing the effects of these new characteristics. Please include copies of the investigational plan, informed consent document, case report forms, final study report, statistical results, adverse events and a financial certification or disclosure statement or both in accordance with 21 CFR 807.87(i).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

ATTACHMENT 1b

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 30, 2006

LPG ONE, INC
C/O MANSOUR CONSULTING, LLC
1308 MORNINGSIDE PARK DRIVE
ALPHARETTA, GA 30022
ATTN: JAY MANSOUR

510(k) Number: K053225
Product: CELLU M6
KEYMODULE I

Extended Until: 16-MAY-2006

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT 2

510(k) Summary
As Required by 21 section 807.92 (c)

1-Submitter Name: LPG One, Inc
2-Address: 801 Brickell Ave. Suite 850. Miami, FL 33131
3-Phone: (305) 379- 8800
4-Fax: (305) 375- 0903
5-Contact Person (Consultant): Jay Mansour of Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA
(678) 908-8180. Fax (678) 623-3765
6-Date summary prepared: May 9th, 2006
7-Device Trade or Proprietary Name: CELLU M6 KEYMODULE i
8-Device Common or usual name: Massager
9-Device Classification Name: Electrical Therapeutic Massager
10-Substantial Equivalency is claimed against the following devices:

1- Shepard Medical's Sport Pump- 510k #K912004
2- Progressive Medical's Multipulse Sequential Compression unit- 510k #K914774
3- Grad-Line's Atlant's- 510k #K974395
4- Model SC-3008 Sequential Circulator- 510k #K043423

11-Description of the Device:

The Cellu M6 Keymodule I electrical therapeutic massager is comprised of a program console housing a vacuum pump and a regulation system. The main treatment head consists of two parallel motorized rollers housed in a chamber which produces both negative pressure above the rollers and positive pressure below the rollers. This technology creates a skin fold between the two rollers in a suction chamber, thus mimicking the "rolled palpation" of manual massage techniques.

This device has the capability to produce both constant and sequential aspiration. Constant aspiration provides a deeper massage, which also mobilizes the muscle fascia. With sequential aspiration, the suction power is cyclically interrupted to provide pulsation to the skin fold between the two rollers and a softer, gentler stroking action of the tissues.

The suction power ranges from 50 to 500 mmHg which is represented by a power level scale ranging from 1 to 10.

12-Intended use of the device: (refer to FDA form attached)

This device is intended for use:
Reduction of secondary lymphedema of the Arm (SLA) Post Mastectomy
Reduction of lymphedematous fibrotic induration
Improvement of primary and secondary lymphedema
Prevention of venous stasis and venous insufficiency
Prevention of deep vein thrombosis (DVT)
Improvement of lymphatic circulation in the treated area

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13-Safety and Effectiveness of the device:

This device is safe and effective as the predicate devices cited above. This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate device. Refer to the explanations/details within the main submission.

FDA file reference number	510k # K912004, K914774, K974395 and K043423	
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**	**Comparison result**
Indications for use	Identical, except "Reduction of lymphedematous fibrotic induration" which does not apply for the predicate devices	
Target population	Identical	
Design	Similar	
Materials		
Performance		
Sterility	Not applicable	
Biocompatibility	Similar	
Mechanical safety		
Chemical safety	Not applicable	
Anatomical sites	Similar	
Human factors		
Energy used and/or delivered		
Compatibility with environment and other devices		
Where used		
Standards met		
Electrical safety		
Thermal safety	NOT APPLICABLE	
Radiation safety		

Not adequate need to describe & say if identical or not.

Refer to the submission for more details.

These can't all be identical this is not truthful & accurate.

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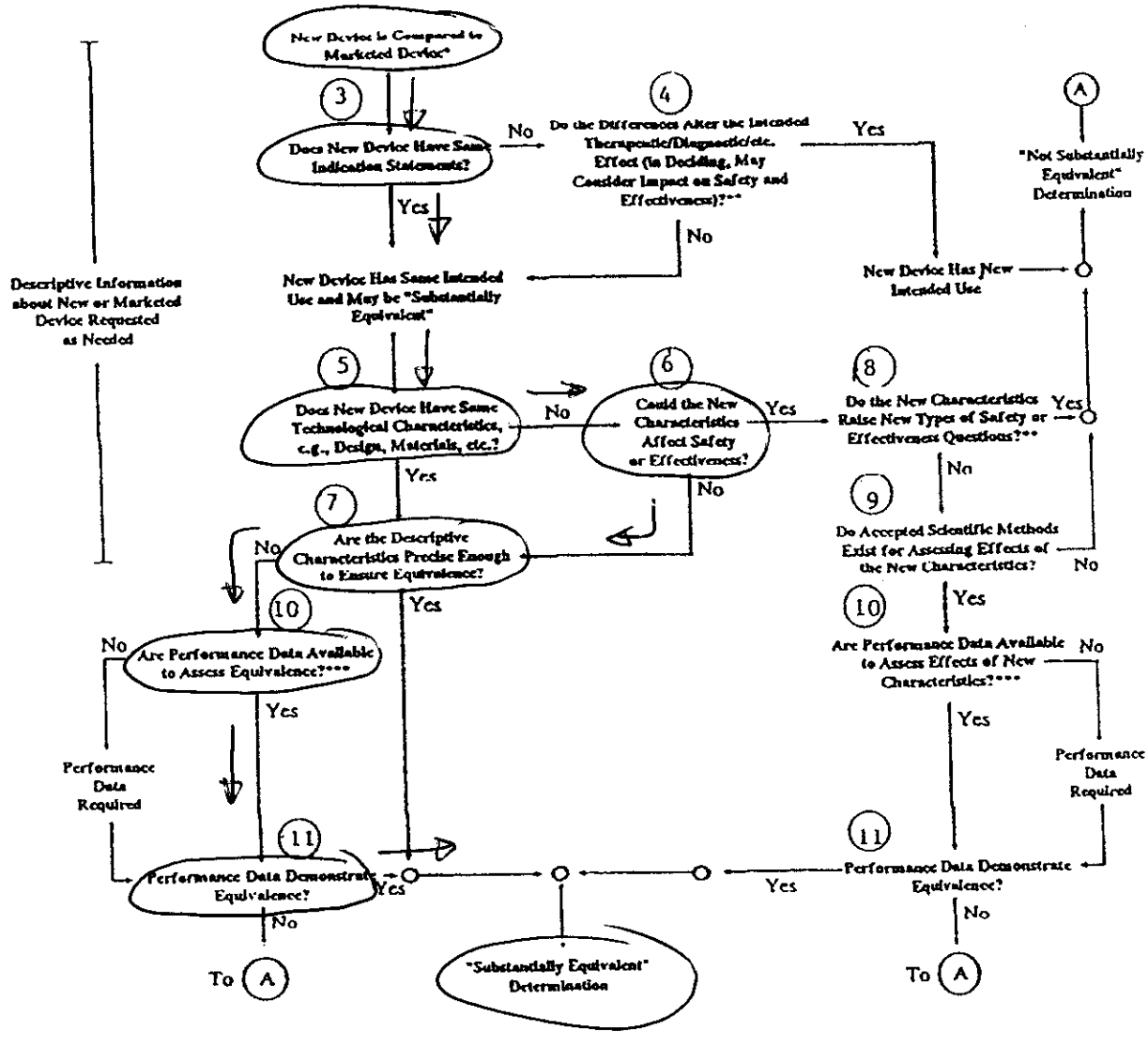
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

PAGE 3

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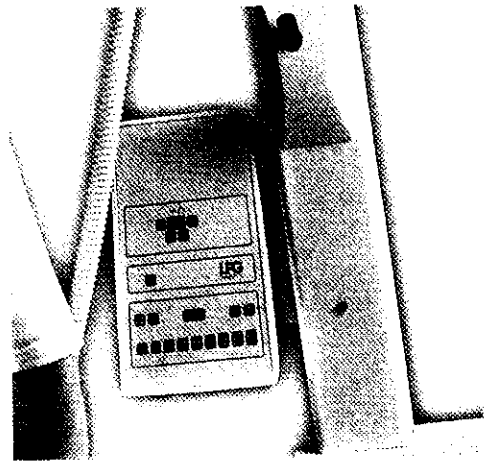
ATTACHMENT 3a

Description/Comparison of the Device

The original version of the LPG therapeutic massage device, the ES1, was classified and distributed in the United States as a Class 1 medical device exempted from pre-market notification[1], product codes 89 ISA and 89 IRO, panel physical medicine. The device name was listed as a Therapeutic Massager (21 CFR Section 890.5660), with a proprietary name of LPG Therapeutic Massager, Model ES1.

Cellu M6 ES1 Model

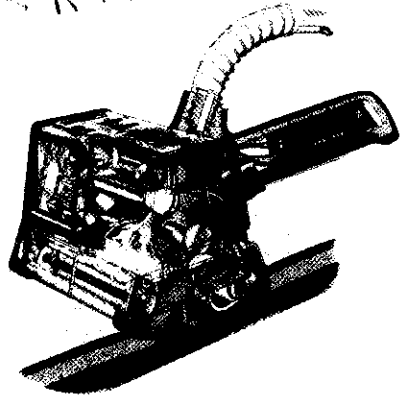


Analog Display

The treatment head of the ES1 model was patented under 4.729.368 US and contained more than 200 individual parts. A front panel (analog) allowed the user to enter the parameters (time, power, main or auxiliary head selection, cleaning mode.) The pump power of the ES1 reached a maximum negative pressure of 650 mb and had a treatment power level scale ranging from 1 to 9. (See comparison table.)

K990445 [illegible]

Treatment power level scale of 1-10.



Cellu M6 ES1 Main Treatment Head

[1] Cleared later on under 510k #K990445 in order to cover the indication for use related to burn rehabilitation, being prescription use

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(b)(4) [redacted]

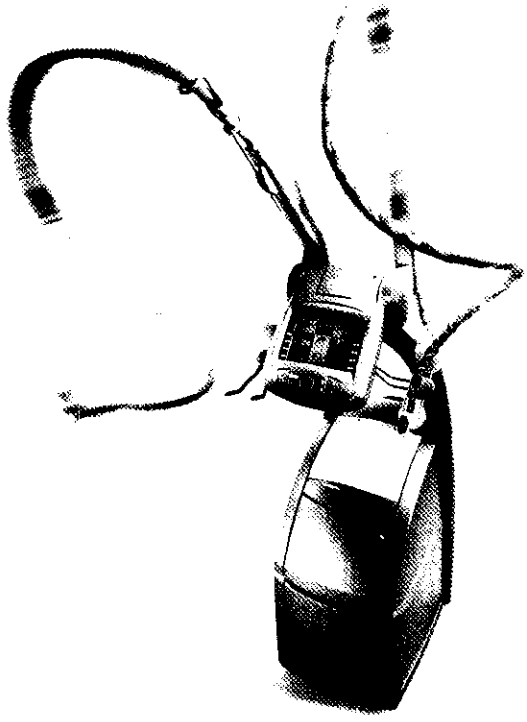
The Cellu M6 Keymodule i is the latest version of the LPG professional machines with a state-of-the art design. Based on the company's internal evaluation system, the Cellu M6 Keymodule i is equivalent to the ES1. Both the ES1 and the Cellu M6 Keymodule i utilize constant aspiration in a closed loop process. However, one cycle of the ES1 is

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted] he improvements to the operating principles of the Cellu M6 Keymodule i allow for increased (b)(4) [redacted]

(b)(4) [redacted]



Cellu M6 Keymodule i Model

Digital Display

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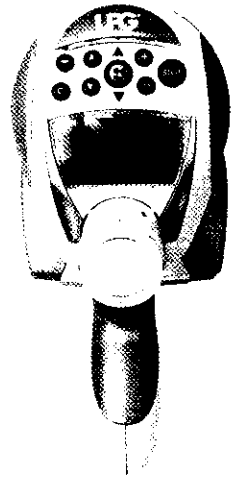
Like the ES1, the Cellu M6 Keymodule i therapeutic massager is comprised of a program console housing a vacuum pump and a regulation system. The improved design of the Cellu M6 Keymodule i updates the front panel to digital technology, providing the user with an extensive pre-programmed menu of 55 programs and 300 different skin folds for customized treatments. The pump power can reach a maximum negative pressure of 700 mb, and has a treatment power level scale ranging from 1 to 10. (See comparison table.)

A regulation bloc regulates the vacuum pressure according to the power selected by the user. (b)(4) [redacted]

The main treatment head is protected by United States patent number 4.729.368 from the ES1 model, as well as by a new patent number of 4.883.047. As with the ES1 model (b)(4) [redacted] Both main treatment head and auxiliary heads have been re-designed for ease of use for the operator and greater efficiency for the client (i.e. lighter weight, swivel hose, creation of different-sized detachable roller heads, choice of spring-loaded or non spring-loaded auxiliary heads.)

As with the ES1, the Cellu M6 Keymodule i treatment contains (b)(4) [redacted] rollers housed in a chamber which produces both negative pressure above the rollers and positive pressure below the rollers. This technology creates a skin fold between the two rollers in the suction chamber, thus mimicking the "rolled palpation" of manual massage techniques. The updated design of the Cellu M6 Keymodule i has the capability to produce both (b)(4) [redacted] aspiration in order to provide a pulsation to the skin and massage the tissues in various ways, including the specific wave-like movement for the lymphedema-related conditions indicated in this paper.



Cellu M6 Keymodule i Main Treatment Head (T70)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The LPG Technique: Applicable for Cellu M6 Keymodule i and ES1

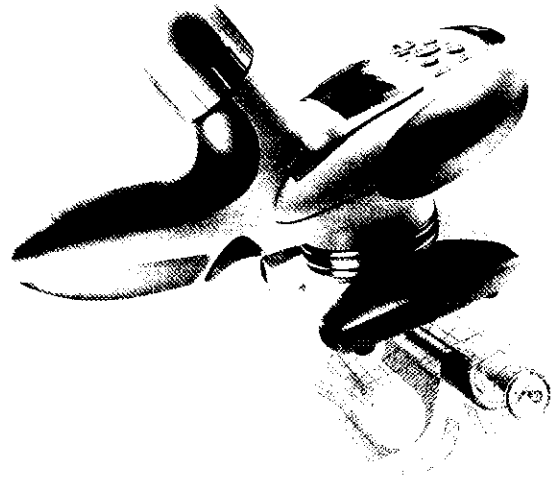
The LPG Technique involves (b)(4) [redacted] accomplished with any version of the LPG therapeutic massager. As pressure is applied to the main treatment head's electrical trigger, (b)(4) [redacted] rotation of the motorized rollers and suction begins. The rollers come together or are drawn apart in relation to the parameters of the program selected, the roller width of the treatment head module selected, and the type of tissue encountered. The suction makes a skin fold, where roller (A) folds the tissue up and roller (B) unfolds it. The head movement is assisted by the rollers' rotation.

Multidirectional maneuvers can be performed with these different roller rotations, allowing them to reach specific tissue layers. (b)(4) [redacted] aspiration settings can be used to perform deeper massage and mobilize more blood flow to the skin's surface, while (b)(4) [redacted] aspiration settings, with a wide variety of duty cycles and frequencies, can be used to perform lighter, more superficial massage and create a pumping compression action on the tissues.

Cellu M6 Keymodule i:
The Cellu M6 Keymodule i version of the machine has the capability to utilize the rollers in a forward, backward, inward or outward direction.

Main treatment head for lymphedema-related conditions:

The Cellu M6 Keymodule i device provides detachable motorized roller treatment heads (Keymodules) which attach to the main head base (T70) and connect to the main hose. The Keymodule treatment heads are each designed for specific applications. For therapeutic use, including the treatment of lymphedema, the Keymodule i.2 is used. The rollers of the i.2 have the most narrow width (24 mm) which leaves more space within the treatment chamber to create a larger skinfold. The ability to treat more tissue surface is better adapted for therapeutic treatment.



Cellu M6 Keymodule i Main Treatment Head (T70)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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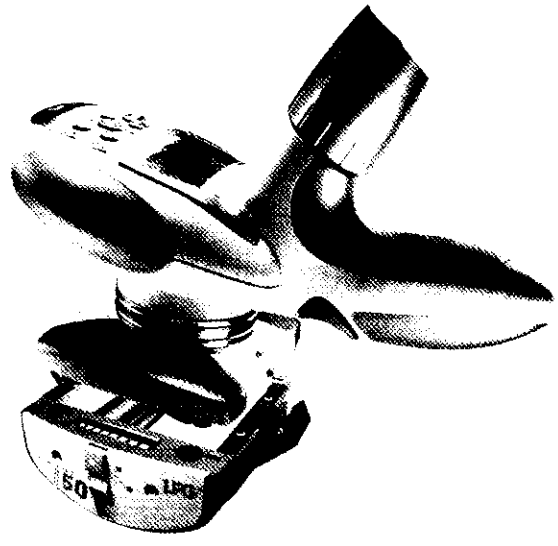
The Keymodule i50 can be used for all indications where a smaller surface area is being treated. Its rollers are slightly larger than the Keymodule i.2 (26 mm), but are shorter in length, measuring 50 mm instead of 70 mm. These shorter rollers can be adapted more efficiently to smaller body parts, such as the upper arm and the calves, which can be difficult to grasp with the longer rollers in the treatment of lymphedema.



Keymodule T70 Treatment Head with i50 Attachment

Auxiliary treatment heads for lymphedema-related conditions:

The Cellu M6 Keymodule i also contains a set of (b)(4) [redacted] auxiliary heads called *Active* heads, which are used for treating lymphedema in smaller areas of the body, such as the axillary area in "Secondary Lymphedema of the Arm Post-Mastectomy." These treatment heads are not motorized (rolling action is operated manually) and they are attached to a separate auxiliary hose on the machine when used. There are three *Active* auxiliary heads: a large one (45 mm x 18 mm), a medium one (30 mm x 14 mm) and a small one (15 mm x 10 mm). The function of the springs in the *Active* auxiliary heads is to allow for optimal movement of the rollers on the tissues when using the sequential aspiration (or pulsating) programs designed for treating lymphedema-related conditions.

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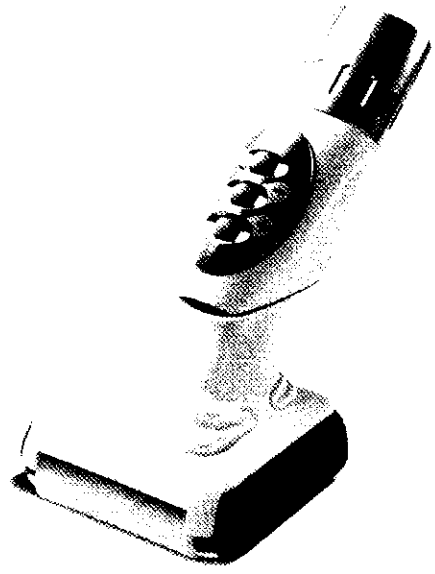

Active Auxiliary Head

Main treatment heads for indications already cleared by the FDA:

The paragraph below is intended ONLY to explain the different other indications for use that use other heads as historical/background information to explain why (b)(4) [redacted] *mentioned earlier in the original submission. It is NOT the intention of this paragraph to include additional heads or indications for use over and above what has been stated in Page R of Tab 7 of the original 510k submission file. It has been already agreed that all indications for use other than the ones stated in Page R of Tab 7 should be cancelled from all related labelings. And indeed, these have been cancelled. Any indications for use other than the ones stated in Page R of Tab 7 of the original 510k submission file will not be part of this device/submission. Accordingly, the following is stated:*

In addition to therapeutic work and lymphedema treatment, the Keymodule i.2 is also designed for use in treating muscle aches and pains, muscle spasms as well as for sports applications, specifically for reduction of delayed onset muscle soreness (DOMS).

With respect to delayed onset muscle soreness, pain associated with DOMS is linked to (b)(4) [redacted]

A study conducted in 1997 by (b)(4) [redacted] and another in (b)(4) [redacted] revealed a significant reduction in the sum of leg circumferences as a result of the treatment by mobilization and drainage of the interstitial fluids. (For details, refer to file (b)(4) [redacted]. FDA (b)(4) [redacted] letter is included at the end of this attachment.)

The Cellu M6 Keymodule i provides two other detachable treatment heads which have exempt claims for aesthetic indications. The Keymodule i.1 is used for "reduction in the appearance of cellulite and circumferential body measurement in the treated areas."

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

The rollers of the Keymodule i.1 have a medium width (26 mm) to create the optimal skinfold size within the treatment chamber for treating skin and subcutaneous fat on fuller body areas.

The Keymodule i.3 is used for aesthetic use as well, but for thinner skin and body areas. The rollers of the i.3 have the largest width (28 mm) to create (b)(4) [redacted] within the treatment chamber for the same aesthetic indications as i.1, but for better adaptation to thinner skin and body areas. The Keymodule i.3 rollers have a "golf ball-like" texture with indentations to provide better (b)(4) [redacted] to the skin and to increase (b)(4) [redacted] It also can be used for general relaxation.

As mentioned above, the Keymodule i50 can also be used for these exempt indications when a smaller surface area is being treated. Likewise, another set of auxiliary heads without springs (*Inactive* auxiliary heads) can be used for treating (b)(4) [redacted] surface areas. These *Inactive* auxiliary heads are used with constant aspiration programs, which are better suited to the static action of the rollers on the tissues.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 10 2000

(b)(4)

[redacted]

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(b)(4)

[redacted]

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ATTACHMENT 3b

CELLU M6 ES1 – CELLU M6 KEYMODULE COMPARISON

K99044 LPG the quantitative massage — need to check air spra

Technical Specifications	Cellu M6 ES1®	Cellu M6 Keymodule i®
Mechanism of action	Aspiration + rollers	Aspiration + rollers
Pump power	Maximum negative pressure : 650 mbar	Maximum negative pressure : 700 mbar
Length of rollers	Main head: 65 mm Aux heads: 45 mm, 30 mm, 15 mm	Main head: 70 mm Main head: 50 mm Aux heads: 45 mm, 30 mm, 15 mm
Diameter of rollers	Main head : 24 mm Auxiliary heads: 18, 14, 10 mm	Main head : 24, 26, 28 mm Auxiliary heads: 18, 14, 10 mm
Motorization of rollers	Main head only (not auxiliary)	Main head only (not auxiliary)
Power scale	(b)(4) [redacted]	
Power used during clinical trials	(b)(4) [redacted]	
Speed of motorized roller rotation	[redacted]	
Power source	Power cord	Power cord
Parameters display	Control panel (analog)	Control panel (digital)
Treatment sites	Body and extremities	Body and extremities

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT 3C

(b)(4)

[redacted]

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ATTACHMENT 3d

(b)(4)

[redacted]

Cellu M6® Keymodule i

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ATTACHMENT 3e

(b)(4)

[redacted]

Mode of Function

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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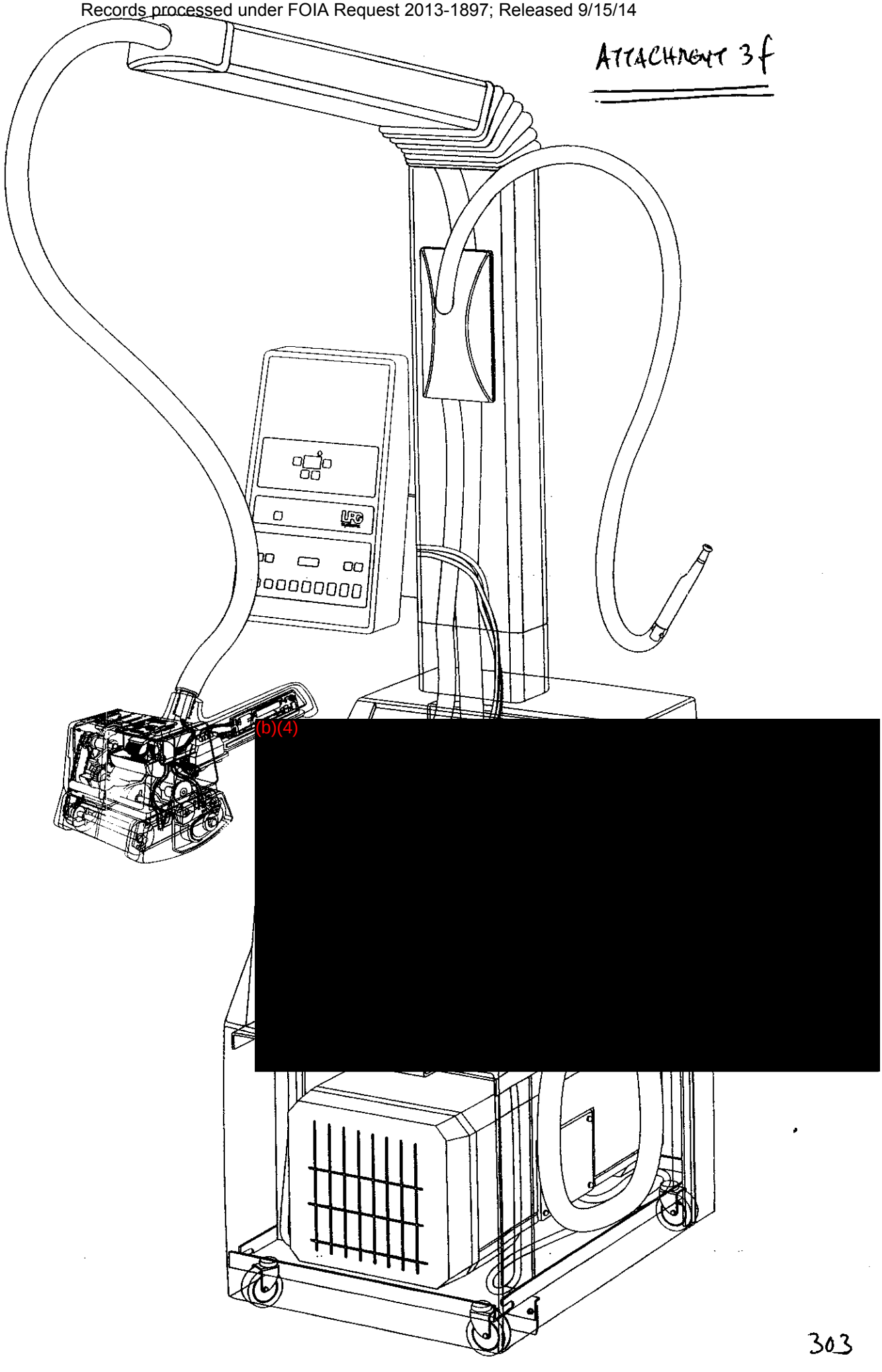
ATTACHMENT 3f



LPG systems

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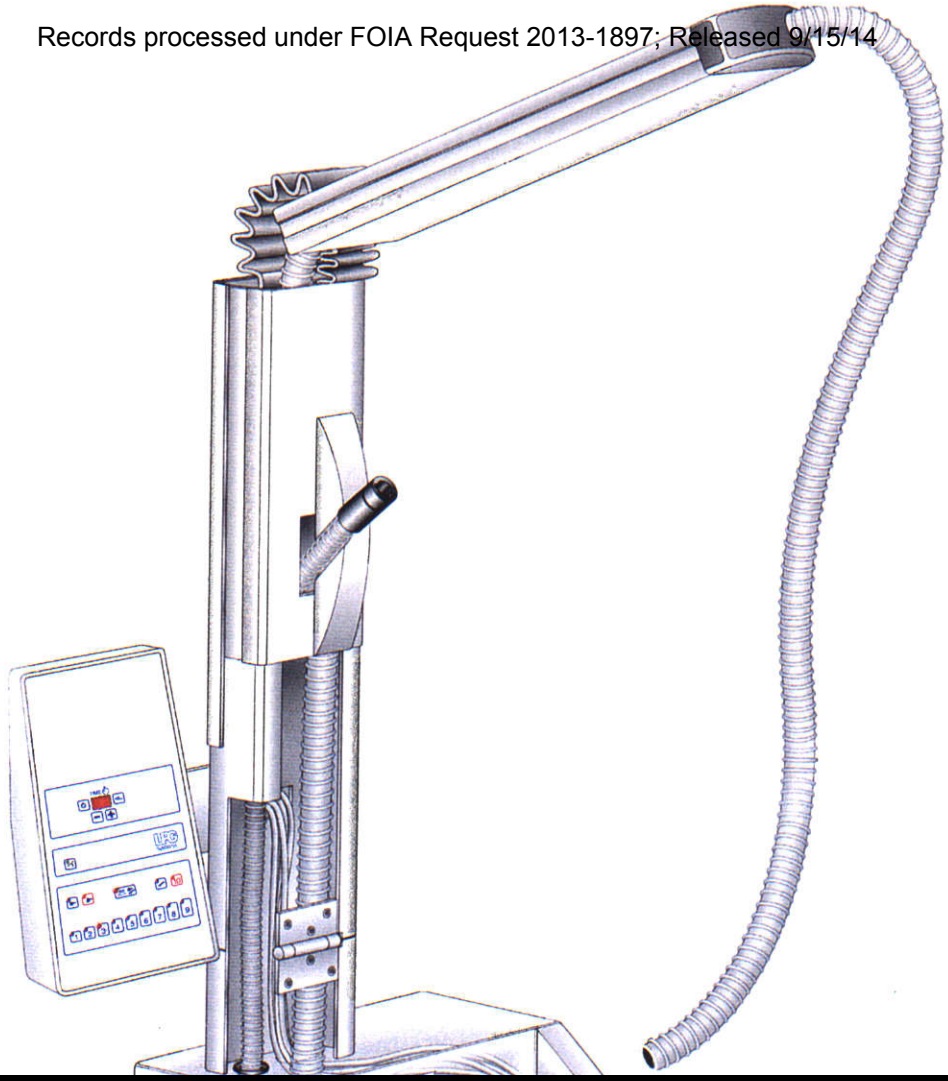

(b)(4)

[redacted]

Questions? Contact FOIA/CDRH/OCL/BID at CDRHFOIASTATUS@fda.hhs.gov or 301-796-8118

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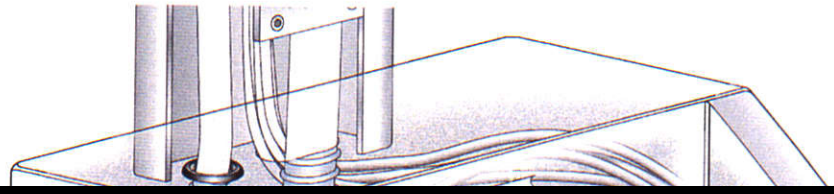

(b)(4)

[redacted]

Artwork done by The Art Machine Inc. • Hollywood, FL • (954)-967-0409

305

Artist, Kevin Ellsworth © 1997

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ATTACHMENT 4

(b)(4)

[redacted]

CELLU M6 KEYMODULE i- COMPONENTS LIST

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TÜV Rheinland Product Safety GmbH

Unternehmensgruppe TÜV Rheinland/Berlin-Brandenburg

ATTACHMENT 5

(b)(4)

[redacted]

Application for : CB-Zertifikat
Certificate No. : DE 02006079 -A1
Techn. appliance : Massagegerät
Massage Appliance
Type : see certificate
Test requirements: IEC 60601-1:1988+A1+A2
IEC 60601-1-4:1996+A1

Dear Madame or Sir

The submitted revision (additional manufacturer) for the above mentioned product has been tested and in this configuration found to be in accordance with the above mentioned requirements.
Please present the attached certificate: Nr. DE 02006079 -A1 together with the basic certificate whenever you are asking for national approvals based on this certificate.
Enclosed please find the certificate: Nr. DE 02006079 -A1

Kind regards

Certification body

Dipl.-Ing. F. Esdohr

Test sample: no, documentation available

TÜV Rheinland Product Safety GmbH
Am Grauen Stein
D-51105 Köln
Telefon: 0180 3112112
Telefax: 0180 3000169
e-mail: safety@tuv.com
http://www.tuv.com/safety

Geschäftsführung:
Dipl.-Ing. Michael Jungnitsch

Amtsgericht Köln HRB25960
Ust-ID Nr.: DE811935490

Bankverbindung
Deutsche Bank Köln
Dresdner Bank Köln

Konto
1315118
9862171

BLZ
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37080040

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IEC | IECEE CB SCHEME

Ref. Certif. No.

DE 2-006079-A1

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE
CERTIFICAT D'ESSAI OC

Product Produit	Massage Appliance
Name and address of the applicant Nom et adresse du demandeur	(b)(4) [redacted]
Name and address of the manufacturer Nom et adresse du fabricant	
Name and address of the factory Nom et adresse de l'usine	
Rating and principal characteristics Valeurs nominales et caractéristiques principales	AC 230V; 50Hz; 920W; 4.0A; Type BF; Class I or AC 220V; 60Hz; 1100W; 4.8A; Type BF; Class I or AC 100V; 50Hz or 60Hz; 1250W; 12.5A; Type BF; Class I
Trade mark (if any) Marque de fabrique (si elle existe)	LPG WORLD SAM
Model/type Ref. Ref. de type	Cellu M6 KeyModule 1
Additional information (if necessary) Information complémentaire (si nécessaire)	- additional manufacturer; - the certificate is based on report ref.nos. 21104611 001 and 21104611 002.
A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	PUBLICATION / EDITION IEC 60601-1:1988+A1+A2 IEC 60601-1-4:1996+A1
As shown in the Test Report Ref. No.which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue une partie de ce Certificat	21104611 001

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

TÜV

TÜV Rheinland Berlin Brandenburg

TÜV Rheinland Product Safety GmbH
Am Grauen Stein · D-51105 Köln
Phone + 49 221 806-1371
Fax + 49 221 806-3935
Mail: trps-certification@de.tuv.com
Web: www.tuv.com

TÜV Rheinland Product Safety GmbH

Date: 16.07.2003

Signature: Dipl.-Ing. F. Esdohr

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AEMC MESURES

7, Georges Méliès street – ZI de Mi-Plaine – 69680 CHASSIEU
Tel: 04.78.40.66.55 – Fax: 04.72.47.00.39 – E-Mail: chassieu@aems-mesures.fr

ATTACHMENT 6a

INTERPRETATION REPORT OF TEST RESULTS IN ELECTROMAGNETIC COMPATIBILITY

No.: (b)(4) [redacted]

COMPANY: (b)(4) [redacted]

PRODUCT: **Massage machine**

DATE: **November 6 and 7, 2002**

The reproduction of this test report is authorized only in its integral form.
It contains 5 pages and no appendix.

L.L.C. with a capital of 1,842,800 Fr. – R.C.S. GRENOBLE B 342 696 994 6 – A.P.E. 742C
Head office: Building "Le saint Georges" – 86, rue de la Liberté – 38180 SEYSSINS
Other laboratories: 665, rue de la Maison Blanche – 78630 ORGEVAL – Tel.: 01.39.75.22.22 – Fax: 01.39.75.97.46
2, Allée du Chêne Vert – 35650 LE RHEU – Tel.: 02.99.14.59.14 – Fax: 02.99.14.64.54

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Records processed under FOIA Request 2013-1897; Released 9/15/14

INTERPRETATION REPORT OF TEST RESULTS IN ELECTROMAGNETIC COMPATIBILITY

Tests in accordance with the specifications of the standards:

CEI 601-1-2
CEI 1000-3-2, CEI 1000-3-3

Product:	**Massage Machine**
Type:	**Cellu M6 KM**
Serial number:	(b)(4)
Manufacturer:	**LPG**
Person in charge:	(b)(4)
Number of the estimate:	(b)(4)
Person attending:	(b)(4)
Dates of the tests:	**November 6 and 7, 2002**
Tester:	(b)(4)

Bibliographical references:

CEI 601-1-2, 1993 edition

***CISPR 11*, 1991 edition**

CEI 1000-4-2, 1995 edition
CEI 1000-4-3, 1996 edition
CEI 1000-4-4, 1995 edition
CEI 1000-4-5, 1995 edition

Observations:
This report covers only the test results for the equipment (or several pieces of equipment) mentioned above.
Partial reproduction of this report may not be possible without the consent of the test laboratory.
(Stamp)
Chassieu, November 8, 2002

Rémi NICOLAS,
(*illegible signature*)

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INTERPRETATION OF TEST RESULTS OF REPORT L02484.2

Compliance of Massage Machine Cellu M6 KM

With the specifications of standard: CEI 601-1-2, 1993 edition

Emission

Disturbing Phenomenon	Frequency band	Limits	Fundamental standard	Result	Observation
Alternating current power supply	0.15 to 0.5 MHz 0.5 to 5 MHz 5 to 30 MHz	Quasi-peak from 66 to 56 dBµV Average from 56 to 46 dBµV Linear decrease with the frequency column Quasi-peak 56 dBµV Average 46 dBµV Quasi-peak 60 dBµV Average 50 dBµV	***CISPR 11*** **Class B**	Satisfactory	The statistical evaluation given in the standard is applied See Note 1
Alternating current power supply	0.15 to 30 MHz	See the fundamental standard Article: Discontinuous Disturbances	***CISPR 14***	Not applicable	
Case	30 to 230 MHz 230 MHz to 1 GHz	30 dBµV/m at 10 m 37 dBµV/m at 10 m	***CISPR 11*** **Class B**		The statistical evaluation given in the standard is applied See Notes 1 and 2

Note 1: Utilization of a common mode coil RN 143-4-02 on the phase and the neutral conductor of the pump.
Note 2: 3 passages (instead of 2 already existing) on the "control card" ferrite.
+ 1 capacitor of 22 nF on the engines of the massage head

(the capacitor is absolutely necessary, even if it is not present in the remaining tests, this does not question the validity of the other tests)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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INTERPRETATION OF TEST RESULTS OF REPORT (b)(4)

Compliance of Massage Machine Cellu M6 KM

With the specifications of standard: CEI 601-1-2, 1993 edition

Immunity

Case Access

Disturbing phenomenon	Test Specification	Fundamental standard	Aptitude Criterion	Result	Observation
Electromagnetic field with a radio-electric frequency modulated in amplitude	26 to 1000 MHz 3 V/m AM 80% 1kHz	**CEI 1000-4-3**	**See standard**	Satisfactory	The specified level is the one of the carrier wave, effective value, before modulation See Note 1
Electrostatic discharges	+/- 4 kV at contact +/- 8 kV in the air	**CEI 1000-4-2**	**See standard**	Satisfactory	See the fundamental standard for the applicability of discharges at contact and/or in the air See Note 1

Note 1: Utilization of a common mode coil RN 143-4-02 on the phase and the neutral conductor of the pump. 3 passages (instead of 2 already existing) on the "control card" ferrite.

Immunity

Power Entry Access

Disturbing phenomenon	Test Specification	Fundamental standard	Aptitude Criterion	Result	Observation
Fast spikes in bursts Common mode	+/- 1 kV 5 / 50 Tr/Th ns Repetition frequency: 5 kHz	**CEI 1000-4-4**	**See standard**	Satisfactory	See Note 1
Impulse wave	1,2 / 50 µs +/- 2 kV in common mode +/- 1 kV in differential mode	**CEI 1000-4-5**	**See standard**	Satisfactory	See Note 1

Note 1: Utilization of a common mode coil RN 143-4-02 on the phase and the neutral conductor of the pump. 3 passages (instead of 2 already existing) on the "control card" ferrite

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tél : 04.78.40.66.55 – Fax : 04.72.47.00.39 – E-Mail : chassieu@aemc-mesures.fr

ATTACHMENT 6 b

RAPPORT D'INTERPRETATION DES RESULTATS D'ESSAIS EN COMPATIBILITE ELECTROMAGNETIQUE

N° : (b)(4) [redacted]

SOCIÉTÉ : (b)(4) [redacted]

PRODUIT : **Machine de massage**

DATE : **les 6 et 7 novembre 2002**

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Il comporte 5 pages sans annexe.

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2, Allée du Chêne Vert - 35650 LE RHEU - Tél. : 02.99.14.59.14 - Fax : 02.99.14.64.54

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RAPPORT D'INTERPRETATION DES RESULTATS D'ESSAIS EN COMPATIBILITE ELECTROMAGNETIQUE

Essais conformément aux spécifications des normes :

CEI 601-1-2
CEI 1000-3-2 , CEI 1000-3-3

Produit :	Machine de massage
Type :	Cellu M6 KM
Numéro de série :	(b)(4) [redacted]
Constructeur :	LPG
Affaire suivie par :	(b)(4) [redacted]
Numéro de devis :	
Personne présente :	
Dates des essais :	les 6 et 7 novembre 2002
Expérimentateur :	(b)(4) [redacted]

Références bibliographiques :

CEI 601-1-2, édition 1993

CISPR 11, édition 1991

CEI 1000-4-2, édition 1995
CEI 1000-4-3, édition 1996
CEI 1000-4-4, édition 1995
CEI 1000-4-5, édition 1995

Observations :
Ce rapport ne couvre que les résultats d'essais de l'équipement (ou des équipements) ci-dessus mentionné(s).
La reproduction partielle de ce rapport ne peut être effectuée sans l'approbation du laboratoire d'essais

Chassieu, le : 8 novembre 2002

Rémi NICOLAS

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INTERPRETATION DES RESULTATS D'ESSAIS DU RAPPORT (b)(4) [redacted]

Conformité de la machine de massage Cellu M6 KM

Aux spécifications de la norme : CEI 601-1-2, édition 1993

Émission

Phénomène perturbateur	Gamme de fréquences	Limites	Norme fondamentale	Résultat	Observation
Alimentation à courant alternatif	0.15 à 0.5 MHz 0.5 à 5 MHz 5 à 30 MHz	Quasi-crête de 66 à 56 dBµV Moyenne de 56 à 46 dBµV Décroissance linéaire avec le log de la fréquence Quasi-crête 56 dBµV Moyenne 46 dBµV Quasi-crête 60 dBµV Moyenne 50 dBµV	*CISPR 11* **Classe B**	Satisfaisant	L'évaluation statistique donnée dans la norme s'applique Voir Note 1
Alimentation à courant alternatif	0.15 à 30 MHz	Voir la norme fondamentale Article : Perturbations discontinue	*CISPR 14*	Non applicable	
Enveloppe	30 à 230 MHz 230 MHz à 1 GHz	30 dBµV/m à 10 m 37 dBµV/m à 10 m	*CISPR 11* **Classe B**	Satisfaisant	L'évaluation statistique donnée dans la norme s'applique Voir Notes 1 et 2

Note 1 : Utilisation d'une self de mode commun RN 143-4-02 sur la phase et le neutre de la pompe.
Note 2 : 3 passages (au lieu de 2 déjà existant) sur la ferrite "carte commande".
+ 1 condensateur de 22 nF sur les moteurs de la tête de massage

(le condensateur est absolument nécessaire, même si elle n'est pas présente dans le reste des essais, cela ne remet pas en cause la validité des autres essais).

315

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INTERPRETATION DES RESULTATS D'ESSAIS DU RAPPORT (b)(4)

Conformité de la machine de massage Cellu M6 KM

Aux spécifications de la norme : CEI 601-1-2, édition 1993

Immunité

Accès enveloppe

Phénomène perturbateur	Spécification d'essais	Norme fondamentale	Critère d'aptitude	Résultat	Observation
Champ électromagnétique à fréquence radioélectrique modulé en amplitude	26 à 1000 MHz 3 V/m AM 80 % 1 kHz	CEI 1000-4-3	Voir norme	Satisfaisant	Le niveau spécifié est celui de la porteuse, en valeur efficace, avant modulation. Voir Note 1
Décharges électrostatiques	+/- 4 kV au contact +/- 8 kV dans l'air	CEI 1000-4-2	Voir norme	Satisfaisant	Voir la norme fondamentale pour l'applicabilité des décharges au contact et/ou des décharges dans l'air. Voir Note 1

Note 1 : Utilisation d'une self de mode commun RN 143-4-02 sur la phase et le neutre de la pompe.
+ 3 passages (au lieu de 2 déjà existant) sur la ferrite 'carte commande'.

Immunité

Accès d'entrée de puissance

Phénomène perturbateur	Spécification d'essais	Norme fondamentale	Critère d'aptitude	Résultat	Observation
Transitoires rapides en salves Mode commun	+/- 1 kV 5 / 50 Tr / Th ns Fréquence de répétition : 5 kHz	CEI 1000-4-4	Voir norme	Satisfaisant	Voir Note 1
Ondes de choc	1,2/50 µs +/- 2 kV en mode commun +/- 1 kV en mode différentiel	CEI 1000-4-5	Voir norme	Satisfaisant	Voir Note 1

Note 1 : Utilisation d'une self de mode commun RN 143-4-02 sur la phase et le neutre de la pompe.
+ 3 passages (au lieu de 2 déjà existant) sur la ferrite 'carte commande'.

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ATTACHMENT 7

PREMARKET SUBMISSION FOR SOFTWARE CONTAINED in: CELLU M6 KEYMODULE i

(b)(4)

[redacted]

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GENERAL ARRANGEMENT

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The purpose of this document is to identify the software used by LPG ONE in order to achieve the required objectives of this 510(k) submission, in addition to the hardware that uses the software.

The device that uses the software and is the subject of this submittal is:

CELLU M6 KEYMODULE i

The device is used for cutaneous tissue treatment.

The corresponding software version for above unit is:

(b)(4)

[redacted]

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1. **Objective**:

   "Cellu M6 Keymodule i" uses rollers to knead the skin and regulated vacuum over the skin being treated. The parameters being controlled are listed in the SRS section below.
   The system is stand-alone.

2. **Components**: The components used to achieve the above objectives are:

   - Stand-alone "Cellu M6 Keymodule i" along with various head attachments.

3. **Approach**: This section of the submittal will have an appendix for the Validation and Verification Testing. Together, they will be part of the overall submission.

4. **Documentation reference**:
   "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued by the FDA on May 11, 2005

5. **Documentation**
   Documentation of this "Book" consists of the following:
   a. General chart showing the different components of the system
   b. Level of concern for the system
   c. General documentation requirements for software
   d. Software general description for the whole system
   e. General hardware description

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6. General chart showing the different components of the system

(b)(4)

[redacted]

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7. **Level of concern for the system**
Find below the level of concern determination.
Answers are in bold and underlined

Major Level of Concern
If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.

1. Does the Software Device qualify as Blood Establishment Computer Software? (Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)
No

2. Is the Software Device intended to be used in combination with a drug or biologic?
No

3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?
No

4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:

a. Does the Software Device control a life supporting or life sustaining function?
No

b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?
No

c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?
No

d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?
No

e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?

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No

Moderate Level of Concern
If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.

1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?
No

2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?
No

3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?
No

If the answers to all of the questions in Tables 1 and 2 above are No, the Level of Concern is Minor.

From the above, **the system's level of concern is Minor.**

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8. General documentation requirements for software

SECTION NUMBER	SOFTWARE DOCUMENTATION	MINOR CONCERN	~~MODERATE CONCERN~~	~~MAJOR CONCERN~~
2, 3.1	Level of Concern	A statement indicating the Level of Concern and a description of the rationale for that level. (see section 7 above)		
3.2	Software Description	A summary overview of the features and software operating environment.		
3.3, 4.3	Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.		
3.4, 4.2	Software Requirements Specification (SRS)	Summary of functional requirements from SRS.	~~The complete SRS document.~~	
3.5	Architecture Design Chart	No documentation is necessary in the submission.	~~Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.~~	
3.6	Software Design Specification (SDS)	No documentation is necessary in the submission.	~~Software design specification document~~	
3.7	Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.		
3.8, 4.1	Software Development Environment Description	No documentation is necessary in the submission.	~~Summary of software life cycle development plan, including a summary of the configuration management and maintenance activities.~~	~~Summary of software life cycle development plan. Annotated list of control documents generated during development process. Include the configuration management and maintenance plan documents.~~
3.9	Verification and Validation Documentation	Software functional test plan, pass / fail criteria, and results	~~Description of V&V activities at the unit, integration and system level. System level test protocol including pass/fail criteria, and tests results.~~	~~Description of V&V activities at the unit, integration and system level. Unit, integration and system level test protocols including pass/fail criteria, test report, summary, and tests results.~~
3.10	Revision Level History	Revision history log, including release version number and date.		
3.11	Unresolved Anomalies (Bugs or Defects)	No documentation is necessary in the submission.	~~List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors.~~	

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9. Software General Description for the whole system

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[redacted]

Further description can be found at the SRS section.
For practical description of the function, please refer enclosed manual.

10. General hardware description

The system consists of 4 main sections:

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[redacted]

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11. Hazard Analysis

The hazard analysis includes the following:
a) the hazardous event;
b) level of concern of the hazard;
c) the cause(s) of the hazard;
d) the method of control;
e) corrective measures taken, including aspects of the device design/requirements, that eliminate, reduce, or warn of a hazardous event, including a discussion of their appropriateness; and
f) testing to demonstrate that the method of control was implemented correctly.

Below is a table that shows possible Hazards and the methods to deal with them:

Hazardous Event	Level of concern	Cause	Method of control	Corrective measures	Testing
Energy hazards					

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[redacted]

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		or operator			
Hazardous Event	Level of concern	Cause	Method of control	Corrective measures	Testing

(b)(4)

[redacted]

Biological hazards

(b)(4)

[redacted]

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		patients.	patient.	required	

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Environmental hazards

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[redacted]

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		labeling			
Hazardous Event	Level of concern	Cause	Method of control	Corrective measures	Testing

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Hazardous Event	Level of concern	Cause	Method of control	Corrective measures	Testing

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		devices			

Hazards arising from functional failure, maintenance & aging

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Hazardous Event	Level of concern	Cause	Method of control	Corrective measures	Testing

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Hazardous Event	Level of concern	Cause	Method of control	Corrective measures	Testing
Hazards arising from software					

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			treatment.		
Hazardous Event	Level of concern	Cause	Method of control	Corrective measures	Testing

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		languages			
Hazardous Event	Level of concern	Cause	Method of control	Corrective measures	Testing

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		the software			
Hazardous Event	Level of concern	Cause	Method of control	Corrective measures	Testing

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12 Software Requirements Specifications

The Software Requirements Specification documents the requirements for the software. This typically includes functional, performance, interface, design, and developmental requirements. Examples of some typical requirements that would be included in a SRS include **(refer section 8 above)**

12.1 Hardware Requirements (Not required)

12.2 Programming Language Requirements (Not required)

12.3 Interface Requirements (Not required)

12.4 Functional Requirements and Software Performance

12.4.1 Software Performance (Not required)

12.4.2 Functional Requirements: See below

Software requirements are divided into 6 sections.

The first section (b)(4) [redacted]
The second secti
The third section
The fourth sectic
The fifth section
The sixth section

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12.4.2.1 Overall system: ***SRS-G-001***

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[redacted]

12.4.2.2 Human Interface:

(b)(4)

[redacted]

12.4.2.3 Regulation:

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12.4.2.4 Principal head:

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[redacted]

12.4.2.5 Auxiliary head:

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12.4.2.6 Maintenance programs

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13 Traceability Analysis

For the system under consideration, please note:

Design specifications documentation is not required.
Design requirements summary is required and provided.
Detailed validation testing requirements are shown in the validation test sheets.
No hazards were found in the hazard analysis above.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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14 Verification and Validation documentation

The verification and validation is confirmed by testing the system in relation with the Software Requirements Specifications.

The signed off test sheets are included in the appendix

15 Revision level history

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[redacted]

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APPENDIX

SOFTWARE VALIDATION, VERIFICATION AND TESTING

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(b)(4) Software Validation, Verification and Testing

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FEB - 1 2005 ATTACHMENT 8

120 W. Commercial Avenue, Moonachie, NJ 07074 _ 201-939-0716 _ 800-888-0908 _ Fax: 201-939-4503

510(k) Summary
Model SC-3008 Sequential Circulator
510(k) Number K013423

Submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

1. APPLICANT'S INFORMATION:
   Ron Motherwell
   Executive Vice President
   PH: 201 939-0716
   FX: 201 939-4503
   Internet: http://www.biocompression.com
   Medical Establishment
   Registration No.: 2424387

2. SUBMITTER'S INFORMATION
   James Jochen Rogers
   General Manager
   Coastal Consulting Group, Ltd.
   P.O. Box 470218
   Broadview Heights, OH 44141
   PH/FX: 440 546.4936
   Mobile: 724 7.13.2298
   E-mail: coastalcg@earthlink.net
   Internet: http://www.coastalcg.com

3. Date: November 27, 2004

4. DEVICE INFORMATION
   DEVICE NAME: Model SC-3008 Sequential Circulator
   Classification Panel: Cardiovascular and Respiratory Devices
   Classification Number: 870.5800
   Product Nomenclature: Compressible Limb Sleeve
   Product Code(s): JOW
   Trade/Proprietary Name: Model SC-3008 Sequential Circulator
   Common Name: Model SC-3008 Sequential Circulator

5. DEVICE CLASSIFICATION:
   Compressible Limb Sleeve Devices are classified as Class II devices, and reviewed by the Division of Cardiovascular Devices.

6. PREDICATE DEVICE(s):
   - K810338 Lymphapress
   - (Pre-amendments) The Sequential Circulator

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7. DEVICE DESCRIPTION:

The device consists of a manual pump (e.g., the user manually adjusts the pressures, while the inflate/deflate cycle times remain constant) and a sleeve or garment containing discrete, segmented inflatable chambers externally applied over the affected extremity. The pump consists of a compressor capable of a maximum pressure of 150mmHg, and provides graduated, or gradient, pressurization to the chambers (e.g., sequential inflation of distal to proximal, with distal chambers inflated to a greater pressure than the proximal ones). . A calibrated dial gauge displays pressure in the range of 0-125mmHg.

As each chamber is inflated, the pressure is held constant until all chambers are inflated, in order to prevent reverse gradient flow. Once all chambers are inflated, they are then all released simultaneously, and the cycle repeats. Pressures within the chambers are adjustable - pressure to chambers 1&2 is controlled by a user-adjusted regulator on the pump. Pressure in chambers 3&4, 5&6, and 7&8 can be individually lowered from the default factory settings.

Garments are available in 10 sizes, and custom garments are available in variations from these standard sizes; an adapter is available to support bilateral treatment:

Arm – Small	Leg – Small	Leg – Adjustable Small
Arm – Medium	Leg – Medium	Leg – Adjustable Medium
Arm – Large	Leg – Large	Leg – Adjustable Large
Arm – w/ Shoulder	Arm – Custom	Leg – Custom

8. INDICATIONS FOR USE:

The Model SC-3008 Sequential Circulator is a manual, sequential, pneumatic compression device intended for the primary or adjunctive \ treatment of primary or secondary lymphedema. The device is also intended for the additional or alternate treatment of venous insufficiency, and chronic venous stasis ulcers associated with venous insufficiency, as well as general treatment of swelling of the extremities. The device is intended for home or hospital use.

9. TECHNOLOGICAL CHARACTERISTICS:

The manufacturer believes that the technological characteristics of the Model SC-3008 Sequential Circulator are substantially similar to those of the predicate devices.

10. PERFORMANCE DATA:

Performance testing was performed and assures that the product meets its specifications.

11. STATEMENT OF SUBSTANTIAL EQUIVALENCE:

Based upon safety and performance testing, compliance with voluntary standards, and comparison to the predicate devices, the manufacturer believes that the Model SC-3008 Sequential Circulator is substantially equivalent to the predicate devices, and does not raise any new questions of safety or effectiveness.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2005

Bio Compression Systems, Inc.
c/o Ned Devine
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, MI 49548

Re: K043423
Model SC-3008 Sequential Circulator
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: December 10, 2004
Received: December 13, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Richards

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K043423

Device Name: Model SC-3008 Sequential Circulator

Indications for Use:

The Model SC-3008 Sequential Circulator is a manual, sequential, pneumatic compression device, intended for the primary or adjunctive treatment of primary or secondary lymphedema. The device is also intended for the additional or alternate treatment of venous insufficiency, and chronic venous stasis ulcers associated with venous insufficiency, as well as general treatment of swelling of the extremities. The device is intended for home or hospital use.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(21 CFR801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Lechner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K043423

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Subject: Pneumatic Compression Systems

Date: Fri, 3 Feb 2006 09:39:05 -0500

From: "Gloria Rozema" <GloriaR@biocompression.com> Add to Address Book Add Mobile Alert

To: drea_volz@yahoo.com

Dear Ms. Volz:

In response to your email of 2/2/06, I apologize for the fact that you were unable to reach us on the 800 number. You should not have any problem if you use 800-888-0908. Our other 800 number was similar to the Florida Insurance number and we received hundreds of calls following each hurricane, etc., so we had that blocked from Florida only. Again, I apologize for the inconvenience.

Our Models SC-2004 and SC-3004 Sequential Circulators have preamendment status, therefore have "grandfathered" FDA approval.

Our Model SC-3008 Sequential Circulator is approved under number K 043423.

I would be happy to send you information regarding our products and studies for which they were used, or any other information which would assist you in your research.

Thank you for contacting Bio Compression Systems.

Gloria Rozema

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ATTACHMENT 9

Falk Cardiovascular Research Center
Stanford University School of Medicine
300 Pasteur Drive
Stanford, California 94305-5406 - (650) 723 6141
Division of Cardiovascular Medicine

Presented here are abstracts from a recently completed study by the Stanford University Center for Lymphatic and Venous Disorders. The study evaluates the use of Pneumatic Sequential Compression for the treatment of postmastectomy lymphedema.

The Stanford University Center for Lymphatic and Venous Disorder is the foremost institution in the country studying the treatment of lymphedema. Bio Compression pumps were used exclusively in this study.

AN EVALUATION OF ADJUNCTIVE INTERMITTENT PNEUMATIC COMPRESSION IN THE ACUTE TREATMENT OF POSTMASTECTOMY LYMPHEDEMA

A. Szuba, R. Ashalu, SG Rockson
Stanford Center for Lymphatic and Venous Disorders,
Stanford University School of Medicine, Stanford, CA USA
Srockson@cvmed.stanford.edu

We investigated the safety and efficacy of adjunctive intermittent pneumatic compression (IPC) for the acute decongestive therapy of post-mastectomy lymphedema. Twenty-three patients were randomized to decongestive lymphatic therapy (DLT) with (Group II) or without (Group I) IPC. DLT included manual lymphatic drainage, bandaging, and exercise, performed daily. In Group II, 30 minutes of IPC was performed daily at 40-50 mm Hg. Arm volume was assessed by tank volumetry.

In Group I, the 11 patients achieved 26% acute arm volume reduction; in Group II, the 12 patients achieved a mean volume reduction of 45.3% (p,<0.05). There were no complications attributable to either DLT or IPC.
Conclusion:, IPC is generally safe and well-tolerated and appears to provide synergistic benefit when used with DLT in the acute decompressive approach to post–mastectomy lymphedema.

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EVALUATION OF INTERMITTENT PNEUMATIC COMPRESSION AS ADJUNCTIVE MAINTENANCE THERAPY IN POSTMASTECTORMY LYMPHEDEMA

A. Szuba, R. Achalu, S.G. Rockson
Stanford Center for Lymphatic and Venous Disorders,
Stanford Univerity School of Medicine, Stanford, CA USA
Srockson@cvmed.stanford.edu

We studied the safety and efficacy of intermittent pneumatic compression therapy as an adjunct to standard decongestive lymphatic therapy in patients with stable post-mastectomy arm lymphedema.
Study design: Randomized, cross-over, 2 month study with 6 month follow-up
Patients and methods: 29 patients with postmastectomy arm lymphedema and without evidence of active cancer were enrolled. Patients were randomized into two groups. Patients assigned to Group I were asked to continue their routine maintenance therapy with use of a Class II compression garment and self–applied manual lymphatic drainage (MLD); patients assigned to Group II were asked to use the intermittent pneumatic compression (IPC) pump for 1 hour daily (40-50mmHg) in addition to conventional therapy (garments + MLD). All patients crossed over to the alternate therapy after one month. Patients who elected to continue chronic use of the pump were evaluated after 6 months. Clinical evaluation was performed at the beginning of
the study, after the first and the second month and after six month follow-up. The evaluation included tank volumetry, skin tonometry, and measurement of range of motion.
Results: 27 patients completed the study. Two patients voluntarily withdrew.

There was a mean volume reduction of 89.5 ml during the month with IPC and volume increase of 32.7 ml during the month of routine maintenance therapy.

The difference was statistically significant ($p<0.05$). There was no difference in tonometry results. Of the 21 patients who completed chronic use of IPC, 19 were available for analysis. After 6 months, there was a further average volume reduction of 29.1 ml (not statistically significant). No adverse effects of IPC were observed.

Conclusion: Intermittent pneumatic compression is safe and well tolerated and may offer additional benefit for patients with postmastectomy lymphedema.

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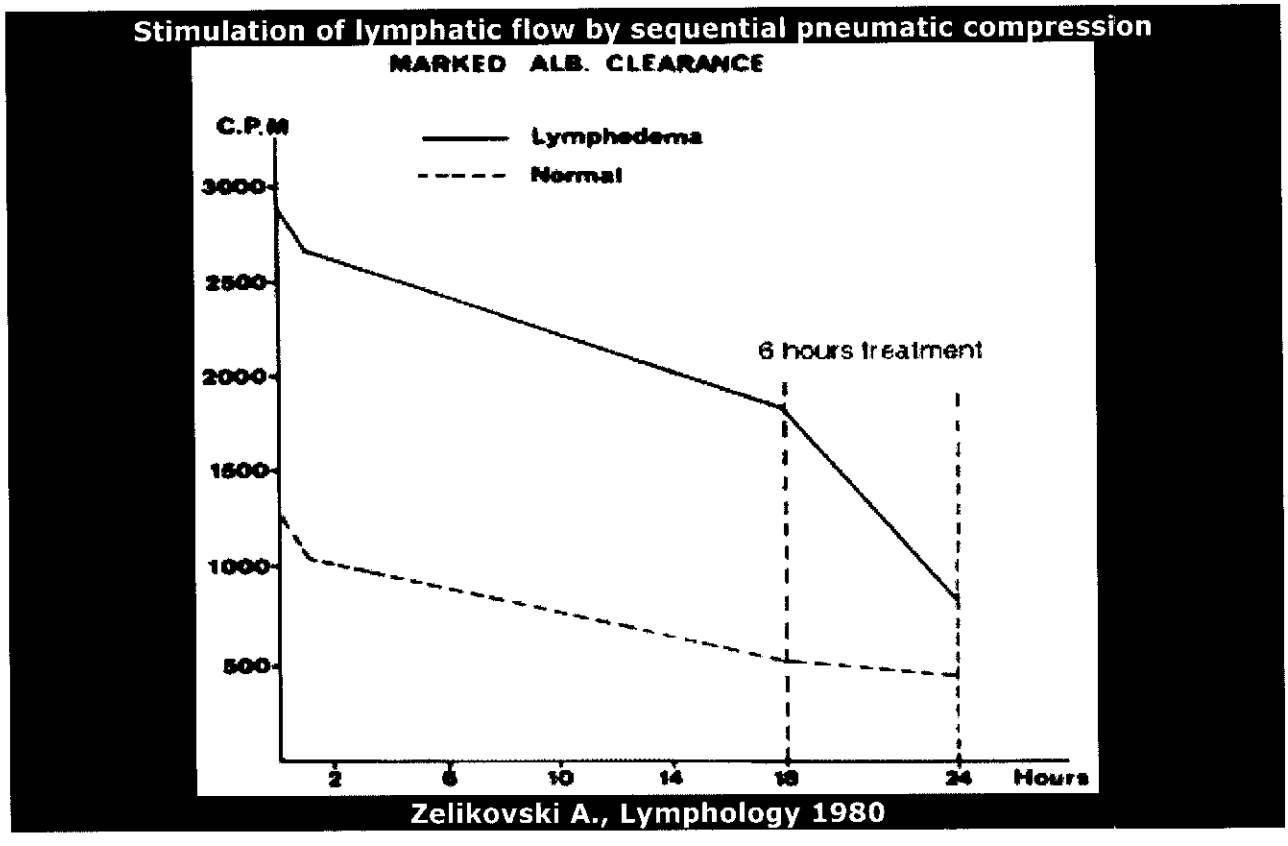

Pneumatic compression in postmastectomy lymphedema - maintenance study results

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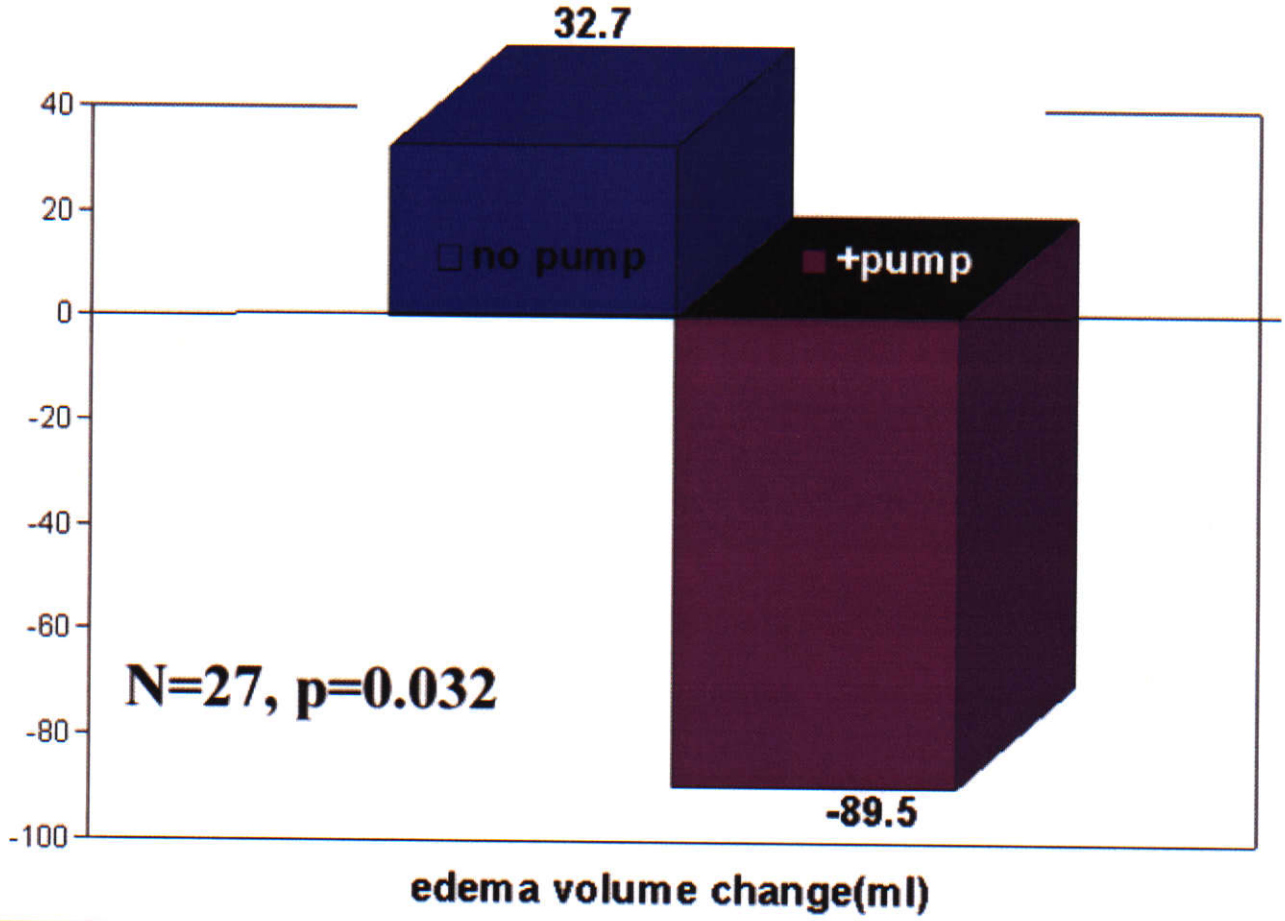

Pneumatic compression in postmastectomy lymphedema - Acute TX results

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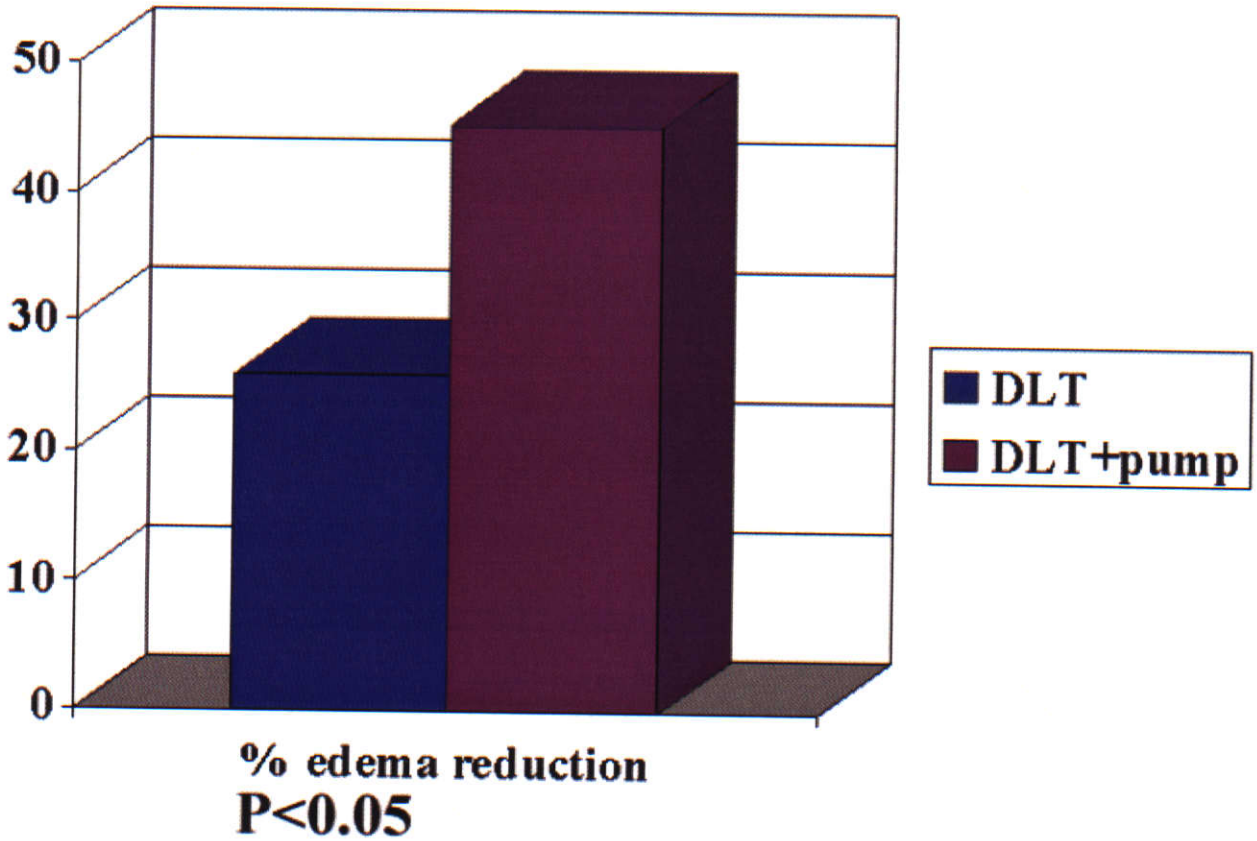

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April 2005

ATTACHMENT 102

This Lymphedema eNews is being generated through your request from our website.

The conference of the American Society of Breast Surgeons was held in Los Angeles (March 16-20). At this meeting, I presented our recent research on the treatment of lymphedema. We recently completed a study evaluating the benefit of using the ReidSleeve combined with an Optiflow/BioCompression system. The Optiflow/BioCompression system uses a ReidSleeve Optiflow insert inside the sleeve of a BioCompression pneumatic pump.

We evaluated the efficacy of this system among patients with moderate to severe upper and lower extremity edema that had failed other treatments. This study was conducted over more than a year and we have long-term evaluation of the patients treated on this study. This system was extremely effective at reducing lymphedema in both the upper and lower extremities. In addition, we made several important observations that were presented at the meeting.

We found that there was a strong correlation with clinical response and duration of treatment. While almost all studies done for the analysis of lymphedema assessed response over a few days or a few weeks, we found that optimal results achieved with several months of treatment. This finding makes sense when we understand how lymphedema occurs.

Lymphedema is the result of the accumulation of excess interstitial fluid. However, the excess accumulation of interstitial fluid results in compensatory responses that result in the accumulation of fibrotic tissue and excess fatty tissue. The fibrotic and fatty tissues cannot be removed quickly by compression. Instead, compression must be applied gently and regularly. With effective mobilization of the interstitial fluid, the fibrotic and fatty tissues can return to normal over time. Our data suggest that this can take several months but the encouraging result is that effective and lasting treatment can be achieved even among patients with moderate to severe lymphedema. However, the compression must be applied so that the already stressed tissues are not further stressed with levels of compression that are too high.

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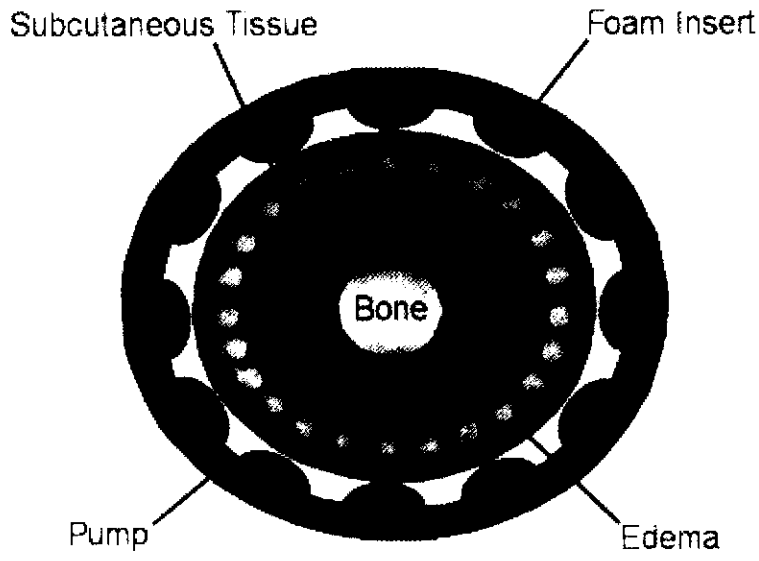

We also observed what we have called the plateau phase. We found that initial reductions in edema are observed within the first few weeks of treatment. The initial reductions in edema are consistent with mobilization of the interstitial fluid. The initial reductions in edema are then followed by plateau phase where the rate of improvement slowed for a period of about 3 to 6 weeks. After the plateau phase, we observed secondary phase with further improvements over time. This secondary phase appears to correlate with removal of excess fibrotic and fatty tissue. This represents true healing of the damage to the tissue caused by lymphedema. The plateau phase was longer among patients with lower extremity edema and more severe edema.

For those who are interested in the details of the presentation I have included the abstract, data and conclusion of this presentation below.

Tony Reid MD, Ph.D.

Title:

Lymphedema: Combined Modality Treatment using the Reid Sleeve and the BioCompression Pneumatic Pump. The OptiflowBC System.

Authors: Renee Robinson, Suzie Willis, Cheri Hoskins, Stephen Morgan, Ann Hafner and Tony Reid MD, Ph.D.

Duke University School of Medicine, Healthtronix Lymphedema Management, Inc. and Peninsula Medical, Inc.

Abstract:

Patients: 35 patients (16 upper extremity/19 lower extremity) with refractory lymphedema were enrolled on a study using the Reid Sleeve in combination with the BioCompression/Optiflow

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system.

Methods. Patients wore the Reid Sleeve at night. During the daytime, the patients used the BioCompression pump with the Reid Sleeve Optiflow insert for 2 sessions of 60 minutes. Circumferential measurements were made at 3-inch intervals along the length of the arm or leg. The unaffected limb was used as control to determine the percent change from expected except when both limbs were effected.

Results. Among patients with upper extremity edema, the reduction in lymphedema increased steadily during treatment and was 24.7, 53.8 and 80.2% at 4, 12 and 28 weeks. The volume reduction at these times was 2310, 2753 and 4047 cubic centimeters. Linear regression analysis demonstrates a highly significant ($p<0.001$) reduction in arm edema during the course of treatment. A plateau phase occurred between weeks 4 and 8. For the patients with leg edema, the average reduction at 4 weeks was 9143 cubic centimeters followed by a period of relatively stable lymphedema until week 12 with an average decrease in lymphedema of 1486 cubic centimeters between weeks 12 and 16. Linear regression analysis demonstrates a significant ($p<0.02$) decrease in leg edema. The plateau phase may represent a tissue repair phase that occurs with effective resolution of residual lymphedema. Subsequent reductions in lymphedema can occur following tissue healing. The plateau phase appears to be more protracted among patients with more serious lymphedema such as patients with leg edema.

Background

Lymphedema is a chronic process due to lymphatic obstruction and the accumulation of a protein-rich interstitial fluid. Chronic inflammation and swelling causes proliferation of fibroblasts and keratinocytes, disruption of normal elastic fibers and the accumulation of subcutaneous lipid deposits. Treatment strategies for lymphedema need to address both facets of this disorder:

1) The acute accumulation of interstitial fluid
2) The chronic adaptive changes

Lymphatic vessels Lymphatic vessels are squeezed by the expansion and recoil of the arterial system contained within the same connective tissue sheath propelling lymphatic fluid forward. Retrograde flow is prevented by numerous one-way valves within the lymphatic vessels. The Optiflow insert dampens the peaks in pressure caused by the pneumatic pumps and maintains a baseline level of compression.

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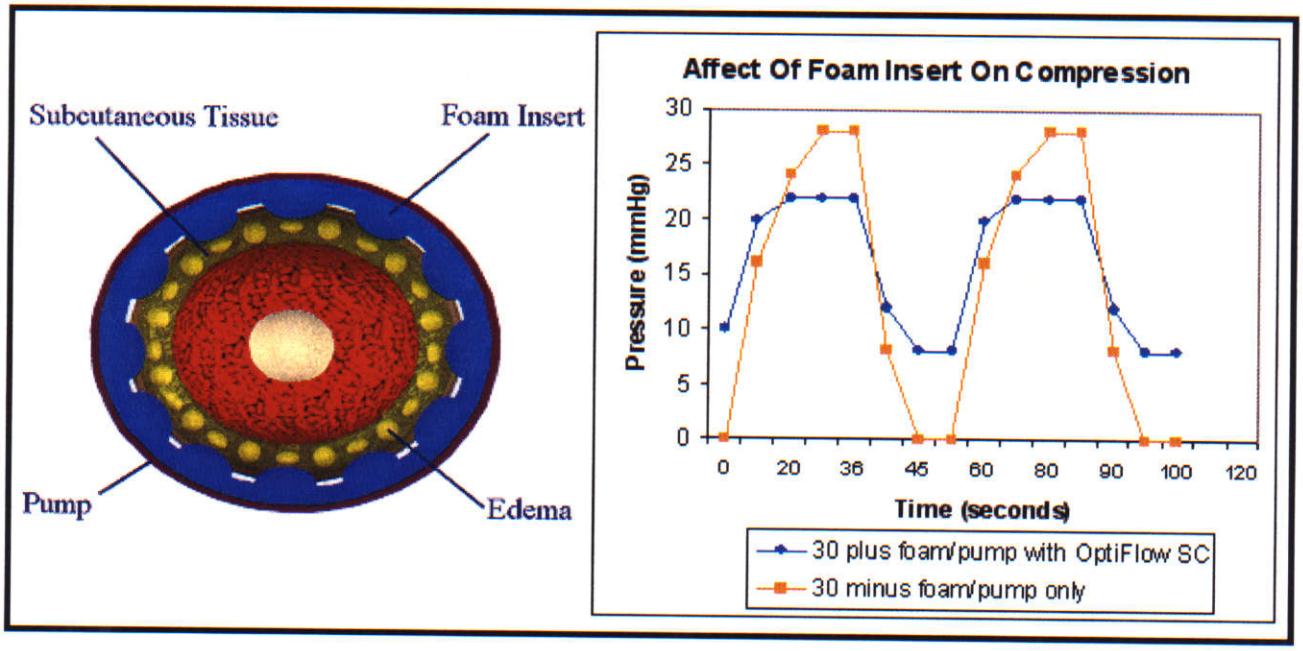

The ReidSleeve utilizes patented technology to provide a gradient of compression within the tissue. Compression is achieved with high and low compression points from resilient but compliant elastic foam, preventing the constriction or tourniquet effect lymphatic venous flow that can occur when compression is applied circumferentially around the arm or leg. The effectiveness of the ReidSleeve has been demonstrated in prior clinical studies.

BioCompression. Intermittent Pneumatic Compression can augment venous and lymphatic flow and is used commonly to prevent deep venous thrombosis among hospitalized patients. Previous randomized studies have demonstrated that intermittent pneumatic compression can help reduce lymphedema.

Rationale for Combination Therapy with ReidSleeve and BioCompression. Intermittent pneumatic compression can prevent static accumulation of venous and lymphatic fluid. The ReidSleeve Optiflow insert can be used inside the pneumatic compression sleeve to further augment venous and lymphatic flow and prevent obstruction due to the tourniquet-effect that can occur with sleeves made of flat, inelastic material. The Optiflow insert dampens the high pressures caused by pneumatic compression and maintains a constant base-line level of compression.

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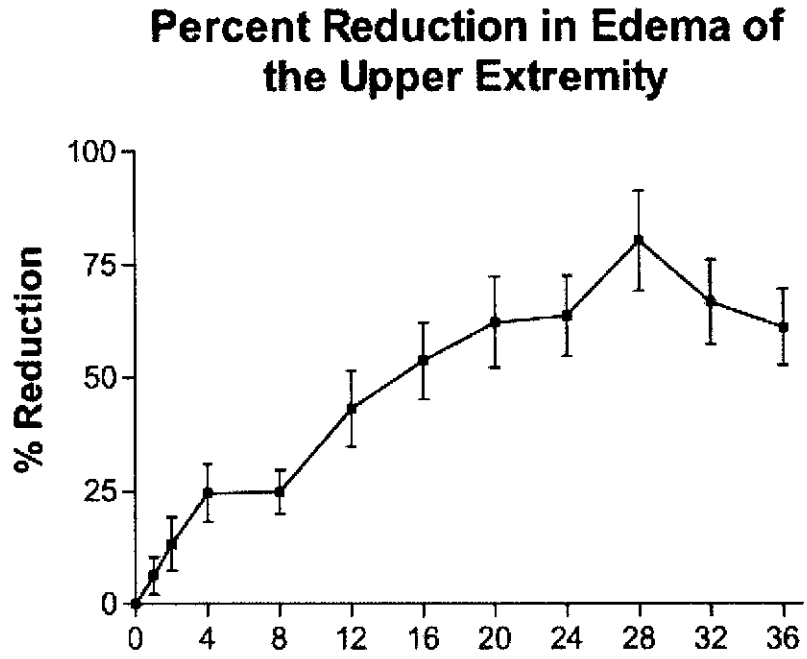
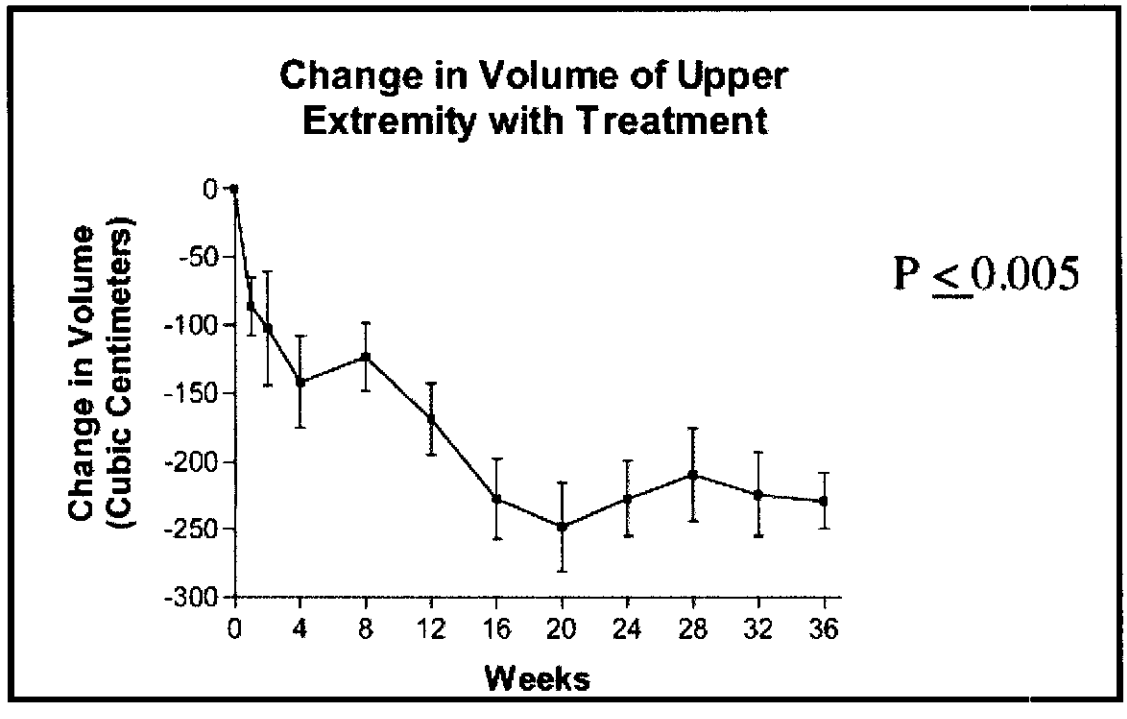


The patients demonstrated rapid and consistent reduction in lymphedema during the first 4 weeks of treatment, achieving a 25% reduction in lymphedema by the 4th week. Between weeks 4 and 8, no significant improvement was observed. Subsequent to week 8, continued reduction was observed. 50% reduction in lymphedema was observed at 16 weeks and 80% reduction was observed at 28 weeks. Between weeks 28 and 36 there is an apparent increase in lymphedema among these patients; however, nearly half of these patients achieved effective control of the lymphedema and entered the maintenance phase of treatment and were seen less frequently. As a result, patients with effectively controlled lymphedema were no longer included at these late time points. Nevertheless, patients with more severe lymphedema were responding and the reduction these patients achieved was 50 to 75% at 36 weeks.



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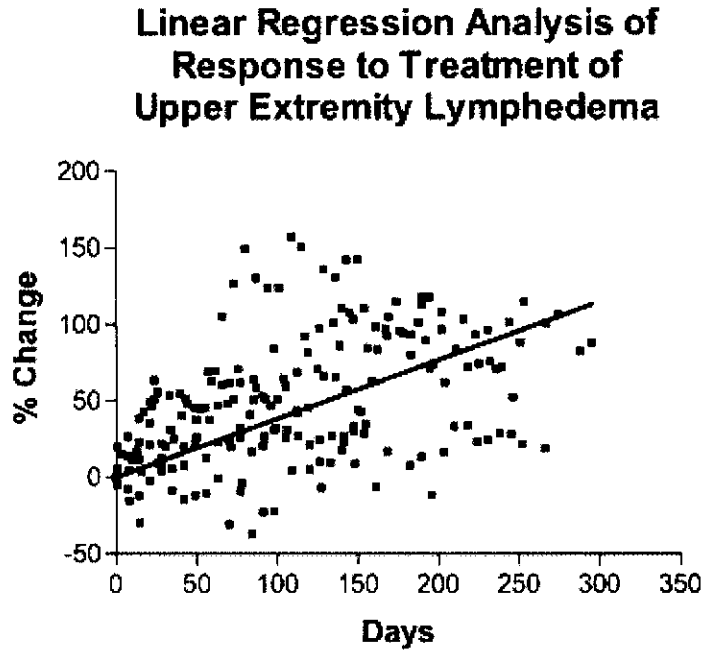
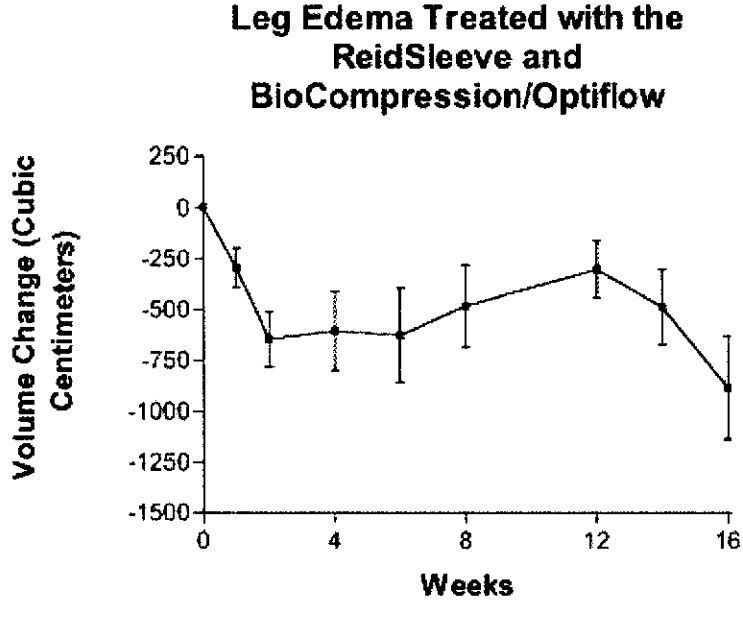


Scattergram of the effect of the ReidSleeve BioCompression/Optiflow System. Linear regression analysis demonstrates progressive decrease in lymphedema with time of treatment.



Effect of Combined Treatment with ReidSleeve and BioCompression Optiflow among patients with lower extremity lymphedema. 19 patients with refractory lymphedema were followed for 16 weeks following initiation of treatment using the Duke protocol. The reduction in tissue volume of the affected extremity is shown.

Conclusions

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1. **Response to Treatment:** The Reid Sleeve used in combination with the BioCompression/Optiflow system provides effective management for lymphedema of the upper and lower extremity. Patients were followed for up to 1 year of treatment and most patients achieved either complete responses or marked reductions in lymphedema.
2. **Linear regression analysis:** These results demonstrated a strong correlation with clinical response and duration of treatment with optimal results achieved with 3 to 12 months of treatment. The analysis also demonstrates that some patients were transiently worse during the first 1 to 3 months of treatment. This was generally due to infections or other medical issues and patients subsequently responded to treatment after controlling infections of other medical problems.
3. **Plateau Phase:** We observed significant initial reductions in edema are observed within the first few weeks of treatment followed by plateau phase and subsequent secondary phase with further improvement at a slower rate. The plateau phase was longer among patients with lower extremity edema and more severe edema. We hypothesize that free interstitial fluid is readily mobilized with initial treatment but that prolonged and durable responses require tissue healing and that the secondary phase occurs with initial effective management of lymphedema and continued treatment.

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ATTACHMENT 10b

Combined Modality Treatment of Lymphedema using the ReidSleeve and the BioCompression/Optiflow System.

Renee Robinson, Lisa A Massa PT CLT, Jennifer Maddox, PT, Nancy Guillett, LMT, CLT-LANA, Katherine Arsenault, MPT, CLT-LANA, Deborah Daugherty, MOT, CLT-LANA, Cheri Hoskins, Stephen Morgan, Ann Hafner and Tony Reid MD, Ph.D.

Duke University School of Medicine (LM, JM), Healthtronix Lymphedema Management, Inc (NG, KA, DD, CH) and Peninsula Medical (RR, SM, AH, TR)

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Abstract

35 patients (16 upper extremity/19 lower extremity) with refractory lymphedema were enrolled on a longitudinal study using the ReidSleeve in combination with the BioCompression/Optiflow system. The primary objective of this study was to evaluate the effectiveness of this combined modality therapy. Patients wore the ReidSleeve at night and used the BioCompression pump with the ReidSleeve Optiflow insert for 2 sessions of 60 minutes during the day with class II compression stocking for the remainder of the day. Among patients with upper extremity edema, the reduction in lymphedema was 24.7, 53.8 and 80.2% at 4, 12 and 28 weeks. Linear regression analysis demonstrates a highly significant ($p<0.001$) reduction in arm edema during the course of treatment. A plateau phase occurred between weeks 4 and 8 weeks. Among patients with lymphedema edema of the lower extremity, the average reduction was 296, 646, 607, 484, 305, and 884 ml at 1, 2, 4, 8, 12 and 16 weeks respectively. These patients demonstrated marked reductions in lymphedema during the first 2 to 4 weeks followed by a period of relatively stable lymphedema until week 12 with a further decrease in average volume of lymphedema of 14496 cubic centimeters by week 16. Linear regression analysis demonstrates a significant ($p<0.001$) decrease in leg edema. The ReidSleeve used in combination with the BioCompression/Optiflow system provides effective management for upper and lower extremity lymphedema.

Introduction

Lymphedema in developed countries is generally secondary to radiation induced damage or surgical resection of lymphatic vessels and nodes resulting in lymphatic obstruction and the accumulation of a protein-rich interstitial fluid. Chronic inflammation caused by the abnormal accumulation of interstitial fluid causes proliferation of fibroblasts, keratinocytes and adipocytes, disruption of normal elastic fibers and the accumulation of subcutaneous lipid deposits. The chronic responses result in the characteristic thickening, hardening and discoloration of the skin. Treatment strategies for lymphedema need to address 1) the acute accumulation of interstital fluid and 2) the chronic adaptive changes that result in thickened and abnormal skin and subcutaneous tissue.

Lymphatic vessels collect fluid from the interstitial area between cells. Lymphatic fluid is propelled forward by the arterial and muscle pumps. Lymphatic vessels are squeezed by the expansion and recoil of the arterial system contained within the same connective tissue sheath. Similarly, the compression of lymphatic vessels by expansion and contraction of muscles during movement propels lymphatic fluid forward. Retrograde flow is prevented by numerous one-way valves within the lymphatic vessels. The resilient foam construction of the ReidSleeve with high and low compression points is designed to simulate and augment the expansion and recoil of the artery and muscle on lymphatic vessels and the effects of the lymphatic gates. A protocol was developed at Duke University combining the ReidSleeve with intermittentgradient, sequential, pneumatic compression. The rationale for this combination was that the ReidSleeve Optiflow insert combined with intermittent sequential pneumatic compression could effectively modulate interstitial pressure, mimick the effects of the muscle pump and enhance the therapeutic impact of each modality. The impact of combined therapy with the ReidSleeve and the BioCompression/Optiflow system is reported.

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Methods:

Design of the study:
Patients were treated by a protocol used at Duke University for the treatment of moderated to severe lymphedema. Patients were fitted for the ReidSleeve Classic and used this garment during the nightime. During the daytime the patients wore class II compression stocking except for 2 sessions of treatment with intermittent sequential pneumatic compression using a BioCompression pump with a ReidSleeve Optiflow insert. The addition of the Optiflow insert resulted in a baseline compression of 4 to 6 mmHg, approximately the level of venous pressure. Intermittent compression was provided by the sequential pneumatic pump. The maximal compression was initially set at 20mmHg and gradually increased in increments of 5mmHg over several hours. The compression was set for each patient at a point that provided comfortable compression without a sensation of congestion or discomfort. If the patient subsequently developed symptoms of discomfort, the pressure was reduced in increments of 5mmHg until the discomfort resolved. The compression of the ReidSleeve Classic was set using the Precise Compression gauge and increased in 5mmHg increments as described above until comfortable compression was obtained without the sensation of congestion or discomfort.

Sequential circumferential measurements using a gauged that provided consistent stretch force during measurements. Measurements were taken every 3 inches over the length of the extremity. The volume of the extremity was calculated with the truncated cone formula. Changes were determined, when possible, as a percentage of excess volume compared to the uninvolved extremity. Many of the patients with lower extremity edema had bilateral involvement. Among these patients the change is shown as absolute volume.

Patients were treated according to the Duke protocol and informed consent was obtained for collection and analysis of the measurements under the auspices of the Duke IRB.

Results:

16 patients with moderate to severe upper extremity edema were treated according the Duke protocol. These patients received treatment with the ReidSleeve Classic as detailed in the methods, coupled with 2 daily treatment with intermittent sequential pneumatic compression using the BioCompression pump with the Optiflow compression insert. The patients wore compression sleeves/stocking during the intervening times. The results of treatment are shown in **Fig. 1**. The patients demonstrated rapid and consistent reduction in lymphedema during the first 4 weeks of treatment, achieving a 25% reduction in lymphedema by the 4th week. 50% reduction in lymphedema was observed at 16 weeks and 80% reduction was observed at 28 weeks. Between weeks 28 and 36 there is an apparent increase in lymphedema among these patients; however, nearly half of these patients achieved effective control of the lymphedema and entered the maintenance phase of treatment and were seen less frequently. As a result, patients with effectively controlled lymphedema were no longer included at these late time points. Nevertheless, patients with more severe lymphedema were responding and the reductions these patients achieved was 50 to 75% at 36 weeks.

Linear regression analysis was used to determine the significance of the reduction in lymphedema with time of treatment (**Fig. 2**). This analysis demonstrates that there is a consistent improvement in lymphedema with time after initiation of treatment with the ReidSleeve-BioCompression/Optiflow system. 50% reduction in lymphedema is seen at approximately 16 weeks. The response to treatment is highly significant ($p<0.001$). By approximately 60 days some patients had achieved reductions in excess of 90%. These patients were placed on

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maintenance therapy and were taken of the study. As a result, the average improvement during subsequent times reflects the patients remaining on study and the average response is lower as the best responding patients were removed. During the initial phase some patients had worsening lymphedema. These exacerbations were transient and due to secondary causes common among patients with moderate to severe lymphedema including infections. When treated these patients were put back on treatment. By 3 to 4 months after initiation of treatment, marked improvement in lymphedema was observed in nearly all patients.

A plateau in response can be seen between weeks 4 and 8 among these patients. The initial rate of reduction was 6.2% per week (**Fig. 1**). Following a leveling off or plateau period, further reductions are observed, however, the rate of reduction is 3.1% per week.

Reductions in excess of 100% are noted in some patients. After effective control of lymphedema, the affected extremity can be smaller than the unaffected extremity. This appears to be due to atrophy of the musculature of the affected extremity.

The results of treatment of patients with lower extremity edema are shown in **Fig. 3**. Mobilization of excess edema can be seen among these patients during the first 2 weeks of therapy. These patients have moderate to severe lymphedema and the average loss of edema observed during the first two weeks is 700cc. The marked decrease in lymphedema observed among these patients was followed by a plateau phase between weeks 2 and 12. Following week 12, further reductions in lymphedema were observed among these patients.

Discussion

Lymphedema is a complex problem. In most cases in the developed countries, lymphedema arises from the disruption of lymphatic vessels and nodes due to surgery, radiation or both. Obstruction of lymphatic flow results in retention of interstitial fluid within the tissue leading to swelling. Retention of interstitial fluids and associated proteins results in chronic inflammatory process that leads to the changes characteristic of lymphedema. This includes thickening and discoloration of the skin, loss of tensile strength of elastic fibers and accumulation of adipocytes and subcutaneous fat. Effective treatment of lymphedema requires the resolution of excess of interstitial fluid and normalization of the compensatory abnormalities of the skin and subcutaneous tissue. Therefore, removal of the accessible interstitial fluid is an important first step in the treatment of lymphedema, but must be followed by reduction of the excess fibroblasts and adipocytes, removal of excess lipid, remodeling of the thickened layers of skin and restoration of the tensile strength of elastic fibers. Effective remodeling of the skin and subcutaneous tissue, requires minimization of the stress on these tissues. To achieve the optimal interstitial pressure that will facilitate removal of excess interstitial fluid and to minimize stress on recovering tissues, we have used the ReidSleeve in combination with the BioCompression/Optiflow system.

The ReidSleeve provides gentle compression using a multitude of high and low compression points. The resilient foam used in the ReidSleeve models the compression normally applied to the lymphatic system by the expansion and recoil of the arterial system and the intermittent compression of the muscle pump. To assure minimal stress on the recovering tissue, soft foam is used at the lowest pressure necessary to achieve reduction of interstitial edema. Excess pressure not only adds increased stress to the tissue but can also lead to compression and obstruction of functioning lymphatic vessels.

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The ReidSleeve Optiflow insert inside of the sequential pneumatic compression chamber to achieve optimal interstitial pressure without causing obstruction. The intermittent compression of the sequential pneumatic pump can augment the massaging effects of the Optiflow insert. Furthermore, the sequential pneumatic pump can be adjusted to optimize the interstitial pressure. The system is designed to provide a baseline compression of approximately 4 to 6 mmHg pressures, a level of compression consistent with venous pressure. During inflation, the pressure exerted increases smoothly and gradually to a peak pressure that can be adjusted to the patients needs. In this protocol, the peak pressures were increased in increments of 5mmHg to achieve reduction in lymphedema without causes the sensation of congestion or discomfort in the extremity. The ReidSleeve was used nightly, the BioCompression/Optiflow system was used for 2 periods of 60 minutes during the day and level II compression sleeves were used for the remainder of daytime wear.

The results from this study demonstrated marked reduction of lymphedema of the upper and lower extremity of patients with moderate to severe lymphedema refractory to other treatments. Patients with upper extremity lymphedema demonstrated a 25% reduction at 4 weeks, 50% reduction at 16 weeks and 80% reduction at 28 weeks. The initial rate of reduction was 6.2% per week. However, this rate decreased to 3.1% per week following a brief plateau phase. The initial response most likely represents removal of excess interstitial fluid. The rate of improvement was slower in subsequent weeks consistent with the remodeling and normalization of the skin and subcutaneous tissues. The long-term treatment of lymhedema is dependent on reversing the skin and subcutaneous tissues. Proliferation of fibroblasts, keratinocytes and adipocytes occur in response to the irritation and stress of the accumulated interstitial fluid. The continued reduction in lymphedema and the improvement in skin tone and color were achieved over the course of treatment demonstrates that this combination of therapies can 1) decrease interstitial edema and 2) facilitate the healing of the skin and subcutaneous tissues.

Marked reductions in lymphedema and improvements in skin and tone and appearance were also observed among patients with lower extremity lymphedema. Many of these patients had bilateral lymphedema that precluded the precise determination of the volume of the unaffected extremity. However, significant absolute volume reductions were observed among these patients with moderate to severe lymphedema over the first 2 to 4 weeks of treatment. This was followed by a protracted plateau phase that was characterized by gradual improvement in skin tone and color. Starting at approximately 12 weeks additional reductions in lymphedema were observed. By maintaining optimal interstitial compression while avoiding unnecessary stress on the tissues during the plateau phase, the necessary tissue repair became evident and provided a basis for further reductions in the subsequent weeks and months. The results of this study demonstrate that because lymphedema is the combination of both interstitial fluid and the compensatory proliferative changes of the skin and subcutaneous tissues, the true measure of success in treating lymphedema should be determined over 4 to 12 months of treatment.

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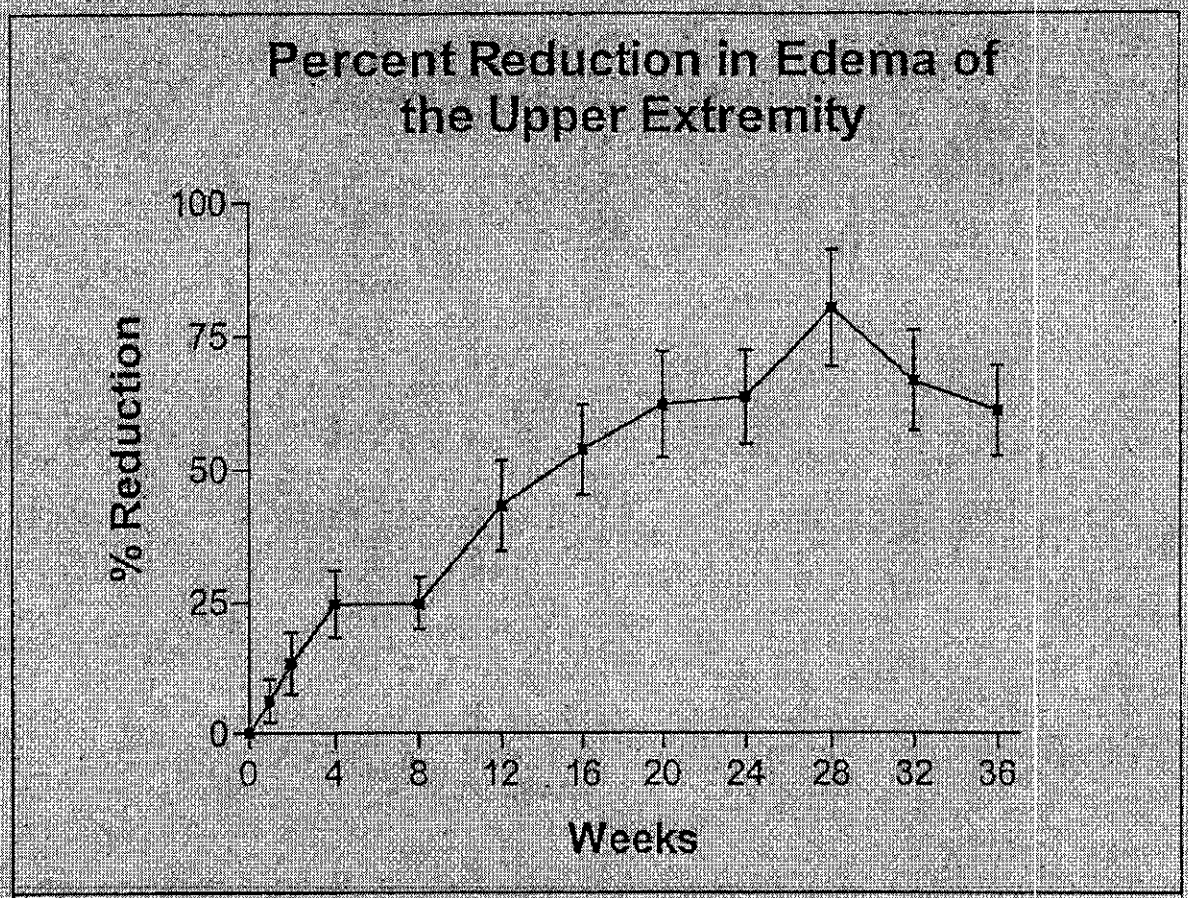

Fig. 1. Effect of Combined Treatment with ReidSleeve and BioCompression/Optiflow. 16 patients with refractory lymphedema were followed for 36 weeks following initiation of treatment using the Duke protocol. The percent reduction in lymphedema was determeined by subtracting the volume of the unaffected extremity from the volume of the affected extremity leaving the amount of excess volume. A 100% reduction would result in normalization of the volume of the affected extremity.

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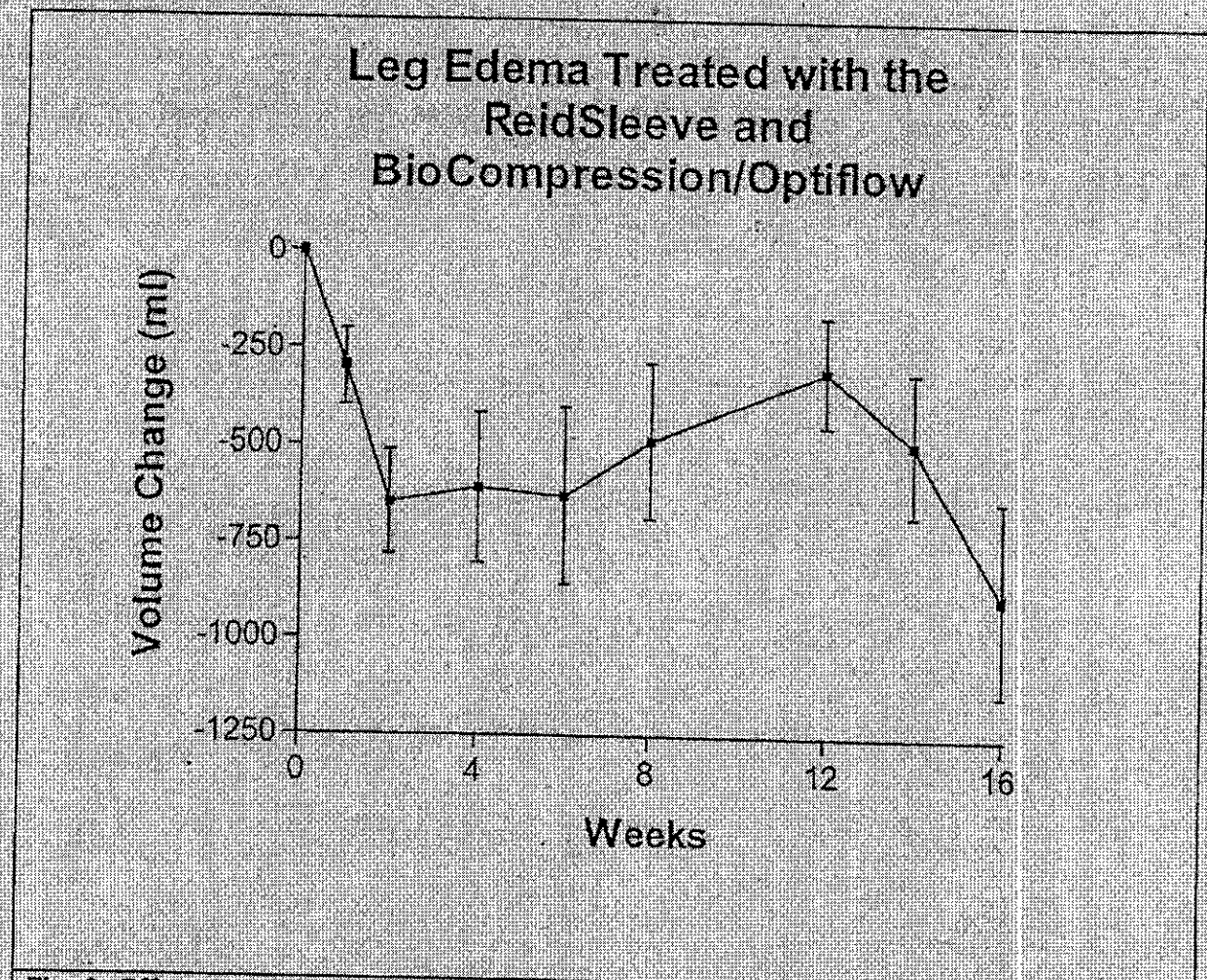

Fig. 3. Effect of Combined Treatment with ReidSleeve and BioCompression/Optiflow among patients with lower extremity lymphedema. 19 patients with refractory lymphedema were followed for 16 weeks following initiation of treatment using the Duke protocol. The reduction in tissue volume of the affected extremity is shown.

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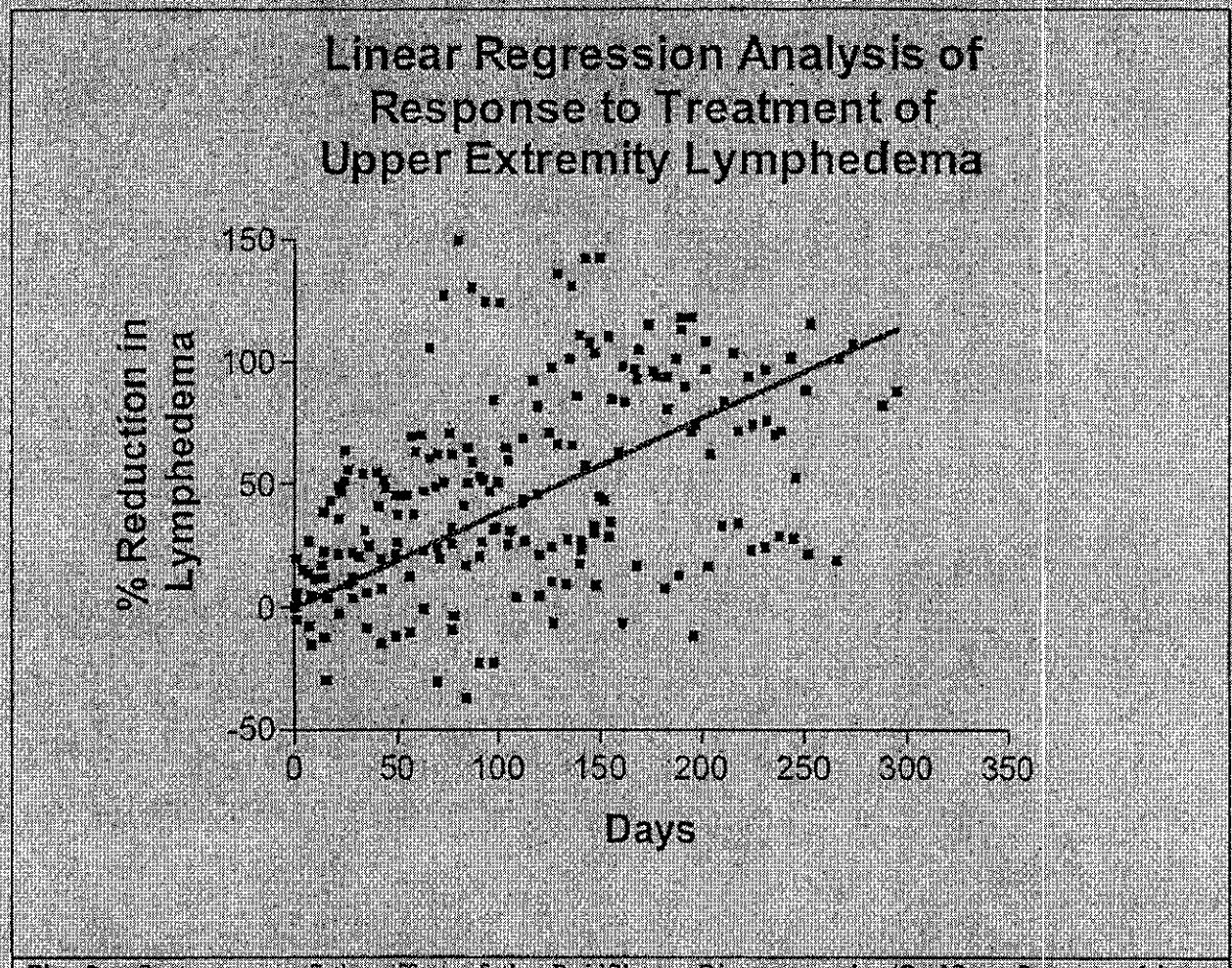

Fig. 2. Scattergram of the effect of the ReidSleeve Biocompression/Optiflow System. Linear regression analysis demonstrates progressive decrease in lymphedema with time of treatment.

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ATTACHMENT 11

MediFocus Guidebook

Lymphedema

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How To Use This Medifocus Guidebook

MediFocus Guidebook Organization and Content

Before you start to review your *Guidebook*, it would be helpful to familiarize yourself with the organization and content of the information that is included in the Guidebook. Your *MediFocus Guidebook* is organized into the following five major sections.

- **Section 1: Background Information** - This section provides detailed information about the organization and content of the *Guidebook* including tips and suggestions for conducting additional research about the condition.

- **Section 2: The Intelligent Patient Overview** - This section is a comprehensive overview of the condition and includes important information about the cause of the disease, signs and symptoms, how the condition is diagnosed, the treatment options, quality of life issues, and questions to ask your doctor.

- **Section 3: Guide to the Medical Literature** - This section opens the door to the latest cutting-edge research and clinical advances recently published in leading medical journals. It consists of an extensive, focused selection of journal article references with links to the PubMed® abstracts (summaries) of the articles. PubMed® is the U.S. National Library of Medicine's database of references and abstracts from more than 4,500 medical and scientific articles published worldwide.

- **Section 4: Centers of Research** - This section is a unique directory of doctors, researchers, hospitals, medical centers, and research institutions with specialized interest and, in many cases, clinical expertise in the management of patients with the condition. You can use the "Centers of Research" directory to contact, consults, or network with leading experts in the field and to locate a hospital or medical center that can help you.

- **Section 5: Tips for Finding and Choosing a Doctor** - This section of your *Guidebook* offers important tips for how to find physicians as well as suggestions for how to make informed choices about choosing a doctor who is right for you.

- **Section 6: Directory of Organizations** - This section of your *Guidebook* is a directory of select disease organizations and support groups that are in the business of helping patients and their families by providing access to information, resources, and services. Many of these organizations can answer your questions, enable you to network with other patients, and help you find a doctor in your geographical area who specializes in managing your condition.

MediFocus Guidebook Formats

This *MediFocus Guidebook* is available in both an *electronic* format as well as a *printed* format. The electronic and printed formats follow the same basic outline with respect to organization and content of the various sections. The primary difference between the two formats pertains to the method of accessing the PubMed® abstracts (summaries) of the journal article references in the "The Guide to the Medical Literature" section (Section 3) of the *Guidebook*.

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- **Electronic Format** - You can easily access the PubMed® abstracts of the journal article references by simply clicking on the "Abstract URL" link for the corresponding article.

- **Printed Format** - If you purchased the printed format of this *MediFocus Guidebook*, you have two options for accessing the PubMed® abstracts of the journal article references in Section 3 of the *Guidebook*:

    - Manually type in the "Abstract URL" information for a specific article directly into your computer's browser (e.g., Internet Explorer, Netscape) and you will be directed to the PubMed® abstract of the article.

    - Use the electronic format of your *Guidebook* to access the journal article abstracts. When you purchased the printed copy of this *Guidebook*, you were also provided free online access to the electronic format of the same *Guidebook* for one year. You can easily access the PubMed® abstracts of the journal article references by simply clicking on the "Abstract URL" link for the corresponding article.

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How to Access Updates of Your Guidebook

With your initial purchase of this *MediFocus Guidebook*, you also have online access to updates of the Guidebook for one full year free of charge. *MediFocus Guidebooks* are updated with new information every 4 months so that you can stay current with the latest developments about your condition. Shortly after the *Guidebook* has been updated, we post the latest updated version (with the new date) on our web site. We invite you to visit our web site every one or two months to check if an updated version of your *Guidebook* has been posted since your last visit.

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- Visit our web site at http://www.medifocus.com
- On the left side of the Home page you will see a listing of the "Diseases and Conditions"
- Click on the name of the disease or condition of your *Guidebook*.
- The latest date of revision (update) of your *Guidebook* is posted within the blue box just below the image of the *Guidebook*.

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1 - Background Information

Introduction

Chronic or life-threatening illnesses can have a devastating impact on both the patient and the family. In today's new world of medicine, many consumers have come to realize that they are the ones who are primarily responsible for their own health care as well as for the health care of their loved ones.

When facing a chronic or life-threatening illness, you need to become an educated consumer in order to make an informed health care decision. Essentially that means finding out everything about the illness - the treatment options, the doctors, and the hospitals - so that you can become an educated health care consumer and make the tough decisions. In the past, consumers would go to a library and read everything available about a particular illness or medical condition. In today's world, many turn to the Internet for their medical information needs.

The first sites visited are usually the well known health "portals" or disease organizations and support groups which contain a general overview of the condition for the layperson. That's a good start but soon all of the basic information is exhausted and the need for more advanced information still exists. What are the latest "cutting-edge" treatment options? What are the results of the most up-to-date clinical trials? Who are the most notable experts? Where are the top-ranked medical institutions and hospitals?

The best source for authoritative medical information in the United States is the National Library of Medicine's medical database called PubMed®, that indexes citations and abstracts (brief summaries) of over 7 million articles from more than 3,800 medical journals published worldwide. PubMed® was developed for medical professionals and is the primary source utilized by health care providers for keeping up with the latest advances in clinical medicine.

A typical PubMed® search for a specific disease or condition, however, usually retrieves hundreds or even thousands of "hits" of journal article citations. That's an avalanche of information that needs to be evaluated and transformed into truly useful knowledge. What are the most relevant journal articles? Which ones apply to your specific situation? Which articles are considered to be the most authoritative - the ones your physician would rely on in making clinical decisions? This is where *Medifocus.com* provides an effective solution.

Medifocus.com has developed an extensive library of *MediFocus Guidebooks* covering a wide spectrum of chronic and life threatening diseases. Each *MediFocus Guidebook* is a high quality, up- to-date digest of "professional-level" medical information consisting of the most relevant citations and abstracts of journal articles published in authoritative, trustworthy medical journals. This information represents the latest advances known to modern medicine for the treatment and management of the condition, including published results from clinical trials. Each *Guidebook* also includes a valuable index of leading authors and medical institutions as well as a directory of disease organizations and support groups. *MediFocus Guidebooks* are reviewed, revised and updated every 4-months to ensure that you receive the latest and most up-to-date information about the specific condition.

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About Your MediFocus Guidebook

Introduction

Your *MediFocus Guidebook* is a valuable resource that represents a comprehensive synthesis of the most up-to-date, advanced medical information published about the condition in well-respected, trustworthy medical journals. It is the same type of professional-level information used by physicians and other health-care professionals to keep abreast of the latest developments in biomedical research and clinical medicine. The *Guidebook* is intended for patients who have a need for more advanced, in-depth medical information than is generally available to consumers from a variety of other resources. The primary goal of a *MediFocus Guidebook* is to educate patients and their families about their treatment options so that they can make informed health-care decisions and become active participants in the medical decision making process.

The *Guidebook* production process involves a team of professionals with expertise in diverse areas including experienced medical database researchers and practicing physicians who serve as members of the *Medifocus.com* Medical Advisory Board (MAB). This team approach to the development and production of the *MediFocus Guidebooks* is designed to ensure the accuracy, completeness, and clinical relevance of the information. The *Guidebook* is intended to serve as a basis for more meaningful discussions between patients and their health-care providers in a joint effort to seek the most appropriate course of treatment for the disease.

Guidebook Organization and Content

Section 1 - Background Information

This section provides detailed information about the organization and content of the *Guidebook* including tips and suggestions for conducting additional research about the condition.

Section 2 - The Intelligent Patient Overview

This section of your *MediFocus Guidebook* represents a detailed overview of the disease or condition specifically written from the patient's perspective. It is designed to satisfy the basic informational needs of consumers and their families who are confronted with the illness and are facing difficult choices. Important aspects which are addressed in "The Intelligent Patient" section include:

- The etiology or cause of the disease
- Signs and symptoms
- How the condition is diagnosed
- The current standard of care for the disease
- Treatment options
- New developments
- Important questions to ask your health care provider

Section 3 - Guide to the Medical Literature

This is a roadmap to important and up-to-date medical literature published about the condition from authoritative, trustworthy medical journals. This is the same information that is used by physicians and researchers to keep up with the latest developments and breakthroughs in clinical medicine and biomedical research. A broad spectrum of articles is included in each *MediFocus Guidebook* to provide information about standard treatments, treatment options, new clinical developments, and advances in research. To

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facilitate your review and analysis of this information, the articles are grouped by specific categories. A typical *MediFocus Guidebook* usually contains one or more of the following article groupings:

- *Review Articles:* Articles included in this category are broad in scope and are intended to provide the reader with a detailed overview of the condition including such important aspects as its cause, diagnosis, treatment, and new advances.

- *General Interest Articles:* These articles are broad in scope and contain supplementary information about the condition that may be of interest to select groups of patients.

- *Drug Therapy:* Articles that provide information about the effectiveness of specific drugs or other biological agents for the treatment of the condition.

- *Surgical Therapy:* Articles that provide information about specific surgical treatments for the condition.

- *Clinical Trials:* Articles in this category summarize studies which compare the safety and efficacy of a new, experimental treatment modality to currently available standard treatments for the condition. In many cases, clinical trials represent the latest advances in the field and may be considered as being on the "cutting edge" of medicine. Some of these experimental treatments may have already been incorporated into clinical practice.

The following information is provided for each of the articles referenced in this section of your *MediFocus Guidebook:*

- Article title
- Author Name(s)
- Institution where the study was done
- Journal reference (Volume, page numbers, year of publication)
- Link to Abstract (brief summary of the actual article)

Linking to Abstracts: Most of the medical journal articles referenced in this section of your *MediFocus Guidebook* include an abstract (brief summary of the actual article) that can be accessed online via the National Library of Medicine's PubMed® database. You can easily access the individual abstracts online via PubMed® from the "electronic" format of your *MediFocus Guidebook* by clicking on the corresponding URL address that is provided for each cited article. If you purchased a printed copy of a *MediFocus Guidebook*, you can still access the article abstracts online by entering the individual URL address for a particular article into your web browser.

Section 4 - Centers of Research

We've compiled a unique directory of doctors, researchers, medical centers, and research institutions with specialized research interest, and in many cases, clinical expertise in the management of the specific medical condition. The "Centers of Research" directory is a valuable resource for quickly identifying and locating leading medical authorities and medical institutions within the United States and other countries that are considered to be at the forefront in clinical research and treatment of the condition.

Inclusion of the names of specific doctors, researchers, hospitals, medical centers, or research institutions in this *MediFocus Guidebook* does not imply endorsement by Medifocus.com, Inc. or any of its affiliates. Consumers are encouraged to conduct additional research to identify health-care professionals, hospitals,

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and medical institutions with expertise in providing specific medical advice, guidance, and treatment for this condition.

Section 5 - Tips on Finding and Choosing a Doctor

One of the most important decisions confronting patients who have been diagnosed with a serious medical condition is finding and choosing a qualified physician who will deliver high-level, quality medical care in accordance with curently accepted guidelines and standards of care. Finding the "best" doctor to manage your condition, however, can be a frustrating and time-consuming experience unless you know what you are looking for and how to go about finding it. This section of your Guidebook offers important tips for how to find physicians as well as suggestions for how to make informed choices about choosing a doctor who is right for you.

Section 6 - Directory of Organizations

This section of your *Guidebook* is a directory of select disease organizations and support groups that are in the business of helping patients and their families by providing access to information, resources, and services. Many of these organizations can answer your questions, enable you to network with other patients, and help you find a doctor in your geographical area who specializes in managing your condition.

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Ordering Full-Text Articles

After reviewing your *MediFocus Guidebook*, you may wish to order the full-text copy of some of the journal article citations that are referenced in the *Guidebook*. There are several options available for obtaining full-text copies of journal articles, however, with the exception of obtaining the article yourself by visiting a nearby medical library, most involve a fee to cover the costs of photocopying, delivering, and paying the copyright royalty fees set by the individual publishers of medical journals.

This section of your *MediFocus Guidebook* provides some basic information about how you can go about obtaining full-text copies of journal articles from various fee-based document delivery resources.

Commercial Document Delivery Services

There are numerous commercial document delivery companies that provide full-text photocopying and delivery services to the general public. The costs may vary from company to company so it is worth your while to carefully shop-around and compare prices. Some of these commercial document delivery services enable you to order articles directly online from the company's web site. You can locate companies that provide document delivery services by typing the key words "document delivery" into any major Internet search engine.

National Library of Medicine's "Loansome Doc" Document Retrieval Services

The National Library of Medicine (NLM), located in Bethesda, Maryland, offers full-text photocopying and delivery of journal articles through its on-line service known as "Loansome Doc". To learn more about how you can order articles using "Loansome Doc", please visit the NLM web site at:
http://www.nlm.nih.gov/pubs/factsheets/loansome_doc.html

Participating "Loansome Doc" Libraries: United States

In the United States there are approximately 250 medical libraries that participate in the National Library of Medicine's "Loansome Doc" document retrieval and delivery services for the general public. Please note that each participating library sets its own policies and charges for providing document retrieval services. To order full-text copies of articles, simply contact a participating "Loansome Doc" medical library in your geographical area and ask to speak with one of the reference librarians. They can answer all of your questions including fees, delivery options, and turn-around time.

Here is how to find a participating "Loansome Doc" library in the U.S. that provides article retrieval services for the general public:

- **United States** - Contact a Regional Medical Library at 1-800-338-7657 (Monday - Friday; 8:30 AM - 5:30 PM). They will provide information about libraries in your area with which you may establish an account for the "Loansome Doc" service.

- **Canada** - Contact the Canada Institute for Scientific and Technical Information (CISTI) at 1-800-668-1222 for information about libraries in your area.

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2 - The Intelligent Patient Overview

LYMPHEDEMA

Introduction

The human body contains two circulatory systems which work together to serve very critical functions:

- The *Cardiovascular System* consists of the blood, blood vessels, and heart. Blood delivers oxygen, nutrients, hormones and antibodies to all parts of the body and carries away waste materials. The heart pumps the blood through the vascular system (arteries, veins, and capillaries) so that circulation continues without any interruption.

- The *Lymphatic System* includes a network of lymphatic vessels, tissue and organs such as bone marrow, spleen, thymus gland, tonsils, appendix, and lymph nodes that contain specialized cells called lymphocytes that help the body fight infection. The complex network of interconnected vessels drains and filters fluid called "lymph" from tissue throughout the body and delivers it into the blood circulatory system via entry points into the subclavian vein. The walls of lymph vessels are thinner than those of veins. Some are found close to the surface of the skin while others course through deeper fatty tissue.

These two life-sustaining systems are responsible for maintaining *homeostasis*, the balance of fluids in the body. The lymphatic system is responsible for draining water, protein, and other by products of cell metabolism from the tissue and transporting them to the cardiovascular circulatory system.

There are several components of the lymphatic system. These include:

- *Lymph* - a clear or straw-colored liquid consisting of water, large-molecule proteins, salts, and waste products (e.g., dead cells)
- *Lymphatic capillaries* - very small vessels located under the skin which are the first point of collection for lymph
- *Pre-collector vessels* - these vessels are larger in diameter than capillaries and are located deeper in the tissue
- *Collector vessels* - these are yet larger than pre-collector vessels located quite deep in the body

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- *Lymph nodes* - dense clusters of tissue which filter lymph
- *Lymph ducts* - these are the largest diameter vessels of which there are two, the *thoracic duct* and the *right lymphatic duct* that drain the lymph into the left and right subclavian veins at the level of the shoulders/neck.

While the circulatory system is based on the constant pumping action of the heart, the lymphatic system depends on more subtle factors to achieve constant drainage, including:

- Pressure changes within the tissue which propel the lymph into draining vessels
- Smooth muscle within the walls of the larger lymphatic pre-collector and collector vessels which contract and push the lymph forward with the help of valves
- Contractions of surrounding structures, such as arteries and muscles which compress lymph vessels and propels fluid forward.

Within the lymph vessels, valves and muscles help move the fluid towards the larger collector vessels. Each section of collector vessels is called a *lymphangion* and fluid is propelled through each lymphangion until it reaches a lymph node.

Lymph nodes range in size from 1 mm to 25 mm, about the size of an almond. There are approximately 600 lymph nodes scattered throughout the trunk with some situated very deep in the tissue and others lying more superficially. They start in the neck region (cervical nodes) continuing down to the armpits (axillary nodes) and groin area (inguinal nodes). Some stand individually while others may be grouped into clusters. The outermost layer of the lymph node consists of densely packed lymphocytes which activate the immune system if needed. Lymphocytes consist of several types of white blood cells which are crucial to protecting the body from infection and overcoming infection that has already become established.

The primary roles of the lymph system are:

- Fighting Infection
    - Producing and storing white blood cells
    - Fighting infection by filtering out antigens (foreign bodies) and initiating the process of destroying them and disposing of them

The primary function of the lymphatic system and its network of interconnected vessels and lymph nodes is to protect and defend the body against invasion by foreign microorganisms such as bacteria, fungi, and viruses. Once these microorganisms invade the body, they eventually enter the lymphatic system which serves as a large "sieve" to trap, destroy, and eliminate the foreign invaders that can cause infections. Specialized white blood cells called *lymphocytes* located within the chain of lymph nodes throughout the body are responsible

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for mobilizing the immune system to defend and fight-off foreign microorganisms.

- Homeostasis
    - Maintaining a steady state of fluid level in tissue (homeostasis) by draining away excess fluid
    - Draining surplus fats, proteins, and other by-products of cell metabolism from the tissue back into the circulatory system.

The lymphatic system is also important in helping to maintain the fluid balance of the body (homeostasis) by filtering, collecting, and returning excess lymph fluid, which is rich in proteins, lymphocytes, and salts, back into the circulatory system.

How Does the Lymphatic System Work?

The lymphatic system is a one-directional system wherein fluid is drained from tissue beginning under the skin and delivered to the subclavian veins for transport to the *vena cava* (major blood vessel which returns blood to the heart). Valves found in the lymph vessels prevent the fluid from reversing direction. The process begins when fluid from blood of *arterial capillaries* (the smallest vessels in the arterial system) seeps into the *interstitial spaces* (spaces between cells and tissue) throughout the body and provides the surrounding cells with nutrients. Changes in pressure in the surrounding tissue forces most of the fluid (80-90%) and waste products to be reabsorbed into the capillaries of the veins and transported back towards the heart. The remaining 10-20% is forced into the lymphatic capillaries where it is propelled by valves and vessel contractions through a series in increasingly larger-diameter vessels, through the lymph nodes, and ultimately into the large subclavian veins which carry all the blood back to the heart.

Thus, through a complex system of pressure created by *filtration* (removal of waste byproducts of cell metabolism) and reabsorption, the interstitial fluid levels in body tissue are kept at a steady level. The continual deposit of fluid from the arterial capillaries is balanced by the continual flow of interstitial fluid into venous and lymph capillaries and fluid buildup in the tissue (edema) is prevented. Interruption of this delicate balance can lead to collection of fluid in the tissue and is called *lymphedema*.

What is Lymphedema?

The term *edema* refers to the accumulation of an excessive amount of fluid in cells, tissues, or organs and is clinically characterized by swelling. A variety of conditions can produce edema including chronic venous insufficiency, infection, and trauma. *Lymphedema* is a progressive condition which may be defined as the swelling of subcutaneous tissue as a

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result of obstruction of lymphatic vessels or lymph nodes resulting in the accumulation of large amounts of lymph in the affected region. Any disease process that interferes or disrupts the normal mechanical process by which the lymphatic system collects, filters, and returns lymph fluid back into the circulatory system can result in excessive accumulation of lymph fluid in the area affected by the blockage. The capacity of the lymphatic system to drain excess fluid away from body tissue is reduced or interrupted. Since the arterial capillaries continue to deliver fluid to the tissue, the volume of fluid increases significantly until the venous capillaries are no longer able to compensate for the defective lymph vessels. At this point, when drainage has been reduced by 80% or more, symptoms of lymphedema become apparent.

Although lymphedema can develop in any area where the normal flow of lymph fluid has been interrupted, it is most commonly seen in the extremities and almost always takes place at the most superficial level of the vessels under the skin (subcutaneous). Other areas where lymphedema can develop include the head/neck region, chest, body cavities, pelvic region, and genitals. When lymph fluid accumulates due to blockage, it can reduce the amount of nutrients that reach the cells and can interfere with wound healing which results in increased risk of infection.

There are varying degrees of severity of lymphedema, from mild swelling to extreme swelling which can cause life-threatening complications. Initially, the patient may notice that one limb is slightly larger than the other. Approximately 50% of patients with mild lymphedema report feelings of heaviness or fullness in the affected limb. As the swelling progresses, clothing it may become difficult to fit clothing over the affected limb. Eventually, the size and weight of the edematous limb may cause fatigue, embarrassment, and have a significant impact on the quality of life. Maximal girth of the limb is usually reached within the first year of onset of symptoms. The earlier the diagnosis of lymphedema is established and treatment initiated, the lower the risk of developing a large distorted limb and multiple skin changes.

Lymphedema may develop immediately after surgery. It is usually mild and resolves within a couple of weeks. If lymphedema develops approximately 6-8 weeks following surgery or radiation, it also typically resolves within a few weeks with treatment. The most common form of lymphedema, however, develops very slowly over time and may become manifest many months or years following treatment. It can be mild or severe but in any case, must be treated as soon as possible and as aggressively as possible to prevent further complications.

Lymphedema differs from *edema* in that edema is a secondary symptom of an underlying medical condition while lymphedema itself is a medical condition. Edema is a result of too much fluid being released from the capillaries into the tissue which overwhelms the capacity of the lymphatic system and results in swelling and fluid accumulation. In lymphedema, on the other hand, it is the lymphatic system itself which is compromised. The capillaries continue to function normally and continue to release their fluid in the interstitial spaces but

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that fluid is not being drained away from the site. The progression of lymphedema occurs when the balance between the increasing lymph load and reduced drainage or outflow capacity becomes too great for any compensatory mechanism to be effective. This is why lymphedema may be latent for many years before the symptoms become evident.

Classification of Lymphedema

The two major types of lymphedema include:

- Primary lymphedema
- Secondary lymphedema

Primary Lymphedema

Primary lymphedema is a rare congenital or inherited condition in which the lymph nodes or lymphatic vessels are either absent or abnormal. The vessels may be characterized by:

- *Hypoplasia* - the lymph collector vessels are so small that they are ineffective
- *Hyperplasia* - the lymph vessels are too large and are ineffective
- *Aplasia* - absence of lymph vessels that lead to the lymph nodes

Primary lymphedema is usually apparent at birth or within the first two years of life and has been linked to several genetic chromosomal abnormalities. Swelling usually affects one lower leg however, edema may also be present in multiple limbs, the genitalia, and face.

There are three types of primary lymphedema:

- *Congenital lymphedema* - This form accounts for up to 25% of cases of primary lymphedema. It affects females twice as often as males and is three times more likely to affect the legs than the arms. Most cases are bilateral (either both arms or both legs) and, while rare, it can also effect the face and genitalia.

- *Lymphedema praecox* - This is the most common form of primary lymphedema and accounts for approximately 90% of all cases. It affects women more than men by a ratio of about 10 to 1 and usually emerges during puberty. Most cases are unilateral and are limited to the foot or calf.

- *Lymphedema tarda* also known as *Meige Disease* - this form of lymphedema becomes apparent only after the age of 35 and accounts for less than 10% of cases of primary lymphedema. Typically, patients have an overabundance of vessels which are very tortuous with many oddly shaped bends and turns. Valves are often absent or malfunctioning.

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Secondary Lymphedema

Secondary lymphedema (called 'lymphedema' in the remainder of the Guidebook) is lymphedema caused by a blockage or interruption of the lymphatic system usually involving the lymph nodes in the groin or armpit area. There is usually an identifiable cause for the inadequate functioning of the lymphatic system such as cancer surgery or radiotherapy. Other causes include:

- Vein stripping (a procedure to remove varicose veins)
- Peripheral vascular surgery
- Burns
- Insect bites
- Infection
- Inflammation
- Trauma

Secondary lymphedema of the arm is most likely to occur following radiotherapy for breast cancer or axillary lymph node dissection (ALND), a procedure used to determine the extent of spread of breast cancer which involves removal of several lymph nodes in the armpit area. This is the most common cause of secondary lymphedema in the US. Lower limb lymphedema follows in up to 47% of patients who have undergone pelvic or genital cancer surgery especially if a procedure involving inguinal or pelvic lymph node dissection or irradiation is performed.

Secondary lymphedema can be further subdivided into acute and chronic subtypes.

Acute Lymphedema

According the National Cancer Institute, there are 4 types of acute lymphedema:

- The first type of acute lymphedema occurs within a few days following the surgical removal of lymph nodes and is typically mild and temporary. This lymphedema usually resolves within a week or two if the limb is elevated and the muscles of the limb are periodically contracted.

- The second type of acute lymphedema is caused by inflammation of either the lymph vessels or veins. This form of lymphedema may occur 6-8 weeks after surgery or radiation therapy. It usually resolves with limb elevation and anti-inflammatory medication.

- The third type of acute lymphedema is caused by a minor injury, such as a burn, or by an insect bite that causes an infection of the skin and lymphatic vessels. It usually resolves with elevation of the limb and antibiotics.

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- The fourth type of acute lymphedema is the most common and occurs very gradually, sometimes not presenting with symptoms until many months or years after surgery or treatment for cancer.

Acute but temporary lymphedema typically lasts less than 6 months and is characterized by soft skin and *pitting* where the skin remains indented when it is pressed. Pitting takes place with most edema and is characterized by a depression in the skin which lasts a few seconds in response to fingertip pressure. The fluid in the tissue is easily displaced, however, as the condition progresses, there is no longer any displacement of the fluid and no depression with fingertip pressure ("non-pitting").

Chronic Lymphedema

This is the most difficult type of lymphedema to treat since the damaged lymphatic system is overwhelmed by the increased volume of fluid and does not respond efficiently to treatment. It is often accompanied by other changes such as fibrotic, "non-pitting" skin. Chronic lymphedema is most often associated with:

- Tumors that arise in the lymph nodes or spread to the node from another place
- Infection and/or injury to lymphatic vessels
- Radiation therapy
- Surgery
- Restricted movement of a limb
- Early or acute lymphedema that was refractory to treatment and could not be controlled.

The National Cancer Institutes describes *-temporary lymphedema* as a condition that lasts less than 6 months and characterized by skin that is soft and pitting. Temporary lymphedema may follow conditions such as inflammation, the inability to move a limb, or deep vein thrombosis in which a blood clot causes blockage in a vein.

Lymphedema and Breast Cancer

There are three interconnecting lymphatic systems in the each breast. Each lymphatic system drains primarily to nodes in the axilla (armpit) with a small portion draining to other sites. Metastatic spread of breast cancer to the axilla occurs in up to 30% of patients and is the strongest prognostic factor for survival. In addition, involvement of the lymph nodes in the spread of disease is crucial for determining the course of treatment, such as whether to undergo chemotherapy, surgery, or radiation therapy.

Until recently, evaluation of the nearby lymph nodes for signs of metastatic spread has typically been carried out with a surgical procedure called axillary lymph node dissection

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(ALND) in which a pad of fat along the bundle of blood vessels and nerves that pass through the arm pit is removed. In this fat there are several lymph nodes which are removed and then studied by a pathologist to determine the presence of cancer cells. There are many side effects of this technique including pain, numbness, injury to the axillary vein, and lymphedema (up to 56% of women). The number of nodes removed increases the risk for development of lymphedema. ALND is still performed under necessary circumstances, such as the presence of a palpable mass in the armpit region of lymph nodes in the context of breast cancer.

A newer technique for mapping the involvement of lymph nodes in breast cancer is called *sentinel lymph node* (SLN) biopsy. It is performed to stage the axilla by identifying the first lymph node that would receive drainage from the tumor and evaluating it for the presence of cancer cells. The *sentinel lymph node* is the first lymph node closest to the breast tumor which is responsible for filtering out the cancer cells which may potentially spread beyond the armpit. Any spread of cancer is most likely to appear in this lymph node. The sentinel lymph node is determined by injecting a blue dye and/or a radioactive tracer into the area around the cancer. As the dye passes through the breast, it follows the same route that cancer cells traveling away from the tumor would follow. The surgeon typically removes the first node that takes up the dye (sentinel node) which is then examined by a pathologist. If cancer cells are detected, the surgeon may recommend the removal of additional lymph nodes and perhaps ALND. Because fewer lymph nodes are removed compared to ALND, the risk of lymphedema is reduced by up to 70% according to some estimates.

It is important to note that SLN is not designed to replace ALND and is not appropriate for all women diagnosed with breast cancer. It is of great importance, however, regardless of which procedure is to be performed, to choose a surgeon who has extensive experience in performing this surgery. There is an abundance of evidence that the rate of complications is considerably lower for patients whose surgeons were sufficiently experienced. This recommendation is also put forth by the International Society of Lymphology.

Risk of Lymphedema and Breast Cancer Treatments

- Risk of lymphedema following standard ALND is approximately 50-56%. Risk of lymphedema increases with the number of lymph nodes removed during ALND.
- Risk is elevated if there is adjuvant radiotherapy to the regional lymph nodes whether it follows breast-conservation therapy (lumpectomy) or mastectomy.
- Risk is much higher for women treated with ALND followed by radiotherapy (9-40%) than for women receiving radiotherapy without ALND.
- Risk is higher for radiotherapy following ALND than radiotherapy following SLN. Evidence indicates that the risk may be reduced by 70% following SLN biopsy.
- Risk of lymphedema increases each year after initial breast cancer treatment involving lymph node dissection.
- Women who have localized breast surgery (lumpectomy) with no axillary intervention (dissection or radiation) are not at risk for developing lymphedema.

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It is thought that one cause of lymphedema may be that radiation causes cellular changes which result in fibrosis of the lymph channels. At the present time, it is not known if there are predisposing factors which may add to the risk of developing lymphedema, such as age or weight. Evidence though does indicate that tumor size and number of lymph nodes removed are positively associated with the development of lymphedema.

Complications of Lymphedema

If lymphedema remains untreated, the patient becomes at high risk for both physical illness and psychological or psychosocial issues that accompany change of body appearance and significant impact on activities of daily life. Some of the complications of untreated lymphedema include:

- Recurrent infections, especially *cellulitis* (a skin infection) and/or *lymphangitis* (infection of the lymph vessels). Cellulitis occurs in up to 50% of patients with lymphedema and is caused by a common pathogen called *beta-hemolytic streptococcus*. Patients are highly prone to reinfection since there is an inadequate response of the immune system which affects prevention as well as overcoming infection. Signs of infection of the skin and subcutaneous tissue include:

  - Redness
  - Elevated skin temperature
  - Pain
  - Swelling
  - Fever, chills

  It is critical that treatment for any infection be initiated immediately since, if left untreated, localized infection can result in abscess, tissue degeneration, and/or sepsis (generalized infection) which is much more difficult to treat.

- Progressive trophic changes to the skin and resulting *elephantiasis* (stage III lymphedema)

- Progressive damage to the lymphatic vessels
- Cosmetic and structural body changes
- Deep vein thrombosis
- Pain due to:

  - Pressure on nerves in area of swelling
  - Muscle involvement such as loss of muscle tissue or scarring

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- *Lymphangiosarcoma* - cancer of the lymph system. There is a 10% risk of developing this condition following 10 years or more of chronic lymphedema. It is commonly observed in post-mastectomy lymphedema (Stewart-Trees Syndrome). The incidence is approximately 0.5% following radical mastectomy. It begins with a red/purple discoloration of the skin. The tumor is highly aggressive and carries a poor prognosis.

Risk Factors for Secondary Lymphedema

- Breast cancer patients are especially at risk of developing secondary lymphedema following surgery (mastectomy or lumpectomy) together with lymph node dissection, and/or cancer radiation therapy to the region of the axillary nodes. It has been estimated that secondary lymphedema develops in 10-40% of breast cancer patients.

- Surgical removal of lymph nodes or radiation therapy following any type of cancer including breast cancer (most common), pelvic area cancers, prostate cancer, or melanoma - areas involving the armpit, groin/pelvis, or head/neck area. The risk of lymphedema increases with the number of lymph nodes removed.

- Cancer involving the lymph nodes (lymphomas)

    - Tumors compressing lymph ducts, such as abdominal or pelvic tumors or tumor invasion of the lymph system.

- Infection or trauma causing a blockage of the lymphatic system

- Chronic venous insufficiency causing venous stasis (slow blood circulation usually in the extremities)

- *Filariasis* - a group of tropical diseases caused by various parasitic roundworms and their larvae that burrow into the lymphatics and are transmitted to humans through a mosquito bite. The parasites can reach 8 cm. in length and usually nest in lymph nodes. This disease occurs primarily in developing countries (tropical and subtropical areas of Southeast Asia, South America, Africa, and the Pacific Islands).

Incidence of Lymphedema

According to the World Health Organization (WHO), 1.1 billion people, or 20% of the world population, live in areas where they are at high risk for developing filariasis. The WHO estimates that 120 million have the condition and that approximately 30% of them show signs of lymphedema.

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In the US, the highest incidence of lymphedema is seen following surgery for breast cancer, particularly after undergoing post-surgical radiation therapy. It is estimated that 10-40% of this patient population develops lymphedema. The prevalence of lymphedema in women treated for breast cancer is thought to be approximately 25-30%. Estimates are that overall, lymphedema affects approximately 0.13 percent of the general US population and that number rises to 0.5 percent for those over 65 years of age.

The incidence of lymphedema is thought to be increasing because of rising survival rates from breast cancer and later developing cases of lymphedema are increasingly reported. Since the latency period of lymphedema can be several years, extended survival will increase the incidence of secondary lymphedema.

Lower Limb Lymphedema

Lower limb lymphedema accounts for the most cases of lymphedema (80%) It can be seen at any age and in approximately 65% of cases, the lymphedema is unilateral. It is found in both men and women. The typical pattern of involvement is that lymphedema is initially seen in the distal part of the leg (towards the feet) and extends proximally over time. Symptoms usually begin with painless swelling but there may be a sensation of heaviness or fullness in the leg particularly in hot weather or at the end of the day. As with upper limb lymphedema, the swelling is initially pitted and skin is soft but over time the subcutaneous tissue becomes fibrotic resulting in no pitting when pressure is applied. The spread of the edema usually takes place in the first year, though enlargement of the limb can continue if treatment is not initiated. The progression of symptoms is similar to upper limb lymphedema.

Diagnosis of Lymphedema

Signs and Symptoms

Every patient who has had cancer surgery or radiation in the breast/armpit region, pelvic/groin region, or abdominal region must be very vigilant for early signs of lymphedema. These may include:

- A sense of tightness in the skin of a limb
- A heavy feeling in a limb
- A change in flexibility of joints such as the hand, wrist, or ankle
- Tightness of jewelry such as a ring or bracelet without weight gain
- One limb appearing larger than the other

Clinical features of lymphedema include:

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- Localized, soft swelling (edema) of the skin and subcutaneous tissue
- Subcutaneous tissue changes (fibrotic)
- Skin changes which occur over time including *hyperkeratosis* (skin thickening) and *papillomatosis* (rough skin)
- In severe cases, the skin can break down and lymph fluid can escape from the wound which increases the risk of infection
- Swelling is usually painless in the early stage of the disease but some people report pain or sensations of heaviness or aching
- Positive Stemmers sign - skin between 2nd and 3rd toes or fingers cannot be lifted up
- Reduced joint flexibility as the physical weight and size of joint increase resulting in reduced dexterity in daily activities, such as driving and washing.
- Increased skin turgor (an abnormality in the skin's ability to change shape and return to normal; change in elasticity of the skin)

Progression of Lymphedema

The early stages of lymphedema are characterized by soft skin and pitting edema where the skin yields to finger pressure and remains temporarily pitted. Initially, the swelling may be intermittent and may be accompanied by a sense of puffiness or heaviness in the arm. At this point, lymphedema is typically highly responsive to therapy. If not treated, however, the increasing pressure of fluid accumulation causes expansion of the lymph vessels which then allows lymph to reverse flow back into the tissue. This may result in pain, redness, heating of the limb, and swelling as well as skin changes from soft, pliant skin to hard and stiff skin. At this point, the lymphedema usually does not respond to conservative treatment any more. Early lymphedema may last for a number of years but eventually will progress if ignored and untreated to become a chronic late stage condition.

As fluid begins to accumulate in the interstitial spaces, massive swelling of the lymph vessels in the limb develops. At this point, the lymphedema is described as "pitting" which means that if a finger is pressed into the skin, a depression will remain temporarily. As the condition progresses, the accumulation of protein and fluid also causes an inflammatory reaction which causes the production of fibrotic tissue (tough fibrous tissue) at which point fibrosis and induration (hardness) develop. When a finger is pressed into the skin at this point, the skin is "non-pitting" meaning that the tough tissue underneath the surface is no longer flexible.

The skin becomes thickened and develops *peau d'orange*, a dimpled appearance which is caused by congested dermal lymphatics. Scaly and /or warty deposits appear on the skin. The skin may also crack or furrow and where that occurs, the skin can become a site for debris and bacteria. This may cause *lymphorrhea*, or the leakage of lymph onto the surface of the skin.

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When the lymphatic system is compromised, and fluid begins to accumulate, the lymphangions try to overcome any blockage by straining to propel the fluid forward but eventually they become overwhelmed and stop functioning. Sometimes the lymphatic system compensates by either creating new branches that connect to other lymph vessels or by increasing the functional level of existing vessels. This usually delays the appearance of symptoms.

At the point where the lymphangions are overwhelmed and can not longer propel the fluid forward, the symptoms of lymphedema being to appear. The walls of the vessels become fibrotic and clots can form which reduces any remaining function. The lymph nodes harden and shrink.

It is thought that the progression of lymphedema may be related to recurrent inflammatory episodes, sometimes caused by bacterial invasion through compromised skin. This further damages the lymphatic system which is already overwhelmed and unable to cope and results in *dematolymphadenopathy* - i.e., infection starts in the skin and moves inward to the lymphatics. Also, inflammatory cells in the skin produce cytokines and growth factors in response to damage to its outer layer (epidermis) and these promote and stimulate the growth of fibrotic tissue and fat. Thus, in later stages of lymphedema, enlargement is not due so much to fluid accumulation as it is to hugely increased amounts of tissue.

As lymphedema progresses, the impact on daily life increases and what begins as a feeling of fullness or mild discomfort may evolve into reduced range of motion of the limb, joint immobility, pain, skin changes, and predisposition to infection. Skin hardens and the prolonged exposure to protein-rich fluid causes an increase in production of collagen, fatty tissue, and connective tissue. This leads to the thickening of the skin and subcutaneous tissue beneath it. The vessel walls thicken, elasticity is reduced, and there is a proliferation of inflammatory cells. This, in turn, leads to increases of fibrous tissue which gives the hard and indurate feel to the limb. Crevices in the skin form as some parts of the limb swell more than others. When this occurs to an extreme, the condition is known as *elephantiasis* (Stage III lymphedema).

Skin Changes

Chronic or longstanding lymphedema typically causes significant changes in skin texture appearance including:

- Dry skin due to swelling which evolves into rough, scaly, and flakey skin
- Taut, shiny skin
- Skinfolds - folds and crevices that appear due to uneven swelling in the limb
- *Hyperkeratosis* - horny, scaly build-up on the skin surface which gives a wart-like appearance. It is caused by a build-up of the stratum corneum layer of skin which is the outermost layer of the epidermis and is made of dead, flat skin cells.

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- *Papillomatosis* - lymph nodules that protrude through the skin and give a cobblestone appearance. It is caused by dilated and distended skin lymphatics which are surrounded by fibrotic tissue.
- *Lymphangioma* - damaged deeper lymphatic vessels become dilated and bulge into the skin giving an appearance of blisters. This is an indication of compromised lymph flow deeper in the lymphatic system
- *Lymphorrhea* - lymph leaks from the build up of fluid under the skin or from a break in the skin. Large amounts of liquid appear on the skin and trickle away from the opening.

As the skin changes evolve and skinfolds increase, turgor (abnormality in the skin's ability to change shape and return to normal), papillomatosis and hyperkeratosis give the skin a thickened texture resembling elephant hide, a condition called elephantiasis. This is seen more often with lymphedema in the lower limbs than in the arms.

If left untreated or uncontrolled, lymphedema can lead to severe complications including:

- Reduced limb function
- Recurrent infections
- Lymphangitis - inflammation of the lymphatic vessels
- Lymphangiosarcoma

Lower limb lymphedema progresses in a similar fashion to upper limb lymphedema. It begins with non-pitting, soft skin edema and asymmetry on the leg. With time, skin changes such as hyperkeratosis and papillomatosis develop and skin turgor increases. It is associated with recurrent infections, cellulitis, and lymphangitis. The breakdown of skin typically entails lymph dripping out of the breaks in the skin, which increases the likelihood of infection. Lymphangiosarcoma is rare.

Grading of Lymphedema

Although the system used for the classification of lymphedema is not universally accepted, the International Society of Lymphology (ISL) issued a consensus statement in 2003 in which it listed a consensus statement regarding diagnosis and treatment of lymphedema. This "best judgment" is accepted by most members of the International Society of Lymphology. The ILS notes that there are four stages of lymphedema:

Stage 0

This is a latent, subclinical condition where there is no overt swelling but lymphatic vessels have been injured and lymphatic pathways disrupted. Stage 0 can exist for several years.

Stage I

This is described as early stage lymphedema where there is fluid accumulation which

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resolves with elevation of the limb and pitting may be present.

Stage II
This stage is characterized by pitting when the skin is pressed and elevation alone no longer resolves the swelling. Late Stage II involves the formation of fibrosis and less evidence of pitting when skin is pressed.

Stage III
This is a late stage of lymphedema and is also called *lymphostatic elephantiasis*. At this point there is no pitting, but one or more skin changes, such as fat deposits, warty overgrowths, and acanthosis (a benign thickening of the skin) may appear.

The severity of each stage can be determined by measuring the volume differences between the affected limb and healthy limb.

<20% increase of one limb - indicates minimal severity 20-40% increase - indicates moderate severity

40% increase - indicates a severe stage of lymphedema

Efforts are underway to establish universally accepted guidelines regarding the classification of lymphedema based on additional parameters such as degree of lymph node dysfunction, rate and type of back flow of lymph, and genetic markers.

To read more about the ISL guidelines, please follow this link:
http://www.u.arizona.edu/~witte/ISL.htm

Differential Diagnosis of Lymphedema

Edema or swelling in a limb can be a secondary manifestation of other medical conditions and must be ruled out before a definite diagnosis of lymphedema can be established. Some of the conditions which need to be eliminated include:

- *Deep vein thrombosis* (DVT) - blood clot usually in the leg which causes an obstruction of venous flow and results in a swollen, warm, painful, calf. Edema is very soft and pitting in nature. It is most often seen following conditions such as recent surgery, immobility, or malignancy. The long term consequence of DVT is chronic venous insufficiency as described below.

- *Chronic venous insufficiency* - a condition in which the absence of or damaged valves or formation of a blood clot in the leg veins causes swelling or pooling of blood in the legs. It is also sometimes referred to as *postphlebotic* and *postthrombotic* syndrome and

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involves the venous networks of the lower extremities. Symptoms include:

- Aching in the legs while sitting or standing
- Chronic itching of the leg
- Discoloration of the skin (dusky blue)
- Venous engorgement
- Varicose veins

- *Myxedema* - a special type of edema which develops due to thyroid disease and caused by abnormal deposits of a mucinous substance under the skin. It is characterized by:

  - Brittle uneven nails
  - Rough skin on knees, soles of the feet, palms of the hands, or elbows
  - Dull, thin hair
  - Discoloration of the skin (yellow/orange)
  - Reduced sweating

- *Lipedema* - this is associated with lower limb lymphedema and is caused by accumulation of fat in the subcutaneous regions usually between the pelvis and ankle. It is characterized by:

  - Swelling of legs(s) but feet are spared
  - Negative Stemmer sign - skin on the upper side of the foot at the base of the 2nd and 3rd toes can be lifted up
  - Age-related - typically appears within 1-2 years of puberty
  - Painful swelling
  - Bruising is common
  - Affects females more than males

- Recurrent cancer - edema due to recurrence of cancer is characterized by:

  - Rapid development and progression
  - Begins centrally in the body and not in the peripheral limbs
  - Skin is not soft and pitting as it is in early lymphedema

- Swelling following arterial reconstruction for bypass surgery - this is common and often associated with thrombus in the veins of the legs. Swelling usually lasts up to 3 months.

- Congestive heart failure - loss of pumping power by the heart results in fluids collecting in the body which overwhelms the heart and causes heart failure
- Kidney failure - loss of the ability of the kidneys to perform its functions such as concentrating urine, excreting waste
- Idiopathic edema - swelling of unknown cause
- *Hypoalbunemia* - abnormally low concentration of albumin in the blood which results in

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edema of the feet, abdomen, lungs, or other areas of the body.

'agnostic Testing

The diagnosis of lymphedema is usually based on a patient's medical history and clinical presentation. The examination includes:

- Clinical examination
- Imaging studies

Clinical Examination

In order to accurately assess the diagnosis of lymphedema, the physician must gather detailed information including:

- History of past surgery
- Time that elapsed between the surgery and the onset of lymphedema
- History of infections
- Any changes the patient noticed in the edematous limb
- Medications that the patient is taking or was taking in the recent past

In addition, the clinician will conduct a thorough examination of the patient and especially of the edematous limb and will focus on aspects such as:

- Limb assessment
    - Comparison of both limbs and measurement of circumference with a tape measure at several places along the limb. Any difference between the limbs greater than 2 cm. is considered to be indicative of lymphedema.
    - Is the lymphedema bilateral or unilateral?
    - Is there pitting?
    - Has fibrosis developed?
    - Can any changes in skin texture be documented such as *peau d'orange* (dimpled skin)?
    - Swelling in the dorsum of the foot (for lower limb lymphedema)
    - "squared off" appearance of toes in the affected foot
    - Signs of hyperkeratosis (thickening of the outer layer of skin) or papillomatosis (multiple benign tumors on the skin)
    - Presence of the Stemmers sign - sign is positive if one cannot pick up the flesh at the base of the 2nd toe or finger. A positive sign is an indicator of advanced lymphedema.
    - Signs of infection such as cellulitis or fungus infection
    - Signs of breaks in the skin, especially in the deep folds between the digits on the affected limb
    - Signs of elephantiasis

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- Presence of pain or discomfort (thought to be present in up to 50% of patients)
- Range of motion of the limb
- The degree of excess limb volume
- Palpating the lymph nodes to check for signs of lymphadenopathy
- Photographs of the limb for future comparison
- Evaluation of the body quadrant to carefully assess the borders of the swelling

- Severity of Lymphedema:

  - Measurement of circumference of involved limb in several places and comparison to the contralateral limb. This is the most popular and most widely used method to determine the severity of lymphedema
  - Volume displacement of water - this is actually the most accurate measure for lymphedema of the upper and lower limbs
  - Tissue response to pressure (tonicity) compared to the contralateral limb
  - *Bioelectrical impedance* quantifies total body fluid and extracellular fluid in the extremity. It directly measures fluid gain or loss
  - Patient questionnaires - patients self-evaluate the severity of lymphedema as it impacts on their quality of life and daily activities

Efforts are underway to standardize the diagnosis and staging of lymphedema. Many of these nical features may help in the differential diagnosis of lymphedema. If there is a need to confirm the diagnosis or to differentiate lymphedema from swelling due to other causes, there are some imaging modalities which may be used. Imaging scans are also useful for determining the extent of remaining lymph function as well as helping determine aspects of treatment.

Imaging Studies

Imaging modalities are very useful in the diagnosis of lymphedema and may be used alone or in combination in order to reach a definitive diagnosis. They include:

- *Lymphoscintigram*
- Computed Tomography (CT) and Magnetic Resonance Imaging (MRI)
- Ultrasound
- Duplex Ultrasound

Lymphoscintigram

This is a diagnostic test that uses a small amount of radioactive material (tracer) to visualize the drainage of fluid by the lymphatic system. This is considered the "gold standard" of imaging modalities for lymphedema and determines functional as well as morphological (anatomical) changes. It is considered the safest and most accepted test for the diagnosis of lymphedema. A radioisotope is injected between the fingers or toes of the effected limb and the movement of that cer is followed on a gamma camera. It is equally accurate for upper and lower limb

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lymphedema.

The test measures the overall function of the lymphatic system including lymph movement and lymph drainage and is useful for imaging lymphatic abnormalities. Lymphoscintigraphy may identify:

- Pathways of lymphatic draining
- Collateral lymph channels
- Backflow (reverse flow) of lymph
- Number of lymph nodes involved
- The speed at which the radioactive substance clears through the lymph system
- The severity of the lymphatic obstruction
- Demarcation of the anatomy and status of lymph vessels
- Differentiation between lower limb edema due to lymph and:

    - Edema of venous origin
    - Postthrombotic disease
    - Lipedema
    - Arterial reconstruction following bypass surgery

Currently there are no universal standards regarding standardization of various components of the procedure including which radiotracers to use, their dose, and the volume of the injection. Even so, the imaging is considered reliable and can usually be replicated. Lymphoscintigraphy has basically replaced lymphangiography which was associated with many complications.

Computed Tomography (CT) and Magnetic Resonance Imaging (MRI)

These imaging tests are useful for evaluating swelling that is caused by chronic venous insufficiency in the lower limb, lipedema and DVT. CT can visualize aspects such as thickened skin of the calf, increased fat density, and a honeycomb appearance typical of lymphedema. Though some clinicians advocate using CT or MRI to aid in diagnosis, their superiority over lymphscintigraphy has not been proven. Theses modalities may be especially effective if a cancerous tumor is suspected.

Ultrasound

This is a technique of producing an image through the use of high-frequency sound waves. In cases of lymphedema, ultrasound is used to measure changes in thickness of the skin due to swelling.

Duplex Ultrasound

This is a specialized type of ultrasound that may be used in patients with lower extremity swelling to measure the degree of impedance of venous return. It evaluates the flow of

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lymph and venous vessels and can also establish the presence of a deep vein thrombosis which may be the cause of the edematous limb.

Treatment Options for Lymphedema

Objectives of Treatment

The objectives of treatment of lymphedema include:

- Prevent progression of lymphedema (e.g. breakdown of skin infection)
- Encourage the flow of lymph through unaffected vessels
- Help patients cope with the psychological aspects of lymphedema
- Improve the patient's overall quality of life

An essential aspect of lymphedema treatment is to educate the patient about the condition and teach preventive measures to minimize or prevent serious complications. Patient education is an important factor in the management of lymphedema in order to better control the condition and prevent complications. Management of lymphedema is a life long endeavor and the more the patient is familiar with the condition, treatment, and parameters of risk, the better and more effectively they can control the progression of the disease.

Currently, there is no general consensus among doctors regarding a uniform, standard treatment of lymphedema, although conservative treatment is typically initiated before more invasive approaches are considered. The lack of controlled clinical trials in this area is one reason for the lack of consensus. Treatment options are individualized to the patient's specific situation and take into account a variety of factors including the medical history, the extent and severity of the lymphedema, and the patient's overall health and lifestyle.

Treatment for lymphedema is a multidisciplinary task and involves several healthcare professionals including:

- Lymphologist - doctor who is a specialist in lymphedema
- Nurse
- Lymphedema therapist - may be an occupational therapist, physical therapist, or massage therapist all of whom should be specially trained in treatment of lymphedema. As yet, there is no national certification of lymphedema therapists but the National Lymphedema Network recommends that therapists undergo a minimum of 135 hours of formal training and they also provide a partial listing of therapists who have conformed to these recommendations. For further information, please follow this link: http://www.lymphnet.org/pdfDocs/trainingnln.pdf
- Psychologist - may be needed to help the patient cope with issues resulting from the significant cosmetic change that can occur in a limb, such as the size and skin changes.

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Self image and social issues can become quite overwhelming for the patient and they need to be addressed in order to minimize the impact of lymphedema on daily functioning.
- Other related professionals related to many issues that the patient may have to deal with, such as skin problems, chronic wound care, loss of employment or reduced income, and reduced quality of life.

It is crucial for the patient to be a full partner in their treatment and to be well educated actively participate in their rehabilitation, treatment, prevention of complications, and safeguarding of the affected limb. The ISL notes that the most accurate indicator of treatment efficacy is the measurement of limb volume before, during, and after treatment.

In general, the treatment options for lymphedema include:

- Complete Decongestive Physiotherapy
- Pneumatic Pumps
- Drug Therapy
- Surgical Therapy

It is important for therapy to start as early and as quickly as possible to minimize damage and progression to fibrosclerotic changes in the tissue as these are irreversible. Strict compliance to treatment protocols is essential even though they may be uncomfortable, inconvenient, or time ısuming. Treatment continues throughout the lifetime of the patient.

Complete Decongestive Physiotherapy

Complete decongestive physiotherapy (CDP) has gained popularity as an effective treatment for lymphedema and aggressive implementation has become the mainstay of all therapy for lymphedema. Complete decongestive physiotherapy consists of the following four inidividual components:

- Manual Lymph Drainage
- Multi-layer compression bandaging
- Exercise therapy
- Meticulous skin/nail care

The objective of CDP is to:

- Encourage lymph movement
- Reduce fibrotic tissue
- Improve the shape of the limb for a better fit for compression sleeve or stocking
- Reverse skin condition

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Complete decongestive physiotherapy has been shown to be very effective in reducing limb volume in several studies. Data indicates that it can lead to a 55-60% reduction in volume in upper extremities and up to 65% reduction in the lower extremities for up to 9 months after initiation of therapy.

CDP in contraindicated in the presence or development of:

- Cellulitis
- Acute bronchitis
- Deep vein thrombosis
- Infection

If the lymphedema is located in an area where therapy needs to be administered in the abdominal area, such as following surgery in the pelvic or groin region, therapy is discontinued in the presence of:

- Pregnancy
- Aortic aneurysm
- Inflammatory bowel disease
- Abdominal pain

Manual Lymph Drainage

Manual lymph drainage (MLD) is a gentle manual treatment technique that is designed to:

- Encourage the development of collateral lymph vessels
- Redirect lymph flow to unobstructed cutaneous lymphatic vessels
- Stimulate the flow of lymph from the congested area where it has accumulated into more centrally located lymphatic vessels that eventually return the lymph back into the venous circulation
- Enhance lymphatic contractility

MLD was developed in 1932 by Dr. E. Vodder, a Danish physician, and his wife. It differs from massage therapy in both technique as well as purpose. Whereas the purpose of massage therapy is to work the "kinks" and "knots" out of tight, tense muscle groups, the focus of MLD is strictly the lymphatic system and seeks to re-route the lymph flow around the blocked areas and direct it towards the lymphatic system. This technique of gentle massage is the only form of therapy that affects the contractility of the lymph vessels. Massage that is too aggressive or too deep can lead to spasm of the lymphatic vessels which can exacerbate the edema.

Massage begins at the neck and proceeds towards the side of the trunk adjacent to the swollen limb. This progression prepares the collateral lymph routes for accommodating the

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increased lymph which will drain away from the limb. The light, rhythmic massage movements move the skin and stimulate the underlying vessels in a specific direction.

The treatment entails gentle, rhythmic, moving and stretching the skin to promote absorption of fluid from interstitial spaces into any functioning lymphatic vessels. If lymph nodes are compromised (not just the vessels) it is important to establish alternative routes for the lymph to flow by rhythmically massaging the area around the damaged nodes. Otherwise, the lymph that flows into the vessels following MLD will have nowhere to drain. Initially, MLD is done once a day and then is slowly reduced as the patient responds. It is administered by professionals, such as physical or occupational therapists, who have undergone proper training in this technique as established by the National Lymphedema Network.

MLD is contraindicated for patients with congestive heart failure, deep vein thrombosis (DVT) or active infection.

Simple lymph drainage (SLD) is a modified form of MLD that the patient or a caregiver can undertake at home. The therapist teaches the patient or caregiver gentle massage movements starting form the area furthest away from the congestion and working towards the torso. Simple lymph drainage is typically performed once a day for approximately 20 minutes and it is essential that it be done regularly. It is important for softening fibrotic tissue and encourages lymph flow. When edema is present in the midline of the body, (e.g., following genital, breast, head, or neck surgery) MLD and SLD are the most useful methods of treatment since placement of a compression garment is impossible.

Compression

Compression of the edematous limb is essential as it stimulates muscle movement which forces the lymph to move through the vessels and help reduce stasis. In addition, it serves to:

- Encourage the drainage of lymph through constant pressure on the limb
- Prevent accumulation of lymph which would increase the swelling
- Create a pressure gradient (pressure changes over an area of tissue) on soft tissue during movement of the limb
- Maintain the size and shape of the limb when the edema has responded to acute treatment

Compression is measured in mmHg (millimeters of mercury) and can be delivered two ways. The treatment chosen depends on the stage of lymphedema and the level of swelling:

- Multilayer bandaging
- Compression garments

Multilayer Bandaging

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Multilayer bandaging involves wrapping several layers of short-stretch bandages around the limb that is affected by lymphedema in order to create a pressure gradient on the soft-tissue during limb movement. The pressure is graduated with the greatest pressure being applied at the periphery (ankle or wrist) and gradually decreasing in intensity towards the trunk. This propels the fluid in an upward direction. The compression bandage provides a rigid support around the limb and compresses the limb only during movement but not when the limb is stationary. The variation in tissue pressure between rest and movement promotes drainage of lymph from the affected limb and also prevents further accumulation of lymph.

Foam rubber pads are interspersed among multilayers of short stretch bandages in order to apply local pressure to fibrotic areas and to create a uniform shape to the limb. This minimizes the chance of the bandages slipping out of place and also helps to evenly distribute the pressure. The combination of pressure and foam pads also encourages the breakdown of fibrotic tissue in the limb. In addition, multilayer bandaging reduces skinfolds and improves the condition of fragile skin. If the skin has breaks with resulting lymphorrhea, the multilayer bandaging is the most effective way of promoting healing of the skin.

Compression bandages are worn overnight as well. Multilayer bandaging usually follows each MLD session. Although this part of treatment is very cumbersome and impossible for a patient to do for himself, it is very effective and is an essential component of treatment in the acute stage of lymphedema. The bandages are reapplied daily in order to compensate for the change in circumference of the limb as the treatment becomes effective and the swelling is reduced.

Compression Garments

Once the initial phase of multilayer bandaging treatment has been completed and the lymphedema is stable, patients are instructed to wear compression hosiery on the affected limb which helps to maintain the size and shape of the limb by preventing swelling and enlargement. Garments have graduated compression so that the least compression is at the end of the extremity and compression increases with closer proximity to the torso. Compression hosiery comes in the form of a sleeve for the arm, a glove for the hand, and tights or stockings for the leg. Each of these garments comes with varying degrees of compression ranging from I which has the least pressure to VI which has the most. The garments are easier for the patient to put on alone and are more comfortable than multilayer bandaging.

Compressive garments provide a semi-rigid, inelastic structure around the lyphadematous limb in order to create pressure on the soft tissue during movement and prevent reaccumulation of fluid following decongestive therapy. Compression garments restore normal lymphatic function and eliminate stasis (lack of movement) of protein and fluid in the tissues by propelling fluid out of the limb with pressure. By acting like a muscle pump, the garments also increase venous and lymphatic drainage. Compression garments are worn all day and may be removed at night when the limb is elevated. The garments are typically

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custom made in order to assure proper fit and maximum efficacy since garments that are too tight can cause exacerbation of lymphedema. They must be fitted and applied only by therapists who have been specially trained.

When the patient is at rest, there is no compression. As the pressure changes with movement, lymph drainage is stimulated. The garments typically need to be replaced every 3-6 months and require a prescription. They are contraindicated in the presence of arterial disease or *postphlebotic syndrome* (a complication that may occur following deep vein thrombosis which may involve symptoms such as persistent edema and pain).

Exercise Therapy

Movement is a critical aspect of care in lymphedema since it involves pumping action of the muscles which propels the lymph forward towards drainage. Care should be taken to ensure that the therapist initiating exercise therapy for lymphedema be sufficiently trained in the management of lymphedema. Exercise of limbs affected by lymphedema helps promote the flow of lymph. Any movement of a limb requires muscle activity which promotes pumping action of the lymph. However, too much exercise increases blood flow which would also increase the levels of interstitial fluid. Thus, the best exercises during the acute phase of lymphedema are low level exercises, such as rotating an ankle, deep abdominal breathing, and moving the arm in a directed fashion, which promote lymph flow. Maintaining muscle tone and range of movement are important also in increasing the flow of lymph. Exercise and deep breathing must be maintained life-long in the ongoing management of lymphedema.

Typically, exercise program should include flexibility, strengthening, and aerobic training. Exercise is usually custom designed and is carried out with compression on the affected limb by use of either multilayer bandages or compression garments. Deep breathing exercises which "work" the chest muscles also help promote the flow of lymph. The physical therapist or doctor will usually prescribe gentle exercise that will stimulate the pumping action of the lymphatic system. Exercise is typically done on a daily basis. Many patients with lymphedema were actively involved in regular sports activities (e.g., running, tennis, racquetball, etc.) before the onset of their lymphedema and may wish to resume these activities as soon as they are physically capable. It is important to talk with your doctor and physical therapist about the potential risks and benefits before resuming your normal exercise routine. Factors such as rough contact, trauma, and excessive activity must be seriously considered.

Another very important element that the patient with lymphedema must keep in mind is the positioning of the edematous limb. During rest, the limb should be elevated or at least in a horizontal position. During sleep, it should always be elevated.

Skin Care

Skin care is an important part of the multidimensional treatment for lymphedema and should

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be carried out in conjunction with other treatments. One vital area of education for patients with lymphedema is appropriate skin care to prevent breakdown of the skin and reduce the risk of infection. Skin acts as a barrier to infection and any breach in the skin is an entry point for bacteria to infiltrate. Since the lymphatic system, which normally acts upon invading bacteria, is compromised the patient with lymphedema is at significant risk of infection. Skin care must be maintained during the lifetime of the patient. Some suggestions to reduce the risk of infection include:

- Keep the skin clean to prevent or minimize the invasion of bacteria
- When cleansing the skin use a mild, non-abrasive soap.
- Avoid cuts or breaks in the skin to prevent bacteria and fungi from penetrating the skin.
- Protect the skin and keep it moist by applying a moisturizer on a regular basis. Ask your doctor or dermatologist to recommend a skin moisturizer which helps maintain the vitality and integrity of the skin. When skin is well hydrated, the outer layer of skin cells become plump - they swell up and fit together better which helps eliminate cracks in the skin. Moisturizers may be differentiated by the ratio of oil to water that they contain. Those with higher oil content trap more moisture in the skin.
    - Moisturizer should be applied at least twice daily but should not be vigorously rubbed on the skin.
    - Moisturizer should be applied generously.
- When drying the skin, avoid rubbing; rather, pat dry each area. Special care should be given to dry areas between the fingers and toes or wherever there are creases or folds that could remain damp if not specifically dried.
- Frequently inspect the skin looking for any cuts or abrasions that occur which should be immediately cleaned and then treated with a topical antibiotic.
- Avoid burns to the skin.
- Avoid skin exposure to extreme heat (saunas, hot-tubs, steam rooms, hot/humid weather, sunburn)
- Use sunscreen generously when going outside

Since an inflammatory response can be elicited by any skin damage, not only bacterial invasion, it is important also to protect the skin from injury. Thus, activities such as blood tests, injections, or blood pressure cuffs should be applied on the arm that is not affected by

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lymphedema.

In the presence of hyperkeratosis, patients must intensively rehydrate the skin with oil-based creams. They should be massaged gently into the skin and, eventually, scaling areas are able to be lifted off the skin. Papillomatosis requires emollients, MLD, and compression. MLD and compression are discontinued in the presence of any skin infection.

If skin complications occur, they must be evaluated and dealt with immediately and all forms of treatment (except for elevation) are suspended temporarily. Skin complications may include:

- *Lymphorrhea* - the condition where lymph leaks out through breaks in the skin may be treated with special dressings, multilayer bandaging, and the use of highly lubricating creams to act as a barrier to the skin.
- *Hyperkeratosis* - the warty, scaly condition may be treated with special ointments containing paraffin. This enables the scales and warts to be lifted easily off the skin without damaging the skin underneath or the superficial lymphatic vessels.
- *Cellulitis* is usually treated with rest and antibiotics.
- *Athlete's foot* is a fungal infection and another port of entry for bacterial invasion. It is treated seriously with topical and/or oral medications. It is important to take measures to prevent its development by using cotton socks, ensuring adequate ventilation around the toes, and drying the area when it gets wet. Athlete's foot is more of an issue for individuals with lower limb lymphedema than for those with lymphedema in other parts of the body.

Pneumatic Pumps

Pneumatic pumps, also known as *pneumatic compression garments*, were originally developed for the treatment of chronic venous insufficiency. These devices resemble a blood pressure cuff and contain a compressor that automatically inflates and deflates the garment to a predetermined pressure. The older "intermittent" pneumatic pumps provide even pressure throughout the limb. The newer devices, known as *sequential pneumatic pumps*, provide sequential compression with varying degrees of pressure along the length of the affected limb.

The pneumatic pump involves the use of a single- or multi- chamber pump which externally pumps the fluid away from the extremity towards the torso. It has been compared to "milking" the limb. However, as the fluid is pumped away from the extremity, it accumulates in the trunk at the base of the extremity. In order to prevent the fluid from accumulating at that point, manual drainage must be initiated to decompress the root of the limb. Though efficacy of the pump is controversial, some clinicians feel that the sequential pneumatic pump is most effective before subcutaneous fibrosclerotic changes take place and

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that the pneumatic pump can actually prevent its development. The treatment is performed either at home or as an outpatient setting.

At one time, pneumatic compression pumps were a standard treatment for lymphedema in the United States, however, their use today is controversial. While some studies have shown that these devices are effective for the treatment of lymphedema, other studies have found them not to be effective and they may even cause harm to the limb. Some studies have shown that fluid flows right back into the edematous limb with the cessation of treatment. The absence of clear guidelines and the lack of standardized treatment protocols has contributed to the controversy surrounding the routine use of these devices in the management of lymphedema.

Treatment with pneumatic pumps is not very popular among patients because:

- It is very expensive
- It is very time consuming
- It does not help break down fibrotic tissue

Pneumatic compression is contraindicated if several conditions are present including, ischemia, reduced blood supply to the limb, congestive heart failure, or deep vein thrombosis.

Drug Therapy

- *Antibiotics* are prescribed for patients with lymphedema at the first sign of *cellulitis*. Cellulitis is an acute inflammation of the connective tissue of skin caused by a bacterial infection.

- *Diuretics* have long been prescribed for patients with lymphedema, however, their use is controversial because they can actually contribute to an increase in the degree of edema by increasing the high-protein concentration in the interstitial spaces. This leads to increased fibrosis and hardening of the skin. Most experts in the field agree that diuretics should not be used as a primary treatment for lymphedema.

- *Benzopyrones* (coumarin and flavonoids) - These drugs have been studied extensively in Australia and Europe for the treatment of lymphedema. Coumarin stimulates macrophages (white blood cells) which break down proteins and also stimulates other elements of the immune system that may promote absorption of protein. The smaller protein fragments pass more easily into functioning venous vessels which helps drain the fluid. Studies have suggested that coumarin is effective in reducing edema in arms, legs, and filarial elephantiasis with a reduction of fluid volume of up to 55%. Onset of positive results is slow and more recent research raises questions about its efficacy in

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general. Moreover, coumarin has been associated with acute liver toxicity and hepatitis. Coumarin is not approved for human use by the U.S. Food and Drug Administration for the treatment of lymphedema.

- *Steroids* - Although steroids are commonly used to treat inflammatory conditions, their use for the treatment of lymphedema is not recommended because they can cause fluid retention and suppress the immune system, thereby, increasing the risk of infections.

The ISL notes that:

- Diuretics may be of benefit under certain circumstances in the initial phases of Complete Decongestive Physiotherapy (CDP) treatment
- Benzopyrones, such as coumarin may be helpful as adjunct treatment but certainly not to replace CDP
- Antibiotics should be used for acute infection and should be considered prophylactically for prevention of recurrent infections
- Medications for lymphedema due to filariasis should include diethylcarbamazine, albendazole, and ivermectin

Surgical Therapy

:gery for lymphedema is usually considered as a treatment option only in rare cases that have not responded to conservative treatments and where the size of the limb and the amount of fibrosis is unacceptable (e.g., elephantiasis). Surgery is a palliative treatment and does not eliminate the need for mechanical drainage following the procedure. The goal of surgery is to reduce the volume of the fluid in the limb in order to improve lymphatic function. To date, there has not been any evidence to document long-term favorable results. Surgery may also be effective for removing excess skin following intensive CDP.

There are two general types of surgical procedures that have been used for the treatment of lymphedema:

- Microsurgical techniques - these techniques augment the rate of return of the lymph to blood circulation. There are two methods used that the ILS describes:

    - *Reconstructive method* - which involves lymph vessel transplantation
    - *Derivative method* - which attempts to restore normal flow of lymph with the creation of new anastomoses (openings) using lympho-venous shunts and/or lymphonodal shunts between existing lymph vessels or between lymphatic and venous vessels.

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The ISL notes that microsurgery appears promising but long term efficacy has not been clearly proven.

- Excisional procedures (also called debulking) are used to surgically remove excess tissue and skin thereby restoring the affected limb to a more normal size. There are two types of excisional procedures, namely *staged excision* and *liposuction*. Both reduce the size of the limb but do not improve lymphatic drainage.

Staged Excision

A portion of the skin and subcutaneous tissue is removed during the initial surgery. After three months, the same procedure is performed in a different area of the extremity. Staged excision has the lowest risk of complications and is considered safe and reliable with consistent improvement.

Potential complications of surgery for lymphedema include:

- Nerve damage
- Skin necrosis
- Ulceration
- Worsening of the edema by causing damage to functioning lymphatic vessels
- Papillomatosis

Liposuction

This technique has shown promise when performed on chronic post-mastectomy lymphedema. Evidence indicates that there are sustained positive results reducing the excess volume of the arm. Some studies suggest that liposuction combined with CDP is more effective than CDP alone. Following surgery, compression therapy must be continued. The ISL recommends modified liposuction for special cases of treating non-fibrotic upper extremity lymphedema following axillary staging for breast cancer and short term results look promising.

The ISL notes that:

- It is imperative that any surgery be done by a surgeon who is highly experienced in performing surgery for lymphedema.
- Resection surgery (excision) should include removal of subcutaneous fat and excess skin.
- The disadvantage of excisional surgery is that, along with removing subcutaneous tissue, there is also a risk of the removal of superficial collateral lymph vessels that may have formed in the course of time under the skin.
- Skin folds may have to be removed following successful CDP.
- Surgery may be helpful for advanced elephantiasis.

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Phases of Treatment for Lymphedema

The International Society of Lymphology (ISL) recommends two phases of treatment for lymphedema:

- Acute intensive phase
- Maintenance phase

Acute Intensive Phase

During the acute phase of treatment, therapy is intense and frequent. In this phase, the size of the affected limb is significantly larger than the normal limb (some clinicians set the criterion at 20% larger than the contralateral limb) and the shape may be distorted. Skin changes may include skin folds, papillomatosis, and/or hyperkeratosis. Each therapist or rehabilitation center sets their own treatment schedules which may be as frequent as twice a day, 5 days a week, and may continue for 4 weeks. Approximately 50% of volume reduction may be achieved though CDP.

The objectives in the acute phase of treatment include:

- Reducing the size of the limb
- Stimulating lymphatic vessels in the contralateral limb and trunk
- Stimulating contractility of lymph vessels to improve movement of lymph and break up fibrotic tissue
- Improving the condition of the skin

Treatment consists of a combination of:

- Manual lymphatic drainage
- Skin care
- Gentle exercise, including range of motion
- Compression with multilayered bandages

Maintenance Phase

When the lymphedema stabilizes and the limb returns to its normal size (for some clinicians the criterion is less than 20% larger than the size of the contralateral limb) and the shape of the limb returns to normal and the skin has softened and is predominantly pitting, the second phase of treatment, called the *maintenance phase* begins. This phase of treatment continues for the lifetime of the patient and consists of:

- Manual lymphatic drainage as needed
- Skin care
- Continued exercise

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- Compression with low stretch elastic stocking or sleeve. The ILS notes the importance of employing only trained personnel to do the multilayer wrapping.

The ISL also notes that:

- If using pneumatic compression for treatment, the sequential gradient pump is preferable and treatment must be followed by a low-stretch elastic sleeve. Gentle massage alone is of limited benefit.
- The role of thermal therapy (soaking limb in warm water) remains unclear.
- Elevation of the limb is effective in reducing swelling but should be followed by low-stretch elastic stocking.
- The efficacy of immunologic therapy (intraarterial injection of autologous lymphocytes) is unclear.
- There is no special diet for the patient with lymphedema (such as a low protein diet), but obese patients should lose weight to reduce bulk.
- Psychosocial support and ongoing effort to improve and maintain quality of life for patients with lymphedema is an integral aspect of treatment

During the maintenance phase, the frequency of treatment is reduced and the patient begins wearing a compression garment during the day and a bandage wrap at night. Eventually, the patient may use a compression sleeve or stocking during the day and nothing at night when the limb must be elevated. Otherwise, all other aspects of therapy remain the same (i.e., continued MLD, meticulous skin care, and exercise).

When lymphedema develops in the presence of severe illness, over a period of time the lymphedema may progress to a point of involving more than just the limb and may extend into the trunk of the body. The condition of the skin may deteriorate due to lymphorrhea, where lymph drips out through breaks in the skin, and the patient may complain of heaviness or reduced range of motion or limb use in general. At that point, treatment is more palliative and aimed at symptom relief rather than improving the lymphedema. Treatment consists of the same modalities used for the acute and maintenance phases but is less aggressive and is flexible to meet the needs of the patient.

Lower Limb Lymphedema

The treatment approach to lower limb lymphedema is similar to that described above in that conservative treatment is initiated immediately after diagnosis. For mild cases, limb elevation may be sufficient to reduce the swelling and, for severe cases, the treatment with complete decongestive physiotherapy (CDP) is more intense. In addition, some practitioners treat patients with heat therapy, which consists of hot water immersion, microwave, and electromagnetic irradiation. Modalities may be combined but continued compression remains essential.

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Pharmacologic treatment with benzopyrones is also effective for lower limb lymphedema but clinical trials are still lacking. Benzopyrones may also be effective for:

- Reducing edema
- Reducing the temperature of the limb
- Increasing softness of the skin
- Reduction of sensations such as heaviness
- Notably fewer incidences of secondary infection

As with conservative treatment, any pharmacologic therapy done is prescribed in combination with CDP. Some small studies indicate that CDP together with medication may be more effective than CDP alone.

Surgery is reserved for refractory cases and is always followed by the wearing of compression garments to prevent recurrence of swelling. The three types of surgical techniques are similar to those used for upper limb lymphedema and include:

- Debulking procedures - these are performed as one or two stage procedures of subcutaneous excision and skin grafting. The *Charles method*, where only the affected area of the limb is excised, may be performed or a modification of the *Homan procedure*, where the entire limb undergoes a two stage excision, may be performed. Surgery is effective for leg function, shape, and reduction of frequency of cellulitis. One of the complications which may occur as a result of debulking is the development of edema of the foot. Cosmetic outcome is thought to be better following two-stage excision.

  The major complications of debulking include:

  - Infection
  - Necrosis of the skin graft
  - Foot edema

- Bypass or microsurgical procedures - this surgery is performed on individuals who have not responded to intense medical therapy. Some procedures seem to be more effective for secondary than primary lymphedema. The various techniques include:

  - Lymphatic-venous anastomosis - a surgical connection is created between lymphatic and venous vessels
  - Lymphovenous bypass - one small study showed a reduction of arm circumference of more than 5 cm. in 70% of patients followed for 6 months with reduction of incidence of cellulitis.

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- Prophylactic surgery is performed on some patients who undergo extensive lymph node removal in the pelvic area and who are, therefore, at increased risk of developing lymphedema. In these cases, *omentoplasty*, may be performed. The omentum is a fold in the peritoneum (tissue that lines the abdomen) that surrounds abdominal organs and is very rich in lymphatics. The surgery helps the abdominal lymph drain into the peritoneal cavity where the omentum helps to absorb the lymph reducing the severity or in some cases the formation of lymphedema of the lower limbs. One study showed that while 50% (5 patients) of the control group developed lymphedema, only 16% (2 patients out of 12) of the surgical group developed postsurgical lymphedema.

Complementary Medicine

There are no studies to prove the efficacy or safety of most complementary and alternative therapies. It is important to notify your health care provider if you are using any alternative therapies, no matter how insignificant or benign they may seem.

Some of the herbal remedies mentioned in the literature that show promise for the treatment of lymphedema include:

- Horse chestnut extract - Studies with a small number of patients indicate that horse chestnut extract may strengthen vessel walls and reduce leakage of fluid into interstitial spaces.
- Some women have reported obtaining relief from:
    - Cayenne pepper
    - Juniper berries
    - Goldenrod
    - Parsley

It is very important to determine if any dietary supplements or herbal preparations may interact with other medications that you may be taking. Your physician must know of any complementary remedies you are employing, regardless of how benign they may seem.

Though there is no diet that is effective for the treatment of lymphedema, it is important that the patient eat a healthy diet in order to promote optimum functioning of the various body functions and to optimize the lymphatic and immune systems to their maximum potential.

Quality of Life Issues and Psychosocial Considerations

One of the most marked changes in the life of the lymphedema patient is adjusting to daily

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involvement in the maintenance phase of treatment and the critical commitment to ongoing compliance. It is a lifelong commitment and very intense. As a consequence, the patient must understand every aspect of their treatment, the rationale behind each component of treatment, anticipated outcomes of treatment, signs to look for which may indicate impending problems and how to respond, and under which circumstances they should contact their health care professional.

At the same time, it is also very important for the various health care professionals involved, such as the lymphologist and physical therapist, to take the time and patience to explain carefully all the parameters involved in self-care for the individual with lymphedema. In addition to discussion, they should provide the patient with written information and instructions that can be studied at home, such as lists of items to be checked for proper skin care by the patient and any other family members, friends, or caregivers who may be involved. They should demonstrate how to use any and all equipment, how to put on and remove the compression garments, and any other pertinent information. It is helpful for healthcare professionals to set short-term as well as long-term goals so that the patient can be motivated to continue with the task of self-management.

The psychological impact of lymphedema is enormous as the patient deals with skin changes, shape changes, and disability that can occur with lymphedema and can result in social isolation. The family of the patient must also adjust to a different image of a loved one. For cancer patients, there is the added fear that lymphedema is connected to recurrence of cancer since the swelling may first appear 10-20 years following surgery. It is important for patients to come to terms with living with a chronic condition that requires meticulous daily care in order to control it. The commitment factor to self help is essential.

A strong social and family support network is an important factor in helping patients with lymphedema better cope with the psychosocial aspects of the condition. For patients who cannot overcome the psychological burden of dealing with their condition, psychological intervention may be necessary. This may consist of psychological counseling, individual or group psychotherapy, cognitive behavior therapy (biofeedback), and anti-anxiety or antidepressant medications.

Patients should also be encouraged to join a lymphedema support group where they can obtain educational materials, keep up with the latest developments in lymphedema research, and share their experiences with others who are coping with the same condition. The National Lymphedema Network (www.lymphnet.org) has extensive information on ways to improve quality of life and find local resources. It is also important for the patient to purchase a special lymphedema-alert necklace or bracelet to alert healthcare professionals about their condition and avoid procedures that may cause complications.

Since patients with lymphedema may have other physical disabilities or limited dexterity due to advanced age or coexisting illness, it is important for caregivers to be included in the

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treatment plan and to be well informed about:

- The role they can play in daily care
- Responsibilities they may need to assume
- Information necessary for them to provide assistance

"Quality of Life" is a multidimensional measure of the impact of a disease or condition on daily activities and includes elements such as:

- Physical well being
- Impact of symptoms relating to the condition on daily life
- Side effects of treatment
- Psychological and social consequences of the condition.

Quality of life is usually measured using a questionnaire that the patient completes at various points beginning with diagnosis and during and/or after treatment. The standard questionnaire is called SF-36 and evaluates the impact of disease on eight areas, including:

- Physical capacity
- Physical aspects of the condition
- Social aspects
- Emotional aspects
- Mental outlook
- Pain
- Overall wellbeing

Scoring of the questionnaire is based on a scale of the patient's responses to each question ranging from 0 which is the lowest score to 100 which indicates little or no impact of lymphedema on quality of life. Quality of life scores rated by patients with lymphedema in various studies show less satisfaction in every area than people without lymphedema. In general, the greater the degree of lymphedema, the lower the quality of life scores. For example, low scores on physical aspects of the condition relate to the impairment of the limb with lymphedema. Although pain is a symptom in only approximately 50% of patients, all lymphedema patients rated that element with a low score since the feeling of tightness or continual inflammation of the limb causes ongoing distress and inconvenience. It is clear that there are many dimensions that need to be treated when a person is diagnosed with lymphedema.

One of the difficulties for women treated for breast cancer is that even when lymphedema is at an early stage and cannot be noticed by others or at a moderate stage but still not obvious, women already report a reduced quality of life. This indicates that even if lymphedema is mild and subtle, it already has significant impact. It is, therefore, important that women with breast cancer be educated regarding early signs of incipient lymphedema so that therapy can

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be initiated as early as possible, thereby, reducing risks for great enlargement of the limb and increasing their quality of life.

Patients with lymphedema face challenges that go far beyond just dealing with the physical aspects of the condition. Because lymphedema can be disfiguring and unsightly, patients must also learn to cope with the potential psychological sequelae of the condition that can have a significant impact on their psychological well-being and quality of life. Patients with lymphedema may develop a negative body image, become more socially withdrawn, and experience reduced sexual desire. Sometimes there may be genital swelling which may be humiliating to the individual and is difficult to treat. They may also experience psychological distress which can lead to:

- Anxiety
- Depression
- Anger
- Frustration
- Loss of self esteem
- Social isolation
- Problems with intimate relationships

The impact of lymphedema can be felt in other areas of daily life, including:

- Job related difficulties due to physical limitations
- Changes in travel plans that may have to be scaled back and can effect employment that involves travel
- Potential loss of income
- Changes and/or disruptions in home and family life responsibilities where others may have to participate more in everyday tasks and chores
- Changes (subtle or overt) in social relationships
- Distress over activity or exercise limitations
- Need to alter or purchase new clothing to accommodate the size of the edematous limb
- Coping with the stares of people in the street
- Inconvenience of dealing with recurrent infection and inflammation
- The burden of spending time each day being so meticulously involved with skin care and compliance with maintenance therapy for lymphedema

Attention must be paid to almost every activity of daily living either in terms of preventing further complications or in terms of controlling the lymphedema. Some of these activities include:

General Precautionary Measures

- Avoid holding heavy, over the shoulder pocketbook or carrying heavy items with the affected arm

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- Elevate the arm or leg at every opportunity
- Refrain from repetitive motion, such as scrubbing, pushing/pulling
- Don't wear tight jewelry
- Avoid temperature extremes
- Avoid smoking and maintain your ideal body weight
- Avoid crossing legs when sitting (lower extremities lymphedema)
- Avoid sitting in one position for prolonged periods of time
- Use the unaffected limb to test water temperature
- Maintain proper body weight for your build to prevent placing an extra burden on your lymphatic system

Skin Care

It is critical for patients with lymphedema to meticulously check their skin for early signs of any changes in the bony landmarks, blood vessels, or skin markings. This is crucial regardless of the stage of lymphedema for it is the only way that complications can be detected early and treatment be initiated immediately. Some suggestions include:

- The edematous limb should be kept clean and dry
- Nails should be clipped or filed and cuticles should not be cut in order to prevent any small cuts or openings in the skin around the nails
- Always use a mild, non-abrasive soap when washing hands, bathing, or showering
- Protect skin by moisturizing daily at least once or twice with creams that contain more oil than water
- Pat the skin dry (don't rub) and pay special attention to area between fingers and toes and to all skinfolds
- Frequently inspect the skin for signs of abrasions or cracks. In any are found, take precautionary care immediately by cleaning the skin and applying antibiotic ointment.
- If the patient is prone to infection, discuss with your healthcare professional whether to keep antibiotic medication in reserve at home as well as taking extra medication when traveling
- Begin treatment with antibiotics at first sign of infection
- Speak to your physician about the possibility of keeping an antibiotic or at least a prescription for an antibiotic at home or keeping it with you when you travel so that you can commence treatment as soon as the need arises
- Do not use razors to shave in order to avoid nicks or scratches.
- Wear gloves while doing any activity that could result in scratches or abrasions, such as gardening or housework
- Keep feet covered when outdoors
- Request that any medical procedure, (such as drawing blood, getting an injection, taking blood pressure) be done on the unaffected arm

Exercise

- Exercise is essential for overall health but be careful to build up intensity, duration, and

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frequency of exercise slowly in order to prevent sudden exacerbation of the edema
- When doing stretching exercises, avoid injury by starting out slowly and gradually increasing intensity
- Rest frequently
- Drink frequently
- Check the edematous limb scrupulously for any changes in size, shape, or texture.

Activity

- Increase the intensity of any activity slowly
- Participate only in sports approved by your doctor
- When swimming, take care to apply waterproof moisturizer or sunscreen before going into the water and reapply when coming out to prevent the skin from drying
- Wear something on your feet at all times if you have leg edema to prevent scratches, abrasions, or fungal infections. This is especially important in a public shower area and on a beach
- Be sure you understand the guidelines for using the compression garments when participating in any activity (e.g., before/after swimming)
- Keep the compression garment nearby since you will have to put it on when you come out of the water
- Shower or bathe after swimming to wash away any chlorine, sand, and other chemicals that might adhere to your skin. Pay special attention to drying areas that could remain damp, such as under the breasts and along skinfolds, fingers and toes
- If hiking, camping, or biking, wear protective clothing to minimize and prevent insect bites and scratches
- Rest frequently and stop at any sign of changes to the edematous limb
- Take along a first aid kit that has everything you would need if you get scratched or cut (e.g., alcohol swabs for cleaning skin, antibiotic cream, and bandages or bandaids for any cuts or scrapes)

Clothing

- Wear loose, comfortable clothing to maximize air circulation around your body. Also, loose fitting clothing may be preferred by individuals who are sensitive about the size of their limb
- Avoid elasticized garments that leave indentation marks in the skin which could damage or constrict superficial lymph vessels (e.g., underwear, socks, tight stretch cuffs on shirts or pants)
- Wear comfortable shoes that don't constrict the feet if you have lymphedema of the leg
- Try to avoid clothing that traps moisture next to your skin
- Do not wear tight jewelry

Maintaining Compression Garments

- Compression garments should be fitted only by a trained professional as compression garments come with many degrees of compression strength. A poorly fitted garment can do more harm than good.

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- Follow the suggestions of the therapist regarding how to put on the compression garments most comfortably
- Compression garments typically need to be changed (new) every 3-6 months.
- It is recommended to have 2 compression garments so that when one is being cleaned, the other is available for use
- Compression garments should be hand washed with special liquid soap that prevents damage to the elastic fibers and to the overall elasticity and compression strength of the garment.

Seasonal Temperature Fluctuations

- Avoid prolonged exposure to any extremes in temperature
- In hot weather, stay cool in breezy or well air-conditioned places
- Avoid being outside during the hottest part of the day
- If you get very hot, cool your body as soon as possible or at least the edematous limb by elevating it and wrapping it in a cold, wet towel
- Drink frequently and stay well hydrated
- Take cool or lukewarm showers or baths. Avoid cold showers.
- Wear loose non-constricting clothing
- Wear clothing that will protect you from sunburn, abrasions, and insect bites
- Use insect repellant. Natural repellants that are citronella-based may be easier on your skin.
- Use sunscreen of at least 20 SPF and apply frequently. Avoid sunburn since this adds a burden to the lymph system.
- In cold weather, avoid exposure to very cold air and when you come inside, watch for any signs of chapping, skin breaks, or increased swelling of the limb.

Air Travel

Air travel significantly impacts lymphedema due to the changes in cabin pressure during flight. When cabin pressure is reduced after takeoff, the surrounding air pressure for the passengers is lower than when they are on the ground. This reduced pressure translates into less pressure available to help push fluid from the interstitial spaces into the lymphatic system. It is, therefore, critical for the patient with lymphedema to create a situation where they can maintain sufficient pressure on the edematous limb to prevent further fluid accumulation in the tissue. This is achieved by wearing a compression garment (or compression bandaging) such as a stocking or tights for the legs or a sleeve and glove for the arms. In this way, the patient can maintain acceptable interstitial pressure and activate the pumping action of the muscles to promote the movement of the lymph.

Protecting the limb by use of compression garments is essential not just for the lymphedema patient, but also for individuals who are at high risk for lymphedema or may have latent lymphedema due to damage to lymphatics or lymph nodes, such as patients who have undergone surgery that involved removal of lymph nodes. Contact your therapist or lymphologist for detailed instructions to follow when you travel by plane.

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In addition to compression garments, precautions that may be taken by the lymphedema patient includes:

- Be careful not to carry heavy luggage or bags with the affected arm
- Wear non-constrictive clothing or jewelry
- Walk frequently during the flight to prevent pooling of fluid around the ankles and to stimulate muscle pumping
- Move your arms frequently during flight to stimulate pumping action that comes with muscle activity
- Drink plenty of water in order to stay well hydrated

Work Habits

- Move about as much as possible and avoid prolonged periods of standing or sitting.
- Keep the edematous limb elevated or at least horizontal, if possible
- Try not to cross legs since this constricts flow of lymph
- Wear proper shoes to give support for lower limb edema and avoid open sandals
- Try to practice deep abdominal breathing exercises throughout the day

New Developments

- Researchers continue to work towards identifying specific gene mutations that are associated with certain hereditary syndromes that cause lymphedema such as *lymphedema-distichiasis (LD) syndrome*, caused by mutations in the FOXC2 gene.

- The use of benzopyrones (coumarin and flavonoids) continues to be investigated for efficacy in treating upper as well as lower limb lymphedema. Research is also underway to find an effective way to reduce the risk of liver toxicity with these drugs.

- Investigators continue to search for the most effective method in debulking lymphedematous limbs and are focusing on the efficacy of combining liposuction with debulking procedures as well as on how to reduce complications following surgery.

- Bypass surgical procedures are being improved. Numerous studies are investigating various shunting procedures and examining the long term results based on reduction of limb circumference.

- Efforts are being made by the International Society of Lymphology to increase basic knowledge about lymphedema, to establish accurate incidence of lymphedema, to standardize diagnostic and therapeutic guidelines, to better understand the molecular basis of lymphedema, and to look at new frontiers of potential treatment such as gene or stem cell therapy, new drugs or surgical procedures, and other ways to restore lymph

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function and improve quality of life.

- Research is ongoing to learn more about risk factors associated with lymphedema to identify patients who are at high risk for developing this condition.

- Investigators are studying the combined effect of gentle lymph drainage combined with deep breathing exercises and early results appear to be encouraging. Click here for additional information: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list*uids=16353491&query*hl=4&itool=pubmed_docsum

- New approaches for lymph drainage are under investigation using an apparatus which encourages articulation of the ankle and contraction of the muscles of the calves and feet. For more information about this technique, please click on the following link: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list*uids=15328758&query*hl=4&itool=pubmed_docsum

- Researchers from Germany reported that treatment with selenium (sodium selenite) enhanced the effect of physical therapy in patients with secondary lymphedema caused by radiation therapy. To read more about treatment with selenium, please click on the following link: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list*uids=15352655&query*hl=11&itool=pubmed_docsum

- Another study indicated a reduction of arm circumference for patients with radiation-induced secondary lymphedema who were treated with selenium. Follow this link to read about the study: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list*uids=12694822&query*hl=5&itool=pubmed_docsum

- A more recent study relating selenium to improvement in secondary head and neck lymphedema can be viewed at the following link: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list*uids=15181321&query*hl=11&itool=pubmed_docsum

- Research is ongoing to evaluate the efficacy of liposuction for the treatment of secondary lymphedema.

- If you are interested in investigating the availability of clinical trials for lymphedema, please visit the following website: http://www.clinicaltrials.gov

Questions to Ask Your Health Care Provider

- What type of lymphedema do I have (primary or secondary)?

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- How can you be sure that my swelling is due to lymphedema and not another underlying medical condition?
- What tests will be necessary to establish the diagnosis?
- What is the grade of my lymphedema (Grade 1, 2, or 3)?
- What are the treatment options for my type and grade of lymphedema?
- Who are the professionals who will be involved in my treatment and how will I put the team together?
- What are the advantages and disadvantages of each of the treatments?
- What type of monitoring will be necessary to evaluate the effectiveness of the treatments?
- How long will I have to continue treatment?
- Who should I call with questions?
- What types of activities should I avoid during and after treatment?
- What type of support do you offer for patients with lymphedema?

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3 - Guide to the Medical Literature

Introduction

This section of your *MediFocus Guidebook* is a comprehensive bibliography of important recent medical literature published about the condition from authoritative, trustworthy medical journals. This is the same information that is used by physicians and researchers to keep up with the latest advances in clinical medicine and biomedical research. A broad spectrum of articles is included in each *MediFocus Guidebook* to provide information about standard treatments, treatment options, new developments, and advances in research.

To facilitate your review and analysis of this information, the articles in this *MediFocus Guidebook* are grouped in the following categories:

- Review Articles - 20 Articles
- General Interest Articles - 37 Articles
- Drug Therapy - 3 Articles
- Surgical Therapy - 5 Articles
- Clinical Trials - 14 Articles
- Complete Decongestive Therapy - 2 Articles
- Compression Therapy - 2 Articles
- Manual Lymphatic Drainage - 2 Articles

The following information is provided for each of the articles referenced in this section of your *MediFocus Guidebook:*

- Title of the article
- Name of the authors
- Institution where the study was done
- Journal reference (Volume, page numbers, year of publication)
- Link to Abstract (brief summary of the actual article)

Linking to Abstracts: Most of the medical journal articles referenced in this section of your *MediFocus Guidebook* include an abstract (brief summary of the actual article) that can be accessed online via the National Library of Medicine's PubMed® database. You can easily access the individual abstracts online via PubMed® from the "electronic" format of your *MediFocus Guidebook* by clicking on the URI that is provided for each cited article. If you purchased a printed copy of the *MediFocus Guidebook*, you can still access the abstracts online by entering the individual URI for a particular abstract into your computer's web browser.

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Recent Literature: What Your Doctor Reads

Database: PubMed <January 2003 to January 2006>

Review Articles

1.

Massage therapy in the treatment of lymphedema. Rationale, results, and applications.

Authors: Bernas, Michael; Witte, Marlys; Kriederman, Benjamin; Summers, Pere; Witte, Charles
Institution: Department of Surgery, University of Arizona, Tucson, Arizona 85724, USA. michaelb@u.arizona.edu
Journal: IEEE Eng Med Biol Mag. 2005 Mar-Apr;24(2):58-68.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=15825847

2.

Narrative review: diseases that masquerade as infectious cellulitis.

Authors: Falagas, Matthew E; Vergidis, Paschalis I
Institution: Alfa HealthCare, Athens, Greece. matthew.falagas@tufts.edu
Journal: Ann Intern Med 2005 Jan 4;142(1):47-55.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15630108

3.

Compression therapy for chronic venous insufficiency.

Authors: Felty, Cindy L; Rooke, Thom W
Institution: Wound Care Clinic, Mayo Clinic, Rochester, MN 55905, USA.
Journal: Semin Vasc Surg 2005 Mar;18(1):36-40.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15791552

4.

Promoting physical exercise in breast cancer care.

Author: Kirshbaum, Marilyn
Institution: University of Sheffield, School of Nursing and Midwifery, Northern General Hospital, Sheffield. m.kirshbaum@sheffield.ac.uk
Journal: Nurs Stand 2005 Jun 22-28;19(41):41-8.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15997896

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5.

Lymphoedema: recognition, assessment and management.

Author: Linnitt, Nina
Institution: South Worcestershire and Wyre Forest PCT's. lymphclinic@strichards.org.uk
Journal: Br J Community Nurs. 2005 Mar;10(3):S20-6.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=15824708

6.

Breast cancer-related lymphedema.

Authors: Morrell RM; Halyard MY; Schild SE; Ali MS; Gunderson LL; Pockaj BA
Institution: Department of Radiation Oncology, Mayo Clinic College of Medicine, Scottsdale, Arizona 85259, USA.
Journal: Mayo Clin Proc. 2005 Nov;80(11):1480-4.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=16295027

7.

Impact of dose and volume on lymphedema.

Authors: Nardone L; Palazzoni G; D'Angelo E; Deodato F; Gambacorta MA; Micciche F; Morganti AG
Institution: Cattedra di Radioterapia, Universita Cattolica del S. Cuore, Policlinico A. Gemelli, Largo A. Gemelh 8, 00168 Roma, Italy. lnardone@rm.unicatt.it
Journal: Rays. 2005 Apr-Jun;30(2):149-55.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=16294908

8.

Treatment of edema.

Authors: O'Brien, James G; Chennubhotla, Shobha A; Chennubhotla, Ramana V
Institution: Department of Family and Geriatric Medicine, University of Louisville School of Medicine, Louisville, Kentucky 40202, USA. jgobri01@gwise.louisville.edu
Journal: Am Fam Physician 2005 Jun 1;71(11):2111-7.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15952439

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9.

Lymphoedema: estimating the size of the problem.

Authors: Williams, Anne F; Franks, Peter J; Moffatt, Christine J
Institution: Centre for Research and Implementation of Clinical Practice, Thames Valley University, London, UK.
Journal: Palliat Med. 2005 Jun;19(4):300-13.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=15984502

10.

A clinically useful method for evaluating lymphedema.

Author: Brown, Jennifer
Institution: jbrown@coh.org
Journal: Clin J Oncol Nurs 2004 Feb;8(1):35-8.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P14983761

11.

Development of the lymphatic vascular system: a mystery unravels.

Authors: Hong, Young-Kwon; Shin, Jay W; Detmar, Michael
Institution: Cutaneous Biology Research Center and Department of Dermatology, Massachusetts General Hospital and Harvard Medical School, Building 149, 13th Street, Charlestown, MA 02129, USA. young.hong@cbrc2.mgh.harvard.edu
Journal: Dev Dyn 2004 Nov;231(3):462-73.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15376314

12.

Lymphoedema in urological cancer.

Authors: Okeke, A A; Bates, D O; Gillatt, D A
Institution: Bristol Urological Institute, Southmead Hospital, Westbury-on-Trym, Bristol, BS10 5NB, UK.
Journal: Eur Urol 2004 Jan;45(1):18-25.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P14667510

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13.

Molecular targeting of lymphatics for therapy.

Authors: Stacker, S A; Hughes, R A; Achen, M G
Institution: Ludwig Institute for Cancer Research, Post Office Box 2008, Royal Melbourne Hospital, Victoria 3050, Australia. Steven.stacker@ludwig.edu.au
Journal: Curr Pharm Des 2004;10(1):65-74.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P14754406

14.

The diagnosis and treatment of peripheral lymphedema. Consensus document of the International Society of Lymphology.

Author:
Journal: Lymphology 2003 Jun;36(2):84-91.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P12926833

15.

Lymphedema management.

Authors: Cheville, Andrea L; McGarvey, Charles L; Petrek, Jeanne A; Russo, Sandra A; Taylor, Marie E; Thiadens, Saskia R J
Institution: Department of Rehabilitation Medicine, University of Pennsylvania Health System, Philadelphia, PA 19104, USA.
Journal: Semin Radiat Oncol 2003 Jul;13(3):290-301.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P12903017

16.

Risk of lymphedema after regional nodal irradiation with breast conservation therapy.

Authors: Coen, John J; Taghian, Alphonse G; Kachnic, Lisa A; Assaad, Sherif I; Powell, Simon N
Institution: Department of Radiation Oncology, Massachusetts General Hospital and Harvard Medical School, Boston, MA 02114, USA. snpowell@partners.org
Journal: Int J Radiat Oncol Biol Phys 2003 Apr 1;55(5):1209-15.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=22541638

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17.

Lymphedema of the external genitalia.

Author: McDougal, W Scott
Institution: Department of Urology, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114, USA.
Journal: J Urol 2003 Sep;170(3):711-6.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P12913680

18.

Lymphoedema.

Author: Penzer, Rebecca
Institution: School of Nursing and Midwifery, University of Southampton. R.H.Penzer@soton.ac.uk
Journal: Nurs Stand 2003 May 14-20;17(35):45-51; quiz 52, 55.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=22657452

19.

Differential diagnosis, investigation, and current treatment of lower limb lymphedema.

Authors: Tiwari, Alok; Cheng, Koon-Sung; Button, Matthew; Myint, Fiona; Hamilton, George
Institution: University Department of Surgery, Royal Free Hospital National Health Service Trust, London, NW3 2QG England.
Journal: Arch Surg 2003 Feb;138(2):152-61.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=22466461

20.

Using reflection in the care of a patient with lymphoedema.

Author: Woods, Mary
Institution: The Royal Marsden Hospital, Sutton, Surrey.
Journal: Br J Nurs 2003 Jul 24-Aug 13;12(14):865-71.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P12951538

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General Interest Articles

21.

Age differences in post-breast cancer lymphedema signs and symptoms.

Authors: Armer, Jane; Fu MR
Institution: MU Sinclair School of Nursing, University of Missouri - Columbia and Nursing Research, Ellis Fischel Cancer Center, Columbia, MO 65211, USA. armer@missouri.edu
Journal: Cancer Nurs. 2005 May-Jun;28(3):200-7; quiz 208-9.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=15915063

22.

Systematic lymphadenectomy in advanced epithelial ovarian cancer: two decades of uncertainty resolved.

Author: Chambers, Setsuko K
Journal: J Natl Cancer Inst 2005 Apr 20;97(8):548-9.
Abstract Link: **ABSTRACT NOT AVAILABLE**

23.

Incidence and risk of arm oedema following treatment for breast cancer: a three-year follow-up study.

Authors: Clark, B; Sitzia, J; Harlow, W
Institution: Worthing and Southlands Hospitals NHS Trust, Worthing Hospital, West Sussex, UK.
Journal: QJM. 2005 May;98(5):343-8. Epub 2005 Apr 8.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=15820971

24.

Severe lower limbs lymphedema following breast carcinoma treatment revealing radiation-induced constrictive pericarditis--a case report.

Authors: Granel, B; Gaudy, C; Serratrice, J; Ene, Nicoleta; Mesana, T; Bonnet, J L; Lepidi, H; Disdier, P; Piana, L; Weiller, P J
Institution: Service de Medecine Interne, CHU Timone, Marseille, France.
Journal: Angiology 2005 Jan-Feb;56(1):119-21.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15678267

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25.

Assessing task ""burden"" of daily activities requiring upper body function among women following breast cancer treatment.

Authors: Hayes, Sandi C; Battistutta, Diana; Parker, Anthony W; Hirst, Cherrell; Newman, Beth
Institution: Centre for Health Research, Faculty of Health, Queensland University of Technology, 4059, Brisbane, Queensland, Australia. sc.hayes@qut.edu.au
Journal: Support Care Cancer 2005 Apr;13(4):255-65. Epub 2004 Nov 18.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15798918

26.

Contemporary issues in management of chronic lymphedema: personal reflection on an experience with 1065 patients.

Author: Lee, B B
Institution: Department of Surgery, Sungkyunkwan University School of Medicine, Seoul, Korea. bblee38@hotmail.com
Journal: Lymphology 2005 Mar;38(1):28-31.
Abstract Link: **ABSTRACT NOT AVAILABLE**

27.

Case study detailing treatment of bilateral lower limb lymphoedema.

Author: Linnitt, Nina
Institution: South Worcestershire PCT, St Richard's Hospice Rose Hill, Worcester. lymphclinic@strichards.org.uk
Journal: Br J Community Nurs 2005 Jun;Suppl:S28-31.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15944503

28.

Noncontrast three-dimensional magnetic resonance imaging vs lymphoscintigraphy in the evaluation of lymph circulation disorders: A comparative study.

Authors: Liu, Ningfei; Wang, Chenguang; Sun, Minghua
Institution: Department of Plastic & Reconstructive Surgery, Shanghai9th People's Hospital, Shanghai Second Medical University, 639 Zhi Zao Ju Rd, Shanghai 200011, China. Liun2002@yahoo.com
Journal: J Vasc Surg 2005 Jan;41(1):69-75.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15696047

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29.

Association between fetal lymphedema and congenital cardiovascular defects in Turner syndrome.

Authors: Loscalzo, Melissa L; Van, Phillip L; Ho, Vincent B; Bakalov, Vladimir K; Rosing, Douglas R; Malone, Carol A; Dietz, Harry C; Bondy, Carolyn A
Institution: McKusick-Nathans Institute of Genetic Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA.
Journal: Pediatrics 2005 Mar;115(3):732-5.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15741379

30.

Psychologic and social sequelae of secondary lymphedema: a review.

Authors: McWayne J; Heiney SP
Institution: School of Education, Francis Marion University, 4822 E. Palmetto Street, Florence, SC 29506, USA. jmcwayne@fmarion.edu
Journal: Cancer. 2005 Aug 1;104(3):457-66.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=15968692

31.

The National Lymphoedema Framework Project.

Authors: Morgan, Phil; Doherty, Debra; Moffatt, Christine; Franks, Peter
Institution: Centre for Research and Implementation of Clinical Practice, Thames Valley University, London.
Journal: Nurs Times 2005 Jun 14-20;101(24):48.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15977477

32.

Axillary vein abnormalities contribute to development of lymphoedema after surgery for breast cancer.

Authors: Pain, S J; Vowler, S; Purushotham, A D
Institution: Cambridge Breast Unit, Addenbrooke's Hospital, Hills Road, Cambridge CB2 2QQ, UK.
Journal: Br J Surg 2005 Mar;92(3):311-5.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15672436

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33.

Porokeratosis in association with lymphoedema.

Authors: Pearson, I C; Cox, N H; Ostlere, L S; Marsden, R A; Mortimer, P S
Institution: Department of Dermatology, St George's Hospital, London, UK. ianpearson@doctors.org.uk
Journal: Clin Exp Dermatol 2005 Mar;30(2):152-4.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15725243

34.

Identifying risk factors for complications following sentinel lymph node biopsy for melanoma.

Authors: Roaten, J Brent; Pearlman, Nate; Gonzalez, Ricardo; Gonzalez, Rene; McCarter, Martin D
Institution: Department of Surgery and Medical Oncology, University of Colorado Health Sciences Center, Denver 80220, USA.
Journal: Arch Surg 2005 Jan;140(1):85-9.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15655211

35.

Lymphedema associated with sirolimus in renal transplant recipients.

Authors: Aboujaoude, Walid; Milgrom, Martin L; Govani, Mahendra V
Institution: Division of Nephrology, Indiana University Medical Center, Indianapolis, Indiana 46202, USA.
Journal: Transplantation 2004 Apr 15;77(7):1094-6.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15087777

36.

Cutaneous angiosarcoma following breast-conserving surgery and radiation: an analysis of 27 cases.

Authors: Billings, Steven D; McKenney, Jesse K; Folpe, Andrew L; Hardacre, Michael C; Weiss, Sharon W
Institution: Department of Pathology and Laboratory Medicine, Indiana University School of Medicine, Indianapolis, IN 46202, USA. sdbillin@iupui.edu
Journal: Am J Surg Pathol 2004 Jun;28(6):781-8.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15166670

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37.

Perceptions of upper-body problems during recovery from breast cancer treatment.

Authors: Collins, Louisa G; Nash, Robyn; Round, Tracey; Newman, Beth
Institution: Centre for Health Research, School of Public Health, Queensland University of Technology, Victoria Park Road, 4059, Kelvin Grove, Brisbane, Queensland, Australia. l1.collins@student.qut.edu.au
Journal: Support Care Cancer 2004 Feb;12(2):106-13. Epub 2003 Oct 31.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P14593521

38.

Prevalence and risk factors for development of lymphedema following breast cancer treatment.

Authors: Deo, S V S; Ray, S; Rath, G K; Shukla, N K; Kar, M; Asthana, S; Raina, V
Institution: Department of Surgical Oncology, Institute Rotary Cancer Hospital, All India Institute of Medical Sciences, New Delhi-110 029, India. svsdeo@yahoo.co.in
Journal: Indian J Cancer 2004 Jan-Mar;41(1):8-12.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15105573

39.

Stewart-Treves syndrome as a rare complication of a hereditary lymphedema.

Authors: Durr, H R; Pellengahr, C; Nerlich, A; Baur, A; Maier, M; Jansson, V
Institution: Department of Orthopaedics and Orthopaedic Surgery, Ludwig-Maximilians-University Munich, Germany. hans_roland.duerr@med.uni-muenchen.de
Journal: Vasa 2004 Feb;33(1):42-5.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15061047

40.

Rotator cuff tendonitis in lymphedema: a retrospective case series.

Authors: Herrera, Joseph E; Stubblefield, Michael D
Institution: New York-Presbyterian Hospital and Hospitals of Columbia and Cornell, New York, USA.
Journal: Arch Phys Med Rehabil 2004 Dec;85(12):1939-42.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15605330

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41.

Lymphedema secondary to postmastectomy radiation: incidence and risk factors.

Authors: Hinrichs, Christian S; Watroba, Nancy L; Rezaishiraz, Hamed; Giese, William; Hurd, Thelma; Fassl, Kathleen A; Edge, Stephen B
Institution: Roswell Park Cancer Institute, Department of Surgical Oncology, Elm and Carlton Streets, Buffalo, NY 14263, USA.
Journal: Ann Surg Oncol 2004 Jun;11(6):573-80.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15172932

42.

Lymphatic mapping improves staging and reduces morbidity in women undergoing total mastectomy for breast carcinoma.

Authors: Langer, Samantha; Guenther, J Michael; Haigh, Philip I; Difronzo, L Andrew
Institution: Department of Surgery, Kaiser Permanente Los Angeles Medical Center, Los Angeles, California 90027, USA.
Journal: Am Surg 2004 Oct;70(10):881-5.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15529842

43.

Dual-frequency ultrasound examination of skin and subcutis thickness in breast cancer-related lymphedema.

Authors: Mellor, Russell H; Bush, Nigel L; Stanton, Anthony W B; Bamber, Jeff C; Levick, J Rodney; Mortimer, Peter S
Institution: Department of Cardiac and Vascular Sciences (Dermatology Unit), St. George's Hospital Medical School, Cranmer Terrace, London, SW17 0RE, UK. rmellor@sghms.ac.uk
Journal: Breast J 2004 Nov-Dec;10(6):496-503.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15569205

44.

Lymphedema after treatment of breast cancer.

Authors: Ozaslan, Cihangir; Kuru, Bekir
Institution: Department of Surgery, Ankara Education and Research Hospital, Ankara, Turkey.
Journal: Am J Surg 2004 Jan;187(1):69-72.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P14706589

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45.

Variation in lymphatic function may predispose to development of breast cancer-related lymphoedema.

Authors: Pain, S J; Purushotham, A D; Barber, R W; Ballinger, J R; Solanki, C K; Mortimer, P S; Peters, A M
Institution: Cambridge Breast Unit, Box 97, Addenbrooke's Hospital, Hills Road, Cambridge CB2 2QQ, UK.
Journal: Eur J Surg Oncol 2004 Jun;30(5):508-14.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15135478

46.

Comparative morbidity of axillary lymph node dissection and the sentinel lymph node technique: implications for patients with breast cancer.

Authors: Silberman, Allan W; McVay, Carie; Cohen, Jason S; Altura, Jack F; Brackert, Sandra; Sarna, Gregory P; Palmer, Daphne; Ko, Albert; Memsic, Leslie
Institution: Divisions of Surgical Oncology, Cedars-Sinai Medical Center, Los Angeles, California, USA. AWS222@aol.com
Journal: Ann Surg 2004 Jul;240(1):1-6.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15213610

47.

Lymphedema after complete axillary node dissection for melanoma: assessment using a new, objective definition.

Authors: Starritt, Emma C; Joseph, David; McKinnon, J Gregory; Lo, Sing Kai; de Wilt, Johannes H W; Thompson, John F
Institution: Sydney Melanoma Unit, Sydney Cancer Centre, Royal Prince Alfred Hospital, Camperdown, Australia.
Journal: Ann Surg 2004 Nov;240(5):866-74.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15492570

48.

Clinical practice guidelines for the care and treatment of breast cancer: 16. Locoregional post-mastectomy radiotherapy.

Authors: Truong, Pauline T; Olivotto, Ivo A; Whelan, Timothy J; Levine, Mark
Institution: BC Cancer Agency-Vancouver Island Centre.
Journal: CMAJ 2004 Apr 13;170(8):1263-73.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15078851

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49.

Improving the physical status and quality of life of women treated for breast cancer: a pilot study of a structured exercise intervention.

Authors: Turner, Jane; Hayes, Sandi; Reul-Hirche, Hildegard
Institution: Department of Psychiatry, University of Queensland, Herston, Queensland, Australia. j.turner@psychiatry.uq.edu.au
Journal: J Surg Oncol 2004 Jun 1;86(3):141-6.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15170652

50.

Overcoming lymphedema.

Author: Brown, Jennifer L
Institution: City of Hope National Medical Center, Duarte, Calif., USA.
Journal: Rehab Manag 2003 Jul;16(6):34-7, 50.
Abstract Link: **ABSTRACT NOT AVAILABLE**

51.

Sentinel lymph node biopsy lowers the rate of lymphedema when compared with standard axillary lymph node dissection.

Authors: Golshan, Mehra; Martin, W Jason; Dowlatshahi, Kambiz
Institution: Department of Surgery, Rush University, Rush Presbyterian St. Luke's Medical Center, Chicago, Illinois, USA.
Journal: Am Surg 2003 Mar;69(3):209-11; discussion 212.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=22564875

52.

Breast cancer patients' experiences of lymphoedema.

Authors: Johansson, K; Holmstrom, H; Nilsson, I; Ingvar, C; Albertsson, M; Ekdahl, C
Institution: Department of Physical Therapy, Lund University, Sweden. karin.johansson@skane.se
Journal: Scand J Caring Sci 2003 Mar;17(1):35-42.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=22470433

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53.

Lymphoedema: an underestimated health problem.

Authors: Moffatt, C J; Franks, P J; Doherty, D C; Williams, A F; Badger, C; Jeffs, E; Bosanquet, N; Mortimer, P S
Institution: Centre for Research and Implementation of Clinical Practice, Faculty of Health & Human Sciences, Thames Valley University, 32-28 Uxbridge Road, London W5 2BS, UK. christine.moffatt@tvu.ac.uk
Journal: QJM 2003 Oct;96(10):731-8.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P14500859

54.

Incidence of clinically significant lymphoedema as a complication following surgery for primary operable breast cancer.

Authors: Rampaul, R S; Mullinger, K; Macmillan, R D; Cid, J; Holmes, S; Morgan, D A L; Blamey, R W
Institution: Breast Cancer Unit, Nottingham City Hospital, Nottingham NG1 5PB, UK. mszrsr@msn1.surgery.nottingham.ac.uk
Journal: Eur J Cancer 2003 Oct;39(15):2165-7.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P14522373

55.

The experience of lower limb lymphedema for women after treatment for gynecologic cancer.

Authors: Ryan, Mary; Stainton, M Colleen; Jaconelli, Carmel; Watts, Sally; MacKenzie, Patricia; Mansberg, Tamar
Institution: Gynaecological Cancer Centre of the Royal Hospital for Women, Randwick, New South Wales, Australia. mryan@mail.usyd.edu.au
Journal: Oncol Nurs Forum 2003 May-Jun;30(3):417-23.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=22605636

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56.

Comparison of morbidity between axillary lymph node dissection and sentinel node biopsy.

Authors: Schijven, M P; Vingerhoets, A J J M; Rutten, H J T; Nieuwenhuijzen, G A P; Roumen, R M H; van Bussel, M E; Voogd, A C
Institution: Department of Surgery, Catharina Hospital Eindhoven, The Netherlands. mschijv@zonnet.nl
Journal: Eur J Surg Oncol 2003 May;29(4):341-50.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=22597416

57.

Lymphoedema and reduced shoulder function as indicators of quality of life after axillary lymph node dissection for invasive breast cancer.

Authors: Voogd, A C; Ververs, J M M A; Vingerhoets, A J J M; Roumen, R M H; Coebergh, J W W; Crommelin, M A
Institution: Eindhoven Cancer Registry, Comprehensive Cancer Centre South, The Netherlands. adri.voogd@epid.unimaas.nl
Journal: Br J Surg 2003 Jan;90(1):76-81.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=22407332

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Drug Therapy

58.

Albendazole for lymphatic filariasis.

Authors: Addiss, David; Critchley, Julia; Ejere, Henry; Garner, Paul; Gelband, Hellen; Gamble, Carrol
Journal: Cochrane Database Syst Rev 2004;(1):CD003753.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P14974034

59.

Infliximab treatment efficacy in lymphoedema associated with ankylosing spondylitis.

Authors: Almodovar, R; Zarco, P; Quiros, F J; Mazzucchelli, R
Journal: Rheumatology (Oxford) 2004 Nov;43(11):1456.
Abstract Link: **ABSTRACT NOT AVAILABLE**

60.

Antibiotics / anti-inflammatories for reducing acute inflammatory episodes in lymphoedema of the limbs.

Authors: Badger, C; Seers, K; Preston, N; Mortimer, P
Journal: Cochrane Database Syst Rev 2004;(2):CD003143.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15106193

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Surgical Therapy

61.

Free muscle flap transfer as a lymphatic bridge for upper extremity lymphedema.

Authors: Classen DA; Irvine L
Institution: Department of Surgery, Division of Plastic Surgery, University of Saskatchewan and Royal University Hospital, Saskatoon, Saskatchewan, Canada.
Journal: J Reconstr Microsurg. 2005 Feb;21(2):93-9.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=15739144

62.

Excisional surgery for chronic advanced lymphedema.

Authors: Kim, Dong-Ik; Huh, Se-Ho; Hwang, Ji-Hye; Joh, Jin-Hyun
Institution: Division of Vascular Surgery, Samsung Medical Center, Sungkyunkwan University School of Medicine, 50 Irwon-Dong, Kangnam-Ku, Seoul 135-710, Korea.
Journal: Surg Today 2004;34(2):134-7.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P14745613

63.

Operations for lymphedema.

Author: Beltramino, R
Institution: Service of Phlebology and Lymphology Sanatorio Parque, Tucuman, Argentina.
Journal: Lymphology 2003 Sep;36(3):107-9.
Abstract Link: **ABSTRACT NOT AVAILABLE**

64.

Long-term follow-up after lymphaticovenular anastomosis for lymphedema in the leg.

Authors: Koshima, Isao; Nanba, Yuzaburo; Tsutsui, Tetsuya; Takahashi, Yoshio; Itoh, Seiko
Institution: Department of Plastic and Reconstructive Surgery, Graduate School of Medicine and Dentistry, Okayama University, Japan.
Journal: J Reconstr Microsurg 2003 May;19(4):209-15.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P12858242

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65.

Follow-up study of upper limb lymphedema patients treated by microsurgical lymphaticovenous implantation (MLVI) combined with compression therapy.

Authors: Yamamoto, Yuhei; Horiuchi, Katsumi; Sasaki, Satoru; Sekido, Mitsuru; Furukawa, Hiroshi; Oyama, Akihiko; Yajima, Kazuyoshi; Sugihara, Tsuneki

Institution: Department of Plastic and Reconstructive Surgery, Graduate School of Medicine, Hokkaido University, Sapporo, Japan. yu-h1@med.hokudai.ac.jp

Journal: Microsurgery 2003;23(1):21-6.

Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=22503431

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66.

The comparison of two different physiotherapy methods in treatment of lymphedema after breast surgery.

Authors: Didem K; Ufuk YS; Serdar S; Zumre A
Institution: School of Physical Therapy and Rehabilitation, Dokuz Eylul University, 35340, Inciralti/Izmir, Turkey. yuzbasioglu@deu.edu.tr
Journal: Breast Cancer Res Treat. 2005 Sep;93(1):49-54.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=16184458

67.

Short-term effects of axillary lymph node clearance surgery on lymphatic physiology of the arm in breast cancer.

Authors: Pain SJ; Barber RW; Solanki CK; Ballinger JR; Britton TB; Mortimer PS; Purushotham AD; Peters AM
Institution: Cambridge Breast Unit, Addenbrooke's Hospital, UK.
Journal: J Appl Physiol. 2005 Dec;99(6):2345-51.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=16288099

68.

Dance and movement program improves quality-of-life measures in breast cancer survivors.

Authors: Sandel SL; Judge JO; Landry N; Faria L; Ouellette R; Majczak M
Institution: MidState Medical Center, Meriden, CT 06450, USA. ssandel@harthosp.org
Journal: Cancer Nurs. 2005 Jul-Aug;28(4):301-9.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=16046894

69.

Literature watch. The addition of manual lymph drainage to compression therapy for breast cancer related lymphedema: a randomized controlled trial.

Author: Szuba A
Institution: Wroclaw Medical University, Wroclaw, Poland.
Journal: Lymphat Res Biol. 2005;3(1):36-41.
Abstract Link: **ABSTRACT NOT AVAILABLE**

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70.

Selenium in the treatment of head and neck lymphedema.

Authors: Bruns, F; Buntzel, J; Mucke, R; Schonekaes, K; Kisters, K; Micke, O
Institution: Department of Radiotherapy, Medical School Hannover, Hannover, Germany.
Journal: Med Princ Pract 2004 Jul-Aug;13(4):185-90.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15181321

71.

Postoperative arm massage: a support for women with lymph node dissection.

Authors: Forchuk, Cheryl; Baruth, Pat; Prendergast, Monique; Holliday, Ronald; Bareham, Ruth; Brimner, Susan; Schulz, Valerie; Chan, Yee Ching Lilian; Yammine, Nadine
Institution: University of Western Ontario, Lawson Health Research Institute (London Health Sciences Centre), London, Ontario, Canada. cforchuk@uwo.ca
Journal: Cancer Nurs 2004 Jan-Feb;27(1):25-33.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15108949

72.

Non-randomised phase II trial of hyperbaric oxygen therapy in patients with chronic arm lymphoedema and tissue fibrosis after radiotherapy for early breast cancer.

Authors: Gothard, Lone; Stanton, Anthony; MacLaren, Julie; Lawrence, David; Hall, Emma; Mortimer, Peter; Parkin, Eileen; Pritchard, Joyce; Risdall, Jane; Sawyer, Robert; Woods, Mary; Yarnold, John
Institution: Department of Radiotherapy, Royal Marsden NHS Trust, Sutton, Surrey SM2 5PT, UK.
Journal: Radiother Oncol 2004 Mar;70(3):217-24.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15064005

73.

Double-blind placebo-controlled randomised trial of vitamin E and pentoxifylline in patients with chronic arm lymphoedema and fibrosis after surgery and radiotherapy for breast cancer.

Authors: Gothard, Lone; Cornes, Paul; Earl, Judith; Hall, Emma; MacLaren, Julie; Mortimer, Peter; Peacock, John; Peckitt, Clare; Woods, Mary; Yarnold, John
Institution: Department of Radiotherapy, Royal Marsden Hospital, Sutton, Surrey, UK.
Journal: Radiother Oncol 2004 Nov;73(2):133-9.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15542159

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74.

The addition of manual lymph drainage to compression therapy for breast cancer related lymphedema: a randomized controlled trial.

Authors: McNeely, Margaret L; Magee, David J; Lees, Alan W; Bagnall, Keith M; Haykowsky, Mark; Hanson, John
Institution: Department of Rehabilitation Medicine, Cross Cancer Institute, Edmonton, Alberta, Canada. mmcneely@ualberta.ca
Journal: Breast Cancer Res Treat 2004 Jul;86(2):95-106.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15319562

75.

Can hyperbaric oxygen therapy reduce breast cancer treatment-related lymphedema? A pilot study.

Authors: Teas, Jane; Cunningham, Joan E; Cone, Lindsie; Jansen, Kel; Raghavan, Senthil K; Nitcheva, Daniela K; Xie, Dawen; Butler, William M
Institution: Department of Health Promotion Education and Behavior, Arnold School of Public Health, University of South Carolina and the South Carolina Cancer Center, Columbia, South Carolina, USA. jane.teas@palmettohealth.org
Journal: J Womens Health (Larchmt) 2004 Nov;13(9):1008-18.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15665658

76.

Predicting breast cancer-related lymphedema using self-reported symptoms.

Authors: Armer, Jane M; Radina, M Elise; Porock, Davina; Culbertson, Scott D
Institution: Sinclair School of Nursing, Ellis Fischel Cancer Center, University of Missouri-Columbia, 65211, USA. armer@missouri.edu
Journal: Nurs Res 2003 Nov-Dec;52(6):370-9.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P14639083

77.

Treatment of postmastectomy lymphedema with low-level laser therapy: a double blind, placebo-controlled trial.

Authors: Carati, Colin J; Anderson, Sandy N; Gannon, Bren J; Piller, Neil B
Institution: Department of Anatomy, School of Medicine, Flinders University, Adelaide, South Australia, Australia. colin.carati@flinders.edu.au
Journal: Cancer 2003 Sep 15;98(6):1114-22.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P12973834

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78.

Effect of upper extremity exercise on secondary lymphedema in breast cancer patients: a pilot study.

Authors: McKenzie, Donald C; Kalda, Andrea L
Institution: Division of Sports Medicine and School of Human Kinetics, University of British Columbia, Vancouver, British Columbia, Canada. kari@interchange.ubc.ca
Journal: J Clin Oncol 2003 Feb 1;21(3):463-6.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=22447184

79.

Selenium in the treatment of radiation-associated secondary lymphedema.

Authors: Micke, Oliver; Bruns, Frank; Mucke, Ralph; Schafer, Ulrich; Glatzel, Michael; DeVries, Alexander F; Schonekaes, Klaus; Kisters, Klaus; Buntzel, Jens
Institution: Department of Radiotherapy, Munster University Hospital, Munster, Germany. omicke@trace-elements.de
Journal: Int J Radiat Oncol Biol Phys 2003 May 1;56(1):40-9.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=22581598

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Complete Decongestive Therapy

80.

The effectiveness of complete decongestive physiotherapy for the treatment of lymphedema following groin dissection for melanoma.

Authors: Hinrichs, Christian S; Gibbs, John F; Driscoll, Deborah; Kepner, James L; Wilkinson, Neal W; Edge, Stephen B; Fassl, Kathleen A; Muir, Robin; Kraybill, William G
Institution: Department of Surgical Oncology, Roswell Park Cancer Institute, State University of New York at Buffalo, Buffalo, New York, USA.
Journal: J Surg Oncol 2004 Mar 15;85(4):187-92.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P14991874

81.

Prospective trial of complete decongestive therapy for upper extremity lymphedema after breast cancer therapy.

Authors: Mondry, Tammy E; Riffenburgh, Robert H; Johnstone, Peter A S
Institution: Breast Health Center, Naval Medical Center, San Diego, California 92134-1005, USA.
Journal: Cancer J 2004 Jan-Feb;10(1):42-8; discussion 17-9.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P15000494

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Compression Therapy

82.

Elvarex compression garments in the management of lymphoedema.

Author: Hampton, Sylvie
Journal: Br J Nurs 2003 Aug 14-Sep 10;12(15):925-6, 928-9.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P12937370

83.

Lymphedema, lipedema, and the open wound: the role of compression therapy.

Authors: Macdonald, John M; Sims, Nancy; Mayrovitz, Harvey N
Institution: Department of Dermatology and Cutaneous Surgery, University of Miami School of Medicine, Miami, FL, USA. Trappermac@uol.com
Journal: Surg Clin North Am 2003 Jun;83(3):639-58.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=22706536

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Manual Lymphatic Drainage

84.

Manual lymphatic drainage for the treatment of acute genital lymphedema.

Authors: Katz, Erin E; Lyon, Mark B; Davis, Diane; Gottlieb, Lawrence J; Brendler, Charles B
Institution: Department of Surgery, Section of Urology, University of Chicago, Chicago, Illinois, USA. ekatz13@hotmail.com
Journal: J Urol 2004 Jul;172(1):157-8.
Abstract Link: **ABSTRACT NOT AVAILABLE**

85.

The experience of manual lymph drainage as an aspect of treatment for lymphoedema.

Author: Woods, Mary
Institution: Lymphoedema Services, The Royal Marsden Hospital, Downs Road, Sutton, Surrey SM2 5PT, UK.
Journal: Int J Palliat Nurs 2003 Aug;9(8):336-42; discussion 342.
Abstract Link: http://www.medifocus.com/abstracts.php?gid=OC030&ID=P12968119

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  - E-mail addresses for individual authors, if listed on their specific publications, is also provided.
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  - Next to each individual author's name is their **institutional affiliation** (hospital, medical center, or research institution) where the study was conducted as listed in their publication(s).
  - In many cases, information about the specific **department** within the medical institution where the individual author was located at the time the study was conducted is also provided.

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5 - Tips on Finding and Choosing a Doctor

Introduction

One of the most important decisions confronting patients who have been diagnosed with a serious medical condition is finding and choosing a qualified physician who will deliver a high level and quality of medical care in accordance with currently accepted guidelines and standards of care. Finding the "best" doctor to manage your condition, however, can be a frustrating and time-consuming experience unless you know what you are looking for and how to go about finding it.

The process of finding and choosing a physician to manage your specific illness or condition is, in some respects, analogous to the process of making a decision about whether or not to invest in a particular stock or mutual fund. After all, you wouldn't invest your hard eared money in a stock or mutual fund without first doing exhaustive research about the stock or fund's past performance, current financial status, and projected future earnings. More than likely you would spend a considerable amount of time and energy doing your own research and consulting with your stock broker before making an informed decision about investing. The same general principle applies to the process of finding and choosing a physician. Although the process requires a considerable investment in terms of both time and energy, the potential payoff can be well worth it--after all, what can be more important than your health and well-being?

This section of your Guidebook offers important tips for how to find physicians as well as suggestions for how to make informed choices about choosing a doctor who is right for you.

Tips for Finding Physicians

Finding a highly qualified, competent, and compassionate physician to manage your specific illness or condition takes a lot of hard work and energy but is an investment that is well-worth the effort. It is important to keep in mind that you are not looking for just any general physician but rather for a physician who has expertise in the treatment and management of your specific illness or condition. Here are some suggestions for where you can turn to identify and locate physicians who specialize in managing your disorder:

- **Your Doctor** - Your family physician (family medicine or internal medicine specialist) is a good starting point for finding a physician who specializes in your illness. Chances are that your doctor already knows several specialists in your geographic area who specialize in your illness and can recommend several names to you. Your doctor can also provide you with information about their qualifications, training, and hospital affiliations.

- **Your Peer Network** - Your family, friends, and co-workers can be a potentially very useful network for helping you find a physician who specializes in your illness. They may know someone else with this condition and may be able to put you in touch with them to find out which doctors they can recommend. If you have friends, neighbors, or relatives who work in hospitals (e.g., nurses, social workers, administrators), they may be a potentially valuable source for helping you find a physician who specializes in your condition.

- **Hospitals and Medical Centers** - Hospitals and medical centers are, potentially, an excellent source

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for finding physicians who specialize in treating specific diseases. Simply contact hospitals and major medical centers in your city, county, or state and ask if they have anyone on their staff who specializes in treating your condition. When you call, ask to speak to someone in the specific Department that cares for patients with the illness. For example, if you have been diagnosed with cancer, ask to speak with someone in the Department of Hematology and Oncology. If you are not sure which Department treats patients with your specific condition, ask to speak to someone in the Department of Medicine since this Department is the umbrella for many other medical specialties.

- **Organizations and Support Groups** - Many disease organizations and support groups that cater to patients with a specific illness or condition maintain physician referral lists and may be able to recommend doctors in your geographic area who specialize in the treatment and management of your specific disorder. Section 6 of your *MediFocus Guidebook* includes a select listing of disease organizations and support groups that you may wish to contact to ask for a physician referral.

- **Managed Care Plans** - If you belong to a managed care plan, you can obtain a list of physicians who belong to the Plan from the plan's membership services office. Keep in mind, however, that your choices will usually be limited to only those doctors who belong to the Plan. If you decide to go outside the Plan, you will likely have to pay for the doctor's services "out of pocket."

- **Medical Journals** - Many doctors based at major medical centers and universities who have special interest in a particular disease or condition conduct research and publish their findings in leading medical journals. Searching the medical literature can help you identify and locate leading physicians who are recognized as experts in their field about a particular illness. Section 4 of your *MediFocus Guidebook* ("Centers of Research") includes an extensive listing of the names and institutional affiliations of physicians and researchers, in the United States and other countries, who have recently published their studies about this specific medical condition in leading medical journals. You can also conduct your own online search for your illness or condition and identify additional authors and hospitals who specialize in the disease using the PubMed database available at http://www.nlm.nih.gov.

- **American Medical Association** - The American Medical Association (AMA) is the nation's largest professional medical association that represents many doctors in the United States and also provides a free physician locator service called "AMA Physician Select" available at http://dbapps.ama-assn.org/aps/amahg.htm. You can search the AMA database by either "Physician Name" or "Medical Specialty". You can find information about physicians including medical school and residency training, area of specialty, and contact information.

- **American Board of Medical Specialists** - The American Board of Medical Specialists (ABMS) publishes a geographical list of board-certified physicians called the Official ABMS Directory of Board Certified Medical Specialists that is available in most public libraries. Physicians who are listed in the ABMS Directory are board-certified in a medical specialty meaning that they have passed rigorous certification examinations administered by a board of medical specialists. There are 24 specialty boards that are recognized by the ABMS and the AMA. Each candidate applying for board certification must pass a written examination given by the specific specialty board and 15 of the specialty boards also require candidates to pass an oral examination in order to obtain board certification. To find out if a particular physician you may be considering is board certified:

    - Visit your local public library and ask for a copy of the Official ABMS Directory of Board Certified Medical Specialists.

    - Search the ABMS web site at http://www.abms.org/login.asp.

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- Call the ABMS toll free at 1-866-275-2267.

American Society of Clinical Oncology - The American Society of Clinical Onclology (ASC)) is the largest professional organization that represents physicians who specialize in treating cancer patients (oncologists). The ASCO provides a searchable database of ASCO members called "Find an Oncologist" that you can access online at http://www.asco.org. You can search the "Find an Oncologist" database for a cancer specialist by name, city, state, country, or specialty area.

American Cancer Society - The American Cancer Society (ACS) is a nationwide voluntary health organization dedicated to helping cancer patients and survivors through research, education, advocacy, and services. The ACS web site http://www.cancer.org is not only an excellent resource for cancer information but also includes a "Message Board" where you can ask questions, exchange ideas, and share stories. The ACS Message Board is also a potentially useful source for locating an oncologist in your geographical area who specializes in your specific type of cancer. You can also contact the ACS toll free by calling 1-800-ACS-2345.

National Comprehensive Cancer Network - The National Comprehensive Cancer Network (NCCN) is an alliance of 19 of the world's leading cancer centers and is dedicated to helping patients and health care professionals make informed decisions about cancer care. You can find a listing of the 19 NCCN member cancer institutions on the NCCN web site at http://www.nccn.org/. You can also search the NCCN "Physician Directory" for doctors located at any of the 19 NCCN member cancer institutions at http://www.nccn.org/physician_directory/SearchPers.asp. This database is an excellent resource for locating leading cancer specialists nationwide who specialize in your specific type of cancer.

National Cancer Institute Clinical Trials Database - The National Cancer Institute (NCI) is part of the National Institutes of Health (NIH) and coordinates the National Cancer Program which conducts and supports research, training, and a variety of other programs dedicated to prevention and treatment of cancer. The NCI maintains an extensive cancer clinical trials database that you can access at http://www.cancer.gov/clinicaltrials. You can search the database for current clinical trials by type of cancer and even limit your search to clinical trials within you geographical area by putting in your Zip Code. The NCI clinical trials database also provides contact information for the physicians who serve as the study coordinators for each clinical trial. This database is a valuable resource for identifying and locating leading physicians in your local area and around the country who are conducting cutting-edge clinical research about your specific type of cancer.

National Center for Complementary and Alternative Medicine - The National Center for Complementary and Alternative Medicine (NCCAM) is part of the National Institutes of Health (NIH) and is dedicated to exploring complementary and alternative medicine healing practices in the context of rigorous scientific research and methodology. The NCCAM web site http://nccam.nih.gov/ includes publications, frequently asked questions, and useful links to other complementary and alternative medicine resources. If you have questions about complementary and alternative medicine practices for your particular illness or medical condition, you can contact the NCCAM Clearinghouse toll-free in the U.S. at 1-888-644-6226 or 301-519-3153. You can also contact the NCCAM Clearinghouse by E-mail: info@nccam.nih.gov.

National Organization for Rare Disorders - The National Organization for Rare Disorders (NORD) is a federation of voluntary health organizations dedicated to helping patients with rare "orphan" diseases and their families. There are over 6,000 rare or "orphan" diseases that are estimated to affect approximately 25 million Americans. You can search NORD's "Rare Diseases Database" for information about rare diseases at http://www.rarediseases.org/search/rdblist.html. In addition to providing useful information about rare diseases, NORD maintains a confidential "Networking Program" for its members to enable them to communicate with

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other patients who suffer from the same disorder. To learn more about NORD's Networking Program, you can send an E mail to: orphan@rarediseases.org.

How to Make Informed Choices About Physicians

It has generally been assumed by many people that the longer a physician has been in practice, the more experience, knowledge, and skills he/she has accumulated and, therefore, the higher the quality of care they provide to their patients. Recent research conducted by a group of doctors from the Harvard Medical School, however, seems to strongly suggest that this premise may not be true. In an article published in February 2005 in the *Annals of Internal Medicine* (Volume 142, No. 4, pp. 260-303), the Harvard researchers seriously challenged the common assumption that the more clinical experience a physician has accumulated, the higher the level of medical care they provide to their patients.

In fact, surprisingly, the researchers found an inverse (opposite) relationship between the number of years that a physician has been in practice (i.e., experience) and the quality of care that the physician provides. In other words, the widely held belief that "practice makes perfect" does not necessarily apply to all physicians and should not be the sole criteria used by patients in their decision analysis for choosing a physician. The underlying message of this study is that the length of time a physician has been in practice does not necessarily equate to a high quality of medical care unless the doctor takes steps to keep abreast with new advances and changing patterns of clinical practice.

Here are some important issues you need to consider and carefully research before making an informed decision about choosing your doctor:

- **Board Certification** - Board certified doctors are required to have extra training after medical school to become specialists in a particular field of medicine and are required to take continuing education courses in order to maintain their board certification status. Check with the American Board of Medical Specialists (ABMS) to determine if a specific physician you are considering is board certified in a particular medical specialty.

- **Experience** - As noted above, research from the Harvard Medical School strongly suggests that how long a physician has been in practice (i.e., experience) does not necessarily correlate with a high level of medical care. The most important issue, therefore, is not how long a doctor has been in practice but rather how much experience the physician has in treating your specific illness or medical condition. Some physicians who have been in practice for many decades may have only treated a small number of patients with the specific disorder, whereas, some younger physicians who have been in practice only a few years may have already treated hundreds of patients with the same disorder. Here are some suggestions for helping you find out about a particular physician's experience in treating your specific illness:

    - Call the physician's office and speak with a staff member such as a nurse or physician's assistant. Ask them for information about how many patients with your specific medical condition the physician treats during the course of a year. Ask how many patients with this condition the physician is currently treating. You will have to call several different physicians' offices in order to have a basis for comparing the numbers of patients.

    - Find out if the physician has published any articles about the condition in reputable medical journals by doing an author search online. You can conduct an online author search using PubMed at http://www.nlm.nih.gov. Simply click on the "PubMed" icon, select the "author" field from the

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"Limits" menu, enter the physician's name (last name followed by first initial), and then click on the "Go" button. The author search will retrieve all articles published by the particular physician you are considering.

- Talk with your family physician and ask if he/she can provide you with any information about the particular physician's experience in treating patients with your specific illness or condition.

- Contact disease organizations and support groups that specialize in helping patients with your specific disorder and ask if they can provide you with any information, including experience, about the physician you are considering.

Medical School Affiliation - Find out if the physician you are considering also has a joint faculty appointment at a medical school. In general, practicing community physicians with a joint academic appointment at a medical school are more likely to be in contact with leading medical experts and may be more up-to-date with the latest advances in research and treatments than community based physicians who are not affiliated with a medical school.

Hospital Affiliation - Find out about the hospitals that the doctor uses. In the event that you need to be treated at a hospital, is the hospital where the physician has admitting privileges nearby to your home or will you (and your family members) have to travel a considerable distance?

Hospital Accreditation - Find out if the hospital where the physician has admitting privileges is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). You can find information about a specific hospital's accreditation status by searching the JCAHO web site at http://www.jcaho.org/quality+check/index.htm. The JCAHO is an independent, not-for-profit organization that evaluates and accredits more than 15,000 health care organizations and programs in the United States. To receive and maintain JCAHO accreditation, a health care organization must undergo an on-site survey by a JCAHO survey team at least every three years and meet specific standards and performance measurements that affect the safety and quality of patient care.

Health Insurance Coverage - Find out if the physician is covered by your health insurance plan. If you belong to a managed care plan (HMO or PPO), you are usually restricted to using specific physicians who also belong to the Plan. If you decide to use a physician who is "outside the network," you will likely have to pay "out of pocket" for the services provided.

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6 - Directory of Organizations

BreastCancer.org
111 Forrest Avenue 1R; Narberth, PA 19072-0222
www.breastcancer.org

Canadian Lymphedema Foundation
414 Cliffe Avenue SW; Calgary, AB; T2S 0Z4 CANADA
info@lymphovenous-canada.ca
lymphovenous-canada.ca

Cancer Information Service; National Cancer Institute
6116 Executive Blvd.; Suite 3036A; Bethesda, MD 20892
800.422.6237; 800.322.8615 (TTY)
www.cancer.gov/cancertopics/pdq/supportivecare/

Circle of Hope Lymphedema Foundation
36 Woodcrest Drive; Prospect, CT 06712
203.758.6138
jt@lymphedemacircleofhope.org
www.lymphedemacircleofhope.org

Lymphatic Research Foundation
100 Forest Drive; East Hills, NY 11548
516.625.9675; 516.625.9410 (fax)
lrf@lymphaticresearch.org
www.lympaticresearach.org

Lymphedema Awareness Foundation
172 Lakeside Circle; Sanford, FL 32773
407.324.3255
laf@elymphnotes.org
www.elymphnotes.org

Lymphedema Information Support Group
16130 Juan Hernandez Drive; Suite 108; Morgan Hills, CA 95037
888.446.4375 408.782.1028; 408.782.1061 (fax)
phyllis@lymphedemasupport.org
www.lymphedemasupport.org

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Lymphoedema Support Network
St. Luke's Crypt; Sydney Street; London SW3 6NH UK
020 7351 4480; 020 7349 9809 (fax)
adminlsn@lymphoedema.freeserve.co.uk
www.lymphoedema.org

National Lymphedema Network
Latham Square; 1611 Telegraph Avenue; Suite 1111; Oakland, CA 94612
800.541.3259; 510.208.3200
nln@lymphnet.org
www.lymphnet.org

Susan B. Komen Breast Cancer Foundation
5005 LBJ Freeway; Suite 250; Dallas, TX 75244
800.462.9273 972.855.1600; 972.855.1605 (fax)
www.komen.org; www.breastcancerinfo.com

The Lymphoedema Society of Australia
94 Cambridge Terrace; Malvern, S.A. 5061 Australia
61+(8) 8271-2198
casley@internode.on.net
www.lymphoedema.org.au

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Complementary and Alternative Medicine Resources

American Academy of Medical Acupuncture

4929 Wilshire Boulevard
Suite 428
Los Angeles, CA 90010
Phone: 323.937.5514
http://www.medicalacupuncture.org

American Association for Acupuncture and Oriental Medicine

1925 West County Road B2
Roseville, MN 55113
Phone: 651.631.0204
http://www.aaaom.org

AAAOM is a group of professional acupuncturists and other interested individuals seeking to: elevate the standards of education and practice of acupuncture and oriental medicine; establish laws governing acupuncture; provide a forum to share information on acupuncture techniques; increase public awareness of acupuncture; support research in the field. Conducts educational programs, compiles statistics and operates a speakerâ€™s bureau. Publishes AAAOM Membership Directory and the American Acupuncturist Newsletter.

American Association of Ayurvedic Medicine

College Medical Associates
1603 North Four Building 144
Fairfield, IA 52556
Phone: 515.472.8477
cma@mum.edu

This organization assists physicians in encouraging patients to utilize transcendental meditation programs to prevent disease and improve health. It also promotes research into the effects of transcendental meditation programs. The organization acts as a clearinghouse for information about Ayurvedic medicine and also operates a physician referral service.

American Association of Naturopathic Physicians

3201 New Mexico Avenue, NW
Suite 350
Washington, DC 20016
Phone (Toll free): 866.538.2267
Phone: 202.895.1392
http://www.naturopathic.org

The AANP offers resources and information regarding disease prevention and health restoration, as well as curricula for naturopathic medical school, and links to other organizations that share our mission to transform the medical paradigm for disease management in health care.

American Chiropractic Association

1701 Clarendon Blvd.
Arlington, VA 22209

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Phone: 800.986.4636
http://www.amerchiro.org

This organization promotes legislation defining chiropractic health care and improves the publicâ€™s awareness and utilization of chiropractic. It conducts chiropractic surveys and statistical studies. It publishes several professional journals as well as the American Chiropractic Association Membership Directory.

American Holistic Medical Association

12101 Menaul Blvd., NE, Suite C
Albuquerque, NM 87112
Phone: 505.292.7788
http://www.holisticmedicine.org

This organization consists of licensed medical doctors, doctors of osteopathy, and medical students who are interested in furthering the practice of holistic health care. The concept of holistic health care stresses the integration of physical, mental, emotional, and spiritual concerns with environmental harmony. The organization publishes several periodicals and also publishes a National Referral Directory of Holistic Practitioners.

American Massage Therapy Association

500 Davis Street, Suite 900
Evanston, IL 60201-4695
Phone (Toll-Free): 877.905.2700
Phone: 847.864.0123
http://www.amtamassage.org

The AMTA is a professional organization that certifies massage therapists and works to advance the profession of massage therapy. Members agree to follow a basic code of ethics and abide by AMTAâ€™s standards of practice. AMTA can assist you to locate therapists in your geographical area who are AMTA members.

National Association for Chiropractic Medicine

1527 Baybrook Drive
Houston, TX 77062
281.280.8262
http://www.chiromed.org

The NACM is a consumer advocacy association of chiropractors and offers consumer assistance in finding member practitioners.

National Center for Complementary and Alternative Medicine (NCCAM) Clearinghouse

POB 7923
Gaithersburg, MD 20898 Phone: 888.644.6226
http://nccam.nih.gov

NCCAM is dedicated to exploring complementary and alternative healing practices in the context of rigorous science, training CAM researchers, and disseminating authoritative information. NCCAM accepts questions and requests for information.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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National Center for Homeopathy

801 North Fairfax Street, Suite 306
Alexandria, VA 22314
Phone: 703.548.7790
http://www.homeopathic.org

The objectives of this organization are to promote the art of healing according to the natural laws of cure from a strictly homeopathic standpoint; to facilitate the study of homeopathy by medical and allied health professionals; to implement the study of homeopathic philosophy and principles among laypersons; and to fund research in the field. The organization publishes several periodicals and also publishes a Directory of Homeopathic Practitioners (cost $6.00).

Office of Dietary Supplements, National Institutes of Health

6100 Executive Boulevard
Room 3B01, MSC 7517
Bethesda, MD 20892-7517
Phone: 301.435.2920
http://dietary-supplements.info.nih.gov

The ODS supports research and publishes research results regarding dietary supplements. It also provides advice regarding research results related to dietary supplements.

Rosenthal Center for Complementary and Alternative Medicine

Columbia Presbyterian Hospital
630 West 168th Street
Box 75
New York, NY 10032
Phone: 212.342.0101
http://rosenthal.hs.columbia.edu

The goal of the Rosenthal Center is to facilitate and conduct rigorous scientific investigation for evaluating the effectiveness, safety, and mechanisms of action of alternative and complementary remedies. It also serves as an internationally known and respected resource of information about complementary and alternative therapies.

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INDICATIONS FOR USE AND DIRECTIONS FOR USE

CELLUM6 KEYMODULE i 510k #K053225			CROSS REFERENCE OF OUR INDICATIONS FOR USE's TERMINOLOGY WITH PREDICATE DEVICES			
Treatment Head and Size		Indications for use (Page R in Tab 7) [ORIGINAL SUBMISSION]	Predicate Shepard K912004	Predicate Progressive K914774	Predicate Atlant's K974395	Bio Compression K043423
Keymodule i2 24 mm x 70 mm (therapeutic treatment head) Keymodule i50 26 mm x 50 mm (for smaller surface areas) T 644 or T 644A 1.8 mm x 4.4 mm T 630 or T 630A 1.3 mm x 3.0 mm T 615 or T615A 1.0 mm x 1.5 mm (auxiliary heads- for smallest surface areas)	31 B2 & B3	Reduction of secondary lymphedema of the arm (SLA) post mastectomy	Acute care of arm and leg swelling	Post mastectomy edema	Lymphedema	Primary or adjunctive treatment of primary or secondary lymphedema; General treatment of swelling in the extremities
	31 B4	Reduction of lymphedematous fibrotic induration	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE
	31 B5					
	31 B6	Prevention of venous stasis and venous insufficiency	Treatment of lymphedema, including post traumatic and rheumatic edema and chronic venous insufficiency and venous stasis ulcers	Venous insufficiencies due to muscle activity	Chronic venous insufficiency; Edema of venous origin	Additional or alternate treatment of venous insufficiency and chronic venous stasis ulcers associated with venous insufficiency
	31 B6	[illegible] venous thrombosis (DVT)	NOT APPLICABLE	[illegible]	[illegible]	NOT APPLICABLE
	31 B6	Improvement of lymphatic circulation in the treated areas	Treatment of chronic edema	Post immobilization edema	NOT APPLICABLE	NOT APPLICABLE

Need data on all heads?

ATTACHMENT 12

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ATTACHMENT 13 PART 1

New Substantial Equivalency

Intermittent Pneumatic Compression (IPC):

Pneumatic compression devices are commonly used in the treatment of lymphedema. Based on our research, many of these devices have premarket status, but no clinical studies were available.

In addition to the predicate devices already presented in our submission (Shepard Sport Pump #K912004, Progressive Multipulse #K914774 and the ATLANT's #K974395) we have found another predicate device which has FDA clearance under #K043423. It is called the Bio Compression Sequential Circulator and has been cleared for the following indications:

- Additional or alternate treatment of venous insufficiency
- Chronic venous stasis ulcers associated with venous insufficiency
- General treatment of swelling of the extremities

This class II device is intended for home or hospital use.

The device consists of a manual pump and a sleeve garment (for upper and lower extremities) that has segmented inflatable chambers. The pump is capable of a maximum pressure of 150mmHg and provides a graduated pressurization to the chambers. The distal chambers are sequentially inflated to a greater pressure than the proximal ones, creating a pressure gradient that mimics the pumping action of the muscles on a normal lymphatic system.

A study conducted at the Stanford University School of Medicine in 2000 investigated the safety and efficacy of intermittent pneumatic compression (IPC) with the Bio Compression device on secondary lymphedema of the arm post-mastectomy. Of 23 subjects, one group was randomized to receive 30 minutes of IPC plus a combined therapy of decongestive lymphatic therapy (DLT), which consisted of manual massage, bandaging and exercise and a compression sleeve (Reid Sleeve), performed daily. The other group received DLT without the Bio Compression device to serve as a control.

Results showed that arm volume was reduced by 26% in the IPC group and by 45.3% in the group with IPC plus combined therapies, demonstrating that IPC is generally safe and well-tolerated in the treatment of post-mastectomy lymphedema. Additionally, intermittent pneumatic compression appears to have a synergistic effect when combined with manual lymphatic drainage, bandaging and exercise.

Another study conducted at the Duke University School of Medicine compared 35 patients (16 with upper extremity edema and 19 with lower extremity edema). This study used the Bio Compression pneumatic pump device with a ReidSleeve Optiflow insert (designed to achieve optimal interstitial pressure without causing

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obstruction) for 2 sessions of 60 minutes each day in combination with a compression sleeve (Reid Sleeve) worn each night. Results showed that upper extremity edema was reduced by 80% at 28 weeks of treatment.

Intermittent pneumatic compression can prevent static accumulation of venous and lymphatic fluid. The rationale for combination therapy with the Reid Sleeve and BioCompression is that the Reid Sleeve Optiflow insert can be used inside of the pneumatic compression sleeve to further augment venous and lymphatic flow and prevent obstruction, due to the tourniquet-effect that can occur with sleeves made of flat, inelastic material. The Optiflow insert dampens the high pressures caused by pneumatic compression and maintains a constant base-line level of compression.

Cellu M6 Keymodule i:

The Cellu M6 Keymodule i also has (b)(4) aspiration and its pump is capable of a maximum pressure of (b) mmHg. The 2005 study conducted in (b)(4) at (b)(4) compared the LPG technique (mechanical rolling massage) to manual lymphatic drainage (MLD) in the treatment of secondary lymphedema of the arm post-mastectomy.

Results demonstrated that whole arm volume was reduced by 136 ml (18.2%), with forearm volume reduction at 101 ml, and upper arm volume reduction at 33 ml.

Resistance to compression measured by a (b)(4) (see Attachment 15b) was also used in this study to assess the level of fibrotic induration (fibrous hardening of the tissue that accompanies lymphedema). A significant change in resistance to compression after treatment was shown in both the upper arm and the forearm. These results demonstrate that the LPG technique performed with the Cellu M6 Keymodule i, and the manual lymphatic drainage technique, both provide an added benefit beyond that of intermittent pneumatic compression. Not only do these techniques successfully reduce lymphedema, they also provide a reduction of fibrotic induration, which is a common and chronic problem for lymphedema sufferers.

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ATTACHMENT 13 PART 2

CLINICAL RESULTS COMPARISON TABLE WITH PREDICATE K043423 AND MLD

	Manual Lymphatic Drainage (MLD) *(Values [redacted] study of LPG Technique)*	Bio Compression Intermittent Pneumatic Compression Pump	LPG Therapeutic Massager - Cellu M6 Keymodule i 2004 Study	LPG Therapeutic Massager – Cellu M6 Keymodule i 2006 Study
Clearance Information	Not Applicable	#K043423	#K053225	#K053225
Volume Whole Arm Reduction (ml)	**142.7 ml** *Tab 24/Page 10 of original submission (see table)*	**89.5 ml** *Tab 14/Page2 of supplement (see attachments 9)*	**133.6 ml** *Tab 24/Page 9 of original submission (see table 1A)*	**186.3 ml** *Tab 27/Page 17 of supplement (see attachment 21a)*
Volume Whole Arm Reduction (%)	**21.3 %** *Tab 24/Page 10 of original submission (see table)*	**26 %** *Tab 14/Page1 of supplement (see attachment 9)*	**18.2 %** *Tab 24/Page9 of original submission (see table 1A)*	**19%** *Tab 27/Page 17 of supplement (see attachment 21a)*
Volume Forearm Reduction (ml)	**129 ml** *Tab 24/Page13 of original submission (see table)*	Not Available	**101.1 ml** *Tab 24/Page12 of original submission (see table)*	**137.7 ml** *Tab 27/Page 17 of supplement (see attachment 21a)*
Volume Forearm Reduction (%)	**19.1%** *Tab 24/Page14 of original submission (see summary)*	Not Available	**19.4%** *Tab 24/Page14 of original submission (see summary)*	**14%** *Tab 27/Page 17 of supplement (see attachment 21a)*
Volume Upper Arm Reduction (ml)	**34 ml** *Tab 24/Page16 of original submission (see figure 3B and table 3B)*	Not Available	**33.5 ml** *Tab 24/Page15 of original submission (see figure 3A and table 3A)*	**48.4 ml** *Tab 27/Page 17 of supplement (see attachment 21a)*
Volume Upper Arm Reduction (%)	Not Available	Not Available	Not Available	**4.9 %** *Tab 27/Page 17 of supplement (see attachment 21a)*
Change in Upper Arm Resistance to Compression* (gms/cm²)	**6.03 gms/cm²*** *Tab 24/Page27 of original submission (see table 7B)*	Not Applicable	**5.84 gms/cm²*** *Tab 24/Page26 of original submission*	**5.50 gms/cm²*** *Tab 27/Page 11 of supplement (see attachment 21a)*
Change in Forearm Resistance to Compression* (gms/cm²)	**4.83 gms/cm²*** *Tab 24/Page27 of original submission (see table 7B)*	Not Applicable	**4.84 gms/cm²*** *Tab 24/Page 26 of original submission*	**4.25 gms/cm²*** *Tab 27/Page 11 of supplement (see attachment 21a)*

*Lower resistance to compression (smaller value) as measured by [redacted] (Attachment 15b) indicates a reduction in fibrotic induration

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ATTACHMENT 14

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

CRITERIA	CelluM6 Keymodule i	Sports Pump	Talley MultiPulse Sequential Compression Unit	ATLANT'S	PREDICATE ADDED: Sequential Circulator Model SC-3008
FDA Registration	**K053225**	**K912004**	**K914774**	**K974395**	**K043423**
Manufacturer	LPG Systems	Shepard Medical Products, Inc.	Progressive Medical Technology/ Talley Group, Ltd.	Grad-Line Corp.	BioCompression Systems, Inc.
Programmable Sequential Time	4-140 cycles per second tissue lifting time	15-220 seconds inflation time 15-175 seconds deflation time	Not Available	1-99 minutes inflation time	30 seconds inflation time 5 seconds deflation time
Sequential Action	Yes; 7 sequential programs for lymphedema	Yes; *(chamber number not available)*	Yes; 10 chambers sequentially filled	Yes; 1 chamber using calibrated linear pressure gradient	Yes; 8 chambers sequentially filled
Usable Pressure Range	[redacted] mmHg (negative pressure)	40-100 mmHg	10-130 mmHg	Not Available	25-100 mmHg
Maximum Pressure	[redacted] mmHg (negative pressure)	Not Available	150 mmHg	10-100 mmHg	150 mmHg
Weight	90 kg	Not Available	11.2 kg	5.5 kg	17.6 kg
Amperage	8.7 amp	Not Available	5 amp	0.5 amp	5 amp
Voltage	115V, 60 Hz	120V	200/250V, 50 Hz	110V, 60 Hz	120 V, 60 Hz
Depth, width, height	60 x 46 x 210 cm	Not Available	43 x 26 x 31 cm	Not Available	14 x 31.75 x 22.22 cm

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ATTACHMENT 1.5a

Three case studies indicating the effectiveness of manual lymph drainage on patients with primary and secondary lymphedema using objective measuring tools

Robert Harris, Neil Piller

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S1360-8592/03/$ - see front matter

Abstract The superficial lymphatic system is divided into areas called lymphatic territories which are separated by watersheds. When the lymphatic system fails to remove its load either due to surgery, radiotherapy or some congenital malformation of it then the fluid (and the proteins and wastes contained within it) accumulates in that territory. Anastomotic connections exist across the watersheds and while they can work unaided, manual lymph drainage (MLD) can significantly help drainage across them into unaffected lymphatic territories. MLD also can help the movement of extracellular fluids into the lymph vessels and then along them. The purpose of the study is to examine the effectiveness of a manual technique in moving fluids and softening hardened tissues using three non-invasive examination tools. We examined the movement of fluids from the affected limbs of three lymphedema patients who underwent a standardized 45-min treatment using the Dr Vodder method of M L D. We chose a typical cross section of patients with either a primary leg, secondary leg or secondary arm lymphedema. The arm lymphedema patient was also measured for return of edema over a 30-min period after the conclusion of treatment and underwent a follow-up control measurement, 2 months later without treatment. The tools used were tonometry, multi-frequency bioelectrical impedance and perometry. All three evaluation tools indicated a movement of fluid to different and unblocked lymphatic territories as well as a softening of tissues in some of the affected limbs. Fluid movements were also detected in the contralateral, apparently normal limbs, even though they were not treated. MLD thus is an effective means of fluid clearance when it has accumulated as a consequence of a failure of the lymphatic system. It seems likely that MLD has a systemic effect on the lymphatic system and that it can improve flow from otherwise normal tissues. It is hypothesized that a series of treatments (as is the norm) would result in even more significant improvements.
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Key words: Manual lymph drainage; Lymphedema; Tonometry; Perometry; Multi-frequency bio-impedance

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Introduction

Although lymphatic drainage techniques appear to work well for the great majority of patients with lymphatic and vascular disorders, there have been very few recorded occasions when the effectiveness of the treatments has been validated objectively (Johansson 2002, Moseley & Piller, 2002, Piller & Harris 2002).

In this exploratory study, which is the precursor of a full study on a series of patients, three cases of chronic lymphatic drainage insufficiency were treated with the Dr Vodder method of manual lymph drainage (MLD). The aim of this study is to objectively determine the impact of the MLD session on compositional changes including limb hardness, fluid distribution, circumference and volumes. This level of objectification is essential if we are to determine the real effect of these very important treatments and to enable health practitioners and patients alike to better know what to expect after a treatment session. Of course more marked results could reasonably be expected following a series of treatments.

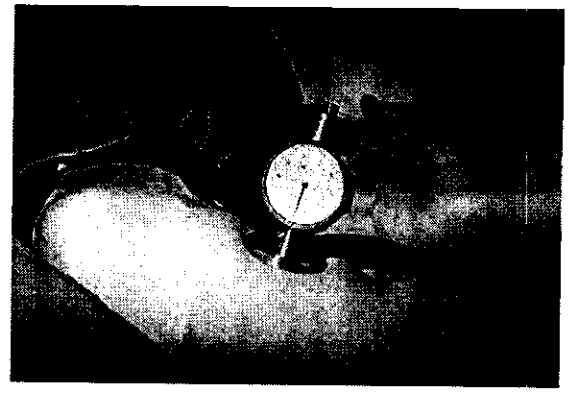

Fig. 1 Tonometer.

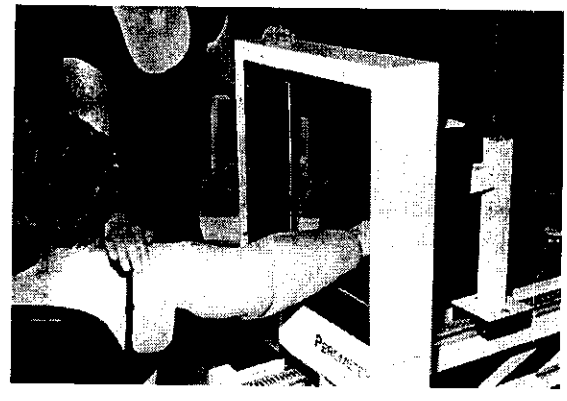

Fig. 2 Perometer.

Methods

The effectiveness of the technique was validated using a range of objective data collection including impact on fibrotic induration, extracellular fluid levels, volume and circumference.

Fibrotic induration assessment by tonometry (Fig. 1)

Tonometry has been frequently used since its inception in 1976 by Clodius, Deak and Piller (Clodius & Piller 1976, Liu & Olzsewski 1992, Bates et al. 1994, Stanton et al. 2000) as a means to detect fibrotic induration in the tissues. Resistance to compression (which relates the extent of fiber build-up) is measured by placing the weight-based tonometer over the mid-point of a lymphatic territory or over a watershed. A measurement is taken of the depth that the plunger penetrates after a period of 2 seconds which is recorded on an analogue scale. All tonometry points were located using anatomical landmarks for reproducibility. For the leg patients, these were on the anterior thigh lymphatic territory on the midline of the thigh; on the posterior thigh on the watershed of the medial and lateral lymphatic territories and on the mid-calf. For the arm patient, these were on the forearm, upper arm, anterior and posterior thorax. The lymphedematous and contralateral normal limbs were always measured with the contralateral (normal one) serving as a control.

All tonometry measurements were taken with the patient supine and rested with the muscles relaxed.

Volume and circumference assessment by perometry (Fig. 2)

Perometry is rapidly becoming the gold standard for the measurement of changes in circumference and volume of affected limbs (Stanton et al. 1997, 2000). Perometry (Pero-systems, Germany) measures the circumference and volume at 3.7-mm intervals by opto-electronic means. When used correctly it is not subject to the measurement error of tapes and through its measurement at 3.7-mm intervals, provides a much more accurate and

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reproducible estimate of volume and circumference and of their changes with time. An additional feature of being able to perform real-time plethysmography is the advantage of being able to follow changes at previously determined positions on the limb.

To measure limb volumes and circumferences, patients were rested prone on a special bed and their foot or hand supported on a rest. After approximately 5 min of rest, the perometer frame was then moved up and down the limb and the segmental volume and circumferences recorded. Again the affected and control limbs were both measured.

Extracellular fluid assessment by multi-frequency bio-impedance (Fig. 3)

Bio-impedance involves the passage of a range of frequencies of electrical current through the tissues (Cornish et al 2001). It is able to give a clear indication of the changes in extracellular and intracellular fluids as well as other compositional changes such as body fat, lean muscle mass, etc. However, for the purpose of the study only changes in total intracellular and extracellular fluids are considered. There are a wide range of bio-impedance analyzers available ranging from the simple yet effective single low (5 kHz) frequency machine (Impedimed, Queensland Australia) for measuring extracellular fluid changes and useful for the independent practitioner, to multi-frequency ones to measure intracellular fluids and to provide estimates of percentage fat (Xitron, United States). The one used in this study was the newly available In-body 3 machine (Daniel Co., Korea). This generates a full body picture and provides a summary analysis (Wantanabe et al. 1989, Cha 1995). Full body changes including changes in the extracellular as well as intracellular fluid distribution in the arms and trunk are recorded in view of the hypothesis that when one part of the body is affected by lymphedema, the whole of the body may suffer fluid distribution changes and that MLD may have systemic effects.

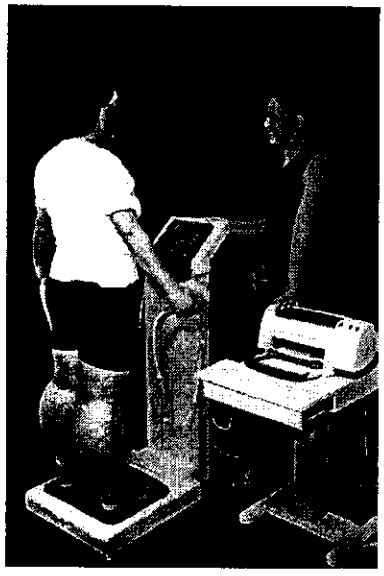

Fig. 3 Bio-impedance.

To measure bio-impedance the patient's palms and soles were moistened with saline and then she or he was asked to stand on the foot plates consisting of four electrodes. They were then asked to hold in each hand, a hand grip dual pole electrode. Measurement which took about 1.5 min was then immediately initiated. At total of eight electrodes administered and recorded current, overcoming some of the problems of 4-point electrode systems.

The Cases

1. Patient with unilateral secondary leg lymphedema (Fig. 4). A 46-year-old woman had a left-sided groin clearance in association with an hysterectomy. She has a left-sided secondary lymphedema. She has experienced subjective and objective changes in the limb for a period of 8 years. She has had regular treatment with lymphatic massage and frequently wears a support garment. She has also been using an aerobic exerciser daily (Moseley & Piller 2002).

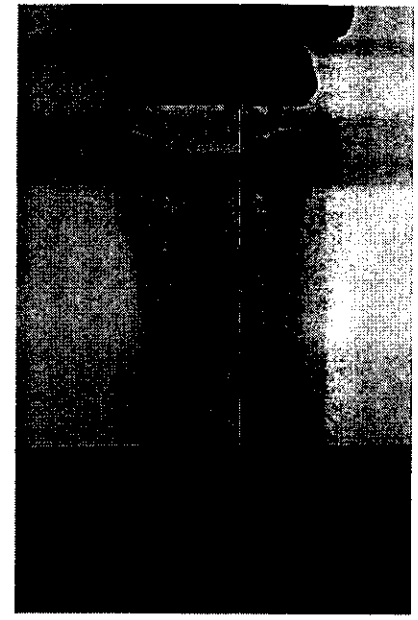

Fig. 4 Patient with secondary leg lymphedema.

2. Patient with primary leg lymphedema (Fig. 5). A 75-year-old male with a primary lymphedema of the left leg of 35 years duration. This patient received compression garments (Jobst) as required, monthly low-level helium neon–gallium arsenide scanning laser and associated lymphatic massage according to the Casely-Smith Technique (Casley-Smith & Casley-Smith, 1997). The patient was very happy with the control and the effectiveness of the previous treatment on the limb but consented to a single session of MLD to see if any further improvement could be obtained.

3. Patient with secondary arm lymphedema (Fig. 6). This 52-year-old patient had undergone a partial mastectomy with axillary clearance, radiation and chemotherapy. She had experienced lymphedema for the past 2 years. She had received

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Fig. 5 Patient with primary leg lymphedema.

Fig. 6 Patient with secondary arm lymphedema.

regular laser therapy and lymphatic massage and wore a compression sleeve to control her lymphedema.

All three patients were happy with their current therapy, but consented to further therapy on the basis that some further improvement may be expected but it was emphasized that this may not be so and that was what the investigation was in part about.

MLD massage techniques

The method employed for the one-off, 45-min treatment of each patient was the Dr Vodder method of MLD. Initially developed by E. Vodder (Wittlinger & Wittlinger 1998) in France in the 1930s, the techniques were later modified and adapted for use with edema patients by Asdonk, Wittlinger and Foeldi (Kurz 1996). For a full description of the Dr Vodder method the reader is referred to previously published articles (Harris 1992, 1994). The techniques used are those taught by the Dr Vodder Schools.

The basic characteristics of the manual techniques are:

(1) Light, rhythmic, alternating pressure with a zero and pressure phase in each stroke.
(2) Skin is stretched and torqued in a bi-directional manner (lengthwise and diagonal).
(3) Pressure and stretch is applied in the desired direction of fluid movement. This may or may not be in the direction of lymph flow, dependant on the particular intervention and interruption to lymph pathways.
(4) Pressure is adapted to local edema conditions. Generally pressure is lighter over soft spongy tissues and firmer over fibrotic tissues.
(5) Maximum pressure used on non-fibrotic tissue is 30–32 mm Hg.

The five basic techniques employed in the Dr Vodder method of MLD are Stationary Circles, Thumb Circles, Pump Technique, Scoop Technique and Rotary Technique. These are described elsewhere (Wittlinger 1998, Kasseroller 1998).

Specific edema movements are variations and adaptations of the basic movements and are prescribed manual techniques, adapted specifically to the type of patient and pathology presented. In an attempt to standardize the treatment procedure, a format was used with each patient according to the pathology, with a specific amount of time spent on each body part within the time span of 45 min.

The patients had been previously assessed at the Flinders Lymphedema Assessment clinic but none of the patients had been treated by the MLD therapist in the past. Patients did however involve themselves in self-management programs as well as in the treatments indicated earlier.

The patients were asked to rest for 30 min upon arrival at the assessment clinic. They were then measured using the three devices described above. The patient was then treated and reassessed immediately after the treatment. The arm lymphedema patient was also measured at 10-min intervals for 30 min after conclusion of treatment. In addition, this patient underwent a second control baseline measurement 2 months later. During the reassessment she was assessed using the perometer and multi-frequency bio-impedance machines and then rested supine for 45 min without treatment. She was then measured four times during a 30 min period after the rest period. This approximated the conditions of the MLD treatment program but with out the actual treatment.

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Results

Case 1 (left-sided secondary leg lymphedema patient)

Tonometry (Table 1)
These figures indicate that the MLD program softened the tissues at all positions measured on the lymphedematous limb. It also indicates a similar but not so great an effect on the supposedly normal contralateral limb. Not withstanding this latter effect, the differences in tissue softness between the limbs were much less post-treatment than they were pre-treatment.

Bio-impedance (Table 2)
These figures indicate that MLD resulted in a reduction in total fluids not only in the massaged lymphedematous limb but also in the apparently normal contralateral one. Given that there is likely to be little effect on the intracellular fluids most of this movement is hypothesized to be extracellular. The fluid removal was accompanied by a concomitant increase in total fluids in the arms and trunk. The sum of the fluid removed from the legs (320 ml) does not equal the amount deposited in the arms and trunk (230 ml) presumably due to the current ability of the equipment to measure only to two decimal points for changes in the fluid measured in liters. Certainly however, the measurement error was less than the changes detected.

Perometry (Table 3)
There were concomitant slight reductions in circumference at each of the measured positions.

These figures support the findings from bio-impedance studies but tend to show a slightly lower reduction in what presumably may be extracellular fluids from the limbs. In total this was 263 ml.

Case 2 (left-sided primary lymphedema patient)

Tonometry (Table 4)
These figures indicate that MLD softened the tissues at all measured positions on the affected limb. They also indicate a similar but not so great an effect on the supposedly normal contralateral limb.

Bio-impedance (Table 5)
These figures indicate that MLD resulted in a reduction in total fluids not only in the massaged lymphedematous limb but also in the apparently normal contralateral one. Given that there is likely to be little effect on the intracellular fluids most of this movement is likely to be extracellular. The removal there was accompanied by a concomitant increase in total fluids in the arms and trunk. The sum of the fluid removed from the legs (270 ml) does not equal the amount deposited in the arms and trunk (410 ml) presumably due to the current ability of the equipment to measure only to two decimal points for changes in the fluid measured in liters.

Perometry (Table 6)
These figures support those above collected from the bio-impedance equipment. Perometry indicated a total volume reduction in both legs of 286 ml while bio-impedance indicated a 270 ml reduction. As with bio-impedance, perometry showed a reduction in the non-massaged limb.

Case 3 (left-sided, secondary arm lymphedema patient)

Tonometry (Table 7)
No discernable patterns were observed after treatment of the lymphedematous limb. In reality, great differences are not expected after such a short treatment regimen; however, there is a possibility that will be explored in the larger trial, that the MLD massage pattern does break up the networking of the collagenous fibers and thus through this mechanism, allow the extracellular fluids to flow more freely.

Table 1 Tonometry: results (Case 1: secondary leg lymphedema; greater values equal softening of tissues)

	LE pre	NO pre	Diff	LE post	NO post	Diff
Ant. thigh	6.7	7.8	−1.1	8.6	8.2	+0.4
Post thigh	7.6	8.4	−0.8	8.4	8.8	−0.4
Calf	4.9	5.7	−0.8	6.7	5.8	+0.9

MLD softened tissues at all positions on both limbs. Differences post-treatment were much less than pre-treatment.

Table 2 Bio-impedance: results (Case 1: secondary leg lymphedema)

Fluid level pre- and immediately post-measurement

	Pre (l)	Post (l)	Difference (ml)
R. arm	1.63	1.65	+20
L. arm	1.61	1.62	+10
Trunk	14.40	14.60	+200
R. leg	4.77	4.62	−150
L. leg (LE)	5.09	4.92	−170

Reduction in fluid level in affected and normal (untreated) limb. Correlation with perometry findings. Increase in trunk fluid indicates displacement from legs.

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Table 3 Perometry: results (Case 1: secondary leg lymphedema)

Volume changes pre- and immediately post-treatment

	Lymphedema leg (ml)	Normal leg (ml)	Total (ml)
Whole limb:	−150	−130	−280
Below knee:	4	−77	

Largest reduction in thigh. Significant reduction in normal (untreated) limb.

Table 4 Tonometry: results (Case 2: primary leg lymphedema; greater values equal softening of tissues)

	LE pre	NO pre	Diff	LE post	NO post	Diff
Ant. thigh	6.2	6.1	+0.1	7.2	6.6	+0.6
Post thigh	5.7	5.0	+0.7	5.9	5.1	−0.8
Calf	3.2	6.1	−2.9	5.4	6.8	−1.4

MLD softened tissues at all positions on both limbs. Differences post-treatment were much less than pre-treatment.

Table 5 Bio-impedance: results (Case 2: primary leg lymphedema)

Fluid level pre- and immediately post-measurement

	Pre (l)	Post (l)	Difference (ml)
R. arm	2.06	2.13	+70
L. arm	2.03	2.07	+40
Trunk	17.20	17.50	+300
R. leg	6.35	6.20	−150
L. leg (LE)	7.24	7.12	−120

Reduction in fluid level in affected and normal (untreated) limb. Correlation with perometry findings. Increase in trunk fluid indicates displacement from legs. Total increase in arms and trunk more than displaced from legs.

Table 6 Perometry: results (Case 2: primary leg lymphedema)

Volume changes pre- and immediately post-treatment

	Lymphedema leg (ml)	Normal leg (ml)	Total (ml)
Whole limb	−131	−155	−286
Below knee	−80	−74	

Largest reduction below knee in affected leg. Significant reduction in normal (untreated) limb.

Bioimpedance (Table 8)

In terms of segmental fluids and their removal, the greatest reduction in the lymphedematous limb occurs immediately after massage with a gradual return to pre-treatment values by 20 min after massage cessation.

Interestingly the normal arm shows a similar pattern. (Table 9)

Slight changes in fluid levels are seen but not as great as when the patient was treated with MLD. Little variation in fluid volume is seen in the normal untreated limb.

Perometry (Table 10)

Immediately post-treatment the normal limb showed a slight increase in its volume over pre-treatment values, perhaps indicating some movement of fluids from the treated lymphedematous limb into the normal one. Within 10 min of the completion of the massage however the normal limb also showed a reduction in volume, to less than the pre-treatment value.

Taking the lymphedematous limb alone the massage resulted in a 308 ml (6.8%) volume reduction in the limb. Ten minutes after the massage had ceased there was a further 50 ml reduction, after 20 min another 35 ml, but 30 min post-treatment there was a 42 ml volume increase over the 20-min reduction. Maximum percentage reduction was 8.7% at 20 min post-treatment.

Taking the normal limb into account, massage had a significant effect in removing 339 ml of volume from the whole of the lymphedematous limb (this amounts to 32% of the difference in volume between the normal and lymphedematous limb). However within 30 min almost 39% of the achieved reduction had returned with this refilling occurring gradually and evenly over this period. After 30 min post-treatment the reduction percentage was 20%. This perhaps provides evidence for the need to provide some form of external support (compression bandaging or garment) after massage (Table 11).

Two months after the initial treatment, the patient was remeasured using the perometer. Only a slight fluctuation (maximum less than 6%) was seen in the change in volume when comparing the normal and treated arms, immediately after the rest phase of 45 min and over a subsequent 30-min measuring period.

Discussion

There has been some discussion in the literature about the possibility that once one section of the body is

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Table 7 Tonometry: results (Case: 3: secondary arm lymphedema; greater values equal softening of tissues)

	LE pre	NO pre	Diff	LE post	NO post	Diff
Fore arm	4.3	5.7	−1.4	3.9	6.3	−2.4
Upper arm	6.8	6.0	+0.8	7.0	8.8	−1.8
Anterior thorax	7.7	9.2	−1.5	7.6	8.5	−0.9
Posterior thorax	3.4	3.2	+0.2	3.2	5.4	−2.2

No discernable patterns emerged after treatment.

Table 8 Bio-impedance: results (Case 3: secondary arm lymphedema)

Fluid level pre and immediately post measurement (volumes are in ml)

	Pre	Post	10 min	20 min	30 min
Affected arm	2170	2020	2080	2180	2250
Change		−150	−90	+10	+80
Normal arm	1420	1320	1350	1400	1420
Change		−100	−70	−20	0
Diff. LE-normal	750	700	730	780	830
Trunk	14,300	13,700	13,900	14,200	14,400

Greatest reduction seen in lymphedema arm immediately after MLD. Gradual return to pre-treatment level after 20 min.

Table 9 Bio-impedance: results (control; Case 3: secondary arm lymphedema)

Fluid level pre- and immediately post-rest (volumes are in ml)

	Pre	Post	10 min	20 min	30 min
Affected arm	2190	2130	2220	2230	2200
Change		−60	+30	+40	+10
Normal arm	1420	1430	1390	1390	1400
Change		+10	−30	−30	−20
Diff. LE–NO	770	700	830	840	800

No trunk measurements taken. Greatest reduction seen in lymphedema arm immediately after rest (but 60% less than when treated).
Procedure confounding factors affecting very limb reacts at rest with time separation between initial study and control (7 weeks).
Little change in normal arm.
Gradual return to pre-treatment level after 20 min.

Table 10 Perometry: results (Case 3: secondary arm lymphedema)

Volume changes pre- and immediately post-treatment (ml)

		LE arm	NO arm	Total	% change
Pre-treatment		4541	3494	1047	0
Post-treatment	0 min	4233	3525	708	32
Post-treatment	10 min	4183	3447	736	30
Post-treatment	20 min	4148	3369	779	26
Post-treatment	30 min	4190	3351	839	20

Slight increase in normal arm after 10 min. Largest % change compared to normal, shown immediately after treatment. Largest reduction in affected arm, shown 20 min. after treatment.

affected by lymphedema that other sections (particularly the contralateral limb) are affected as well (Pecking et al. 1983, Foeldi et al. 1989). The results of this study support this hypothesis since improvements in extracellular fluid content and tissue softness were observed for each of the case studies in the contralateral limb as well as in the lymphedematous one (excepting the arm patient). Of course it may be that these three studies were in some way abnormal in terms of lymphatic drainage but this was not examined. However, the multi-frequency bio-impedance analysis output indicated that the fluid distribution was within the normal range in the "normal" limb. This is an exciting area which remains to be investigated.

There has also been some evidence of the ability of lymphatic massage to facilitate fluid movement through the superficial lymphatic system via inguinal-axillary anastomoses to the lymph systems of the axillary area (Piller et al. 1998). The information collected from the In-body bio-impedance machine indicates that this may be so since there were slight (presumably transient) increases in total fluids in both arms when the legs were treated. As would be expected, there were rather significant accumulations (200–300 ml) of additional fluid transiently in the trunk in both case studies involving treatment of the legs.

In all three case studies the MLD was concentrated on the left lymphedematous limb; however, there were similar although not so marked changes in the right, apparently normal limbs. This suggests an interlinkage of the lymphatic system and in one way supports the current knowledge about the anastomotic connections between the lymphatic territories. It also suggests that a problem in one part of the lymphatic system may manifest itself remotely. However when the cause of the problem is removed (i.e. of poor entry into the lymphatics, poor flow along them, or inadequate clearance into a lymph node) then the system can

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Table 11 Perometry: results (Control; Case 3: secondary arm lymphedema)

Volume changes pre- and immediately post-treatment (ml)

		LE arm	NO arm	Total	% change
Pre-treatment		4430	3226	1204	0
45-min rest	0 min	4413	3234	1179	2
Post-rest	10 min	4367	3235	1132	6
Post-rest	20 min	4499	3217	1202	0
Post-rest	60 min	4414	3274	1140	5

Slight increase in normal arm after 10 min. Largest % change compared to normal, shown 10 min post-rest. Largest reduction in affected arm, shown immediately after rest.

correct itself in other parts of the body.

In two of the cases, post-MLD tonometry showed a softening of all sites of measurement but this was most pronounced in the calf area of the lymphedematous legs. However, softening also occurred in the major lymphatic territories of the anterior thigh and in the posterior thigh watershed area. In both cases there were reductions in the range of 2–3% in the volume of the normal and affected limb subsequent to MLD. While this is a small reduction it must be remembered that these patients were receiving the best currently available treatment and were well educated in terms of caring and managing their limbs. Also this was the outcome from a single treatment session. We expect (and there is evidence from other studies: Hutzschenreuter et al. 1991, Hutzschenrenter & Herpertz 1993, Boris et al. 1997) that a series of treatments achieves a cumulative result in terms of limb improvements.

These case studies, using a range of modern fluid, fiber and volume change detection equipment indicate that a single session of the Dr Vodder method of MLD has a relatively quick and clinically significant effect on limb fluid distribution and tissue softness. The study results do show that the effect of even a single MLD massage can be measured. The control study on the arm lymphedema patient indicates that without treatment, there is little change in fluid volume and extracellular fluid content of the affected and non-affected limbs. It is proposed to undertake a longer term longitudinal study of the effect of MLD in combination with other supporting treatment such as bandaging and garments in a more strictly controlled environment where there is no need for the patient to move from the supine to standing position for some measurements and to make multiple objective measures at each stage of the process. Normally a patient receives a number of massage and bandaging sessions not a single MLD session without bandaging, as was tested here.

Conclusion

Three objective techniques of tonometry to assess tissue softness, multi-frequency bio-impedance to assess total and extracellular fluids and perometry to assess volume and circumference changes were used to objectively assess the effect of a single session of MLD on a patient with primary leg lymphedema, a patient with secondary leg lymphedema, and a patient with secondary arm lymphedema.

A single session of MLD has been shown to have what appears to be a significant clinical effect on the total fluid levels (mainly represented by extracellular fluids) in the massaged and affected lymphedematous limbs. Also recorded was a softening of the tissues of all of the major lymphatic territories.

Surprisingly there were also reductions in the total fluid levels of the apparently normal, contralateral limb even though the MLD massage was not performed here. Post-MLD measurements demonstrated that there were concomitant increases in the total fluid content of the trunk area in both cases of leg lymphedema and a slight increase in fluids in the arms.

A follow-up controlled pilot study is proposed to test the effect of multiple MLD sessions in combination with the normal line of other support including bandaging and garments.

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REFERENCES

Bates DO, Levick JR, Mortimer PS 1994 Quantification of rate of depth of pitting in human edema using an electronic tonometer. Lymphology 27: 159–172

Boris M, Weindorf S, Lasinski B 1997 Persistence of lymphedema reduction after noninvasive complex lymphedema therapy. Oncology 11 1

Casley-Smith JR, Casley-Smith JR 1997 Lymphoedema—A Guide for Therapists and Patients. Lymphoedema Association of Australia, Adelaide

Cha K et al. 1995 Multi frequency bioelectrical impedance estimates the distribution of body water. Journal of Applied Physiology 79: 1319

Clodius L, Deak L, Piller NB 1976 A new instrument for the evaluation of fibre in lymphoedema. Lymphology 9: 1–5

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Records processed under FOIA Request 2013-1897; Released 9/15/14

Cornish BH, Chapman M, Hirst C et al. 2001 Early diagnosis of lymphoedema using multifrequency bioimpedance. Lymphology 34: 2–11

Foeldi E, Foeldi M, Clodius L 1989 The lymphoedema chaos – a lancet. Annals of Plastic Surgery 22: 6

Harris R 1992 The Vodder method, an introduction to manual lymph drainage. Massage Therapy Journal 31: 1

Harris R 1994 Edema and its treatment in massage therapy. Journal of Soft Tissue Manipulation 1: 4

Hutzschenreuter P, Herpertz U 1993 Primary and secondary lymphedema in children treated with manual lymph drainage and compression therapy. European Journal of Lymphology 4: 14

Hutzschenreuter P, Wittlinger H, Wittlinger G, Kurz I 1991 Post mastectomy arm lymphedema: treated by manual lymph drainage and compression bandage therapy. European Journal of Physical Medicine and Rehabilitation 1: 6

Johansson SK 2002 Lymphoedema and Breast Cancer. A Physiotherapeutic Approach. Studentlitteratur, Lund University, Lund. ISBN: 91-628-5117-9

Kasseroller, R 1998 Compendium of Dr Vodder's Manual Lymph Drainage, Haug, Heidelberg, 1st Ed.

Kurz I 1996 Textbook of Dr Vodder's Manual Lymph Drainage (Treatment Manual), Vol. 3, 3rd Ed. Haug, Heidelberg

Liu N, Olszewski W 1992 Use of tonometry to assess lower extremity lymphoedema. Lymphology 25: 155–158

Moseley A, Piller N 2002 Combined opto-electronic perometry and bio-impedance to measure objectively the effectiveness of a new treatment intervention for chronic secondary leg lymphoedema. Lymphology 35: 136–143

Pecking A, Cluzan R, Despret-Curly JP 1983 Indirect lymphoscintigraphy in patients with limb edema. In Progress in Lymphology, Proceedings of the 9th International Congress of Lymphology, Tel Aviv.

Piller NB, Goodear M, Peter D 1998 Lymphoscintigraphic evidence supports the evidence of axillo-anastomotic pathways in a patient with chronic secondary leg lymphoedema subsequent to inguinal node clearance and radiotherapy. European Journal of Lymphology 6: 97–100

Piller NB, Harris R 2002 Objective measurement of the effectiveness of a single session of manual lymphatic drainage on primary and secondary lymphoedema of the lower leg. Lymphology 35(Suppl): 289–292

Stanton AWB, Badger C, Sitza J 2000 Non invasive assessment of the lymphoedematous limb. Lymphology 33: 122–135

Stanton A, Northfield J, Holyroyd BP 1997 Validation of an optoelectronic limb volumeter (perometer). Lymphology 30: 77–97

Wantanabe RK, Miura K, Inoue K 1989 Evaluation of leg oedema using a multi-frequency impedance meter on patients with lymphatic obstruction. Lymphology 22: 85–92

Wittlinger H, Wittlinger G 1998 Introduction to Dr Vodder's Manual Lymph Drainage, Vol. I, 6th Ed. Haug, Heidelberg

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ATTACHMENT 15b

Tissue

(b)(4)

[redacted]

An accurate, easily used assessment tool to measure lymphedema patients

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Development and Usage of (b)(4) [redacted]

Developed in (b)(4) [redacted] in collaboration with the (b)(4) [redacted] (b)(4) [redacted] the Tissue (b)(4) [redacted] is an easy-to-use, fast, accurate and reproducible method of assessing pitting edema and fibrotic changes in edematous and lymphedematous tissues.

Pitting edema results when there is a displacement of extracellular fluid and is present in stage 1 lymphedema (ISL 1995). Over time, chronic inflammatory changes result in the progressive fibrotic indurations of tissues (Stage 2 lymphedema – ISL Grade 2). Assessing the rate of this change and the impact of your treatment and the patient's management of this fibrosis is crucial since fibrosis is one of the major factors that can lead to poor lymph drainage and poor treatment outcomes.

What is the (b)(4) [redacted]

The (b)(4) [redacted] has a weight of 200 grams that gently [redacted] onto the skin. The depth of penetration of the (b)(4) [redacted] is accurately recorded on a dial, to a resolution of 0.01mm.

This tool is quick and easy to use in any clinic setting. It is a mechanical device and does not require electricity or batteries. It is approx.11 cm (4 inches) in height and 5cm (2 inches) wide. It is made of stainless steel with a plastic base and is easy to clean. It comes with a full set of instructions.

(b)(4) [redacted] will provide a limited warranty for one year against mechanical defect, including free return shipping for the first three months of the warranty period if defective.

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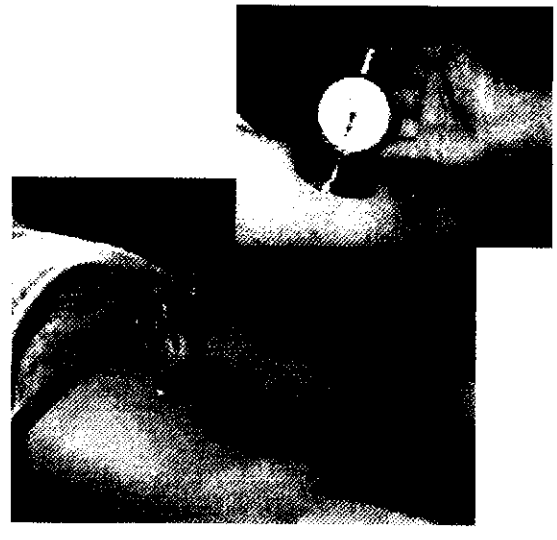
Why use a (b)(4) [redacted]

Monitoring Change



Appropriate treatment for lymphedema requires accurate objective, diagnosis of the pathophysiologic changes. These changes can be monitored by the use of tonometry.

(b)(4) [redacted] measures the resistance of tissues to compression, in the major lymphatic territories. This provides a sensitive measure of fluid and fibrous accumulation within the tissues and of the progress of the territory or the limb from the initial fluid-rich stage through the fatty middle stage to the fibrous end point stage.

(b)(4) [redacted] is able to monitor the effect of treatment and progression of lymphedema. With fibrosis, tissue resistance to compression increases, resulting in low plunger penetration and a low numerical indication.

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Objective of Accurate Charting

Routine measurement through a course of treatment may indicate an increasing plunger penetration due to a softening of the sclerotic tissue. Accurate charting of lymphedema and the course of treatment is essential in order to provide objective data to patients, referring physicians, insurers and research projects and provides evidence for your actions.

Important Considerations

In using the (b)(4) [redacted], there are two important points to be aware of:

Firstly, it does not measure absolute amounts of fiber or changes in it. The measure is a relative one. That is why its best information comes when you are able to get a baseline (pre-treatment) indication (b)(4) [redacted] (b)(4) [redacted] of the affected lymph territories or limbs and track the changes as the patient is treated. Secondly, it is also important to try to get a contralateral reference point on a normal limb. This will allow you to see how other apparently normal lymphatic territories are progressing and allow you to assess the progress of the affected limb against the non-affected limb.

Reference

1. Bates DO, Levick JR and Mortimer PS (1994), 'Quantification of Rate and Depth of Pitting in Human Edema Using an Electronic Tonometer', Lymphology 27, pp 159 – 172

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ATTACHMENT 16

Schedule 1

Contract Details

(b)(4)

[redacted]

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(b)(4)

[redacted]

(b)(4)

[redacted]

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Schedule 2

Research Program

conducted on

A randomized matched pair trial of the LPG technique on breast cancer related secondary arm lymphoedema

on behalf of
LPG Systems

Background: Fluid accumulation in the tissues is a manifestation of a great range of other disorders or diseases, including heart problems, inflammations associated with infection or arthritis, renal disorders and a whole range of other conditions. In order to provide a good testing basis we have chosen lymphoedema. The reasons why it is a good test model is that firstly unless something clearly works the condition worsens and secondly we have many very accurate tests to determine how the parameters of these fluid filled tissues change.

The model: Lymphoedema is present when the circumference difference between the limbs is 2 cms or more in a number of measured positions. This equates to a volume difference of 200 mls or more. However, long before this there are many subtle changes occurring in the tissues and in the cells which comprise them which are usually accompanied by patient reports about how the limb feels in terms of sensations of heaviness, tension, aches and pains and often changes in mobility.

Clinically manifest lymphoedema occurs in about 30% of patients who have surgery and radiotherapy to the armpit associated with breast cancer or groin or lower abdominal area associated with bowel, prostate, cervical, bladder or reproductive system cancers, although its possible that many more are affected as is indicated by studies on subjective indicators as indicated above which show up to 60% of patients being affected. Estimates suggest over 160,000 people in Australia have clinically discernible lymphoedemas and that number again with other problems such as range of movement, tension, heaviness pain etc. The problem is the same the world over where ever there is surgery and or radiotherapy for treatment of breast and of course other cancers.

Why do people get lymphoedema? Surgery removes the major lymph nodes in the groin thus significantly compromising the deep lymphatic drainage collectors while the radiotherapy (where ever it is targeted) destroys or damages remaining collectors and any superficial lymph capillaries. The scar tissue formed through surgery acts as a physical barrier to the regrowth of the deep lymph collectors since they are known not to be able to re-bud through more than about 0.5 mm of scar tissue and the generalised fibrotic induration associated with the radio therapy slows or prevents the movement of lymph through such areas as well as slowing or preventing the regrowth of lymphatic capillaries.

(b)(4)

[redacted]

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The progression of lymphoedema

At first there are subtle changes in the tissues including changes in the Po_2, intra cellular and extracellular enzyme levels, the distribution of cell types and the local accumulation of metabolic products and proteins whose net result is a mild low level but chronic inflammatory process. Subsequent to this is a progressive fibrotic induration of the tissues. This may be localised at first but it may spread widely throughout the tissues that are the sites from which lymph would normally leave, but now cannot. The localised problem then becomes a generalised one and the subsequent increase in lymph load combined with a slow progressive reduction in the lymph transport capacity means widespread changes in the tissues, eventually resulting in a change in the size of the limb which can be detected by circumference or volume changes.

There are many treatment and management strategies to halt or reverse these changes ranging from simple elevation of the limb (to reduce the effects of gravity and facilitate lymph drainage through remaining lymph pathways), to special forms of lymphatic massage (which help load up the pulsatile lymph collectors and help them pump better and help open new pathways for fluid drainage), to laser (which increases the rate of beating of the lymph collectors, and helps break up directly and indirectly, the fibrous tissues) to exercise and Tai chi/Qi Gong (which helps vary total tissue pressure, thus helping the movement of fluids into the collecting lymphatic vessels and their pumping), to hydrotherapy, support garments and simple strategies like improved skin care (which help reduce the lymphatic load). Not every treatment is suitable to all individuals and the plethora of treatments may be an indication that to date an effective treatment for lymphoedema has yet to be found.

All of these strategies can be grouped into those which improve lymph outflow from the limb or those which reduce the lymph load. Those which improve the outflow do it by either stimulating or allowing the re-growth of new lymphatic capillaries or make the remaining lymphatic system work better. These are collectively called lympho-genic or lympho-stimulatory activities.

The end point of these strategies is a reduction in the 'swampiness" of the tissues, an improvement in the flow of nutrients to the tissues and wastes from them as well as an increase in the levels of oxygen in the them. It is the initial reduction in oxygen levels which is one of the key reasons for significant changes in cell populations and their activity levels and the problem of lymphoedema.

LPG

Some basic and relatively uncontrolled clinical studies of the LPG technique have been shown to improve tissue oxygen levels, reduce fibrotic induration, reduce hypertrophied skin, improve lymph and possibly blood flow and be likely to facilitate wound healing. Most of the research to date however is based on (b)(4) [redacted]

(b)(4) [redacted] These later aspects may be difficult to do in a trial of the type envisaged.) Some of the

(b)(4) [redacted]

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experimental data namely that of Adcock (2001) do indicate the importance of using the same (and trained) operator.

Since the events described above are key ones in improving the conditions in a chronic lymphoedema would be worthwhile to test this apparatus on patients with chronic secondary lymphoedema of the limbs. We would suggest upper limbs due to the homogeneity of the condition and the relative lack of confounding variables. Pilot exploratory use of the Endermologie unit and anecdotal reports from a few mastectomy and lower leg and lipoedema patients (and what I can recall seeing of its use in Argentina and recently in Genoa and Rome) showed some significant but variable reductions in limb circumferences, in free extracellular fluids and in the patients subjective indicators of how the lymphoedematous limb(s) felt. This was particularly so for one patient with a severe lipoedema who I understand was treated in Sydney and who I met some two years ago. On this basis and on the basis of a large volume of anecdotal information available from previous research (b)(4) [redacted] it would seem that a trial is worth to test the equipment as it is currently presented at the recommended usage frequencies.

Manual Lymphatic Drainage

CDT has been proven to reduce limb volume (Vignes et al 2002; Kriederman et al 2002) and subjective complaints like pain (Johansson et al 1988). Physiologically, it reduces microlymphatic hypertension (Franzeck et al 1997) and decreases expression of the pro-inflammatory genes responsible for the fibrosclerotic reactivity (Földi et al 2000).

A randomized controlled crossover study has been done to investigate the effect of MLD against self lymphatic drainage (Williams et al 2002). The results shown that MLD significantly reduces excess limb volume, reduces dermal thickness in the upper arm, and improves emotional function.

There is still no study evaluating the optimal treatment time for a MLD treatment. A study done by Piller and Harris (2001) did show that a one-off 45-minute MLD treatment helped in the reduction of the tissue resistance to compression and also limb volume reduction.

The optimal treatment duration of either a treatment program with MLD or that with SPC are still not standardized (Harris et al 2001). For the intensive treatment, it is believed that a four-week treatment program is effective in reducing the initial volume of the lymphedematous limbs (Leduc et al 2000; Weissleder and Schuchhardt 2001).

Objectives

To determine if the LPG Technique using the Cellu M6 Keymodule (and any modification to its operating parameters) can;

Reduce the size and volume of a chronically lymphoedematous limb

Reduce the levels of extracellular fluids in the lymphoedematous limb

(b)(4) [redacted]

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Reduce the amount and extent of fibrotically indurated tissues in the limb

Improve lymphatic transport capacity (confined to a sub sample of 10)

Improve range of movement of the limb

Improve patients subjective indicators such as aches and pains, tension, heaviness, pins and needles and other problems normally associated with a chronically lymphoedematous limb.

NB "limb" means arm; "Lymphoedema" is being used as a representative model of a large range of other conditions/disorders whose end point is the accumulation of fluids in the tissues.

Methods

Design

Matched Pair

Patients will be randomly allocated to either the control group who will receive Manual Lymphatic Drainage (MLD) and an experimental group who will receive the LPG technique. All patients will be supplied with normal educational materials appropriate to the care of their limb. Randomisation would occur after the first interview to determine suitability for the trial. Allocation to the control or experimental group will mean the opposite allocation for their nearest match.

The comparison against this "gold standard" of MLD is greatly beneficial since it sets the context of the LPG effect and indicates its performance against a well known benchmark. In terms of anticipated outcomes there would be significant positives irrespective of how it performed against the "gold standard". The comparison with MLD adds cost to the trial since as well as the LPG treatment the MLD would also have to be administered.

A random stratification process may also be used since its moderately well evidenced that the response of a lymphoedematous limb to treatment is dependant on a number of major points, these being the extent of fibrotic induration (which correlates with the duration of lymphoedema), the age of the patient and the extent of other confounders such as poor skin, and out of normal range BMI. In this stratification process the outcome would be an analysis similar to a matched pairs design.

Minimal sample size for the study will be 50 lymphoe ema limbs (although final numbers will be determined by sub group heterogeneity and by determination of what constitutes a significant out come measure) with these being distributed by the described strategies into the LPG and the MLD treatment groups. Due to the often whole body effect of massage and other techniques on the lymphatic system (Harris and Piller 2002) the contra-lateral limb will also be tested in both groups.

Conduct of the trials on humans will be subject to the approval of, and any conditions imposed by, the relevant (b)(4) [redacted] and Medical Centre ethics committees.

(b)(4) [redacted]

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Duration of treatment

The optimal duration would appear to be 4 weeks use with the patient being treated at FMC lymphoedema assessment clinic 4 times per week with 25 minutess per LPG session. The gold standard comparison would be the Dr Vodder School Manual Lymphatic Drainage program as at the moment it has reasonable objectification and is strongly regarded around the world as the best. Ideally the MLD program should be of similar duration however there is no 25 minute program. The standard MLD arm massaging sessions are 45 minutes duration. It is normal to apply external pressure in the form of a low compression bandage after these 2 treatments (MLD and LPG).

Subjects will receive 45 minutes of MLD in Vodder method to the neck, trunk, and the lymphoedematous upper extremity (Weissleder and Schuchhardt 2001) on 4 occasions over a 7 day period for four weeks. It will be delivered by a certified MLD and CDT therapist trained in Vodder method.

It should be noted that there is a possibility that maximal reductions are gained before this time but that even if this is so, the continuance of the treatments may show positive effects that hitherto have not been observed.

Duration of study

- 9 months
- Starting of the study : May 1st 2004
- End of study : March 2005

The complete study would take 9 months assuming : 4 LPG treatments (or control MLD treatments) per week, the recruitment of two suitable patients per week and a steady state of 8 patients in each of the control and treatment groups.

Subject inclusion criteria

Patients must be willing and able to come to (b)(4) for treatment which will either be LPG or MLD.

Patients presenting and or diagnosed with clinically manifest chronic secondary unilateral arm lymphoedema. These patients will be late grade 1 but with the key determinants showing a firm location in the grade 2 (ISL classification) region. This would mean that the corrected (for arm dominance) volume difference would be 10% or more. Generally this means a circumference difference of 2 cm or more in the key measurement positions. Volume difference is used in preference to circumference difference since for larger framed persons 2 cm difference is relatively insignificant, while for smaller frame persons it is very significant.

Duration of lymphoedema will be generally greater than 1 year. However a lesser period may be used if there is significant indications of fibrotic induration of the major lymphatic territories as detected by tonometry. (b)(4) will be used as the prime determinant of entry and time a second one. This means that the rate of progression of the lymphoedema can be accounted for.

(b)(4)

[redacted]

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Patients with anterior chest wall radiotherapy will be included and will most likely represent a sub sample if enough and if there is any differences detected in their response to treatment.

Age will not be a prime determinant of entry. The status and staging and thus the progress of the lymphoedema development will be of greatest importance. Patients however need to be mobile and able to well undergo the treatments we will offer. This will generally mean that most people will be under 65 years.

BMI will be logged as part of the clinical trial parameters but will generally not be used as an inclusion criterion. Those with high BMI's may form an interesting subgroup with their combination of lymphoedema and obesity. It may be that LPG treatment has a role to play not only in lymphoedema but also in obesity.

Subject exclusion criteria

Unavailability of patient to attend all sessions.

Current uncontrolled cancer

Recent surgery, 1 month in any other part of the body

Hypertension

Underlying lipoedema

Using Diuretics or Corticotherapy any physiotherapy for less than 3 months

Underlying primary lymphoedema

Note on criteria

It would not matter if the patients were having other treatments (ie current best treatment) but certainly these other treatments would be ceased upon commencement of this current trial. Ideally, however patients would be asked to cease other treatments at least two weeks prior to the trial for both the treatment and control groups. For treatments which are known to have a long term treatment effect and which are well evidenced then it is likely that the known duration of that treatment effect period would the minimum with an additional two week margin. In some cases this may mean a three month exclusion period. Attempts will be made to match patients in terms of prior treatment, although this will not be a primary determinant.

In view of the now documented effects of mild exercise on lymphoedematous limbs all patients will be discouraged from the undertaking of any formed exercise programs during the extent of the trial. Normal activity will be encouraged.

Clinical Assessment procedures and timing

Each patient will be assessed prior to entry into the study to confirm suitability.

(b)(4)

[redacted]

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Suitable patients will have the following standard tests performed immediately prior to the first treatment and at a weekly intervals (at the end of the treatment for the given week) until the completion of the trial. Patients will be reassessed one month and two months after the completion of the trial for longer term benefits.

(b)(4) [redacted] measurements will be made pre and post every session. These indicate very accurately the levels of segmental fluids in the limbs and is an important measurement tool to indicate the progress of the treatment.

Assessment will include standard assessment procedures currently used in the Lymphoedema Assessment Clinic.

Subjective indication of problems such as heaviness, tension, bursting pains, pins and needles, areas of paraesthesia logged on 5 point lichert scales.

Objective determination by (b)(4) [redacted] of the levels of fibrotic induration in each of the major limb and thoracic territories.

Objective determination of limb volumes using perometery (circumference measurement in 200 positions on the limb and volume determination calculated from this).

Objective determination of the amount of free extracellular and intracellular fluids by (b)(4) [redacted].

Objective determination of range of movement using a (b)(4) [redacted].

Objective determination of the depth of subcutaneous tissues and of compositional change in a sub group on selected sites corresponding to (b)(4) [redacted] sites

Lymphoscintigraphy (sub. Group of ten in each group) before and after 4 weeks of treatment.

Details of procedures

Measurement

Limb circumferences and volume

Limb volume can be calculated, using segmental circumferential measurements taken, by considering the limb as a cylinder or a frustrum (Lennihan and Mackereth 1973; Sitzia 1995; Sander et al 2002; Karges et al 2003). It serves good intra- and interrater reliability (Sander et al 2002). Studies by Sitzia (1995), Sander et al (2002) and Karges et al 2003 shown that a frustum formula is more accurate than a cylindrical formula in assessing the upper limb volume and it is also proved to have high correlation (r = 0.98) with the volume measured by the water displacement method (Stranden 1981). However, perometry is more accurate and more reproducible and validation studies have previously been performed (Stanton et al 1997, 2000). All limbs will be measured using perometry in this study. The perometer (b)(4) [redacted] a square measuring frame that contains rows of infra-red light emitting diodes on two sides and rows of corresponding senses on the opposite two sides. The patient sits at one end with the foot resting

(b)(4) [redacted]

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centrally on an adjustable support. The frame is then moved along the length of the leg from the ankle to thigh. The limb casts shadows in two planes and using the cross-sectional information obtained, a computer builds up a whole leg volume and circumferential picture (at 3mm intervals) of the entire leg. It has been validated on both healthy volunteers and patients with oedema related conditions.

Tissue resistance to compression – the tonometer reading

A swollen extremity may have smaller girth measurement as a result of the soft tissue shrinkage particularly if there is tissue fibrosis (Clodius et al 1976; Stanton 2000) and is therefore more resistant to compression (Clodius et al 1976, Liu and Olszewski 1992). A tissue (b)(4) has been used to provide the extent of tissue elasticity of lymphedema patients after courses of treatment and it is supported by various studies (Clodius et al 1976; Piller & Clodius 1976; Liu and Olszewski 1992, Kar et al 1992; Bates el al 1994; Chen et al 1988; Piller and Thelander 1998; Piller and Harris 2001). In this study A mechanical tissue (b)(4) with a (b)(4) weight (b)(4) will be used to measure the tissue resistance to compression on the lymphedematous extremities. A single point on the upper arm and on the forearm will be used for the measurement. Three measurements will be taken at each body point and the average reading will be taken. The relative tissue resistance to compression at a specific point will be reflected by the ratio (R) = ((b)(4) reading of a point on the lymphaedematous upper extremity) / ((b)(4) reading of the corresponding point on the unaffected upper extremity). Intra-rater reliability of the (b)(4) measurement has been conducted and good results were obtained. In this study however, only one person will be involved in measurement taking.

Fluid content using multi frequency (b)(4)

The (b)(4) machine used in this clinical trial will be the (b)(4) manufactured (b)(4) (b)(4) a multi-frequency body and segmental analyser (5kHz - 500kHz) where the patient stands erect on electrode footplates and holds electrodes in the hands, resulting in 8 electrode contact sites. The multi-frequency technique accurately quantifies both total body fluid and extracellular fluid in extremities (Ross, 1989, Watanabi, 1989), having the ability to quantify lymph fluid changes as it can distinguish among the gain or loss of fluid from fat and muscle (Luksaki, 1987, Luksaki et al 1994). (b)(4) validity in measuring body fluid in both healthy adults and patients has been proven, (Luksaki, 1987, Mikes 1988, Cornish et al 1996, 2000) including in lymphoedema (Ward et al 1992).

(b)(4)

A sub group of 10 patients from the trial who volunteered to undergo (b)(4) before and after treatment to assess the affect of the LPG on lymphatic transport capacity would be optimal. It is not necessary to conduct this test in the MLD group. Lymphatic transport capacity will be determined at entry into the study and at the end of 28 days of treatment with the LPG technique. (b)(4) requires the injection of a (b)(4) intra cutaneously into the web spacing of the toes in two positions. The rate of clearance

(b)(4)

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from the injection site is measured along with arrival times in the nodes and clearance from the limbs. This gives a clear functional indication of lymphatic transport capacity (Piller et al 1998) and as well can be used as a subjective indicator of problem areas in the lymphatic territories where situations of dermal back flow are occurring. (b)(4) [redacted] will normally be conducted a day or two prior to the start of the MLD treatment and then within 3 days of its cessation.

(b)(4) [redacted]

Dermal thickness may change during treatment and for the LPG group there is some benefit in measuring these changes as well as determining quantitative changes in the extent of fibrotic induration. This will be determined in a subgroup using techniques of fractal (b)(4) [redacted]. Scans would be conducted at the (b)(4) [redacted] points for comparative purposes.

Physical and Biochemical examination:

Blood Pressure and Heart Rate will be measured each week to ascertain whether the LPG technique/Control has any influence on these.

Subjective measurements:

A questionnaire assessing participants subjective symptoms, including pain, heaviness, tightness, pins and needles, cramping, burning sensations and perceived limb size may be administered each week, but most likely pre and post treatment period. Participants will be asked to rate their symptoms on a 0-10 scale as used in the McGill Quality of Life Questionnaire, where zero equates to no problem and 10 is rated as the worst imaginable. This scaling system has been previously validated.

Persons Conducting the Study

All work would be supervised by (b) (6) [redacted]. Persons with relevant expertise would be contracted in to perform specific tasks *ie* statistical advice and analysis, (b)(4) [redacted].

All assessments will be made by a specially employed research assistant (or other qualified persons such as the breast nurses). If we are to compare against the gold standard of MLD then the person employed to do this would also have to be an appropriately trained one, of which there are a number in (b)(4) [redacted]. Treatment using the LPG technique would be given using an appropriately trained person.

Broader use of the findings

a) **Vascular oedemas**: There are many hundreds of thousands of people (men and women) who have a range of vascular problems related to varicosities, to diabetes, compromised cardiovascular function and a range of other diseases and disorders who have as their end points similar tissue changes as those on lymphoedemas. The major difference is that in lymphoedemas it is the lymphatic system which has failed to remove the fluids which accumulate in the tissues since it has been

(b)(4) [redacted]

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damaged or destroyed while in the oedemas there is too much fluid to remove even for a normally functioning lymphatic system. (Generally where is an excess load on the lymphatic system though increased leakage from the vascular system). The end result is really the same – that is increased fluid accumulations of extracellular fluids between the cells of the tissues initially followed by fibrous induration and a whole range of changes in cell populations, oxygen levels and the ability of the non specific defence systems (the macrophages) to work properly. This (as in lymphoedemas) leads to an increased risk of infection which is a serious on going problem in this group of patients.

A similar independent trial could be conducted for those patients with lymphoedema of the lower limbs or vascular oedemas, who may or may not have vascular or diabetic ulcers. In this study the major variant would be the determination of flood flow by using laser doppler.

Should the LPG technique be beneficial in secondary lymphoedemas through this trial some of the findings could be extrapolated in to the areas of the above described oedemas with the possibility of significant benefit in this area for this very large group of patients as well.

b) **Primary Lymphoedemas:** About 10% of all lymphoedemas are primary – These people have inadequate numbers of lymph vessels. Thus lymph drainage is generally poor again resulting in fluid accumulations in the tissues and a range of other chronic changes as described for secondary lymphoedemas.

Should the LPG technique be beneficial in secondary lymphoedemas through this trial some of the findings could be extrapolated validly into the area of primary lymphoedemas, with the possibility of significant benefit in this area for these patients as well.

c) **Burns:** Again due to similar cellular and tissue changes there is the possibility that findings of the lymphoedema study could be extrapolated to this group of patients as well.

d) **Obesity:** Due to some similarities with lymphoedemas and lipoedemas and cellulite and obesity and the often compounded nature of these, there may be an ability to extrapolate the findings from the high BMI subgroup to these areas.

References

(b)(4)

[redacted]

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Records processed under FOIA Request 2013-1897; Released 9/15/14

Badger C: guidelines for the calculation of limb volume based on surface measurements. *British Lymphology Interest Group Newsletter* 1993;7:3-7.

Badger CMA, Peacock JL, Mortimer PS: A randomized, controlled, parallel-group clinical trial comparing multiplayer bandaging followed by hosiery versus hosiery alone in the treatment of patients with lymphedema of the limb. Cancer 2000;88:2832-7.

Bates DO, Levick, Mortimer PS: Quantification of rate and depth of pitting in human edema using an electronic tonometer. *Lymphology* 1994; 27:159-172.

Bergan JJ, Sparks S, Angle N: A comparison of compression pumps in the treatment of lymphedema. *Vasc Surg* 1998; 32:455-462.

Bohm D, Odaishchi M, Beyerlain C et al Total body water: changes during dialysis estimated by bioimpedance analysis. *Infusiontherapie* 1990; 17 (suppl 3): 75-8.

Brennan MJ, Miller LT: Overview of treatment options and review of the current role and use of compression garments, intermittent pumps, and exercise in the management of lymphedema. *Cancer* 1998; 83:2821-7.

Browning C 1997 Lymphoedema: Prevelance, risk factors and management: A review of research. NHMRC National Breast Cancer Centre.

Caseley-Smith J Measuring and representing peripheral oedema and its alterations. Lymphology 1994; 27(2): 56-70.

Cha K, Chertow G, Gonzalez J et al Multifrequency bioelectrical impedance estimates the distribution of body water. *Am Physiol Soc* 1995; 1316-19

Chen HC, O'Brien BM, Pribaz JJ: The use of tissue tonometry in the assessment of upper extremity lymphoedema. *Brit J Plast Surg* 1988; 41:399-402.

Clodius L, Deak L, Piller NB: A new instrument for the evaluation of tissue tonicity in lymphoedema. *Lymphology* 1976; 9:1-5.

Cornish B, Bunce I & Ward L et al Bioelectrical impedance for monitoring the efficacy of lymphoedema treatment programmes. *Breast Cancer Res & Treat* 1996; 38: 169-76

Cornish B, Chapman M, Hirst C et al Early diagnosis of lymphedema using multifrequency bioimpedance. *Lymphology* 2001; 34(1): 2-11

Dini D., Mastro LD, Gozza A, et al: The role of pneumatic compression in the treatment of postmastectomy lymphedema. A randomized phase III study. *Ann Oncol* 1998; 9:187-90.

Földi E, Sauerwald A, Hennig B: Effect of complex decongestive physiotherapy on gene expression for the inflammatory response in peripheral lymphedema. *Lymphology* 2000;33:19-23.

(b)(4)

[redacted]

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Records processed under FOIA Request 2013-1897; Released 9/15/14

Foster K & Lukaski H Whole-body impedance - what does it measure? *Am J Clin Nutr* 1996; 64(suppl): 388S-396S

Franzeck UK, Spiegel I, Fischer M, et al: Combined physical therapy for lymphedema evaluated by fluorescence microlymphography and lymph capillary pressure measurements. *J Vasc Res* 1997; 34:306-11.

Harris S, Hugi MR, Olivotto IA, et al: Clinical practice guidelines for the care and treatment of breast cancer : 11. Lymphedema. *Can Med Assoc J* 2001; 164:191-9.

Johansson K, Albertsson M, Ingvar C, et al: Effects of compression bandaging with or without manual lymph drainage treatment in patients with postoperative arm lymphedema. *Lymphology* 1999; 32:103-110.

Johansson K, Lie E, Ekdahl C, et al: A randomized study comparing manual lymph drainage with sequential pneumatic compression for treatment of postoperative arm lymphedema. *Lymphology* 1998; 31:56-64.

Kar SK, Kar PK, Mania J: Tissue tonometry: a useful tool for assessing filarial lymphoedema. *Lymphology* 1992; 25:55-61.

Karges JR, Mark BE, Stikeleather SJ, et al: Concurrent validity of upper-extremity volume estimates: comparison of calculated volume derived from girth measurements and water displacement volume. *Phys Ther* 2003; 83:134-45.

Kichula C, Sunyong S, Cheongmin S et al Evaluation of segmental bioelectrical impedance analysis (SBIA) for measuring muscle distribution. *J Ichper* 1997; 11-14

Kriederman B, Myloyde T, Bernas M, et al: Limb volume reduction after physical treatment by compression and/or massage in a rodent model of peripheral lymphedema. *Lymphology* 2002; 35:23-7.

Kushner R, Schoeller D, Fjeild C et al Is the impedance index (ht^2/R) significant in predicting total body water? *Am J Clin Nutr* 1992; 56: 835-9

Labs K, Tschoepl M, Gamba G et al The reliability of leg circumference assessment: a comparison of spring tape measurements and optoelectronic volumetry. *Vasc Med* 2000; 5(2): 69-74

Latchford S, Casley-Smith JR: Estimating limb volumes and laterations in peripheral edema from circumferences measured at different intervals. *Lymphology* 1997; 30: 161-4.

Leduc O, Bourgeois P, Leduc A: Manual of lymphatic drainage: scintigraphic demonstration of its efficacy on colloidal protein reabsorption. In: *Progress in lymphology IX*, 1988, Elsevier, Amsterdam: Excerpta Medica.

Leduc O, Dereppe H, Hoylaerts M, et al: Hemodynamic effects of pressotherapy. In: *Progress in lymphology XII*, 1990, Elsevier, Amsterdam: Excerpta Medica, 1990: 431-4.

(b)(4)

[redacted]

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Records processed under FOIA Request 2013-1897; Released 9/15/14

Leduc O, Klien P, Rasquin C et al Relability of a volume measuring device (Volumeter®) for human limbs. Eur J Lymphol 1992; 3: 53-6.

Leduc O, Leduc A, Bourgeois P, et al: The physical treatment of upper limb edema. *Cancer* 1998; 83:2835-9.

Lennihan R, Mackereth M: Calculating volume changes in a swollen extremity from surface measurements. *Am J Surg* 1973;126: 649-52.

Liu NF, Olszewski W: Use of tonometry to assess lower extremity lymphedema. *Lymphology* 1992;25: 155-8.

Logan V 1995 Incidence and prevalence of lymphoedema: a literature review. *Journal of Clinical Nursing* 4: 213-219.

Lukaski H Methods for the assessment of human body composition: traditional and new. *Amer J Clin Nutrit* 1987; 46: 537-56.

Lukaski H, Siders W, Nielsen E et al Total body water in pregnancy: assessment by using bioelectrical impedance. *Amer J Clin Nutr* 1994; 59: 578-85.

Manjula Y, Kate V, Ananthakrishnan N: Evaluation of sequential intermittent pneumatic compression for filarial lymphoedema. *Natl Med J India* 2002; 15:192-4.

Megens A, Harris SR: Physical therapist management of lymphedema following treatment for breast cancer: a critical review of its effectiveness. *Phys Ther* 1998;78: 1302-11.

Mikes D, Cha B, Dym C et al Bioelectrical impedance analysis revisited. *Lymphology* 1999; 32 (4): 157-65.

Moholkar K & Fenelon G Diurnal variations in volume of the foot and ankle. *J Foot Ankle Surg* 2001; 40(5): 302-4.

National Institutes of Health Technology Bioelectrical impedance analysis in body composition measurement: National Institutes of Health Technology Assessment Conference Statement. *Am J Clin Nutr* 1196; 64(suppl): 524S-532S

Pappas CJ, Donnell TF: Long-term results of compression treatment for lymphedema. *J Vasc Surg* 1992;16: 555-64.

Petlund C 1990 Prevalence and incidence of chronic lymphoedema in a Western Europe country. *In* Nishi M, Uchino S & Yabuki S (Eds) *Progress in Lymphology XII*: 391-394.

Piller N, Cornish B: Bio-impedance and tonometry: benefits and limitions as diagnostic tools in lymph and other oedemas. In: *Proceedings of the 3rd Australasian Lymphology Association Conference*, 2000, Melbourne, 2000:49-58.

Piller N, Goodear M & Peter D 1998 Lymphoscintigraphic evidence supports the existence of axillo-inguinal anastomotic pathways in a patient with chronic

(b)(4)

[redacted]

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Records processed under FOIA Request 2013-1897; Released 9/15/14

secondary leg lymphoedema subsequent to inguinal node clearance and radiotherapy. *The European Journal of Lymphology* VI (24): 97-99.

Piller N, O'Connor M: *The Lymphoedema Handbook: Causes, Effects & Management*. 1st ed. Melbourne: Hill of Content, 2002:17-25.

Piller NB, Clodius L (1976) The use of tissue tonometry as a diagnostic aid in extremity lymphoedema, a determination of its conservative treatment with benzopyrones. *Lymphology* 9: 127.

Piller NB, Harris R: Where does the fluid go? Objective measurement of fluid movement around the body using perometry and bio-impedance in two case studies of chronic primary and secondary lymphoedema. In: *Proceedings of the 4th Australasian Lymphology Association Conference*, 2001, Adelaide, 2001: 85-91.

Harris, R and Piller, NB Evaluierung der Behandslungseffekivitat - objective Messungen Zur Wirking der Manuellen Lymphdrainage *Lympholgie* 2002 2, December 93-96.

Piller NB, Thelander A: Treatment of chronic postmastectomy lymphedema with low level laser therapy: a 2.5 year follow-up. *Lymphology* 1998;31: 74-86.

Portney LG, Watkins MP: *Fonundations of Clinical Research. Applications To Practice.* 2nd ed. New Jersey: Prentice Hall Health, Upper Saddle River, 2000.

Ross R, Leger L, Martin et al Sensitivity of bioelectrical impedance to detect changes in human body composition. *J Appl Physiol* 1989; 22: 85-92.

Segal K, Gutin B, Presta E et al Estimation of human body composition by electrical impedance methods: a comparative study. *Amer Physiol Soc* 1985; 85: 1565, 1571.

Segers P, Belgrado JP, Leduc A, et al: Excessive pressure in multichambered cuffs used for sequential compression therapy. *Phys Ther* 2002;82:1000-8.

Sitzia J: Volume measurement in lymphoedema treatment: examination of formulae. *Eur J Cancer Care* 1995;4: 11-6.

Stanton A, Northfield J, Holroyd B et al Validation of an optoelectronic limb volumeter (perometer). *Lymphology* 1997; 30(2): 77-97.

Stanton AWB, Badger C, Sitzia J: Non-invasive assessment of the lymphedematous limb. *Lymphology* 2000;33: 122-35.

Stranden E: A comparison between surface measurements and water displacement volumetry for the quantification of leg edema. *J Oslo City Hosp* 1981; 31:153-5.

Swedborg I: Effectiveness of combined methods of physiotherapy for post-mastectomy lymphoedema. *Scand J Rehab Med* 1980; 12:77-85.

Szuba A, Achalu R, Rockson SG: Decongestive lymphatic therapy for patients with breast carcinoma-associated lymphedema. *Cancer* 2002; 95:2260-7.

(b)(4)

[redacted]

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Records processed under FOIA Request 2013-1897; Released 9/15/14

Tierney S, Aslam N, Rennie K et al Infrared optoelectronic volumetry, the ideal way to measure limb volume. *Eur J Vasc Endovas Surg* 1996; 12(4): 412-7.

Vignes S, Champagne A, Poisson O: [Management of lymphedema: experience of the Cognacq-Jay Hospital]. [French] [Abstract] *Revue de Medecine Interne* 2002;23 (Suppl): 414-20.

Ward L, Bunce I, Cornish B et al Multi-frequency bioelectrical empedance augments the diagnosis and management of lymphoedema in post-mastectomy patients. *Euro J Clin Invest* 1992; 22: 751-54.

Ward L, Byrne N, Rutter K et al Reliability of multiple frequency bioelectrical impedance analysis: an inter-machine comparison. *Am J Human Biol* 1997; 9: 63-72.

Watanbe R, Miura A, Inoue K et al Evaluation of leg edema using a multifrequency impedance meter in patients with lymphatic obstruction. *Lymphology* 1989; 22: 85-92.

Weissleder H., Schuchhardt C: *Lymphoedema. Diagnosis and Therapy.* 3rd ed. Koln: Viavital Verlag GmbH, 2001.

Williams AF, Vadgama A, Franks A, et al: A randomized controlled crossover study of manual lymphatic drainage therapy in women with breast cancer-related lymphoedema. *Eu J Cancer Care* 2002;11: 254-61.

(b)(4)

[redacted]

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ATTACHMENT 17

Participant Information Sheet

THE EFFECT OF MANUAL LYMPHATIC DRAINAGE OR MECHANISED MASSAGE ON POST MASTECTOMY ARM LYMPHOEDEMA

You are invited to take part in a study exploring the effect of different massages plus compression bandaging on secondary lymphoedema of the arm. The swelling in your arm is related to the build up of fluid in the tissues, with massage being advocated as a therapy that helps to remove this fluid. This study aims to investigate some of the changes that occur in the arm in response to massage.

Manual lymphatic drainage is a specific form of massage that is designed to move fluid out of the swollen arm. It involves massaging the whole upper body (torso and neck) plus the lymphoedema arm using light skin stroking. It has been shown to reduce limb volume, improve limb tissues, subjective complaints like pain and emotional well being.

The machine based massage uses two moving rollers that shift over the skin to deliver a light massage. Pilot studies of this equipment have shown that it improves lymphatic drainage, limb tissues and decreases functional discomfort. The compression bandaging is applied after the massage with the aim of maintaining any reduction that occurred as a result of the massage. The compression bandaging involves a layer of softban followed by a layer of thick stretch bandaging with is applied to the whole arm and exerts compression. You will be allowed to remove the bandaging to have a shower. The benefits of these massage therapies plus bandaging, can not however be assured.

If you choose to participate, you will be assessed for your suitability for the trial and if successful, will be randomly separated into one of two groups:

- Group one: will consist of 25 participants who will receive 45 minutes of manual lymphatic drainage followed by compression bandaging 4 times a week for 4 weeks then a 1 month post treatment follow up measurement.
- Group two: will consist of 25 participants who will receive 25 minutes of mechanised massage followed by compression bandaging 4 times a week for 4 weeks then a 1 month post treatment follow up measurement.

The manual lymphatic drainage massage and compression bandaging will be performed by an allied health professional trained in the techniques. A trained health professional will apply the mechanised massage equipment and monitor its progress.

All participants will be assessed by a qualified Registered Nurse/Researcher regularly throughout the trial. To see what is happening to your arm regular measurements will need to be taken. These measurements will need to be taken immediately before the first massage, at weekly intervals (after the third massage) and then 1 month after treatment to assess for any ongoing affects. You will be asked to attend the (b)(4) [redacted] for these measurements and the massage session, with each visit taking approximately 1 hour.

The person taking your arm measurements through out the trial will not know which form of massage you are receiving, so please do not discuss this with him/her at the measurement sessions. The measurements to be taken are outlined below:

The following measurements carry no risks and are non-invasive:

- 1 (b)(4) [redacted]: this measures the hardness/softness of the arm tissues. It involves placing a metal disk on the surface of the skin on the front of the forearm, the upper arm, above your collar bone and on your back near your shoulder blade*.

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chair and resting the arm in a horizontal position whilst the arm is scanned by the perometry machine, which takes measurements at every 3mm*.

- (b)(4) this measures how much fluid is in the arm tissue. It involves standing on an electronic machine (like scales) and holding two handles in the hands.

- Blood Pressure and Pulse: this will involve taking blood pressure with a standardised pressure cuff (using the non-affected arm) and taking the pulse at the wrist.

- Questionnaires: A series of questions about your condition and how your arm feels.

* These measurements plus the massage will require you to remove your shirt, but all massage sessions and measurements will be conducted in privacy.

A sub-group of 10 volunteers will be asked to undergo the following techniques:

- (b)(4) d: This is a non-invasive measurement which involves applying gel and the ultrasound head to both forearms, upper arms, above your collarbones and on your back near your shoulder blades. This allows us to see how the tissues in these areas are responding to the massage. These measurements will be performed before and after the 4 weeks of massage. Each measurement session will take approximately 30 minutes.

(b)(4) This is an invasive procedure which involves the injection of radioactive dye which may cause stinging into the web space in between the middle and index finger of the lymphoedemateous arm. The dye is picked up by the lymphatic system and moved up the arm. This movement of the dye is photographed by a gamma camera over a 4-5 hour period so we can assess how well the lymphatic system is functioning and whether this function is improved by massage. This measurement will be performed before and after the 4 weeks of massage. Each measurement session will take approximately 4-5 hours. These procedures will expose you to some radiation, but the risk from this will be very small indeed. The amount of radiation will be no more than you would normally receive in about one month from natural background radiation sources in the environment.

- Photography: this will involve taking a picture of the upper body and arms with a digital camera before and after 4 weeks of treatment. Your face will be blocked out in these photos so you won't be able to be identified. Taking photos will allow us to assess the visual decrease in arm volume and to see how this correlates with the other arm measurements that are taken through out the trial.

There are no known side effects from massage. The compression bandaging will be applied by a health professional trained in the technique, but there is the possibility that it maybe applied too tightly. If you feel that the bandaging is too tight or you experience pins & needles or numbness in the arm, please remove the bandaging straight away and report it to the clinical investigators. If you experience any discomfort during the massage session please report it and a Registered Nurse will be on hand to assess you. If you have any problems in your neck, arm or upper torso please let the person who is administering the massage and bandaging know.

All those who participate will have their parking costs re-imbursed as a gesture of appreciation. Those who volunteer to undergo lymphoscintigraphy will be given a voucher for the Volunteers Café that entitles them to free tea or coffee, a sandwich and a scone as they are required to be at (b)(4) for 4-5 hours for scanning.

Your involvement in this study is entirely voluntary, and your non-participation will not affect any future treatment at the (b)(4) (including the (b)(4) in any way. Should you decide to withdraw from the study you may do so freely, at anytime and

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Clinic.

All records containing your personal information will remain confidential and no information that could lead to your identification will be released. Study data will be kept for 16 years in a locked cabinet by the researchers. The company sponsoring this trial will have access to the information gained but will be given no information that could lead to your identification.

Should you require further details about the project, either before, during or after the study, you may contact (b)(4) [redacted] or alternatively [redacted].

This study has been reviewed by the (b)(4) [redacted] Ethics Committee. Should you wish to discuss the project with someone not directly involved, in particular in relation to matters concerning policies, information about the conduct of the study or your rights as a participant, or should you wish to make a confidential complaint, you may contact the (b)(4) [redacted].

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

CONSENT TO PARTICIPATION IN RESEARCH

I, _____ Request and give consent to
(first or given names) (surname)

My involvement in the research project 'The effect of manual lymphatic drainage or mechanised massage on post mastectomy lymphoedema'
(short title of research project)

I acknowledge that the nature, purpose and contemplated effects of the research project, especially as far as they affect me and (N/A) have been fully explained
(my [foetus] baby, if applicable)

to my satisfaction by (b) (6) [redacted] and my consent is given voluntarily

I acknowledge that the detail(s) of the following procedure(s):

- Manual lymphatic drainage
- Mechanised massage
- Compression bandaging

(b)(4) [redacted]

- Arm volume and circumference (perometry)
- Questionnaires
- Blood Pressure and pulse measurements
- Arm (b)(4) [redacted] (voluntary)
- Lymphoscintigraphy (voluntary)
- (b)(4) [redacted] (voluntary)

has/have been explained to me, including indications of risks; any discomfort involved; anticipation of length of time and the frequency with which the procedure(s) will be performed.

I have understood and am satisfied with the explanations that I have been given.

I have been provided with a written information sheet.

I understand that my involvement in this research project and/or the procedure(s) may not be of any dire benefit to me and that I may withdraw my consent at any stage without affecting my rights or t responsibilities of the researchers in any respect

I understand that any payment made to me is simply an expression of gratitude for assistance in this resear project.

I declare that I am over the age of 18 years.

Signature of research subject: _____ Date: _____

Signature of Witness: _____

Printed Name of Witness: _____

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HOW TO FIND US!!!

We are now located (b)(4) [redacted]

Walk from the carpark through the northern entrance of the hospital (this entrance is straight in front of (b)(4) [redacted]

Walk down the corridor to the lifts. Take these lifts to level 5, once you step out of the lift you will be in (b)(4) [redacted]

Take the left hand corridor through (b)(4) [redacted] to the double doors (you should see signs saying (b)(4) [redacted]

Go through the blue double doors and turn **left** in to the corridor, then turn **right** – we are in this area.

If you have any troubles ask to use any phone in the hospital and ring: (b)(4) [redacted]

Refer to the attached map.

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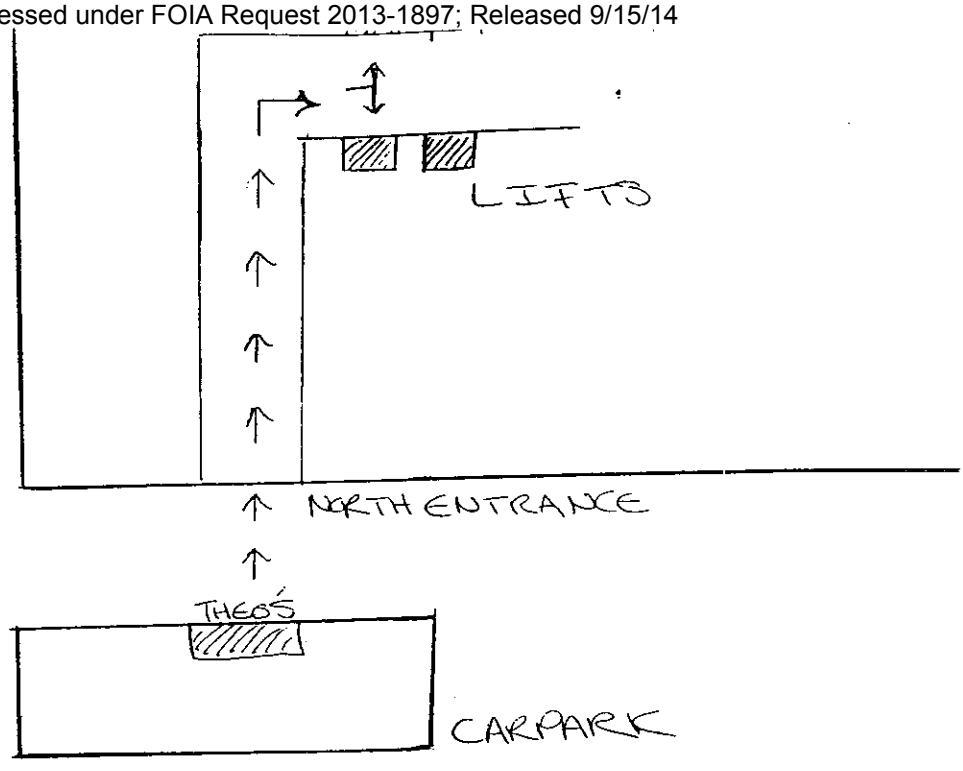
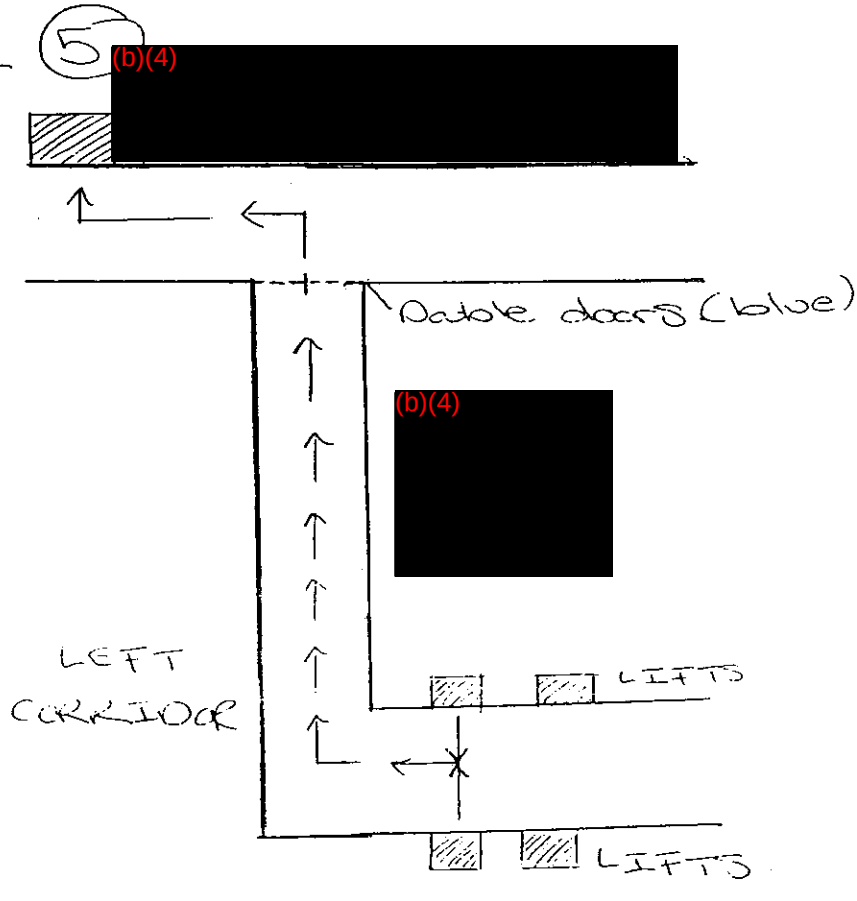
GROUND LEVEL (Known as level 2)



LEVEL 5



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ATTACHMENT 18

Randomised, single blinded trial of the effectiveness of manual lymphatic massage (MLD) and machine based massage (LPG) on Post Mastectomy Arm Lymphoedema

BACKGROUND HISTORY

Name: **Age:**

Weight: **Height:**

Affected arm: ☐ Left ☐ Right

Arm dominance: ☐ Left ☐ Right

Surgical Details

Type of Surgery: Date of Surgery:

Nodes removed: Positive nodes:

Chemotherapy: Radiotherapy:

Area:

Background History

Do you (please tick boxes applicable to you)

Have Hypertension (high blood pressure)? ☐ Yes ☐ No

Smoke? ☐ Yes ☐ No ____Yrs

Have Congestive heart problems? ☐ Yes ☐ No

Have Diabetes? ☐ Yes ☐ No

Have thyroid problems? ☐ Yes ☐ No

Arthritis in the hand or arm joints? ☐ Yes ☐ No

Any other problems which might be relevant? (please specify): _____

_____

_____

Are you post-menopausal? ☐ Yes ☐ No

If so, are you on any Hormone Replacement Therapy (HRT)? ☐ Yes ☐ No

If yes, please indicate what therapy: _____

_____

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When was the your last treatment for your arm? (please tick a box):

☐ N/A ☐ 1 month ago ☐ 2-6 months ago ☐ > 6mths ☐ > 1 year

What sort of treatment was it? _____

_____

_____

Do you wear arm compression at present? _____

_____

Lymphoedema Onset

When did you first notice changes in your arm? Date: _____

Cause: _____

When did you first notice a size difference? Date: _____

Cause: _____

Progression: Is your arm worse in the evening, but resolves in the morning? ☐ Yes ☐ No

Changes with the weather, gets worse when it is hot? ☐ Yes ☐ No

Prior details: Have you had any prior trauma to that arm or collarbone? ☐ Yes ☐ No

If yes, please give details: _____

_____

Current status: Latent phase ☐

Mild ☐

Moderate ☐

Severe ☐

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CLINICAL DATA

Randomised, single blinded trial of the effectiveness of manual lymphatic massage (MLD) and machine based massage (LPG) on Post Mastectomy Arm Lymphoedema

Name: _____ Date: _____ Visit No: _____

LPG DRAINAGE PATTERN

Program	Altered Time	Altered Pattern/Comment
1: Prepare anastomosis		
2: Mobilization		
3: Drainage		

BANDAGING

	Used/Comments
Hand	
Foam	
Elastic Bandaging	

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CLINICAL DATA

Randomised, single blinded trial of the effectiveness of manual lymphatic massage (MLD) and machine based massage (LPG) on Post Mastectomy Arm Lymphoedema.

Name:_____ Date:_____ Visit No:_____

MANUAL LYMPHATIC DRAINAGE PATTERN

Body Part	Time	Comments

BANDAGING

	Used/Comments
Hand	
Foam	
Elastic Bandaging	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CLINICAL DATA

Randomised, single blinded trial of the effectiveness of manual lymphatic massage (MLD) and machine based massage (LPG) on Post Mastectomy Arm Lymphoedema

Name:_____

THERAPISTS CASENOTES/COMMENTS

Visit	Comments
1	
2	
3	
4	
5	
6	
7	

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8	
9	
10	
11	
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16	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CLINICAL DATA

Randomised, single blinded trial of the effectiveness of manual lymphatic massage (MLD) and machine based massage (LPG) on Post Mastectomy Arm Lymphoedema

Name: _____ Date: _____ Visit No: _____

* To be asked before each massage session

1. Have you done anything that may have caused your arm to swell? _____

2. Do you have any problems with the elastic bandaging? _____

3. How did you feel after the previous massage session (this maybe positive or negative comments)? _____

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Randomised, single blinded trial of the effectiveness of manual lymphatic massage (MLD) and machine based massage (LPG) on Post Mastectomy Arm Lymphoedema

BIODATA

Visit:

Name: **Date:** **Time:**

BP: **Pulse:**

Tonometry:

	R	L		R	L
Anterior Forearm			Mid Clavicular Line		
Anterior Upper Arm			Posterior Scapula		

Subjective Symptoms:

The questions below relate to how your arm feels. A score of 1 indicates that you have none of that feeling at all in your arm and a score of 10 is the most severe amount of that feeling ever imaginable. Currently, how would you rate the following?

	NONE									WORST IMAGINABLE
PAIN	1	2	3	4	5	6	7	8	9	10
HEAVINESS	1	2	3	4	5	6	7	8	9	10
TIGHTNESS	1	2	3	4	5	6	7	8	9	10
ARM HARDNESS	1	2	3	4	5	6	7	8	9	10
ARM TEMPERATURE	1	2	3	4	5	6	7	8	9	10
CRAMPS	1	2	3	4	5	6	7	8	9	10
PINS & NEEDLES	1	2	3	4	5	6	7	8	9	10
ARM SIZE DIFFERENCE	1	2	3	4	5	6	7	8	9	10
RANGE OF MOVEMENT	1	2	3	4	5	6	7	8	9	10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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BANDAGING INFORMATION AND CARE

The compression bandaging will be applied after each massage session, it will be applied by a trained professional and will involve the following:

- A stockingette which is applied to the arm
- Gauze which is applied to the fingers
- Foam which is wrapped around the whole arm
- 2-3 layers of short stretch elastic bandaging applied to the whole arm

The bandaging is applied to help retain any reduction achieved by the massage. It is desirable that the bandaging is left on over night and removed before showering the next morning. You will not be required to wear the bandaging over the weekend, only during active treatment.

However we understand that the bandaging can feel quite firm and maybe uncomfortable to sleep in, if this is the case you are free to remove the bandaging, please indicate on the logbook that it was removed and what time it was removed.

The bandaging is meant to be firm, **however** if it feels excessively tight, if you feel pins and needles tingling or numbness in the fingers or if the fingers feel cool, remove the bandaging **immediately** and report it to the clinical investigators, Ph: (b)(4) [redacted] during working hours or [redacted] after hours.

You will be given two sets of elastic bandaging, which will allow time for washing. The elastic **bandaging must be washed before each treatment session and brought with you each time you come in for a massage session. The washing is important as it helps to maintain the elasticity of the bandages. Please wash the bandaging according to the following instructions:**

Everyday

- Rinse elastic bandages in lukewarm or cool water – NO detergent
- Elastic bandages maybe put in the washing machine on a gentle cycle
- Dry elastic bandages away from direct sunlight – DO NOT tumble dry
- Once dry, roll elastic bandages and bring to the next massage session
- Cotton sleeve maybe washed if desired
- DO NOT wash foam padding or gauze bandaging

Once a Week

- As above, but elastic bandaging is washed in mild detergent

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PARTICIPANT LOG BOOK – FOR COMPRESSION BANDAGING

Using the key and table below, please indicate how long you wore the compression bandaging for:

Key

W = The bandaging was worn for the whole time, except for removal for showering.

R = The bandaging was removed, please record what time you took the bandaging off.

✓ = Please tick the 'washed' column to show that you have washed the elastic bandages following the instruction sheet.

	Day 1	Washed	Day 2	Washed	Day 3	Washed	Day 4	Washed	Day 5-7
Week 1									OFF
Week 2									OFF
Week 3									OFF
Week 4									OFF

Comments: _____

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ATTACHMENT 19

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: February 28, 2006.

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

(b)(4) [redacted]

(1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		

(2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

(3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Michel Van Welden	Chief Operating Officer
FIRM/ORGANIZATION LPG ONE Inc	
SIGNATURE	DATE

(b) (6) [redacted]

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

FORM FDA 3454 (2/03)

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ATTACHMENT 20

(b)(4) Study 2006

Introduction

At the time of our initial submission of 510(k) #K053225, we had presented a clinical study conducted by (b) (6) comparing the LPG technique with manual lymphatic drainage (MLD) in the treatment of secondary lymphedema of the arm post-mastectomy (SLA). The study showed positive results for reducing arm volume, as well as for reducing fibrotic induration that commonly accompanies the condition of lymphedema. **The additional results obtained by this follow up study are not intended to replace the results previously reported, but to demonstrate our efforts in on-going research in order to offer the best possible protocol for treatment.**

Since then, however, a subsequent study was conducted in (b)(4) also by (b) (6) looking at the same condition. This clinical trial tested the effectiveness of a revised LPG treatment protocol on 10 women with secondary lymphedema of the arm post-mastectomy. (MLD was not tested in this trial.) The new treatment protocol incorporated the use of the Keymodule i50 motorized treatment head (instead of the manual auxiliary treatment head) mainly on the back and upper arm. Drainage movements across the chest to the opposite (unaffected) axilla were added, as well as draining time on the back area at the end of the treatment protocol, which increased the overall total treatment time from 25 to 30 minutes.

All participants had arm lymphedema post breast cancer treatment, and were required to have not had active treatment for the arm or LPG treatments prior to recruitment. Six evaluation methods were used instead of eight in the 2004 study: (b)(4) perometry (arm volume), (b)(4) (tissue composition) clinical photography, blood pressure & pulse and subjective symptom rating. The measurement schedule was identical to the original trial.

The subjects all had secondary lymphedema of the arm post-mastectomy for greater than 1 year plus significant indication of fibrotic induration as detected by (b)(4) (See Attachment 21.) The study showed positive results for reducing arm volume (whole arm volume was reduced by 136 ml or 18.2%, with forearm volume reduction at 101 ml, and upper arm volume reduction at 33 ml.) Reduction of fibrotic induration which typically accompanies the condition of lymphedema was assessed by noting the resistance to compression measured by a (b)(4) A significant change in resistance to compression after treatment was shown in both the upper arm and the forearm. (Lower (b)(4) values represent reduction in fibrotic induration.)

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Conclusion

The new treatment protocol was shown to be more effective than the original protocol tested in (b)(4). This new protocol has greater reductions in arm fluid and volume. (Reduction of whole arm volume = 39% improvement, reduction of forearm volume = 36.2% improvement, reduction of upper arm volume = 44.5% improvement.) This is related to the extra treatment time spent and the use of the more powerful i50 treatment head. There was also no transient increase in upper arm volume (measured by perometry) as occurred in the original (b)(4) trial, indicating that the extra drainage time incorporated into this new protocol has negated this problem. The greatest reductions and improvements were seen to occur after the first 2 weeks of treatment, indicating that results happen more rapidly with the motorized treatment head. Since this is the case, a shorter treatment time could be used, although treatment weeks 3 and 4 may be important in helping to maintain the initial losses.

There were improvements in all subjective symptoms. Patients stated that they found the treatment generally enjoyable, and felt that it improved limb discomfort. All parameters measured during the trial increased at the 1-month followup with no parameters returning to the original pre-treatment levels. This demonstrates the importance of both self maintenance (the majority of women performed self massage and wore a compression sleeve over the followup period), and the importance of ongoing treatment in the maintenance of this chronic and progressive condition.

Overall, this new protocol resulted in arm fluid and volume reductions and improvements in (b)(4) readings, as well as subjective symptoms. The main significance is that the results were achieved sooner with the addition of the motorized i50 treatment head, and there was a greater impact on softening of fibrosis (reduction of fibrotic induration). The new treatment protocol is also advantageous in that the additional drainage time negates an increase in upper arm volume.

(Refer to attachment 13 to verify that the new protocol provides better results than the previous protocol.)

The addendum to the original LPG (b)(4) clinical study further demonstrates the effectiveness of the Cellu M6 Keymodule *i* in the reduction of secondary lymphedema of the arm post-mastectomy beyond that of the pneumatic compression device.

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Moreover, not only does the Cellu M6 Keymodule *i* successfully reduce this type of lymphedema, it also provides a reduction of fibrotic induration, which is a common and chronic problem for lymphedema sufferers. Cellu M6 Keymodule *i* is a superior device to pneumatic compression as being effective in the treatment of secondary lymphedema of the arm post-mastectomy and accompanying fibrotic induration.

(b) (6), (b) (4)

[redacted]

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ATTACHMENT 21a

(b)(4)

[redacted]

TRIAL OF THE EFFECTIVENESS OF A NEW LPG® TREATMENT PROTOCOL ON 10 WOMEN WITH POST MASTECTOMY ARM LYMPHOEDEMA

Final Report

(b)(4) [redacted]

Submitted by

(b) (6), (b) (4)

[redacted]

Flinders Consulting Pty Ltd

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Introduction

This clinical trial tested the effectiveness of a revised LPG® treatment protocol on 10 women with post mastectomy arm lymphoedema. This new treatment protocol incorporated the use of the I50 treatment head mainly on the back and upper arm, the addition of drainage across the chest to the opposite (unaffected) axilla and the addition of draining time on the back area at the end of the treatment protocol. This increased the treatment time to 30 minutes.

Women with arm lymphoedema post breast cancer treatment (total or partial mastectomy ± radiotherapy ± chemotherapy) were recruited into the trial. Participants were required to not have undergone active treatment for the arm prior to trial entry and to not have had LPG® treatment before. The measurement techniques undertaken in this trial included; (b)(4) [redacted] (body composition and segmental fluids), perometry (arm volume), (b)(4) [redacted] (tissue composition), clinical photography, blood pressure & pulse and subjective symptom rating. The measurement schedule was identical to the original trial undertaken at the (b)(4) [redacted]

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Table 1. Breast Cancer Treatment & General Medical History

	LPG
Age	**60.3yrs** (± 7.6) (45 - 72yrs)
Part. Mastectomy + Axillary Cl. Tot. Mastectomy + Axillary Cl.	2 (20.0%) 8 (80.0%)
Nodes removed: 11 – 20 21 – 30 > 30 all K/N	1 (10.0%) 3 (30.0%) 1 (10.0%) 1 (10.0%) 1 (10.0%)
Radiotherapy: Yes No	9 (90.0%) 1 (10.0%)
Area: Breast only Axilla only Breast + axilla Breast + axilla + supra-clavicular Breast + axilla + lateral + supraclavicular	3 (30.0%) 1 (10.0%) 2 (20.0%) 2 (20.0%) 1 (10.0%)
Hypertension: Yes No	5 (50.0%) 5 (50.0%)
Heart Disorders: Yes No	- 10 (100.0%)
Smoker Yes Previous No	- 1 (10.0%) 9 (90.0%)
Thyroid Dysfunction: Yes No	1 (10.0%) 9 (90.0%)
Diabetes: Borderline Yes – diet controlled Yes – medication controlled No	 - 1 (10.0%) 1 (10.0%) 8 (80.0%)
Arthritis (in aff. arm): Yes No	2 (20.0%) 8 (80.0%)

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Relevant Problems:	
Breast reconstruction	2 (20.0%)
Prophylactic mastectomy	1 (20.0%)
Lateral epicondylitis	1 (20.0%)
Scar on affected arm	1 (10.0%)
Query wrist carpel tunnel	1 (10.0%)

Table 2. Lymphoedema History

Lymphoedema Onset After Tx:	**24.2mths** (± 24.1) (2 - 60mths)
Cause of Lymphoedema:	
Flight	1 (10.0%)
Over use	1 (10.0%)
Radiotherapy	2 (20.0%)
Post chemotherapy	1 (10.0%)
Venepuncture	1 (10.0%)
K/N	4 (40.0%)
Worse in evening: Yes	6 (60.0%)
No	4 (40.0%)
Worse in hot weather: Yes	8 (80.0%)
No	2 (20.0%)
Previous arm injury: Yes	2 (20.0%)
No	8 (80.0%)
Lymphoedema Status:	
Mild	3 (30.0%)
Moderate	4 (40.0%)
Severe	3 (30.0%)

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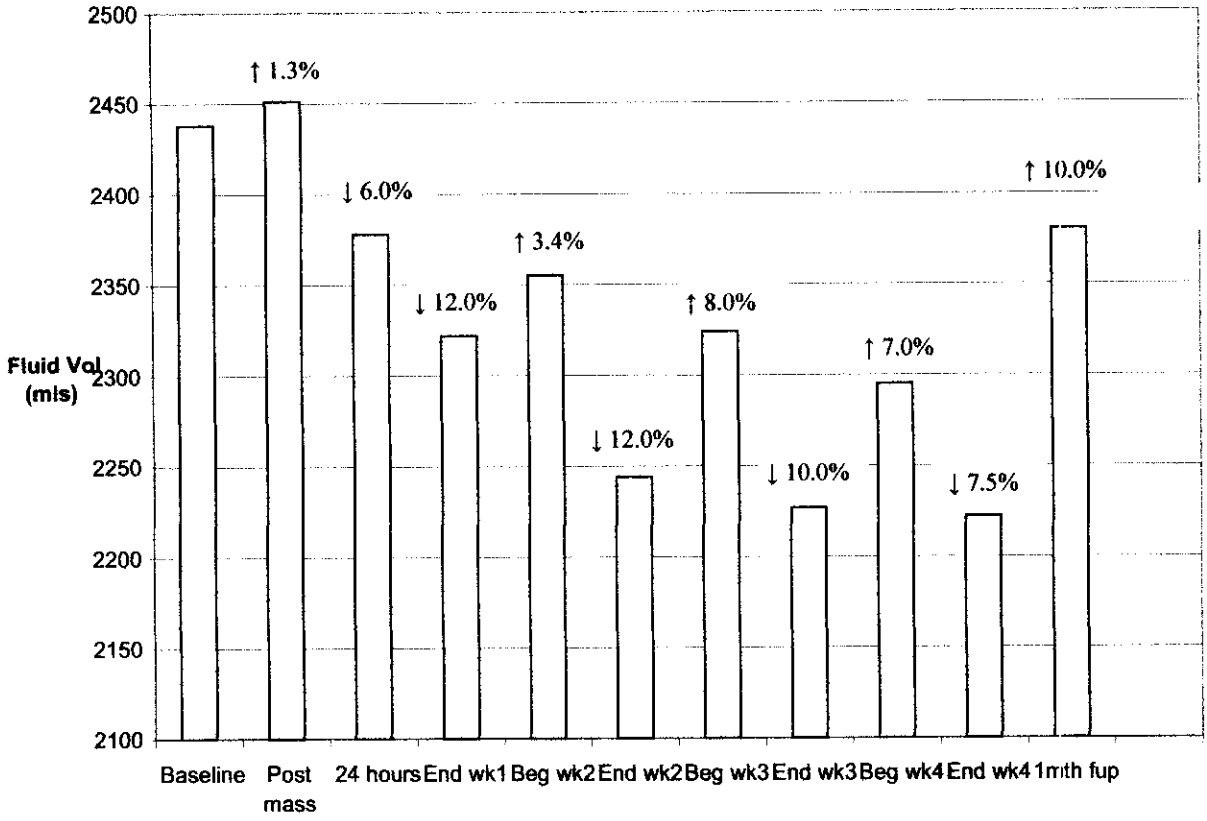
Figure1. Change in affected arm fluid (as measured via (b)(4) over trial duration



	Mean Change (mls)	Std. Dev. (±)	p
Baseline v's After 1st treatment	+13.0	80.6	0.622
Baseline v's After 24 hours	-60.0	92.5	0.070
Baseline v's End of week 1	-116.0	139.5	**0.027**
End week 1 v's Beginning week 2	+33.0	169.0	0.552
Beginning wk 2 v's End of week 2	-111.0	157.2	**0.052**
End week 2 v's Beginning week 3	+80.0	124.9	0.073
Beginning wk 3 v's End of week 3	-97.0	161.2	0.090
End week 3 v's Beginning week 4	+68.0	140.1	0.159
Beginning wk 4 v's End of week 4	-73.0	116.7	0.079
Baseline v's End of week 4	-216.0	223.1	**0.014**
End wk 4 v's 1 mth follow up	+97.8	190.9	0.163

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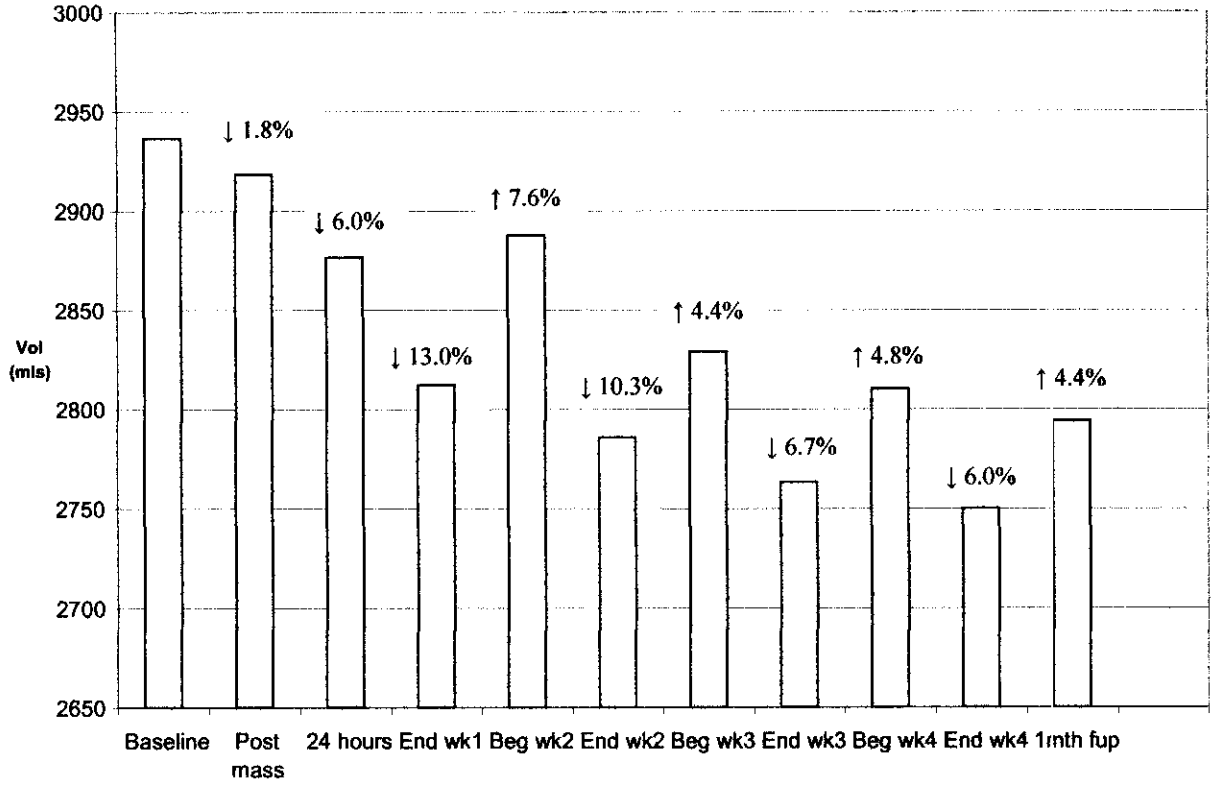
Figure 2. Change in affected whole arm volume (as measured via perometry) over trial duration



	Mean Change (mls)	Std. Dev. (±)	p
Baseline v's After 1st treatment	-17.5	26.4	0.063
Baseline v's After 24 hours	-59.5	64.9	**0.018**
Baseline v's End of week 1	-124.1	95.0	**0.003**
End week 1 v's Beginning week 2	+75.6	25.2	**0.015**
Beginning wk 2 v's End of week 2	-101.9	55.4	**0.000**
End week 2 v's Beginning week 3	+42.9	55.8	**0.038**
Beginning wk 3 v's End of week 3	-65.7	73.9	**0.020**
End week 3 v's Beginning week 4	+46.9	52.3	**0.020**
Beginning wk 4 v's End of week 4	-60.2	50.0	**0.004**
Baseline v's End of week 4	-186.3	139.8	**0.002**
End wk 4 v's 1 mth follow up	+44.1	147.8	0.370

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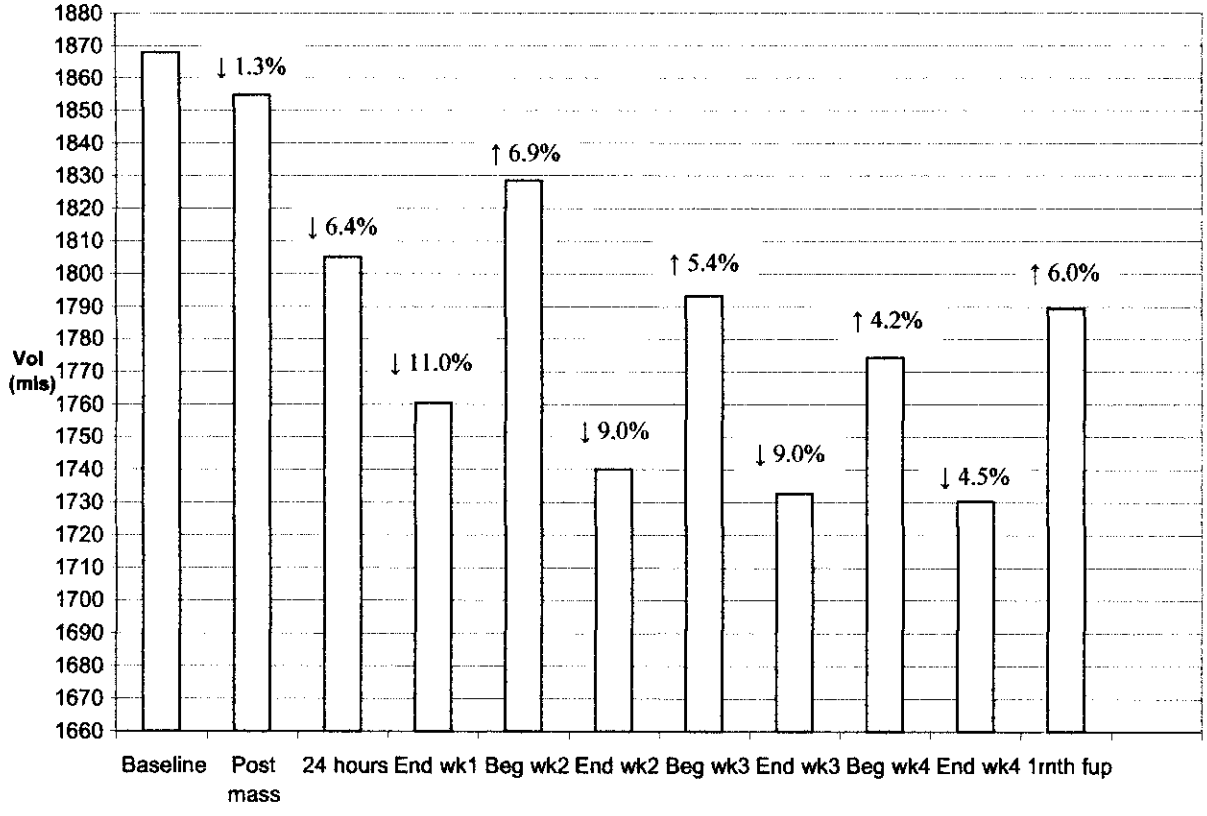
Figure 3. Change in affected forearm volume (as measured via perometry) over trial duration



	Mean Change (mls)	Std. Dev. (±)	p
Baseline v's After 1st treatment	-13.1	28.9	0.185
Baseline v's After 24 hours	-62.8	54.0	**0.005**
Baseline v's End of week 1	-107.5	66.2	**0.001**
End week 1 v's Beginning week 2	+68.0	63.5	**0.008**
Beginning wk 2 v's End of week 2	-88.4	66.9	**0.002**
End week 2 v's Beginning week 3	+53.2	50.3	**0.009**
Beginning wk 3 v's End of week 3	-60.6	63.8	**0.015**
End week 3 v's Beginning week 4	+41.6	40.6	**0.010**
Beginning wk 4 v's End of week 4	-44.1	37.0	**0.004**
Baseline v's End of week 4	-137.7	110.0	**0.003**
End wk 4 v's 1 mth follow up	+60.0	105.5	0.349

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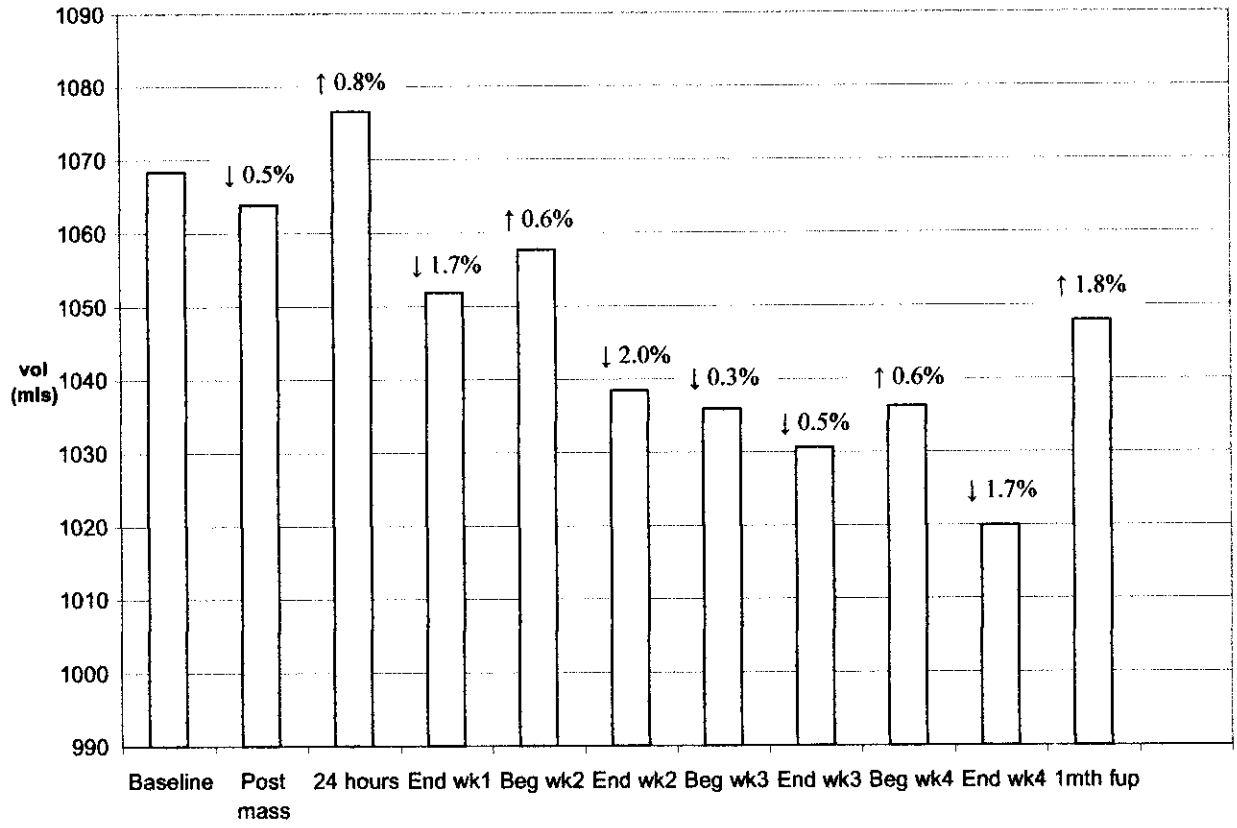
Figure 4. Change in affected upper arm volume (as measured via (b)(4) over trial duration



	Mean Change (mls)	Std. Dev. (±)	p
Baseline v's After 1st treatment	-4.5	10.9	0.226
Baseline v's After 24 hours	+8.2	28.5	0.387
Baseline v's End of week 1	-16.5	35.5	0.165
End week 1 v's Beginning week 2	+5.9	28.7	0.532
Beginning wk 2 v's End of week 2	-19.3	13.0	**0.001**
End week 2 v's Beginning week 3	-2.5	16.9	0.645
Beginning wk 3 v's End of week 3	-5.3	17.8	0.371
End week 3 v's Beginning week 4	+5.6	28.8	0.551
Beginning wk 4 v's End of week 4	-16.3	27.5	0.093
Baseline v's End of week 4	-48.4	33.5	**0.001**
End wk 4 v's 1 mth follow up	+18.0	37.5	0.857

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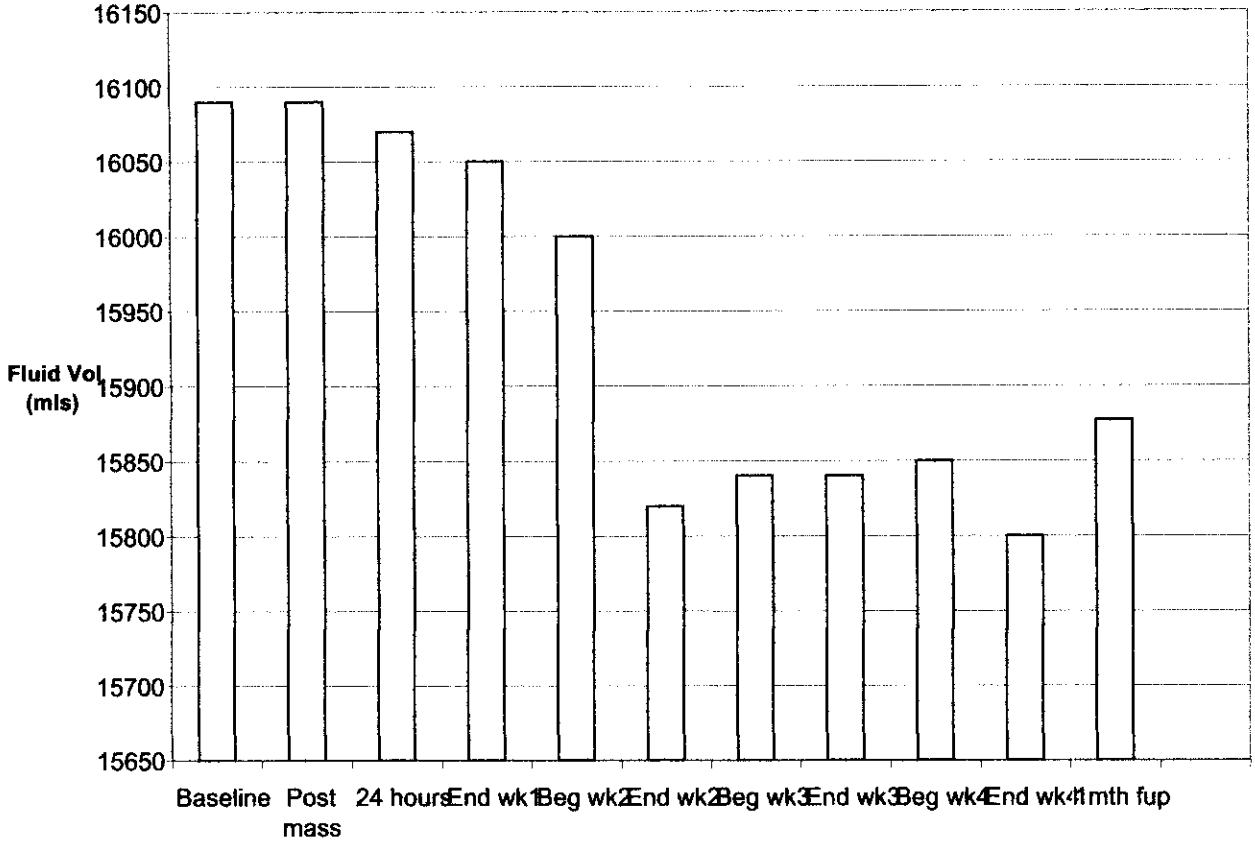
Figure 5. Change in truncal fluid (as measured via bioimpedance) over trial duration



	Mean Change (mls)	Std. Dev. (±)	p
Baseline v's After 1st treatment	0.0	141.4	1.000
Baseline v's After 24 hours	-20.0	225.1	0.785
Baseline v's End of week 1	-40.0	306.2	0.689
End week 1 v's Beginning week 2	-50.0	514.8	0.766
Beginning wk 2 v's End of week 2	-180.0	385.3	0.174
End week 2 v's Beginning week 3	+20.0	319.0	0.847
Beginning wk 3 v's End of week 3	0.0	278.9	1.000
End week 3 v's Beginning week 4	+10.0	354.2	0.931
Beginning wk 4 v's End of week 4	-50.0	365.9	0.676
Baseline v's End of week 4	-290.0	438.3	0.066
End wk 4 v's 1 mth follow up	+77.8	345.6	0.519

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Table 6. Change in Weight (Kg's), Fat Mass (Kg's), Percentage Fat (%) & Body Mass Index (Kg/m²) at end of trial and at 1 month follow up

	Baseline	***End of Trial***	***p***	***1 Month F/up****	***p***
Weight (Kg's)	**75.0** (±13.2)	**74.5** (±12.4)	0.289	**76.0** (±11.3)	0.290
Fat Mass (Kg's)	**27.4** (±8.6)	**27.5** (±7.9)	0.670	**27.9** (±13.2)	**0.030**
Percentage Fat (%)	**36.0** (±5.0)	**36.4** (±4.4)	0.168	**36.3** (±4.1)	0.189
Body Mass Index (Kg/m²)	**30.0** (±4.7)	**29.8** (±4.4)	0.212	**30.4** (±3.8)	0.267

* compared to end of trial

Table 7. Change in Systolic (mmHg), Dystolic (mmHg) and Pulse (bpm) at end of trial and at 1 month follow up

	Baseline	***End of Trial***	***p***	***1 Month F/up****	***p***
Pulse (bpm)	**72.0** (±12.6)	**67.6** (±7.2)	0.120	**71.8** (±12.3)	0.108
Systolic (mmHg)	**128.2** (±10.6)	**126.1** (±6.6)	0.311	**131.1** (±8.7)	0.151
Dystolic (mmHg)	**80.6** (±7.0)	**78.1** (±7.0)	0.267	**82.0** (±6.6)	0.065

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Table 8. Change in (b)(4) measurements (gms/cm^2) over trial duration

Parameter	Pre	Post	p =
Forearm (anterior)			
Baseline v's after 1st treatment	4.25 (± 0.66)	4.64 (± 1.00)	0.115
Baseline v's 24 hours	4.25 (± 0.66)	4.35 (± 0.83)	0.482
Baseline v's end of wk 1	4.25 (± 0.66)	4.34 (± 0.80)	0.550
Beginning wk 2 v's end wk 2	4.07 (± 0.77)	4.31 (± 0.87)	0.248
Beginning wk 3 v's end wk 3	4.27 (± 0.95)	4.25 (± 0.76)	0.933
Beginning wk 4 v's end wk 4	4.19 (± 0.77)	4.52 (± 1.07)	**0.020**
Baseline v's End of trial	4.25 (± 0.66)	4.52 (± 1.07)	0.223
End of trial v's 1mth follow up	4.52 (± 1.07)	4.05 (± 0.86)	0.076
Upper Arm (anterior)			
Baseline v's after 1st treatment	5.50 (± 1.13)	5.91 (± 0.95)	0.327
Baseline v's 24 hours	5.50 (± 1.13)	5.17 (± 1.12)	0.354
Baseline v's end of wk 1	5.50 (± 1.13)	5.32 (± 0.96)	0.597
Beginning wk 2 v's end wk 2	5.29 (± 1.03)	4.99 (± 0.80)	0.301
Beginning wk 3 v's end wk 3	5.34 (± 0.82)	4.92 (± 1.39)	0.330
Beginning wk 4 v's end wk 4	5.51 (± 0.66)	5.17 (± 1.02)	0.264
Baseline v's End of trial	5.50 (± 1.13)	5.17 (± 1.02)	0.311
End of trial v's 1mth follow up	5.17 (± 1.02)	5.38 (± 1.32)	0.465
Anterior Thorax			
Baseline v's after 1st treatment	8.64 (± 2.47)	8.53 (± 2.36)	0.900
Baseline v's 24 hours	8.64 (± 2.47)	8.52 (± 2.55)	0.814
Baseline v's end of wk 1	8.64 (± 2.47)	8.99 (± 2.04)	0.439
Beginning wk 2 v's end wk 2	8.71 (± 2.12)	8.28 (± 2.27)	0.368
Beginning wk 3 v's end wk 3	8.61 (± 2.18)	8.30 (± 2.37)	0.493
Beginning wk 4 v's end wk 4	8.58 (± 2.26)	8.68 (± 2.08)	0.822
Baseline v's End of trial	8.64 (± 2.47)	8.68 (± 2.08)	0.921
End of trial v's 1mth follow up	8.68 (± 2.08)	8.03 (± 2.25)	0.244

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Table 8. Change in (b)(4) [redacted] measurements (gms/cm^2) over trial duration cont.

Parameter	Pre	Post	p =
Posterior Thorax			
Baseline v's after 1st treatment	3.34 (± 0.96)	3.24 (± 0.63)	0.760
Baseline v's 24 hours	3.34 (± 0.96)	3.40 (± 1.00)	0.814
Baseline v's end of wk 1	3.34 (± 0.96)	3.27 (± 0.76)	0.793
Beginning wk 2 v's end wk 2	3.36 (± 0.98)	2.99 (± 0.84)	0.097
Beginning wk 3 v's end wk 3	3.24 (± 0.92)	3.20 (± 0.70)	0.854
Beginning wk 4 v's end wk 4	3.16 (± 0.81)	4.01 (± 1.77)	0.171
Baseline v's End of trial	3.34 (± 0.96)	4.01 (± 1.77)	0.221
End of trial v's 1mth follow up	4.01 (± 1.77)	3.69 (± 0.79)	0.434

Table 9. Change in Subjective Symptoms over trial duration

(based upon a 10 point likert scale, 1 = no problem, 10 = worse imaginable problem)

	Pre	Post	p =
Pain			
Baseline v's after 1st treatment	2.7 (± 2.7)	1.4 (± 0.9)	0.083
Baseline v's 24 hours	2.7 (± 2.7)	1.5 (± 1.3)	0.193
Baseline v's end of wk 1	2.7 (± 2.7)	1.0 (± 0.0)	0.082
Beginning wk 2 v's end wk 2	2.5 (± 1.9)	1.1 (± 0.3)	**0.039**
Beginning wk 3 v's end wk 3	1.4 (± 1.3)	1.0 (± 0.0)	0.343
Beginning wk 4 v's end wk 4	1.2 (± 0.6)	1.0 (± 0.0)	0.343
Baseline v's End of trial	2.7 (± 2.7)	1.0 (± 0.0)	0.082
End of trial v's 1mth follow up	1.0 (± 0.0)	2.0 (± 1.5)	0.063
Heaviness			
Baseline v's after 1st treatment	4.7 (± 3.1)	3.3 (± 1.9)	**0.025**
Baseline v's 24 hours	4.7 (± 3.1)	3.1 (± 2.0)	**0.011**
Baseline v's end of wk 1	4.7 (± 3.1)	2.1 (± 1.7)	**0.013**
Beginning wk 2 v's end wk 2	3.3 (± 2.3)	2.1 (± 1.4)	0.148
Beginning wk 3 v's end wk 3	2.9 (± 2.1)	1.6 (± 1.3)	**0.028**
Beginning wk 4 v's end wk 4	2.0 (± 1.3)	1.5 (± 1.3)	0.464
Baseline v's End of trial	4.7 (± 3.1)	1.5 (± 1.3)	**0.007**
End of trial v's 1mth follow up	1.5 (± 1.3)	2.6 (± 1.9)	0.120

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	Pre	Post	p
Tightness			
Baseline v's after 1st treatment	4.8 (± 2.6)	2.9 (± 2.3)	**0.004**
Baseline v's 24 hours	4.8 (± 2.6)	2.7 (± 2.0)	**0.016**
Baseline v's end of wk 1	4.8 (± 2.6)	2.1 (± 1.7)	**0.003**
Beginning wk 2 v's end wk 2	2.9 (± 1.9)	2.0 (± 1.4)	0.095
Beginning wk 3 v's end wk 3	2.8 (± 1.5)	1.8 (± 1.3)	**0.042**
Beginning wk 4 v's end wk 4	2.4 (± 1.5)	1.8 (± 1.3)	0.217
Baseline v's End of trial	4.8 (± 2.6)	1.8 (± 1.3)	**0.001**
End of trial v's 1mth follow up	1.8 (± 1.3)	2.6 (± 2.2)	0.235
Tissue Hardness			
Baseline v's after 1st treatment	4.4 (± 2.9)	3.3 (± 2.2)	**0.032**
Baseline v's 24 hours	4.4 (± 2.9)	3.1 (± 2.2)	**0.028**
Baseline v's end of wk 1	4.4 (± 2.9)	1.9 (± 1.9)	**0.013**
Beginning wk 2 v's end wk 2	2.8 (± 2.1)	2.1 (± 1.8)	**0.010**
Beginning wk 3 v's end wk 3	2.3 (± 1.8)	1.9 (± 1.3)	0.104
Beginning wk 4 v's end wk 4	2.0 (± 1.3)	2.0 (± 1.6)	1.000
Baseline v's End of trial	4.4 (± 2.9)	2.0 (± 1.6)	**0.011**
End of trial v's 1mth follow up	2.0 (± 1.6)	2.7 (± 2.3)	0.373
Arm Temperature			
Baseline v's after 1st treatment	1.9 (± 1.5)	1.9 (± 1.7)	1.000
Baseline v's 24 hours	1.9 (± 1.5)	1.5 (± 1.3)	0.168
Baseline v's end of wk 1	1.9 (± 1.5)	1.1 (± 0.3)	0.121
Beginning wk 2 v's end wk 2	1.0 (± 0.0)	1.2 (± 0.4)	0.168
Beginning wk 3 v's end wk 3	1.1 (± 0.3)	1.1 (± 0.3)	1.000
Beginning wk 4 v's end wk 4	1.1 (± 0.3)	1.1 (± 0.3)	1.000
Baseline v's End of trial	1.9 (± 1.5)	1.1 (± 0.3)	0.087
End of trial v's 1mth follow up	1.1 (± 0.3)	1.0 (± 0.0)	0.343
Cramping	No change	No change	No change

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	Pre	Post	p
Pins & Needles (P&N's)			
Baseline v's after 1st treatment	2.6 (± 2.4)	1.7 (± 1.5)	0.171
Baseline v's 24 hours	2.6 (± 2.4)	1.8 (± 1.7)	0.210
Baseline v's end of wk 1	2.6 (± 2.4)	1.1 (± 0.3)	0.071
Beginning wk 2 v's end wk 2	2.6 (± 2.7)	1.4 (± 1.3)	0.104
Beginning wk 3 v's end wk 3	1.4 (± 1.4)	1.7 (± 1.6)	0.462
Beginning wk 4 v's end wk 4	1.3 (± 0.9)	1.4 (± 1.3)	0.343
Baseline v's End of trial	2.6 (± 2.4)	1.4 (± 1.3)	0.133
End of trial v's 1mth follow up	1.4 (± 1.3)	2.5 (± 2.1)	0.066
Arm Size			
Baseline v's after 1st treatment	6.3 (± 2.3)	5.9 (± 2.3)	0.104
Baseline v's 24 hours	6.3 (± 2.3)	5.6 (± 2.4)	**0.025**
Baseline v's end of wk 1	6.3 (± 2.3)	4.7 (± 1.8)	**0.001**
Beginning wk 2 v's end wk 2	5.2 (± 2.5)	3.9 (± 2.4)	**0.009**
Beginning wk 3 v's end wk 3	4.7 (± 2.2)	4.3 (± 2.3)	0.309
Beginning wk 4 v's end wk 4	4.4 (± 2.2)	3.9 (± 2.2)	**0.052**
Baseline v's End of trial	6.3 (± 2.3)	3.9 (± 2.2))	**0.003**
End of trial v's 1mth follow up	3.9 (± 2.2)	4.2 (± 2.0)	0.576
Arm Range of Movement			
Baseline v's after 1st treatment	3.6 (± 2.5)	3.6 (± 2.5)	1.000
Baseline v's 24 hours	3.6 (± 2.5)	3.5 (± 2.5)	0.343
Baseline v's end of wk 1	3.6 (± 2.5)	2.6 (± 2.5)	0.128
Beginning wk 2 v's end wk 2	2.3 (± 2.3)	2.2 (± 1.9)	0.758
Beginning wk 3 v's end wk 3	2.0 (± 1.7)	1.6 (± 1.1)	0.462
Beginning wk 4 v's end wk 4	1.4 (± 1.0)	1.4 (± 0.9)	1.000
Baseline v's End of trial	3.6 (± 2.5)	1.4 (± 0.9)	**0.013**
End of trial v's 1mth follow up	1.4 (± 0.9)	2.3 (± 1.8)	0.068

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Table 10a. Positive Subjective Comments (average percent)

Comment	Percent
Limb looked smaller	100%
Felt good post-Tx	90%
Limb felt smaller	70%
Improved self-image/confidence	50%
Limb felt lighter	40%
Limb felt normal	30%
Limb felt less tight	20%
Limb felt better	20%
Less limb pain/ache	20%
Tx relaxing	20%
Limb in best condition since developed Lo/for a long time	20%
Tx enjoyable	10%
Slept better post-Tx	10%
Felt less fat by week 4	10%
Chest less swollen above mastectomy scar	10%
Increased ROM at shoulder	10%
Area of fibrosis reduced	10%
Radiation scarring on chest less tight	10%
Most effective Lo Tx	10%

Table 10b. Negative Subjective Comments (average percent)

Comment	Percent
Tired post-Tx	50%
Increased urination	40%*
Increased thirst	30%*
Headache post-Tx	20%
Pain/altered sensation of dorsum of hand post-Tx	10%
Upper arm felt tender post-Tx	10%
Ache in upper arm post-Tx	10%
Slept worse post-Tx	10%
Felt cold-post-Tx	10%

* Increased urination and thirst were predominately experienced in the first week of treatment.

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Table 11. Bandaging compliance and adverse events over trial duration

	Week 1	Week 2	Week 3	Week 4
Bandaging Compliance:				
Slightly	10%	10%	-	-
Moderately	40%	30%	30%	30%
Completely	50%	60%	60%	60%
Wore compression sleeve	-	-	10%	10%
Puffy/swollen fingers	10%	-	-	-
Disturbed sleep	10%	-	-	-
Bandaging uncomfortable	90%	20%	30%	20%
Itching	10%	10%	10%	-
Redness/chaffing/blistering	30%	10%	30%	-

Table 12. Sleeve compliance, self massage and adverse events over the 1 moth follow up period

	1 Month
Sleeve Compliance:	
Slightly	10%
Moderately	20%
Completely	70%
Not at all	-
Self massage	90%
Adverse Events:	
Scratch on arm	10%
Rib fracture	10%
Blister	10%
Shoulder injury	10%
Flu	10%

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Discussion

At the end of four weeks of treatment there had been a 216ml (22% actual oedema; p = 0.014) fluid reduction from the affected arm, as measured by (b)(4) [redacted]. Whole arm volume (as measured by perometry) reduced by 186.3mls (19% actual oedema; p = 0.002), with the forearm region reducing by 137.7mls (14% actual oedema; p = 0.003) and the upper arm region by 48.4mls (4.9% actual oedema; p = 0.001). These reductions were greater in comparison to the original (2004) trial. (See Table) Fluid and volume parameters increased at the 1 month follow up as in the prior trial. Both the (b)(4) [redacted] and perometry measurements demonstrated that the majority of arm fluid loss and volume reduction occurred after the first 2 weeks of treatment, with the arm fluid loss, forearm and whole arm reductions all being statistically significant at this time point. Further reductions did occur over treatment weeks 3 and 4, but these were not as large in comparison to treatment weeks 1 and 2.

Parameter	End of Trial		1 month f/up		**% change (b)(4) [redacted] end of trial**
	(b)(4) [redacted]		[redacted]		
Arm Fluid (b)(4) [redacted]	- 182.5	- 216.0	+ 50.6	+ 97.8	**18.3 % better**
Arm Volume (Perometry)	- 133.6	- 186.3	+ 16.6	+ 44.1	**39% better**
Forearm Volume (b)(4) [redacted]	- 101.1	- 137.7	+ 17.7	+ 60.0	**36.2% better**
Upper arm Vol. (Perometry)	- 33.5	- 48.4	+ 12.6	+ 18.0	**44.5% better**
Truncal Fluid (b)(4) [redacted]	- 341.7	- 290.0	+ 100.0	+ 77.8	**49% worse**

Initially there were small reductions in truncal fluid, with the greatest loss again occurring at the end of 2 weeks of treatment (180mls, p = n.s.). At trial end there had been an overall truncal fluid reduction of 290mls (p = 0.066), with some fluid return at 1 month (77.8mls). There was a slight weight reduction (0.5kgs, p = n.s.) at the end of 4 weeks of treatment, but minimal changes in body fat mass, percentage fat or body mass index, indicating that this weight loss was most probably related to the fluid reductions. At trial end there were reductions in resting pulse and blood pressure, which is most likely related to patients feeling more relaxed (with some patients stating that they found the treatments to be relaxing). Pulse and blood pressure increased slightly at the 1 month follow up.

(b)(4) [redacted] readings of the lymphatic territories demonstrated that there was softening in the forearm and upper arm territories directly after the first treatment, which was not seen to occur in the original (2004) trial. The softening in the upper arm territory may be related to the use of the I50 head in this region. Interestingly, the (b)(4) [redacted] readings taken in the upper arm territory deteriorated slightly over the treatment weeks, which may be related to fluid being moved out of this region or perhaps increased muscle tone (as the arm muscles have to work against the compression bandaging). This probably warrants further investigation. The anterior thorax territory had the greatest improvement after the first week of treatment, whilst the posterior thorax territory was improved by the end of trial. The improvement (and therefore softening) in the posterior thorax territory was greater than the improvement in the original (b)(4) [redacted] trial, which is most likely related to the increased treatment time spent in this area with the new treatment protocol. All measurements taken in the lymphatic territories deteriorated at the 1 follow up indicating the need for follow-up treatment.

There were reductions in all subjective symptoms at trial end, with statistically significant reductions in heaviness (p = 0.007), tightness (p = 0.001), tissue hardness (p = 0.011), perceived arm size (p = 0.003) and arm range of movement (p = 0.013). Reductions occurred in the majority of subjective symptoms (except for range of movement and arm temperature) directly after the first treatment, with steady reductions occurring in all subjective symptoms over trial duration. All subjective symptoms increased at

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the 1 month follow up. The reductions in subjective symptoms were similar to those that occurred in the original ([redacted] trial.
(b)(4)

The massage treatment was generally well tolerated, with patients stating that it improved limb comfort and self confidence and that the treatment sessions were relaxing. Interestingly, some women reported scar softening and less swelling around scar tissue after treatment, even though these areas were not specifically targeted. The major negative comments were increased urination, thirst and headaches, which is most likely related to the mobilization of fluid. There was also reported discomfort related to the compression bandaging, including itchiness, redness and interrupted sleeping patterns.

Conclusions

The new treatment protocol certainly appears to be generally more effective than the original protocol tested in [redacted] This new protocol had greater reductions in arm fluid and volume and softening in the posterior thorax territory, which is most likely related to the extra treatment time spent specifically in this area the use of the I50 treatment head. There was also no transient increase in upper arm volume (as measured by perometry) as occurred in the original ([redacted] trial, indicating that the extra drainage time incorporated into this new protocol has negated this problem. The greatest reductions and improvements were seen to occur after the first 2 weeks of treatment, indicating that perhaps a shorter treatment time could be used. However, treatment weeks 3 and 4 maybe important in helping to maintain the initial losses. There were improvements in all subjective symptoms and patients stated that they found the treatment generally enjoyable and felt that it improved limb discomfort. All parameters measured during the trial increased at 1 month follow up, with no parameters returning to the original pre-treatment levels. This demonstrates the importance of both self maintenance (the majority of women performed self massage and wore a compression sleeve over the follow up period) and the importance of ongoing treatment in the maintenance of this chronic and progressive condition.

Overall this new protocol resulted in truncal fluid, arm fluid and volume reductions and improvements in [redacted] readings (specifically in the posterior thorax) and subjective symptoms. The new treatment protocol appears to be advantageous in that the additional drainage time negates an increase in upper arm volume and softens tissue in the posterior thorax territory. It must be emphasised that this protocol should be delivered by a trained health professional who understands the underlying pathophysiology of lymphoedema and who can continually assess the patient's response to treatment. Patient education and maintenance is also important, as this will help to maintain some of the improvements obtained from this intensive treatment protocol.
(b)(4)

Recommendations

We would strongly recommend that the new protocol be used in preference to the older protocol when treating patients with secondary arm lymphoedema. The issue of the increased truncal fluids is a minor one due to the range of potential confounding variables and while there is more truncal fluids than the [redacted] trial percentage wise the change is minimal when considering the total volume of truncal fluids.
(b)(4)

(b)(4)
[redacted]

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ATTACHMENT 21 b

Breast Cancer Related Secondary Arm Lymphedema

(Secondary Lymphedema of the Arm Post Mastectomy)

Practice Protocol 2nd Study 2006

Australia (N. Piller)

Breast cancer related secondary arm lymphedema

The following protocol should first be set up in a free menu. (See Operator's Manual pg. 30.)
- Program 1: sequential mode: cycle ratio 30%, frequency 80 Hertz; V1= 60, V2 = 40
- Program 2: continuous mode.
- Program 3: sequential mode: cycle ratio 40%, frequency 75 Hertz; V1= 60, V2 = 40

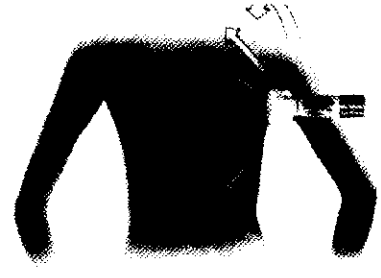
Protocol

1. To prepare the anastomosis (7 minutes)

Development of the trans-thoracic back and front anastomosis with I50, from the borderline of the edema to the lymph node area.

- Program 1
- **I 50** (or active auxiliary head: T 644-A or T 630-A)
  (The treatment head is chosen according to the morphology of the treated area.)
- Direct line.
- Layouts: to the node area: opposed axillary nodes, thoracics on back, cervicals, abdomino-thoracics nodes.
- Intensity: 1 - 3 (never painful)

Caution: Decrease the intensity if the skin shows any signs of durable hyperemia, pain or inflammatory reaction.



Over edema towards the lymph node area.

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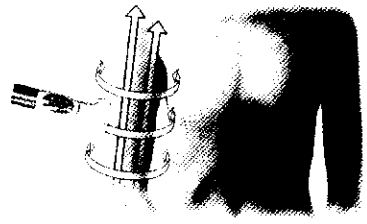
2. To mobilize the fibrotic induration (12 minutes)

On the edema.

- Program 2
- **I 50** (or Inactive auxiliary head: T 644 - T 630 - T 615)
  (The treatment head is chosen according to the morphology of the treated area.)
- Direct line
- Layouts: disto-proximal, longitudinal, ascending and transversely with proximo-disto-proximal. Always finish with longitudinal layouts.
- Order: proximo-distal by segment of limb (arm → forearm → hand)
- Intensity: 1 – 3

Caution: Decrease the intensity if the skin shows any signs of durable hyperemia, pain or inflammatory reaction.



1. Disto-proximal
2. Proximo-disto-proximal progression
3. Disto-proximal

3. To drain the upper limb (11 minutes total: 5 + 6 minutes)

On the edema.

- Program 3
- **I50** (or active auxiliary head: T 644-A or - T 630 A-T 615-A)
  (The treatment head is chosen according to the morphology of the treated areas.)
- When using I50, the pace of the maneuvers is a little faster than the roller speed.

Phase 1: 5 minutes

- Direct line
- Layouts: disto-proximal, longitudinal, ascending and transversely with proximo-disto-proximal.
- Order: segment of limb: arm → forearm → hand
- Intensity: 2 - 4

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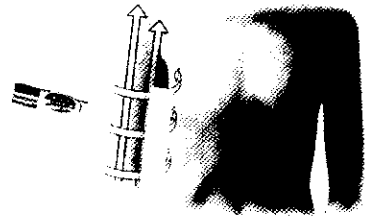
Phase 2: 6 minutes

- Direct line
- Layouts: longitudinal ascending
- Order : Disto-proximal starting from the hand → forearm →arm
- Finish in side lying with longitudinal layouts + back up to the shoulder and to the back (anastomoses).
- Intensity: 2 - 4

Caution: Decrease the intensity if the skin shows any signs of durable hyperemia, pain or inflammatory reaction



Complete session: 30 minutes

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(b)(4) Agreement

(b)(4) Agreement

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(b)(4) Agreement

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(b)(4) Agreement

(b)(4) [redacted]

ATTACHMENT 22 – cont'd

Schedule 1
Contract Details

Item 1 – Term
The term of the Contract shall be from date of signature until (b)(4) [redacted] (b)(4) [redacted] unless otherwise agreed.

Item 2 – Primary Site
The research will be conducted at the (b)(4) [redacted] (b)(4) [redacted] and undertaken according to all regulations and guidelines applying in the Site, including compliance with all ethics requirements.

Item 3 – Specified Persons
(b)(4) [redacted]

Item 4 – Client's Nominated Agent
(b)(4) [redacted]

Item 5 – Reporting Requirements
Reports detailing technical progress and expenditure incurred will be forwarded to the Client before the (b)(4) [redacted]
A comprehensive final technical report and financial report will be submitted within (b)(4) [redacted] of the conclusion of the Project.

Item 6 – Payments
(b)(4) [redacted]

(b)(4) [redacted]

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Schedule 2
Research Program
Trialing of the modified LPG technique on secondary arm lymphoedema with a one and two month follow-up

Conducted on behalf of
LPG Systems

Background
Results from the initial study on LPG-Endermologie treatment of secondary arm lymphoedema indicated excellent outcomes in terms the impact of the LPG treatment on the swollen arm and other parts of the affected body. In particular it showed significant reductions in pain, heaviness, tightness, tissue hardness, pins and needles and the perceived size of the limb when looking from the patient perspective. Objectively and specifically there were important softening of the tissues of the lymphatic territories of the forearm and upper arms. Of particular interest was the softening of the anterior thorax but not such an improvement in the posterior thorax. Objectively this also showed as a reduction in the distance from the deep to the superficial fascias in the upper arm and anterior thorax. Certainly this, when combined with tonometry results indicated a reduction in the extent of fibrotic induration here.

However, the data of the removal of the fluids in the affected arm and of the changes in the size of the affected arm indicated that the upper arm was perhaps not being cleared as well as the forearm. This was in part a consequence of the pattern of treatment (minimal time clearing the upper arm) and the fact that the posterior watersheds and territories were not optimally cleared. There is also some indication in the findings that the anterior lateral aspects of the thoracic territory were not optimally cleared as well.

(b)(4) [redacted]

Accordingly the following additional sub group investigation is proposed.

Objective
To determine if the modified LPG Technique (adding another 5 minutes to the protocol and concentrating more on the upper arm and posterior and anterior thoracic territories) for treatment of secondary arm lymphoedema is better than the

(b)(4) [redacted]

Reduce the size and volume of a chronically lymphoedematous limb
Reduce the levels of extra-cellular fluids in the lymphoedematous limb
Reduce the amount and extent of fibrotically indurated tissues in the upper and lower limb and anterior and posterior thoracic area
Reduce truncal fluids
Improve range of movement of the limb

(b)(4) [redacted]

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(b)(4)

Improve patients subjective indicators such as aches and pains, tension, heaviness, pins and needles and other problems normally associated with a chronically lymphoedematous limb.

NB "limb" means arm; "Lymphoedema" is being used as a representative model of a large range of other conditions/disorders whose end point is the accumulation of fluids in the tissues.

Methods

Design

Since there has already been a comparison with the gold standard of MLD it is not necessary to repeat a design stage.

We will make every attempt to again try to recruit 10 new patients who have never received LPG treatment and with the same inclusion criteria as in the previous study. Minimal final sample size for the study will be 10 lymphoedema limbs. Based on previous trial data and on patient dropout and the need to ensure data at all measurement points it means we would have to initially expect to recruit 15 patients.

Note: Due to the often whole body effect of massage such as what LPG treatment offers, and some evidence in the prior study, the contra-lateral (normal) limb will also be measured.

Conduct of the trials on humans will be subject to the approval of, and any conditions imposed by, the relevant (b)(4) ethics committees.

Duration of study

The modified treatment will be applied for a period of 4 weeks use with the patient being treated at (b)(4) 4 times per week with 30 minutes per LPG session. In order to match the prior study patients would be given a short stretch elastic bandage after each treatment to facilitate treatment maintenance. Patients would be encouraged to wear this over weekend breaks as previously.

Patients would receive one and two month follow ups.

It is envisaged the main body of the study would take 3 months assuming: 4 LPG treatments per week and allowing for ethics re-approval, the recruitment of two suitable patients per week and a steady state of 8 patients.

Inclusion criteria

Patients must have a carer or partner willing and able to come to (b)(4) for 12 treatments (4 per week for four weeks) and be able to present at the follow-up (at one and two months after the end of the LPG treatment).

Patients presenting and or diagnosed with clinically manifest chronic secondary unilateral arm lymphoedema. These patients will be late grade 1 but with the key determinants showing a firm location in the grade 2 (ISL classification) region. This would mean that the corrected (for arm dominance) volume difference would be 10% or more. Generally this means a circumference difference of 2 cm or more in the key measurement positions. Volume difference is used in preference to circumference difference since for larger framed persons 2 cm difference is relatively insignificant, while for smaller frame persons it is very significant. (b)(4)

(b)(4)

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(b)(4)

Duration of lymphoedema greater than 1 year or a lesser period if there is significant indications of fibrotic induration of the major lymphatic territories as detected by (b)(4)

Patients who have never been treated with the LPG technique

BMI = 22 - 30

Exclusion criteria
Unavailability of patient to attend all sessions.
Current uncontrolled cancer
Recent surgery, 1 month in any other part of the body
Uncontrolled Hypertension
Underlying lipoedema
Underlying primary lymphoedema
Using Diuretics or Corticotherapy and / or any physiotherapy for less than 3 months.

Notes on criteria
It would not matter if the patients were having other treatments (other than Diuretics or Corticotherapy and / or any physiotherapy - cf. "Exclusion criteria") but certainly these other treatments would be ceased upon commencement of this current trial. Ideally, however patients would be asked to cease other treatments at least two weeks prior to the trial .

For treatments which are known to have a long term treatment effect and which are well evidenced then it is likely that the known duration of that treatment effect period would the minimum with an additional two week margin. In some cases this may mean a three month exclusion period.

In view of the now documented effects of mild exercise on lymphoedematous limbs all patients will be discouraged from the undertaking of any formed exercise programs during the extent of the trial. Normal activity will be encouraged.

Clinical Assessment procedures and timing
Each patient will be assessed prior to entry into the study to confirm suitability. Suitable patients will have the following standard tests performed immediately prior to the first treatment and at a weekly intervals (at the end of the fourth treatment for the week) until the completion of the trial at 28 days. Patients will be reassessed one month and two months after the completion of the trial for longer term benefits.

Assessment will include standard assessment procedures currently used in the
(b)(4)

Subjective indication of problems such as heaviness, tension, bursting pains, pins and needles, areas of paraesthesia logged on 5 point lichert scales.
(b)(4)

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Objective determination by (b)(4) of the levels of fibrotic induration in each of the major limb and thoracic territories.

Objective determination of limb volumes using perometery (circumference measurement in 200 positions on the limb and volume determination calculated from this).

Objective determination of the amount of free extra-cellular and intracellular fluids by (b)(4).

Objective determination of range of movement would be made using a goniometer.

Details of procedures

Measurement (as previously detailed)
Limb circumferences and volume - Perometry
Limb volume can be calculated, using segmental circumferential measurements taken, by considering the limb as a cylinder or a frustrum (Lennihan and Mackereth 1973; Sitzia 1995; Sander et al 2002; Karges et al 2003). It serves good intra- and interrater reliability (Sander et al 2002). Studies by Sitzia (1995), Sander et al (2002) and Karges et al 2003 shown that a frustum formula is more accurate than a cylindrical formula in assessing the upper limb volume and it is also proved to have high correlation (r=.98) with the volume measured by the water displacement method (Stranden 1981). However, perometry is more accurate and more reproducible and validation studies have previously been performed. (Stanton et al 1997, 2000) All limbs will be measured using perometry in this study. The perometer (Perosystems, Germany) is a square measuring frame that contains rows of infra-red light emitting diodes on two sides and rows of corresponding senses on the opposite two sides. The patient sits at one end with the foot resting centrally on an adjustable support. The frame is then moved along the length of the leg from the ankle to thigh. The limb casts shadows in two planes and using the cross-sectional information obtained, a computer builds up a whole leg volume and circumferential picture (at 3mm intervals) of the entire leg. It has been validated on both healthy volunteers and patients with oedema related conditions.

Tissue resistance to compression – (b)(4)
A swollen extremity may have smaller girth measurement as a result of the soft tissue shrinkage particularly if there is tissue fibrosis (Clodius et al 1976; Stanton 2000) and is therefore more resistant to compression (Clodius et al 1976, Liu and Olszewski 1992). A tissue (b)(4) has been used to provide the extent of tissue elasticity of lymphedema patients after courses of treatment and it is supported by various studies (Clodius et al 1976; Piller & Clodius 1976; Liu and Olszewski 1992, Kar et al 1992; Bates el al 1994; Chen et al 1988; Piller and Thelander 1998; Piller and Harris 2001). In this study a mechanical tissue (b)(4) with a 200g weight (b)(4) will be used to measure the tissue resistance to compression on the lymphedematous extremities. A single point on the upper arm and on the forearm as well as on the anterior and posterior thoracic area will be used for the measurement. Three measurements will be taken (b)(4) (b)(4)

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(b)(4)

at each body point and the average reading will be taken. The relative tissue resistance to compression at a specific point will be reflected by the ratio (R) = ((b)(4) reading of a point on the lymphaedematous upper extremity) / ((b)(4) reading of the corresponding point on the unaffected upper extremity). Intra-rater reliability of the tonometer measurement has been conducted and good results were obtained. In this study however, only one person will be involved in measurement taking.

Fluid Content - multi frequency (b)(4)
The (b)(4) machine used in this clinical trial will be the (b)(4) manufactured in (b)(4) The (b)(4) a multi-frequency body and segmental analyser (5kHz - 500kHz) where the patient stands erect on electrode footplates and holds electrodes in the hands, resulting in 8 electrode contact sites. The multi-frequency technique accurately quantifies both total body fluid and extracellular fluid in extremities (Ross, 1989, Watanabi,1989), having the ability to quantify lymph fluid changes as it can distinguish among the gain or loss of fluid from fat and muscle. (Luksaki, 1987, Luksaki et al 1994). (b)(4) validity in measuring body fluid in both healthy adults and patients has been proven, (Luksaki, 1987, Mikes 1988, Cornish et al 1996, 2000) including in lymphoedema. (Ward et al 1992). Information will also be collected about changes in truncal fluids as well as in the contralateral limb

Objective determination of range of movement - goniometer:

Subjective measurements: - Visual Analogue and other scales
A questionnaire assessing participants subjective symptoms, including pain, heaviness, tightness, pins and needles, cramping, burning sensations and perceived limb size may be administered each week- but most likely pre and post treatment period. Participants will be asked to rate their symptoms on a 0-10 scale as used in the McGill Quality of Life Questionnaire, where zero equates to no problem and 10 is rated as the worst imaginable. This scaling system has been previously validated

Persons conducting the Study
All work would be supervised by (b) (6). Persons with relevant expertise contracted in to perform specific tasks.

All assessments will be made in a blinded fashion by our research officer (b) (6) or trained research nurse. Treatment using the LPG technique would be given using an appropriately trained person who has been briefed regarding the new technique (b) (6)

(b)(4)

6.30

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(b)(4)

[redacted]

Budget – modified LPG technique and a 1 month follow-up

(b)(4)

[redacted]

(b)(4)

[redacted]

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ATTACHMENT 23

Participant Information Sheet

THE EFFECT OF MECHANISED MASSAGE ON POST MASTECTOMY ARM LYMPHOEDEMA

You are invited to take part in a study exploring the effect of mechanised massage plus compression bandaging on secondary lymphoedema of the arm. The swelling in your arm is related to the build up of fluid in the tissues, with massage being advocated as a therapy that helps to remove this fluid. This study aims to investigate some of the changes that occur in the arm in response to massage.

The machine based massage uses two moving rollers that shift over the skin to deliver a light massage. Pilot studies of this equipment have shown that it improves lymphatic drainage, limb tissues and decreases functional discomfort. The compression bandaging is applied after the massage with the aim of maintaining any reduction that occurred as a result of the massage. The compression bandaging involves a layer of foam followed by a layer of thick stretch bandaging with is applied to the whole arm and exerts compression. You will be allowed to remove the bandaging to have a shower. The benefits of these massage therapies plus bandaging, can not however be assured.

If you choose to participate, you will be assessed for your suitability for the trial and if successful will be allocated to the following treatment group:

- A final total of 10 participants will receive approximately 30 minutes of mechanised massage followed by compression bandaging 4 times a week for 4 weeks then a 1 month post treatment follow up measurement.

The drainage and compression bandaging will be performed by an allied health professional trained in the techniques. A trained health professional will apply the mechanised massage equipment and monitor its progress.

All participants will be assessed by a qualified Registered Nurse/Researcher regularly throughout the trial. To see what is happening to your arm regular measurements will need to be taken. These measurements will need to be taken immediately before the first massage, at weekly intervals (after the third massage) and then 1 month after treatment to assess for any ongoing affects. You will be asked to attend the (b)(4) [redacted] for these measurements and the massage session, with each visit taking approximately 1 hour.

The person taking your arm measurements through out the trial will not know which form of massage you are receiving, so please do not discuss this with him/her at the measurement sessions. The measurements to be taken are outlined below:

The following measurements carry no risks and are non-invasive:

- (b)(4) [redacted]: this measures the hardness/softness of the arm tissues. It involves placing a metal disk on the surface of the skin on the front of the forearm, the upper arm, above your collar bone and on your back near your shoulder blade*.

- Perometry: this measures the circumference and volume of the arms. It involves sitting in a chair and resting the arm in a horizontal position whilst the arm is scanned by the perometry machine, which takes measurements at every 3mm*.

- (b)(4) [redacted]: this measures how much fluid is in the arm tissue. It involves standing on an electronic machine (like scales) and holding two handles in the hands.

- Blood Pressure and Pulse: this will involve taking blood pressure with a standardised pressure cuff (using the non-affected arm) and taking the pulse at the wrist.

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- Questionnaires: A series of questions about your condition and how your arm feels.

* These measurements plus the massage will require you to remove your shirt, but all massage sessions and measurements will be conducted in privacy.

There are no known side effects from the massage. The compression bandaging will be applied by a health professional trained in the technique, but there is the possibility that it maybe applied too tightly. If you feel that the bandaging is too tight or you experience pins & needles or numbness in the arm, please remove the bandaging straight away and report it to the clinical investigators. If you experience any discomfort during the massage session please report it and a Registered Nurse will be on hand to assess you. If you have any problems in your neck, arm or upper torso please let the person who is administering the massage and bandaging know.

All those who participate will have their parking costs re-imbursed as a gesture of appreciation.

Your involvement in this study is entirely voluntary, and your non-participation will not affect any future treatment at the (b)(4) [redacted]) in any way. Should you decide to withdraw from the study you may do so freely, at anytime and without prejudice to any future treatment at the (b)(4) [redacted] a (b)(4) [redacted].

All records containing your personal information will remain confidential and no information that could lead to your identification will be released. Study data will be kept for 16 years in a locked cabinet by the researchers. The company sponsoring this trial will have access to the information gained but will be given no information that could lead to your identification.

Should you require further details about the project, either before, during or after the study, you may contact (b) (6) [redacted].

This study has been reviewed by the (b)(4) [redacted] Ethics Committee. Should you wish to discuss the project with someone not directly involved, in particular in relation to matters concerning policies, information about the conduct of the study or your rights as a participant, or should you wish to make a confidential complaint, you may contact the (b)(4) [redacted]

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(b)(4) [redacted]

CONSENT TO PARTICIPATION IN RESEARCH

I, _____ Request and give consent to
(first or given names) (surname)

My involvement in the research project 'The effect of mechanised massage on post mastectomy lymphoedema'
(short title of research project)

I acknowledge that the nature, purpose and contemplated effects of the research project, especially as far as they affect me and (N/A) have been fully explained
(my [foetus] baby, if applicable)

to my satisfaction by (b) (6) [redacted] and my consent is given voluntarily
(first or given names) (surname)

I acknowledge that the detail(s) of the following procedure(s):

- Mechanised massage
- Compression bandaging

(b)(4) [redacted]

- Arm volume and circumference (perometry)
- Questionnaires
- Blood Pressure and pulse measurements

has/have been explained to me, including indications of risks; any discomfort involved; anticipation of length of time and the frequency with which the procedure(s) will be performed.

I have understood and am satisfied with the explanations that I have been given.

I have been provided with a written information sheet.

I understand that my involvement in this research project and/or the procedure(s) may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect

I understand that any payment made to me is simply an expression of gratitude for assistance in this research project.

I declare that I am over the age of 18 years.

Signature of research subject: _____ Date: _____

Signature of Witness: _____

Printed Name of Witness: _____

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ATTACHMENT 24

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: February 28, 2006.

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

(b)(4)

(1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		

(2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

(3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

(b) (6)

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

FORM FDA 3454 (2/03)

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Addendum to Form FDA 3454

(b) (6)

[redacted]

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ATTACHMENT 25-1 BROCHURE

CELLU M6® KEYMODULE *i*

LPG

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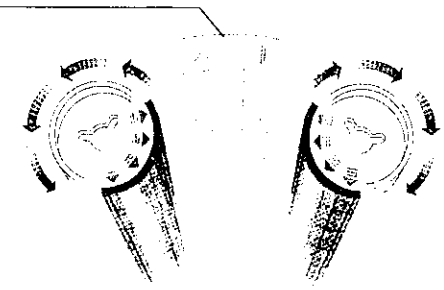
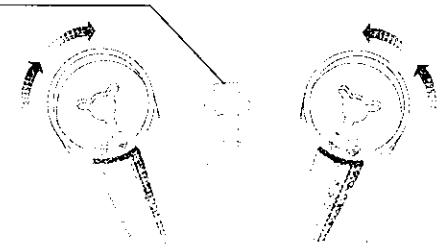
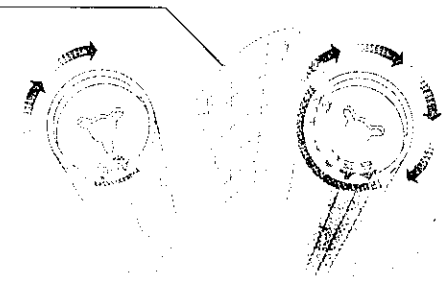
KEYMODULE /



ROLL'IN
the direction of rotation of the 2 rollers converges towards the inside of the treatment chamber.



ROLL'OUT
the direction of rotation of the 2 rollers diverges towards the outside of the treatment chamber.



ROLL'UP
Adjustment of the speed differential between the rollers allows the fold to be moulded accurately.

CUTANEOU

INDEPENDENT DOUBLE MOTORISATION

In order to allow the operator to treat the encountered tissue precisely, LPG has invented a new technology that is opening up unexplored fields of research. A technology where each roller comprises a miniaturised motor that gives it unprecedented independence (speed and direction of rotation) inside an airtight, mobile treatment chamber. This specific technological feature enables the operator to obtain a large variety of skin folds in terms of their shape, depth and thickness.

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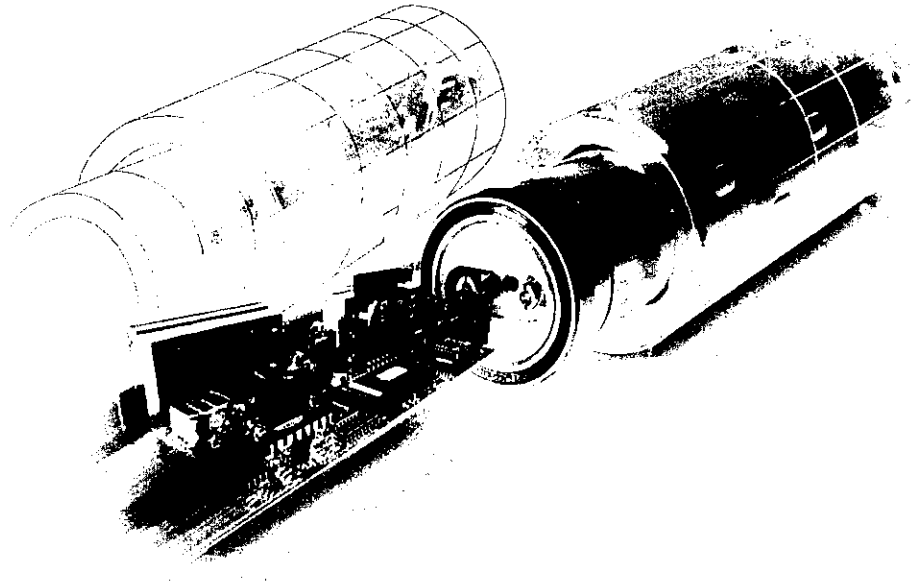
FLEXIBILITY

TISSUE TREATMENT IN ALL ITS DIMENSIONS

Each roller incorporates a miniaturised high-technology motor, thereby allowing it unprecedented autonomy (speed and direction of rotation).



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SELECTIVITY

THERAPEUTIC BENEFITS

- Venous stasis
- Venous insufficiency
- Deep vein thrombosis
- Primary lymphedema
- Secondary lymphedema of the arm post-mastectomy
- Lymphedematous fibrotic induration
- Secondary lymphedema

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE OR ON THE ORDER OF A CLINICIAN LICENSED BY THE LAW OF THE STATE WHERE HE/SHE PRACTICES TO USE OR ORDER THE USE OF THE DEVICE

A NEW INTELLIGENT INTERFACE

The ***Cellu M6 Keymodule i*** is your gateway to the field of therapeutics. Fast and intuitive navigation will enable you to achieve your goal: targeted results that will satisfy your patients.

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Use of the Keymodule device is contraindicated for:

The CelluM6 Keymodule i should not be used on certain areas or under certain conditions.

1. This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.

2. Do not treat wounds, infected areas, skin tumors, open sores, scars form recent surgery, the eyes, intra-cavity areas, mucous membranes, the genitals or directly over nipples.

3. Do not treat patients with infectious progressive illnesses.

4. Do not treat patients with active cancer or a growing tumor. (Consult with the doctor if the patient has had a case history of tumors or is in remission.)

5. Do not treat patients with skin cancer, tumors and other cancerous lesions in the area to be treated.

6. Do not treat patients suffering from inexplicable and persistent pain without seeking medical advice or without training in the LPG technique in this particular area.

7. Do not treat patients following invasive medical treatment without seeking the medical advice of the doctor or surgeon who performed this operation, or without training in the LPG technique in this particular area.

8. Not recommended for anyone under medical care for circulatory conditions without first consulting a physician.

9. Not recommended for pregnant women.

10. Stop treatment immediately if patient experiences any pain and consult the physician.

11. Avoid possible bruising. Use caution when determining a patient's sensitivity level.

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ATTACHMENT 25-2 DIRECTIONS FOR USE

What is this if not part of the user's manual?

Cellu M6 Keymodule i

? (Refer to Operator's Manual) where is this.

This device is indicated for use for the following:

- Reduction of secondary lymphedema of the arm (SLA) post mastectomy
- Reduction of lymphedematous fibrotic induration
- Improvement of primary and secondary lymphedema
- Prevention of venous stasis and venous insufficiency
- Prevention of deep vein thrombosis (DVT)
- Improvement of lymphatic circulation in the treated areas

Directions for Use

The directions for use for this device are illustrated in this section over the following pages. For maximum efficiency, the treatment heads should be chosen according to the morphology of the treated area as illustrated below:

Motorized Heads:

i.2	for largest surface areas (such as the thigh)
i50	for the upper arm in the treatment of SLA

Auxiliary Heads (*Active-Inactive*):

T644-A/T644	(as needed for small areas)
T630-A/T630	(as needed for smaller areas)
T615-A/T615	(as needed for smallest areas)

Active auxiliary heads are loaded with springs behind the rollers. The function of the springs in the *Active* auxiliary heads is to allow for optimal movement of the rollers on the tissues when using sequential aspiration (or pulsating) programs designed to create the pump or wave-like action when treating lymphedema-related conditions.

Inactive heads do not have springs behind the rollers, and are meant to be used with constant suction settings for more static and deeper actions, such as that use to mobilize fibrotic induration.

In addition to the directions for use for each program, all of the protocols are also recommended for the improvement of lymphatic circulation in the treated areas. Therefore, there is no specific direction for use for this claim, as it is implied by all the others.

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A CLINICIAN LICENSED BY THE LAW OF THE STATE WHERE HE/SHE PRACTICES TO USE OR ORDER THE USE OF THE DEVICE

Needs to be prominent

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Secondary Lymphedema of the Arm Post Mastectomy

To prepare: 7 min.

EVALUATION ■ OEDEMA, POST RADIOTHERAPY FIBROSIS

OBJECTIVE ■ TO PREPARE THE ANASTOMOSIS

MANŒUVER ■ DIRECT LINE

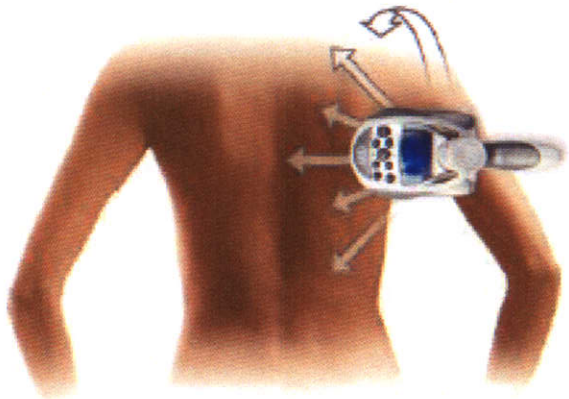
CYCLE: 30

FREQUENCY: 80

V1: 60

V2: 40

POWER: 1-3



> Over irradiated area towards the lymph nodes area. Front / back.

To mobilize: 12 min.

EVALUATION ■ ŒDEMA, FIBROSIS

OBJECTIVE ■ TO MOBILIZE

MANŒUVERS ■ ARM, FOREARM, HAND TRANSVERSAL, LONGITUDINAL ASCENDING DIRECT LINE

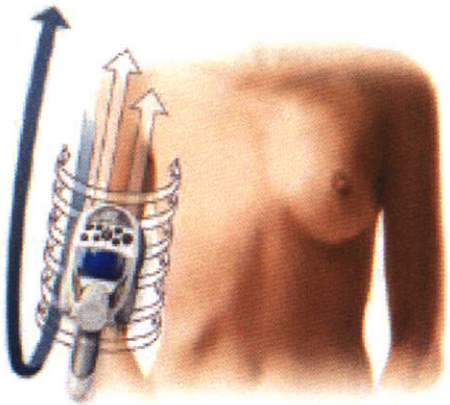
CYCLE: 100

FREQUENCY: 0

V1: 80

V2: 40

POWER: 1-3



The treatment head is chosen according to the morphology of the treated area (i50 ; auxiliary heads).

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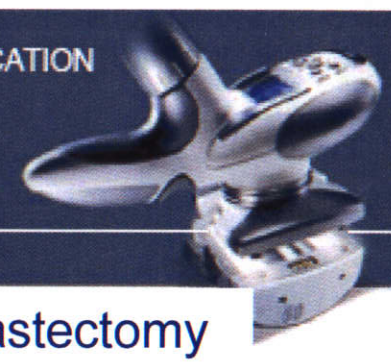
i50

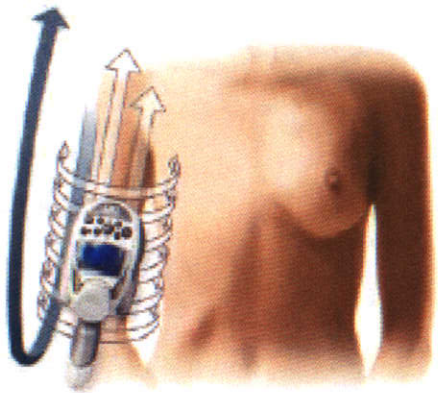


Secondary Lymphedema of the Arm Post Mastectomy

To drain - phase 1: 5 min.

EVALUATION OBJECTIVE MANŒUVERS
- ŒDEMA
- TO DRAIN LYMPH
- TRANSVERSAL, ARM, FOREARM, HAND LONGITUDINAL ASCENDING DIRECT LINE

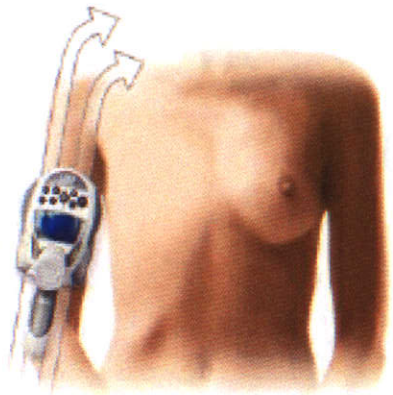
CYCLE: 40
FREQUENCY: 75
V1: 60
V2: 40
POWER: 2-4



To drain - phase 2: 6 min.

EVALUATION OBJECTIVE MANŒUVERS
- ŒDEMA
- TO DRAIN LYMPH
- HAND, FOREARM, ARM LONGITUDINAL ASCENDING DIRECT LINE

CYCLE: 40
FREQUENCY: 75
V1: 60
V2: 40
POWER: 2-4



The treatment head is chosen according to the morphology of the treated area (i50 ; auxiliary heads).

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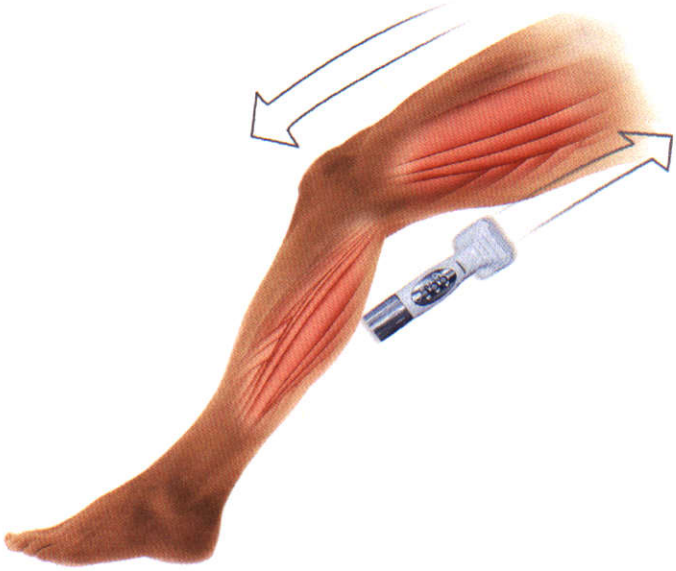
Fibrotic Induration

to mechanize

EVALUATION: LOSS OF MOBILITY, FIBROSIS
OBJECTIVE: TO MECHANIZE
MANŒUVERS:
LONGITUDINAL
DIRECT LINE, SLIDE
MUSCLE, TENDON, LIGAMENT
CYCLE: 30
FREQUENCY: 90
V1: 80
V2: 40
POWER: 5.0 +



to mobilize

EVALUATION: LOSS OF MOBILITY, FIBROSIS
OBJECTIVE: TO MOBILIZE
MANŒUVERS:
LONGITUDINAL
DIRECT LINE, SLIDE
BOUNCING + TWIST
MUSCLE, TENDON
CYCLE: 100
FREQUENCY: 0
V1: 60
V2: 40
POWER: 2.0 +

➜ **Specificity:**
- With limitation of joint amplitude.

- All indicated protocols are also recommended for the improvement of lymphatic circulation in the treated areas.
- The treatment head is chosen according to the morphology of the treated area (i2 ; auxiliary heads).

The treatment head is chosen according to the morphology of the treated area.

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Réf. : 100 58 65 PR. GB - KMI - 1.2 - A

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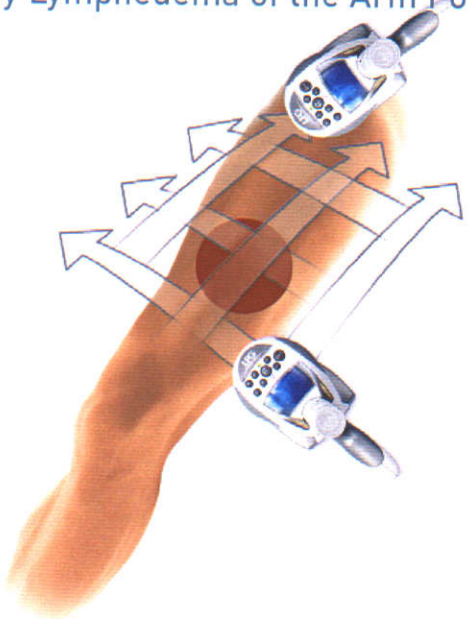
Primary and Secondary Lymphedema
(other than Secondary Lymphedema of the Arm Post-Mastectomy)

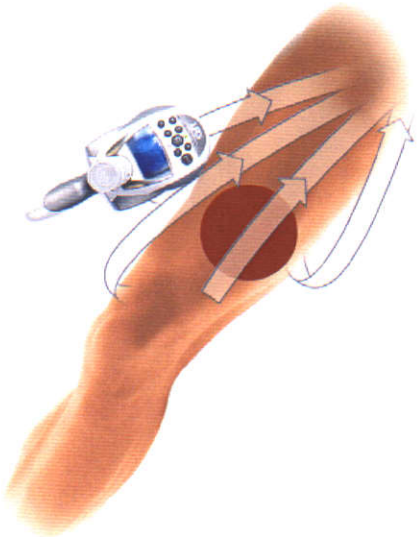
to collect

EVALUATION: EDEMA
OBJECTIVE: TO COLLECT
MANŒUVERS: **GRID**
DIRECT LINE
CYCLE: 40
FREQUENCY: 80
POWER: 3.0 +



to drain

EVALUATION: EDEMA
OBJECTIVE: TO DRAIN
MANŒUVERS: **LYMPHATIC PATHWAY**
DIRECT LINE
CYCLE: 40
FREQUENCY: 4
POWER: 2.0 +



- All indicated protocols are also recommended for the improvement of lymphatic circulation in the treated areas.
- The treatment head is chosen according to the morphology of the treated area (i2 ; auxiliary heads).

The treatment head is chosen according to the morphology of the treated area.

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Réf. : 100 58 65 PR. GB - KMI - 5.1 - A

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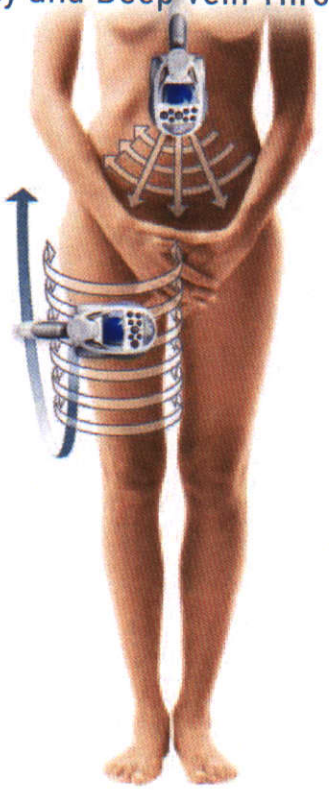
Venous Stasis, Venous Insufficiency and Deep Vein Thrombosis (DVT)

to drain

EVALUATION	EDEMA, HEAVY LEGS	CYCLE: 40
OBJECTIVE	TO DRAIN	FREQUENCY: 75
MANŒUVERS	TRANSVERSAL	V1: 80
	DIRECT LINE	V2: 60
		POWER: 2.0 +

to mobilize

OBJECTIVE	TO MOBILIZE	
MANŒUVERS	TRANSVERSAL	CYCLE: 100
	DIRECT LINE	FREQUENCY: 0
	BOUNCING	V1: 80
		V2: 60
		POWER: 2.0 +

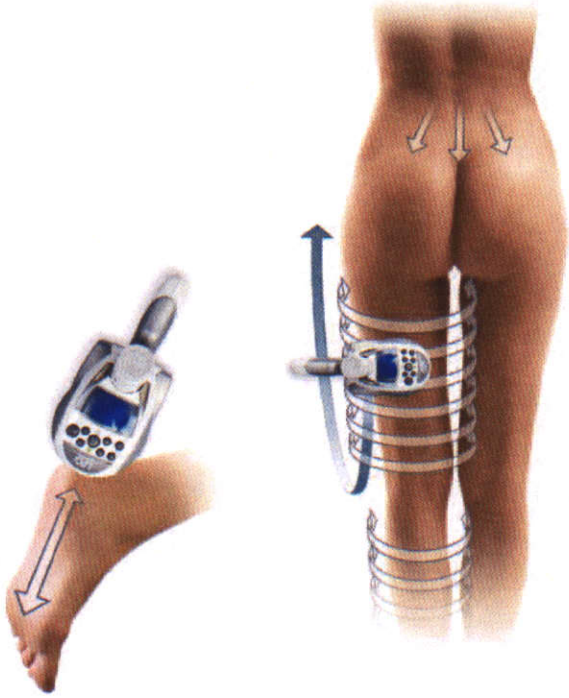


to drain

EVALUATION	EDEMA, HEAVY LEGS	CYCLE: 40
OBJECTIVE	TO DRAIN	FREQUENCY: 75
MANŒUVERS	TRANSVERSAL	V1: 80
	DIRECT LINE	V2: 60
		POWER: 2.0 +

to mobilize

OBJECTIVE	TO MOBILIZE	CYCLE: 100
MANŒUVERS	TRANSVERSAL	FREQUENCY: 0
	BOUNCING	V1: 80
	DIRECT LINE	V2: 60
		POWER: 2.0 +



➜ + Foot sole.

- All indicated protocols are also recommended for the improvement of lymphatic circulation in the treated areas.
- The treatment head is chosen according to the morphology of the treated area (i2 ; auxiliary heads).

The treatment head is chosen according to the morphology of the treated area.

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PR. GB - KMI - 4.1 - A

Réf. : 100 58 65

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Use of the Keymodule device is contraindicated for:

The CelluM6 Keymodule i should not be used on certain areas or under certain conditions.

1. This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.

2. Do not treat wounds, infected areas, skin tumors, open sores, scars form recent surgery, the eyes, intra-cavity areas, mucous membranes, the genitals or directly over nipples.

3. Do not treat patients with infectious progressive illnesses.

4. Do not treat patients with active cancer or a growing tumor. (Consult with the doctor if the patient has had a case history of tumors or is in remission.)

5. Do not treat patients with skin cancer, tumors and other cancerous lesions in the area to be treated.

6. Do not treat patients suffering from inexplicable and persistent pain without seeking medical advice or without training in the LPG technique in this particular area.

7. Do not treat patients following invasive medical treatment without seeking the medical advice of the doctor or surgeon who performed this operation, or without training in the LPG technique in this particular area.

8. Not recommended for anyone under medical care for circulatory conditions without first consulting a physician.

9. Not recommended for pregnant women.

10. Stop treatment immediately if patient experiences any pain and consult the physician.

11. Avoid possible bruising. Use caution when determining a patient's sensitivity level.

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ATTACHMENT 25.3 MANUAL

OPERATOR'S MANUAL

cellum6
KEYMODULE

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Registered trademark

OPERATOR'S MANUAL

cellum6®
KEYMODULE

Please read the complete manual carefully before using your equipment.

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GU 2-250

Edition B dated 01/01/05

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Congratulations on the purchase of your Cellu M6® Keymodule ***i***. This model represents the fruits of numerous years of experience in the design and production of sub-cutaneous and cutaneous tissue treatment systems. You will experience fully the technical perfection and reliability of LPG Systems®, which is the leader in this sector. This operator's manual contains the operating description, directives basic maintenance information and the safety instructions. We would like to point out that the use of your equipment requires the prior attendance of a specific operator training session provided by LPG Systems®. If you have any doubts whatsoever concerning the operation or maintenance of your equipment, please do not hesitate to contact LPG Systems® Customer Service Center:

Tel: 888.730.0144
Fax: 888.571.0040

In order to respond better to customer requirements or expectations, LPG Systems® is continuously researching ways of improving the design and quality of its products. This will explain the few minor differences between your equipment and the item described in this guide.

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Package contents

- One Cellu M6® Keymodule *i* unit
- One main T70 head
- Keymodule®
- One supply cable
- A set of auxiliary heads
- One operator's manual
- One maintenance kit
- Supplies kit

Please do not discard unpacking instructions.

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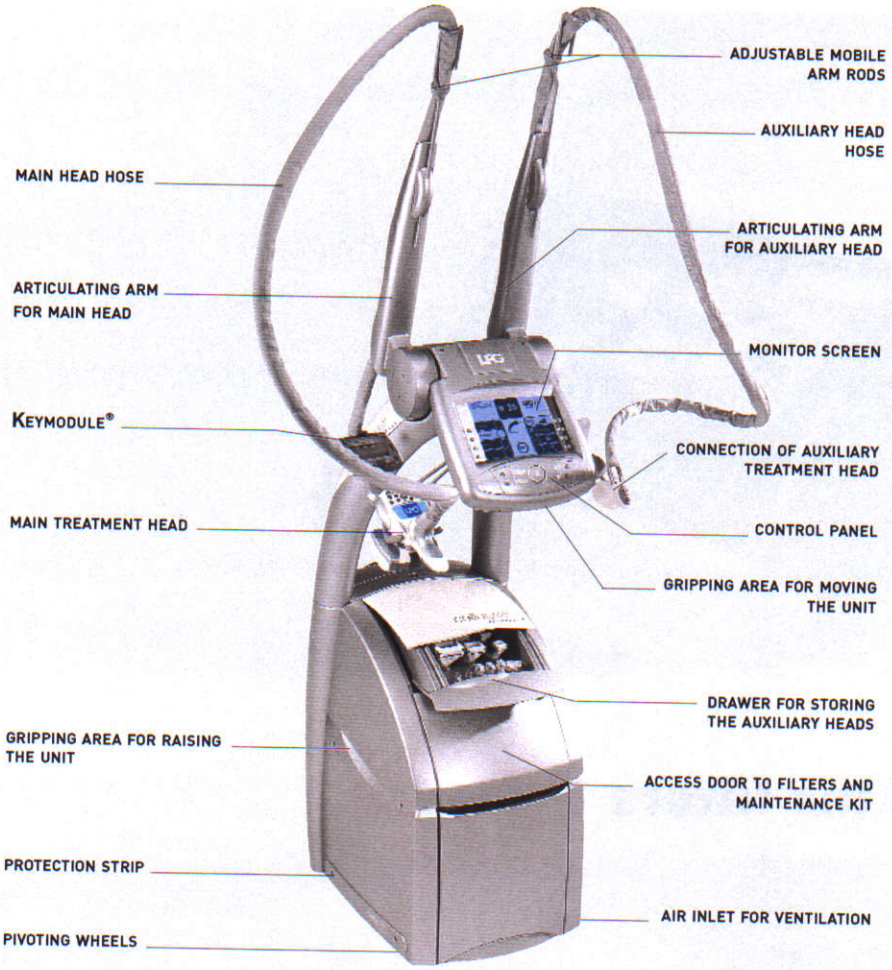
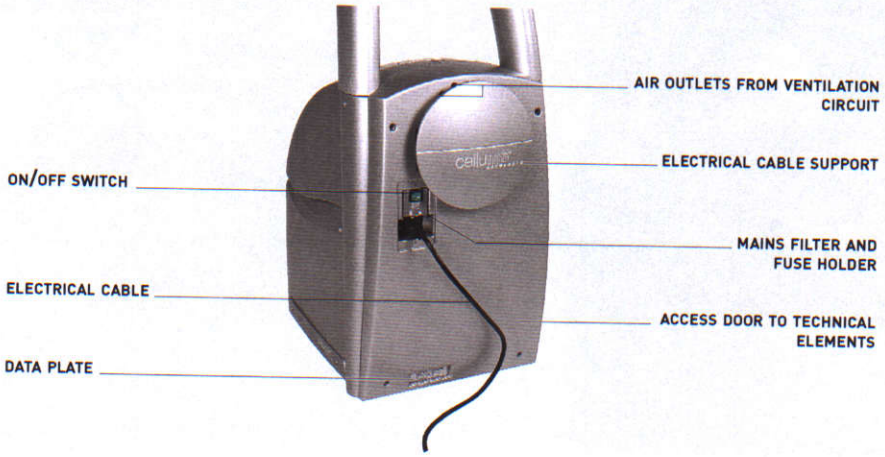
Cellu M6® Keymodule *i*



BEFORE USE MAKE SURE THAT THE SUPPLY CABLE IS COMPLETELY UNWOUND



The unit can only operate if it is connected to the mains by its supply cable and provided the on switch has been actuated and the green voltage light is on. When the unit is switched on, the pump starts to run automatically for about ten seconds for priming.

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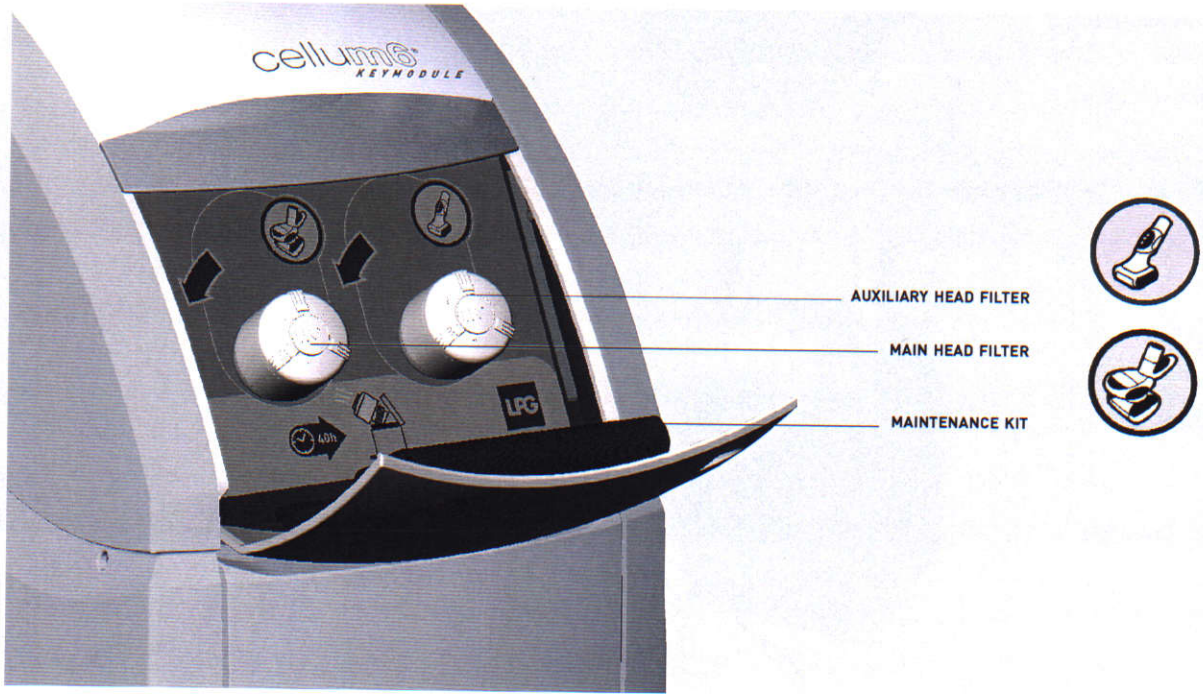
Drawer for storing the series 600 auxiliary heads

Access to the filters



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Control panel

Main head

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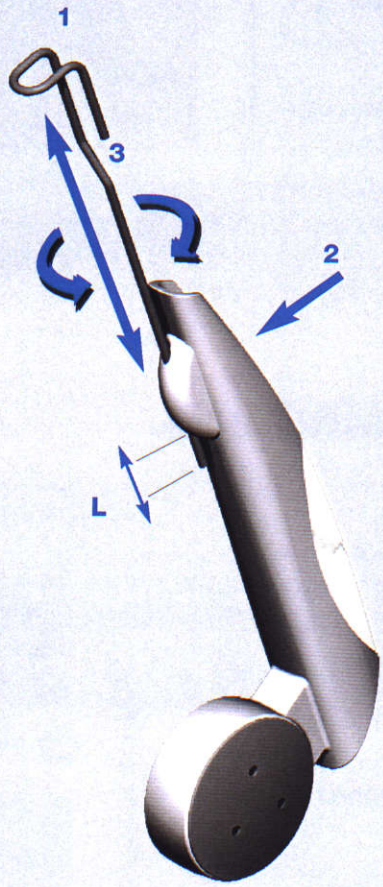
Adjusting the articulating arm rods

It is possible to personalize the position of the 2 articulating arm rods (depending on size and working position of the operator) so as to obtain even greater freedom of movement.

- Remove the hose from its housing on the articulating arm rod by pulling on the self-grip collar (**1**)
- Loosen the locking screws using the large hexagonal spanner (**2**)
- Adjust the rod to the length required position (**3**)
  (recommended length L=10 to 20 mm)
- Retighten the screw (**2**)
- Repeat the same operation for the second arm.



Fully unwind the electrical cable from its support, to ensure good ventilation of the unit.

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Precautions

- Check that the supply voltage of the unit indicated on the data plate complies with the mains voltage.
- The unit must be connected to a grounded outlet in accordance with current electrical standards.
- Never use the unit on a dusty, uneven floor, or in a moist atmosphere.
- Check that the inlet to the ventilation circuit is always unobstructed.
- Avoid operating the unit in a room where the ambient temperature exceeds 40° C.
- Fully unwind the electrical cable from its support to ensure good ventilation of the unit.
- Switch the unit off if it is not going to be used for a long period. In this case, operate the machine for a 1/2 an hour approximately every 8 weeks.
- Do not allow solid debris or liquid to be sucked into the unit, as these could cause damage.
- Never use the auxiliary adapter as a treatment head or allow it to come into direct contact with the skin.
- Do not use the main head to carry out treatment of the scalp.
- Only use the treatment heads supplied with your unit or recommended by LPG®.
- Only use LPG Systems® treatment garments.
- Never use the unit for purposes other than those recommended by LPG Systems®.
- LPG Systems® will not be liable for any inappropriate use of the equipment.
- With respect to treated tissue, some parameters may cause pain or tissue lesions. The operator must be particularly attentive to the sensations felt by the person undergoing treatment when :
  - the intensity is greater than 4 in continuous or sequential mode (for frequencies less than 4 Hz).
  - the system has changed to reverse mode (rollers rotating in opposite direction).
- The operator must ensure that the parameters (intensity, sequentiality, differential, ...) are always adapted to the cutaneous tissue being treated.

Where the unit has not been used for a long time, it is possible that marks may form on the ground where the wheels are. This phenomenon is the result of a chemical reaction between the components of some floorings and those of the wheels of the Cellu M6® Keymodule i.

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Contraindications

The CelluM6® Keymodule i should not be used on certain areas or under certain conditions.

- This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.
- Do not treat wounds, infected areas, skin tumors, open sores, scars form recent surgery, the eyes, intra-cavity areas, mucous membranes, the genitals or directly over nipples.
- Do not treat patients with infectious progressive illnesses.
- Do not treat patients with active cancer or a growing tumor. (Consult with the doctor if the patient has had a case history of tumors or is in remission.)
- This device is contraindicated for skin cancer, tumors and other cancerous lesions in the area to be treated.
- Do not treat patients suffering from inexplicable and persistent pain without seeking medical advice or without training in the LPG technique in this particular area.
- Do not treat patients following invasive medical treatment without seeking the medical advice of the doctor or surgeon who performed this operation, or without training in the LPG technique in this particular area.
- Not recommended for anyone under medical care for circulatory conditions without first consulting a physician.
- Not recommended for pregnant women.
- Stop treatment immediately if patient experiences any pain and consult the physician. Avoid possible bruising. Use caution when determining a patient's sensitivity level.

Needs to be provided

- Federal law restricts this device to sale or on the order of a clinician licensed by the law of the state where he/she practices to use/order the use of the device.

This unit contains programs to help the operator obtain the best anticipated results for each case undergoing treatment. Under no circumstances may these programs be construed as a guarantee of successful treatment, which varies, depending on the morphology, physiology and eating behavior of each patient.

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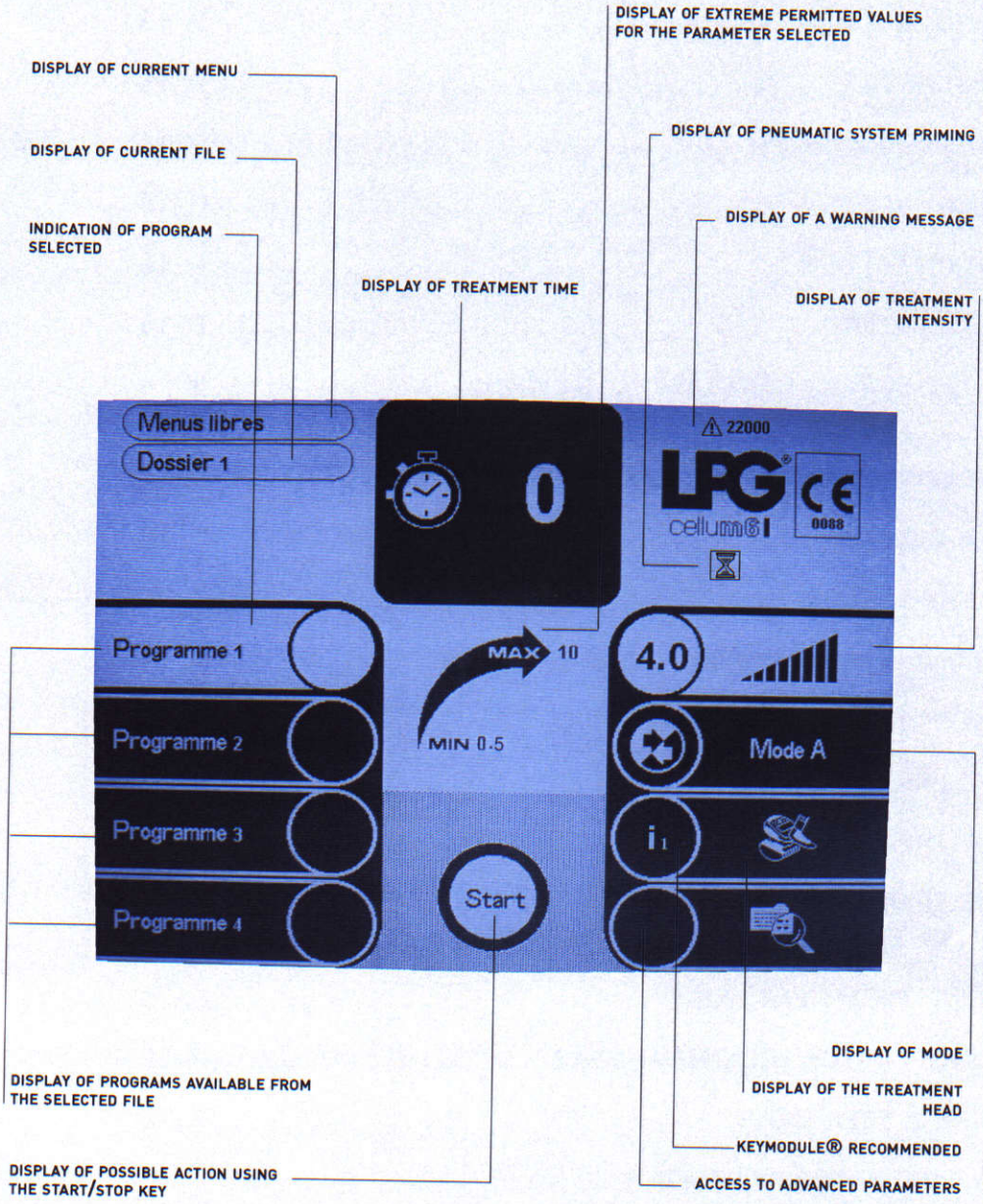
Monitor screen



The parameter selected is a reverse video.

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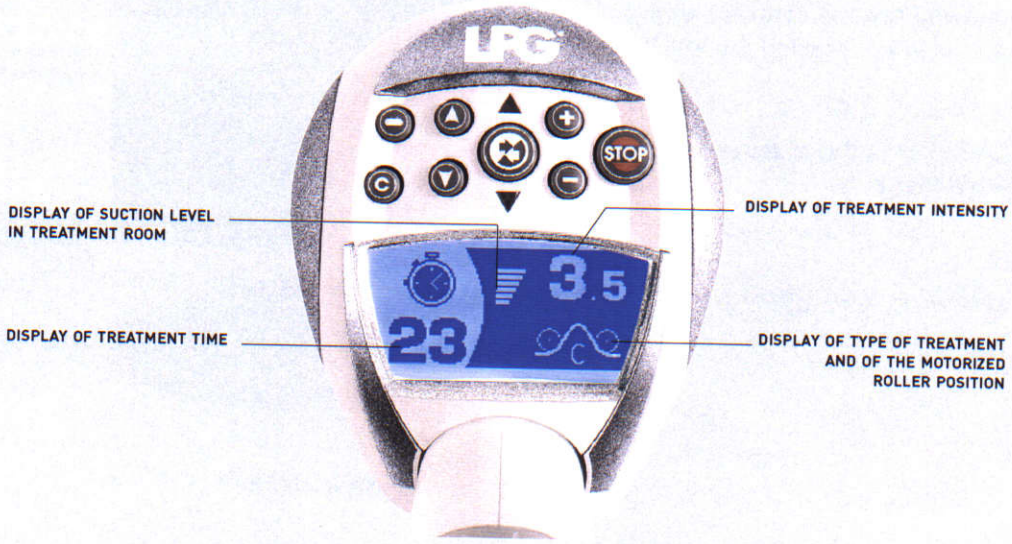
Main head screen



Power (on/off controls)

Treatment is started by pressing the START/STOP key once the icon is displayed.
Treatment is stopped by pressing the same key once the icon is displayed.
When starting up the pump, pressing the VALID key for a long time initiates the treatment time to the default value, according to the field of application.
On starting and stopping the pump, a priming phase automatically sets in for a few seconds.
This is displayed by a flashing icon or by simultaneous audible beeps. The user can proceed with no action during this period.

The unit can only be started when it is switched on. If the equipment is not used, it will automatically go to standby mode after 3 minutes. Press any key on the control panel to reactivate the unit.

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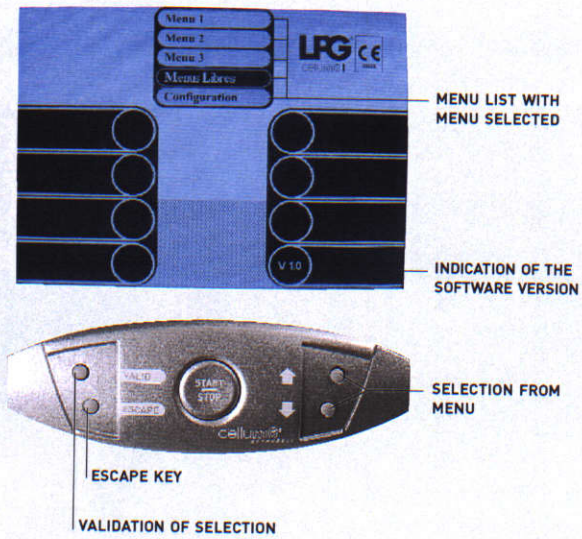
Menu screen

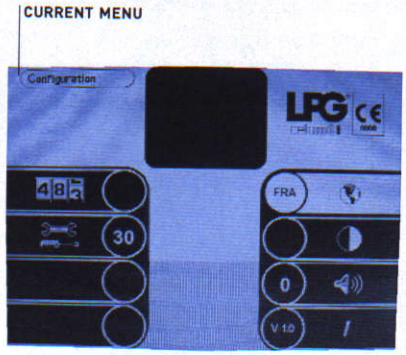
Use the navigation keys to select the required menu and reverse contrast, then confirm your choice by pressing the VALID key.

Use the ESCAPE key in the event of error or to exit from a menu.



Configuration screen

The CONFIGURATION menu will allow you to select the language of use, adjust the contrast, select and adjust the keyboard beep and to consult the TIME METER and other maintenance functions.



A menu is selected when it is in reverse video.

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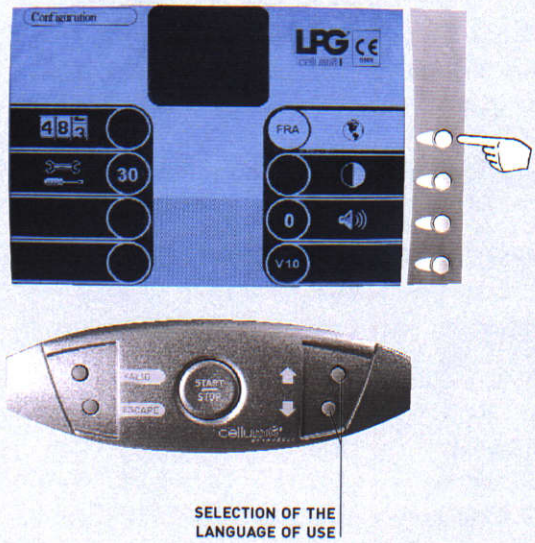
Language selection

To choose the language of use for your equipment, select the icon by pressing the appropriate key and then use the nagivation keys to scroll down the various programmed languages.

Once the language of use has been decided upon, press the ESCAPE key to return to the MENU screen or, if you want to proceed with another setting, press the key corresponding to the parameter you wish to change.

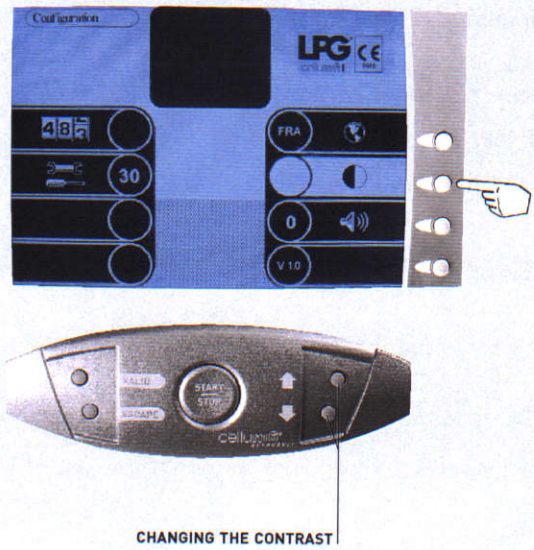


Adjusting the screen contrast

The screen brightness is pre-set at the factory so as to provide optimum contrast for an ambient temperature of 22° C. However, this parameter may be changed.

To adjust the screen contrast from the control panel, select the icon by pressing the appropriate key and then use the navigation keys to change the contrast.

Once the contrast has been adjusted, press the ESCAPE key to return to the MENU screen or, if you want to proceed with another adjustment, press the key corresponding to the parameter you want to change.



Sudden changes in temperature will affect the screen contrast. In such cases, wait for the brightness to stabilize before proceeding with any adjustment.

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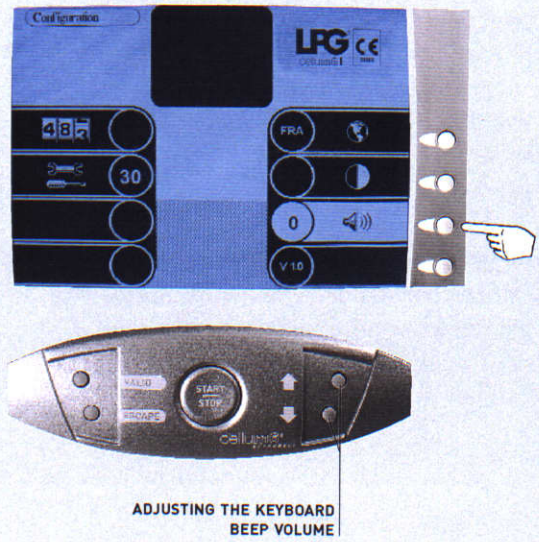
Selection/adjustment of the keyboard beep and control panel

Each time one of the keys of the control panel of your Cellu M6® Keymodule *i* is pressed, a beep will sound. The volume and pitch can be adjusted.

Adjusting the keyboard beep volume:

This adjustment is made via the CONFIGURATION screen. Select the icon by pressing the appropriate key and by using the navigation keys to adjust the keyboard beep volume:

- 0: silent
- 1: weak
- 2: average
- 3: loud

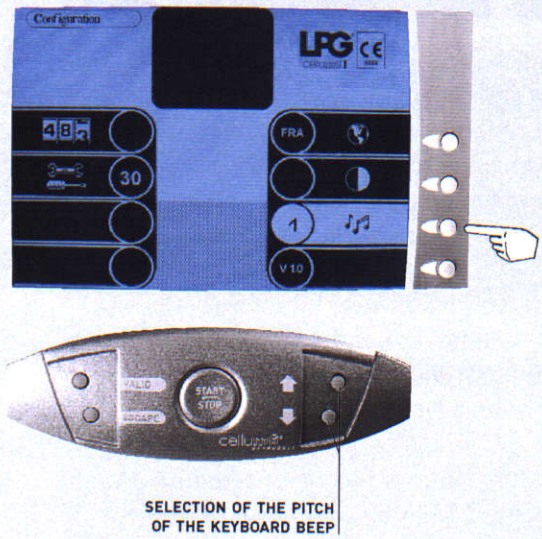


ADJUSTING THE KEYBOARD BEEP VOLUME

Selecting the keyboard beep pitch:

This selection is made via the CONFIGURATION screen. Select the icon by pressing the appropriate key and by using the navigation keys to change the pitch of the keyboard beep:

- 1: a high pitch
- 2: medium pitch
- 3: low pitch



SELECTION OF THE PITCH OF THE KEYBOARD BEEP

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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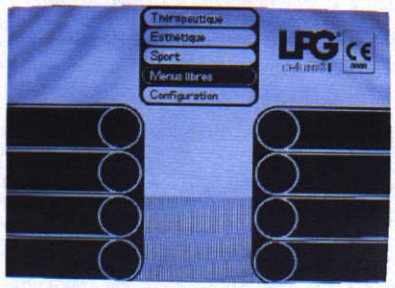
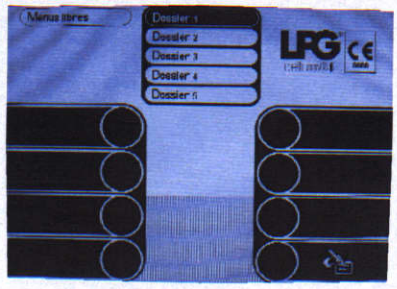
Selecting a program

When you are at the root menu, you can select from the areas of aesthetics, therapeutics or sport.

At any time during program selection, you can return to the previous menu by pressing ESCAPE.

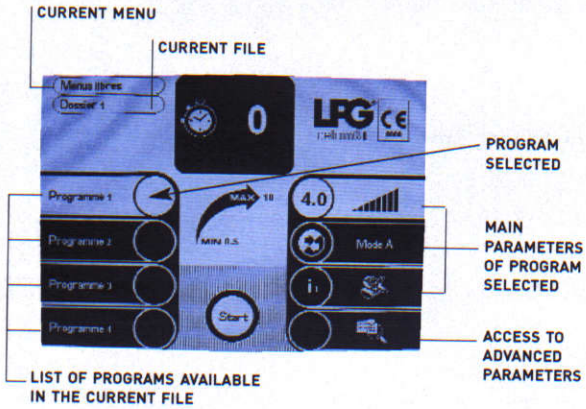
Select the appropriate area and then press VALID. You will now access the FILES.





Now select the appropriate FILE by pressing VALID. You now get to PROGRAM MENU.

You can now select the program you require and change the treatment intensity values, the mode and treatment head.



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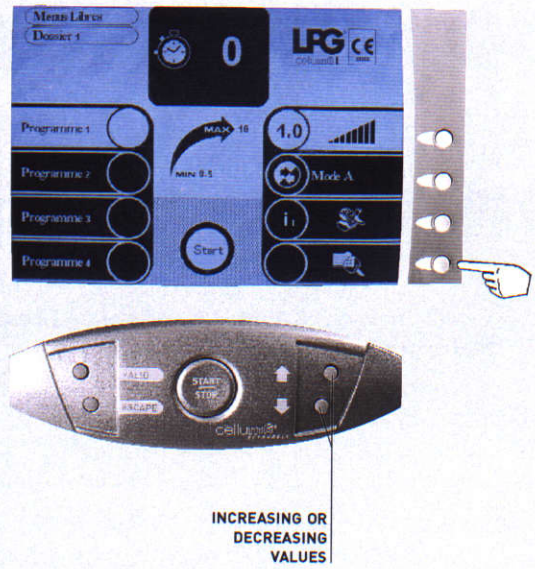
Records processed under FOIA Request 2013-1897; Released 9/15/14

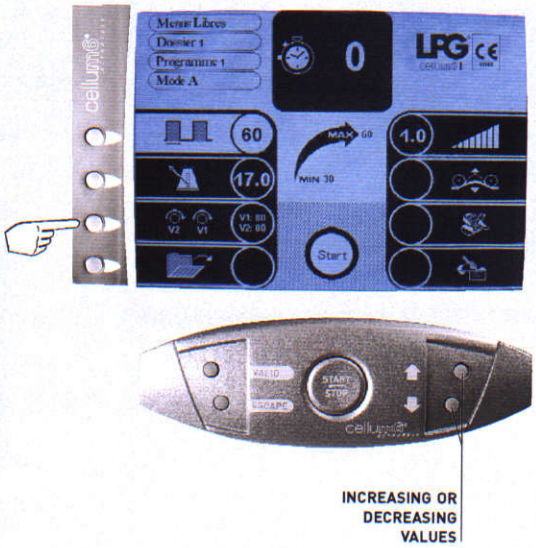
Selecting a program

Once you are in the program, you can gain access to the advanced parameters to see the pre-programmed parameter values by clicking on the icon. Increase or decrease the values using the arrows. The screen will tell you if you are in continuous or sequential mode via the icon.



You can also have access to the roller parameters (differential with respect to direction and speed) in order to amend the other parameters in the same way.

Press Start/Stop to start the treatment.



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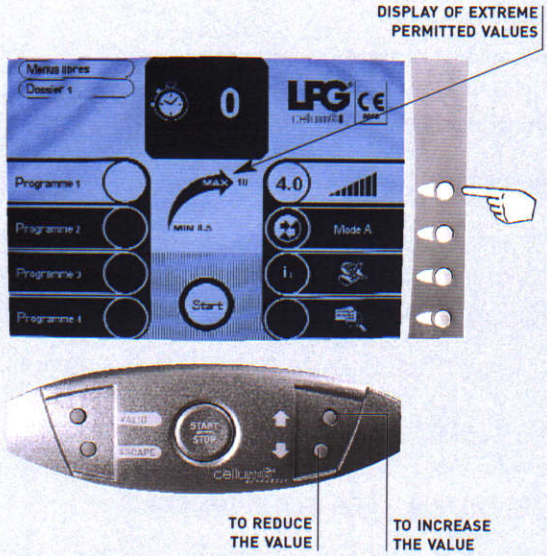
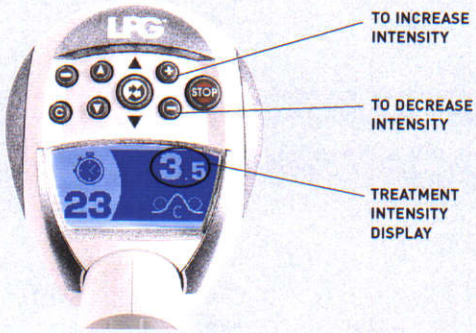
Adjusting the treatment intensity

1) From the control panel,
select the treatment INTENSITY adjustment parameter by pressing the appropriate key; the parameter is displayed as a reverse video.

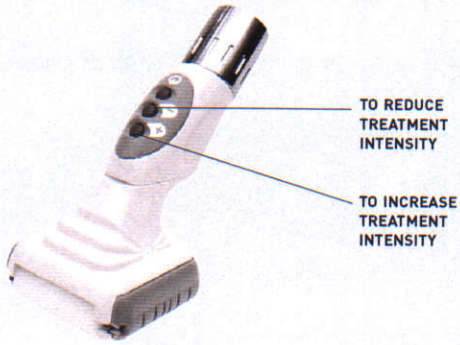
Now use the navigation keys to increase or decrease the treatment INTENSITY within the limits of the extreme permitted values.



2) From the main head,
set or adjust the required treatment INTENSITY by pressing the keys ⊕ or ⊖.



3) From the auxiliary head,
set or adjust the required treatment INTENSITY by pressing the keys ⊕ or ⊖ from the auxiliary head control.



The treatment intensity selected is continuously checked by an electronic vacuum sensor. However, too high a treatment intensity or a badly adjusted treatment intensity may lead to pain and traumatize the cutaneous tissue, thereby encouraging the onset of bruising.

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Selecting continuous or sequential treatment

ONLY FROM A FREE MENU

You can select the type of treatment (CONTINUOUS or SEQUENTIAL) you require from all the programs in the FREE MENU.

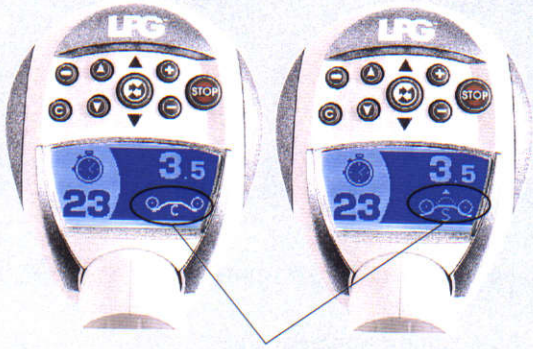
CONTINUOUS TYPE TREATMENT

To do this, go to the ADVANCED PARAMETERS screen of the FREE PROGRAM you selected and successively press the key, corresponding to the type of treatment.

SEQUENTIAL TYPE TREATMENT

At all times, the type of treatment you programmed will be displayed on the screen of the main head.

When you use a PARAMETERIZED PROGRAM, the type of treatment is defined by the program and cannot be changed; however, the screen of the main head will inform you of the type of treatment.



DISPLAY OF TYPE OF TREATMENT

If you work with continuous suction, the sequence-forming parameters (cycle and frequency ratio) will not be accessible.

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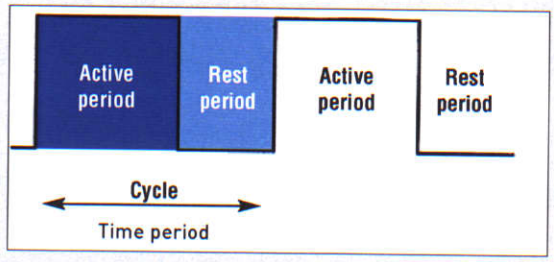
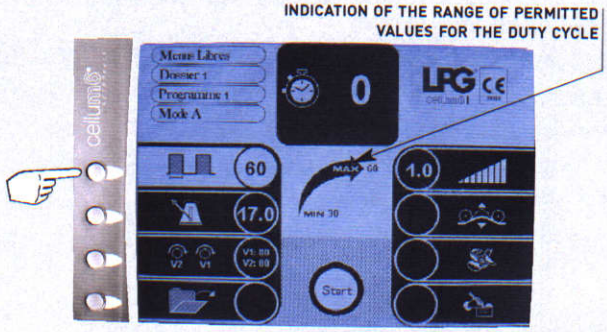
Setting the duty cycle

FOR SEQUENTIAL TYPE TREATMENT ONLY

The sequential mode can be compared with the throbbing of a tissular seizure; this throbbing is characterized by two parameters – frequency and the duty cycle. The frequency corresponds to the number of beats over a given period of time (cycle). The duty cycle corresponds to a time of activity over a given period of time (cycle). The sequentiality can therefore be shown as follows:
When setting the frequency, the cycle time is increased or decreased. When setting the duty cycle, the phase of activity over one cycle is increased or decreased.



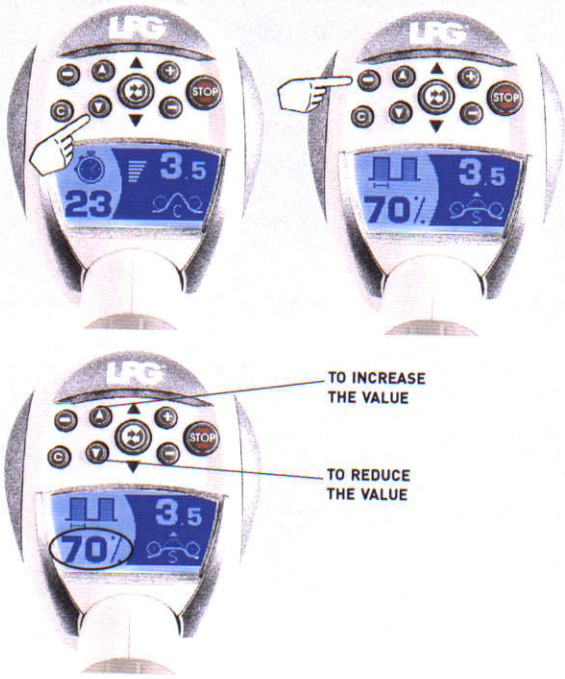


1) From the control panel,

to proceed with setting the DUTY CYCLE, first go into ADVANCED PARAMETERS of the program selected. To do this, press the KEY corresponding to ADVANCED PARAMETERS. Now select the DUTY CYCLE parameter by pressing the corresponding key.
Then use the nagivation keys to adjust the DUTY CYCLE within the range of permitted values.

2) From the main head,

press a ▼ key to display the value of the DUTY CYCLE parameter. Validate by pressing the ⊖ key, and the DUTY CYCLE value will start to flash. Now use the ▲ or ▼ keys to set this parameter to your convenience. Validate with the ⊖ key.
Use the C key to return to the monitor screen.



Certain value combinations between the duty cycle and the frequency are invalid. This is to prevent improper treatment configurations.

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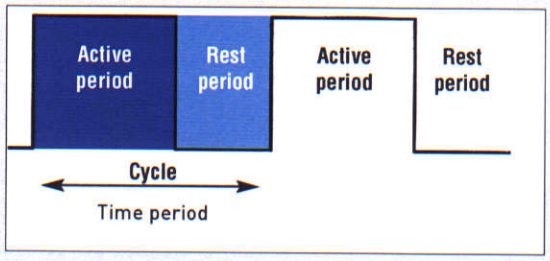
Setting the frequency

FOR SEQUENTIAL TYPE TREATMENT ONLY

The sequential mode can be compared with the throbbing of a tissular seizure; this throbbing is characterized by two parameters – frequency and the duty cycle. The frequency corresponds to the number of beats over a given period of time (cycle). The duty cycle corresponds to a time of activity over a given period of time (cycle).
The sequentiality can therefore be shown as follows:

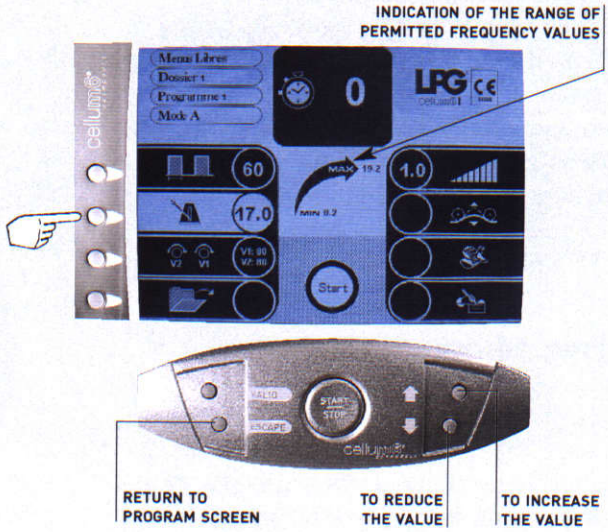
- when setting the frequency, the cycle time is increased or decreased
- when setting the duty cycle, the phase of activity over one cycle is increased or decreased.



1) From the control panel,
to proceed with setting the FREQUENCY, first go into ADVANCED PARAMETERS of the program selected. To do this, press the KEY corresponding to ADVANCED PARAMETERS.

Now select the FREQUENCY parameter by pressing on the corresponding key.

Then use the nagivation keys to adjust the FREQUENCY within the range of permitted values.



Certain value combinations between the duty cycle and the frequency are impossible. This is to prevent absurd treatment configurations.

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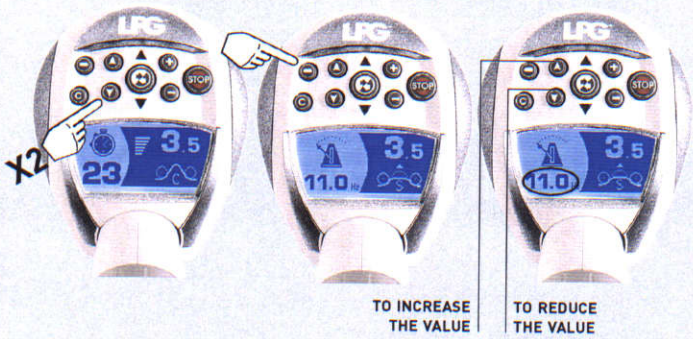
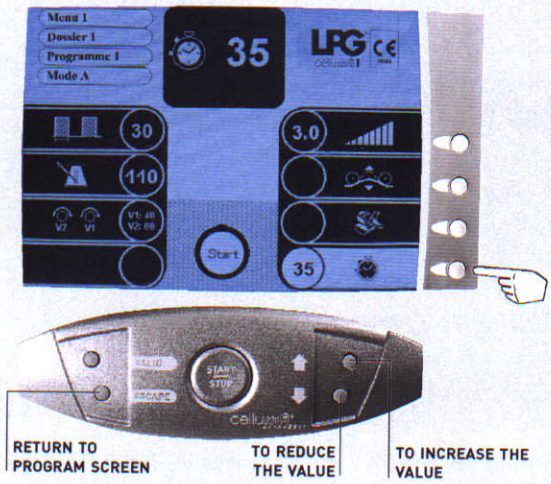
Setting the frequency

2) From the main head,
press a key twice in succession to display the value of the FREQUENCY parameter.
Validate by pressing the key , and the FREQUENCY value will start to flash. Now use the and keys to set this parameter to your convenience.
Validate with the key.
Use the key to return to the monitor screen.



Setting the treatment time

Setting the treatment time is only possible for those programs already offering a treatment time.
In such cases, time starts to decrease, minute by minute and at all times shows the remaining treatment time; once the time reaches 0, the machine will automatically stop.
Where no time is suggested, as in the FREE MENU, the time starts to increase minute by minute and at all times shows the time lapsed since the start of the session; you decide to stop the machine once the time you recommended has been reached.
It is consequently impossible and useless to proceed with any modification to this parameter.
In order to set the treatment TIME, first go the ADVANCED PARAMETERS of the program selected. To do this, press the key corresponding to the ADVANCED PARAMETERS.



Select the treatment TIME by pressing the appropriate key and use the navigation keys to increase or decrease the treatment TIME from 0 to 99 minutes.
A short press corresponds to one minute.
A long press corresponds to ten minutes.

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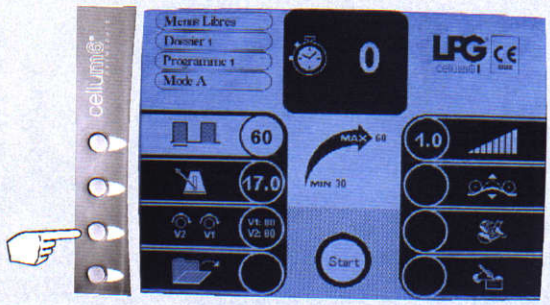
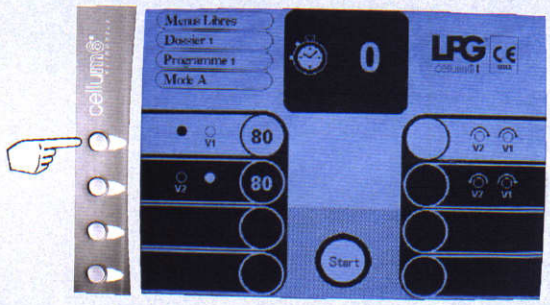
Setting the speed and direction of rotation of the rollers of the main head

The ROLLER SPEED AND DIRECTION OF ROTATION of the main head can be adjusted independently for each of the two rollers.
To proceed with adjusting these parameters, go to ADVANCED PARAMETERS. To do this, press the key corresponding to ADVANCED PARAMETERS.



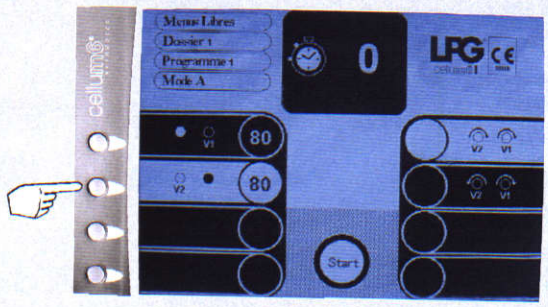
Then select the ROLLER SPEED AND DIRECTION OF ROTATION parameter by pressing the corresponding key.



Select the parameter for adjusting the front roller V1 (in relation to the direction of head movement), by pressing the corresponding key.
Set the speed of rotation of roller V1 from 0 to 100% by using the navigation keys.
The settings go in 10s.

TO RETURN TO THE ADVANCED PARAMETERS SCREEN | TO REDUCE THE VALUE | TO INCREASE THE VALUE

Select the parameter for adjusting the rear roller V2 (in relation to the direction of head movement), by pressing the corresponding key.
Set the speed of rotation of roller V2 from 0 to 100% by using the navigation keys.
The settings go in 10s.



TO RETURN TO THE ADVANCED PARAMETERS SCREEN | TO REDUCE THE VALUE | TO INCREASE THE VALUE

Warning: Setting the roller speed is only possible if the main head is selected.

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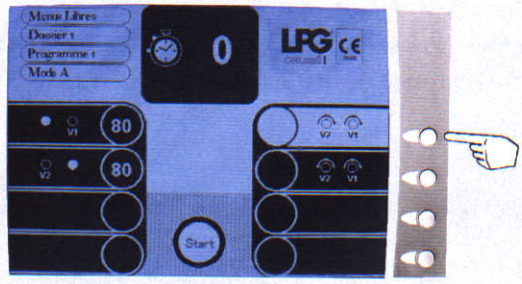
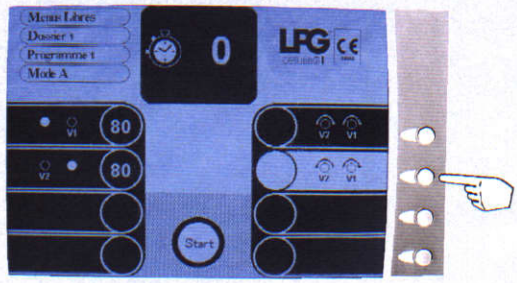
Setting the speed and direction of rotation of the rollers of the main head

If you want the two rollers of the main head to turn in the same direction, select parameter V1 and V2 to run in the same direction by pressing the corresponding key.



If you want the two rollers of the main head to turn in the opposite direction, select parameter V1 and V2 to run in the opposite direction by pressing the corresponding key.



Selecting the treatment mode

For some programs, the Cellu M6® Keymodule ***i*** offers you the option to select from two treatment modes, which entails different settings of certain parameters, for the same program.

1) From the control panel,
Successively press the selection key corresponding to the mode, so that you can change from one mode to the other.

Ensure that the parameters are always adapted to the cutaneous tissue undergoing treatment.

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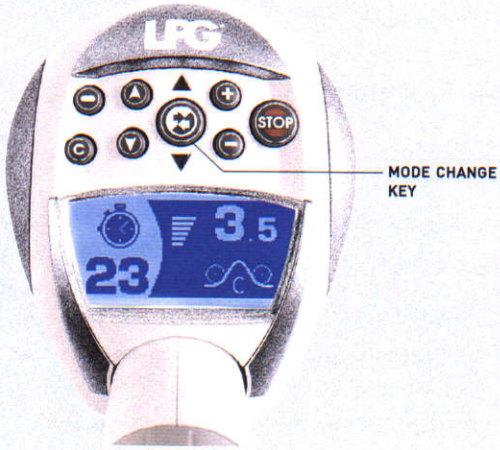
Selecting the treatment mode

2) From the main head, use the central key to go from one mode to the other.



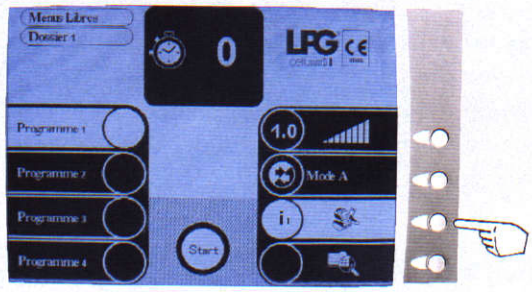
Selecting the type of treatment head

The choice governing the type of head is based on the treatment to be carried out and the type of area being treated.

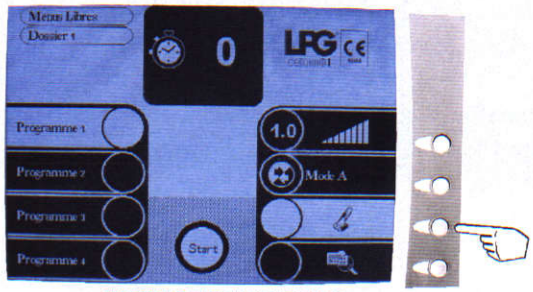
Select the type of head required by successively pressing the appropriate selection key.

Direct selection by pressing a key of the selected head when suction is not efficient.

Comment: when the auxiliary head type is selected, it is not possible to access "*setting the roller speed and direction of rotation*" for the main head.



SELECTING THE MAIN HEAD



SELECTING THE AUXILIARY HEAD

Never proceed with this setting when the treatment head is in contact with the cutaneous tissue.

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Programming a free menu

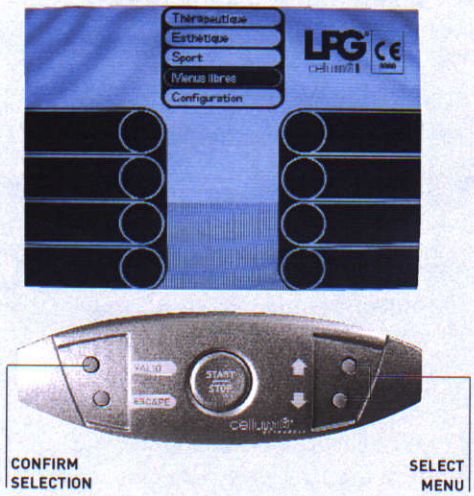
Select a MENU by using the navigation keys and then confirm by pressing the VALID key.

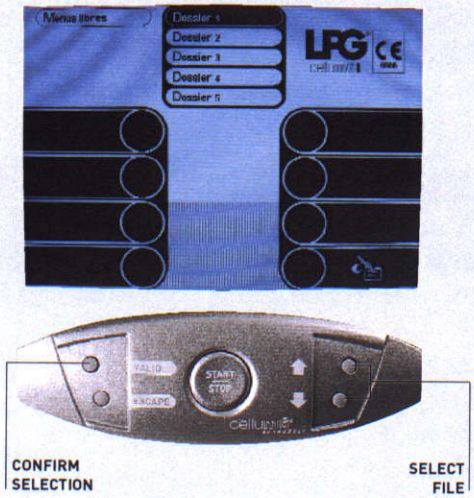
Then, in the same way, select a FILE and confirm by pressing the VALID key.

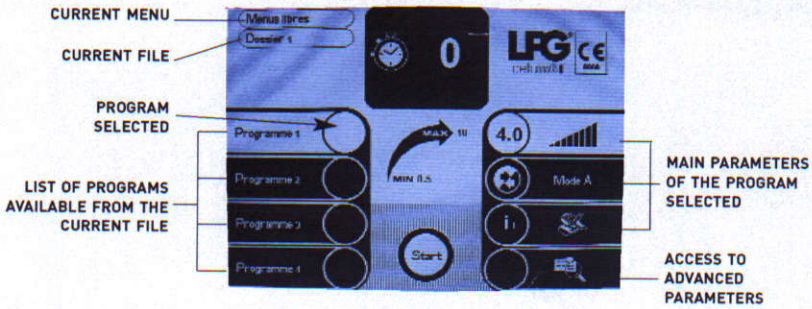
The PROGRAM, at the top left, is selected by default and its main parameters can be seen on the right side of the screen.

Then, referring to the relevant sections, set the different parameters of the selected PROGRAM :

- Treatment intensity
- Duty cycle (for sequential type treatment)
- Frequency (for sequential type treatment)
- Motorized roller speed and direction of rotation (for treatment with the main head)







Each program contains adjustments specific to a treatment, originating from our research and assessment center. However, the parameters that characterize these programs may be modified at any time during treatment by the operator. Once the unit is shut down or the program window comes on, all these settings will revert to the factory configuration.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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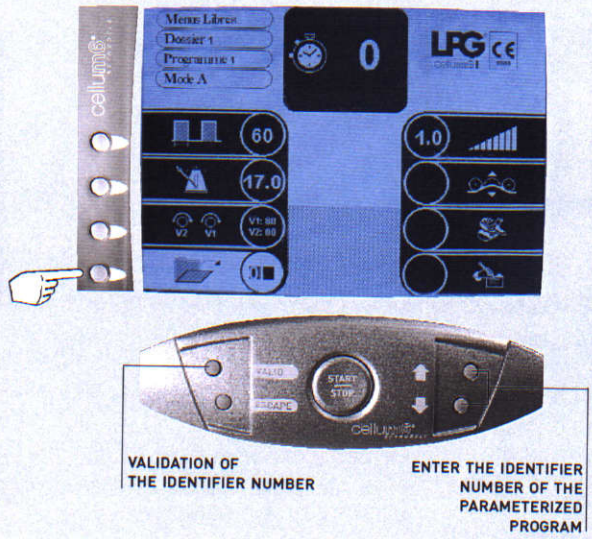
Creating a free program based on a parameterized program

This function allows you to create a FREE PROGRAM on the basis of a PARAMETERIZED PROGRAM.
From the ADVANCED PARAMETERS screen of a FREE PROGRAM, select the icon by pressing the relevant key.



Now go to the PROGRAM LIST in order to identify the program number to recall the parameters.

Use the navigation keys to enter the number you identified and then validate. The parameters of your FREE PROGRAM are now copied to the PARAMETERIZED PROGRAM you selected. Now finalize your FREE PROGRAM by adapting the various treatment parameters you want to carry out.

Make sure that the parameters of your program are adapted to the cutaneous tissue undergoing treatment.

Programming and the use of a free menu is at the operator's option and is his responsibility alone.

Refer to the precautions and contra-indications on pages 74 and 75.

! *The adjustments made to the free program parameters are automatically stored and can be reused at a later stage.*

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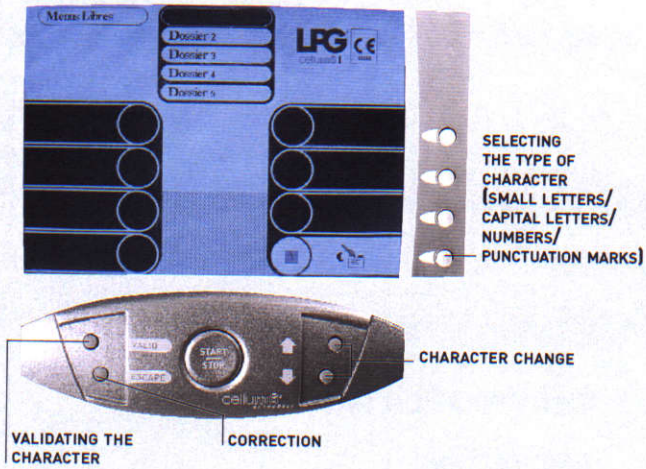
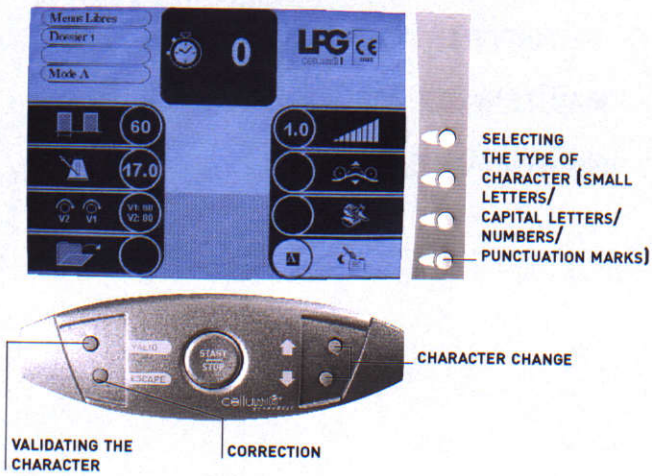
Personalization of file names from the free menu

Having selected a FILE from the FREE MENU, select the icon by pressing the corresponding key.
Press the selection key to choose the type of character (capital letters, small letters, number or punctuation marks) which will make up the new name of your FILE.
Use the navigation keys to scroll the characters available for each category and validate your choice by pressing the VALID key.
Warning: The name you give to your FILE must not exceed 16 characters.
After having entered the last character, hold the VALID in order to put the new name into service.



Personalization of program names from the free menu

After selecting a PROGRAM from the FREE MENU, select the icon by pressing the relevant key.
Press the select key to choose the type of character (capital letters, small letters, numbers or punctuation marks) which will make up the new name of your PROGRAM.
Use the navigation keys to scroll the characters available for each category and validate your choice by pressing the VALID key.
Warning: The name you give to your PROGRAM must not exceed 16 characters.
After having entered the last character, hold the VALID in order to put the new name into service.



This function is only possible in free menu

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

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MAINTENANCE KIT . . . . . .P. 40

MAINTENANCE FILE . . . . . .P. 40

ALL THE MAINTENANCE OPERATIONS DESCRIBED IN THIS SECTION MUST BE CARRIED OUT WITH THE UNIT SWITCHED OFF AND THE POWER CABLE DISCONNECTED.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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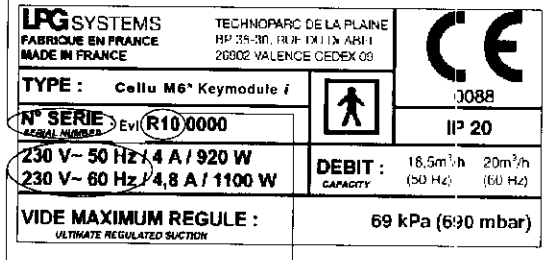
Identification rating plate

Your unit is identified by a serial number shown on the rating plate.
The rating plate also shows the permitted supply voltage for the unit.

When you contact LPG Systems® Customer Service because of a technical problem, please indicate the serial number of your Cellu M6® Keymodule *i*.
The letter indicates the year of manufacture:
R = 2001, S = 2002, T = 2003, U = 2004...
while the two figures indicate the month of production :
01 = January, 02 = February, 03 = March...

SERIAL NUMBER



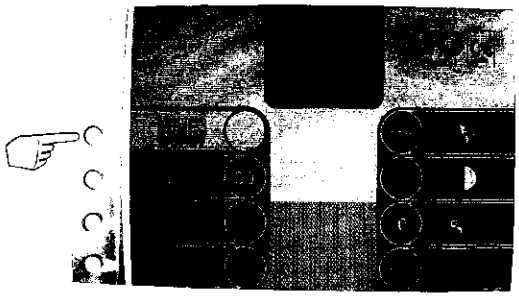
SUPPLY VOLTAGE AND FREQUENCY

YEAR AND MONTH OF MANUFACTURE

Time meters

Your unit comprises several TIME METERS that total the operating hours of the various units for periodic maintenance purposes.
These meters can be seen at control panel level, from the CONFIGURATION screen and MAIN HEAD screen.
Access the TIME METERS by pressing the key relating to the icon .

FROM THE CONTROL PANEL



The identification rating plate is located on the bottom, behind the unit.

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Time meters

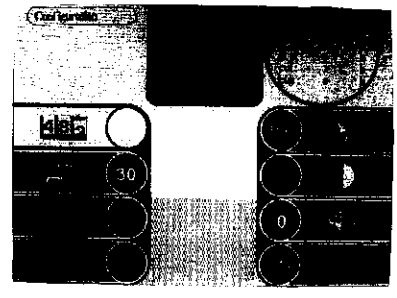
CHM: Machine Time Meter that totals the number of hours your machine has been operating.

CHTP: Main Head filter Time Meter totals the number of hours the main head has been operating.

CHTA: Auxiliary Head filter Time Meter totals the number of hours the auxiliary head has been operating.

CUT: Main Head Unit Meter totals the number of hours the main head has been operating.

CUS: Keymodule® Unit Meter totals the number of hours the Keymodule® connected to the main head has been operating.



To display the TIME METERS of the main head, go to the MAINTENANCE MENU of the main head by pressing the key twice in succession .

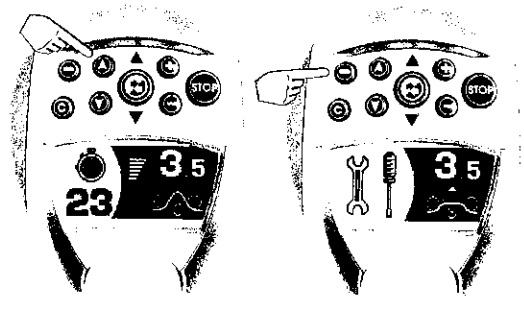
From the MAINTENANCE MENU, one press on the key will display the TIME METERS of the main head.

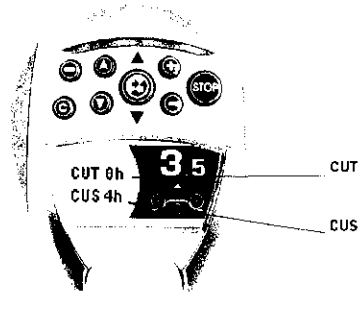
CUT: Main Head Unit Meter totals the number of hours the body of the main head has been operating.

CUS: Keymodule® Unit Meter totals the number of hours the Keymodule® of the main head has been operating.

Press the key twice in succession to return to the monitor screen.

FROM THE MAIN HEAD





For further information, please see pages 98 and 99 (Replacing filter cartridges).

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Cleaning the unit

We recommend that you clean your unit as often as possible, not only for reasons of hygiene and aesthetics but also because cleaning the unit will help keep it in a good state of repair and extend its life.

Using a vacuum cleaner with fine nozzle, clean the following sections:

- The inside of the access drawer to the auxiliary heads, (having already removed all the auxiliary heads)
- The inside of the access door to the filters

Using a moist sponge, clean the following sections:

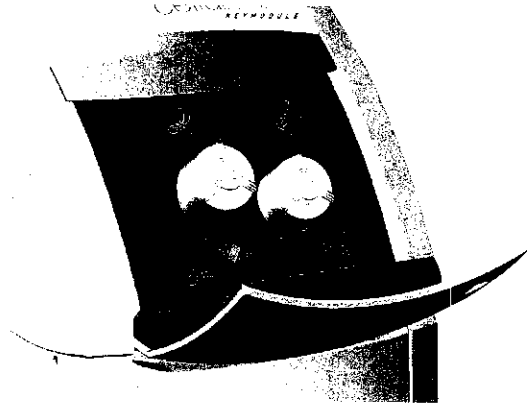
- All the external hoods
- Hoses
- The power cable

Using a cloth soaked with a little domestic cleaning product not containing alcohol, clean the following sections:

- Monitor screen and control panel
- The inside of the access drawer to the auxiliary heads
- The inside of the access door to the filters

Replacing filter cartridges

Your unit accommodates 2 filters. One is for filtering the circuit of the main head while the other filters the circuit of the auxiliary heads. The filter cartridge guarantees the efficiency of your unit and extends its useful life. Remember to change the cartridge every forty hours.



Do not use aggressive products, such as acetone, trichloroethylene or alcohol at 90°, or abrasive sponges.

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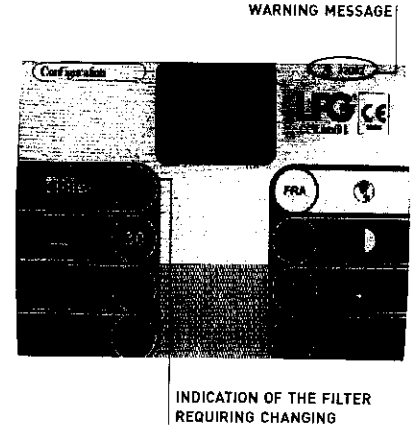
Replacing filter cartridges

Replacement of filter cartridges:
If a filter change request occurs, a warning message is displayed at the top right of the CONTROL screen of the control panel and an icon showing the filter that requires changing appears in the CONFIGURATION screen. This happens each time the pump shuts down until the filter change has been acknowledged.



1 = Main head filter (warning message number: 22000)

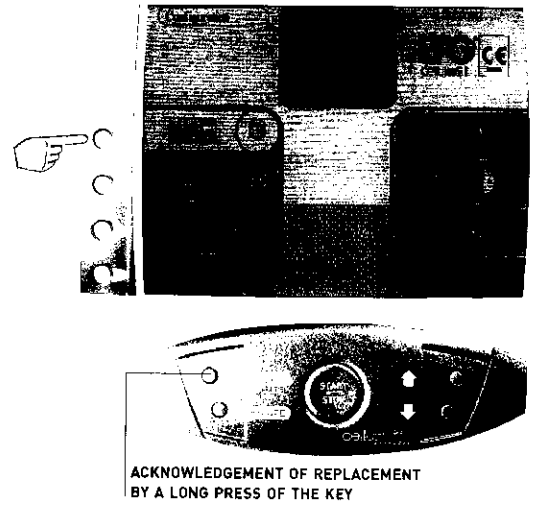
2 = Auxiliary head filter (warning message number: 22001)

Open the filter access hood. Unscrew the filter cartridge and replace with a new one.

Once the cartridge is in place, validate the operation by selecting the icon representing the filter you have just changed, by pressing the appropriate key and hold the VALID.

To confirm replacement, the icon depicting the filter disappears.

Remember to purchase new cartridge filters from LPG Systems® Customer Service, so that you always have a spare on hand.



Never use your unit without LPG® filter cartridges.

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Replacing fuses

Your unit is protected against short-circuits by 2 ceramic 6.3 mm x 32 mm time-delay fuses.

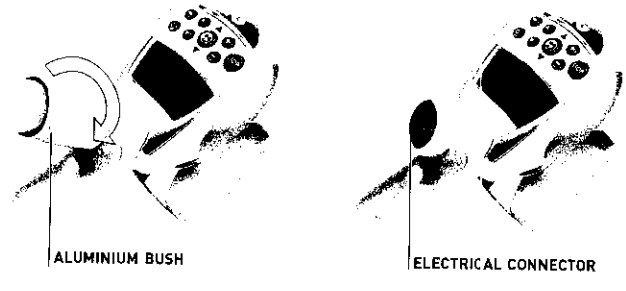
Fuse replacement:

- Disconnect the supply cable from the mains
- Loosen one of the 2 fuse holders
- Remove the fuse
- Repeat the same operation for the second fuse holder
- Replace with the fuses supplied in the maintenance kit.

Remember to purchase new fuses from LPG Systems® Customer Service, so that you always have a spare on hand.

Instructions for disconnecting the treatment heads

Because of its rapid-fit twist connection, the main treatment head can easily be disconnected from its hose by loosening the aluminium connection bush.



To connect the head, take hold of the hose and proceed with its electrical connection and then screw tight by tightening the aluminium bush.

If fuses with the incorrect rating are used, this could result in damage to the entire electrical system. See page 107 concerning the identification of fuse ratings to be used

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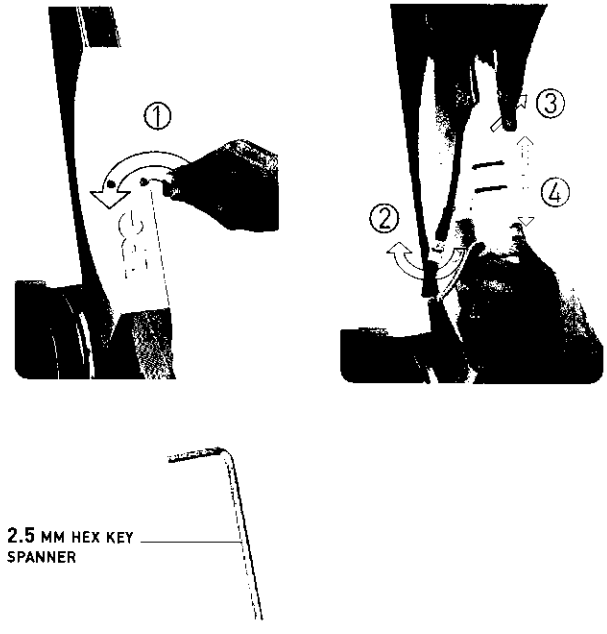
Instructions for disconnecting the treatment heads

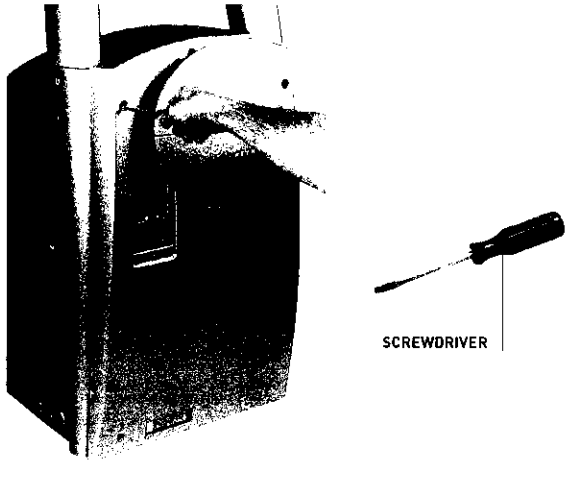
Disconnecting the treatment heads and hoses is quick and easy.

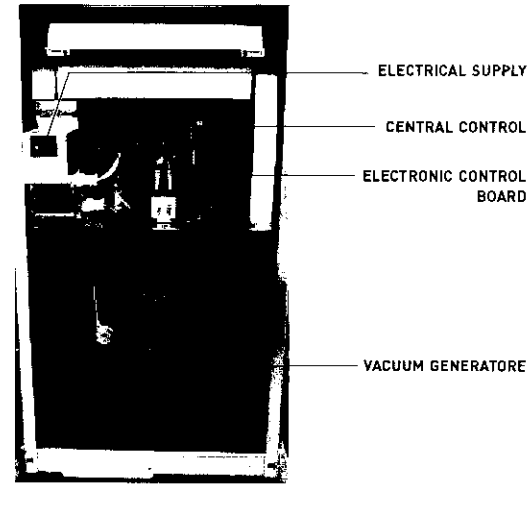
1 : Loosen the two screws and remove the rear screen located on the mobile arm, using the small, hex key.
2 : Loosen and disconnect the electric connection.
3 : Remove the plastic connection from its housing.
4 : Disconnect the plastic connection.



Access to the technical items

Disconnect the supply cable. Open the rear door to gain access to the technical elements using a screwdriver. Only loosen the 4 fixing screws a quarter turn.





Connection system identical for the two circuits.

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Replacing the filters of the vacuum generator

The vacuum generator has two filter cartridges:

- One paper cartridge at the inlet, on the left side
- One metal cartridge on the discharge side, on the right side

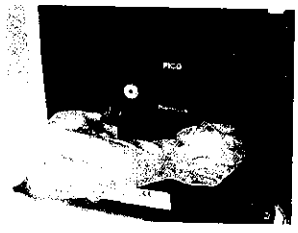
These two cartridges must be replaced after every 1000 hours of operation.
If a filter change request occurs, a warning message is displayed at the top right of the CONTROL screen of the control panel and an icon showing the pump filters that require changing appears in the CONFIGURATION screen. This happens each time the pump shuts down until the filter change has been acknowledged.

= Vacuum pump filter (warning message number: 22002)

No special tool is required for this operation.

1 : Open the rear door to gain access to the technical elements
2 : Loosen the two knurled nuts of the vacuum generator hood
3 : Unscrew the cover
4 : Unscrew the central knurled nut
5 : Remove the cartridge from the spring
6 : Replace with a new cartridge
7 : Repeat the same operation for the second cartridge
8 : Once the new filters are in place, validate the operation by selecting the icon representing the filters you have just changed, by pressing the appropriate key and hold the VALID.

To confirm replacement, the icon depicting the filters disappears.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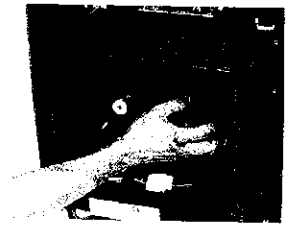
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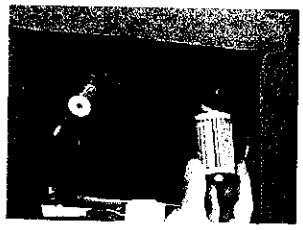
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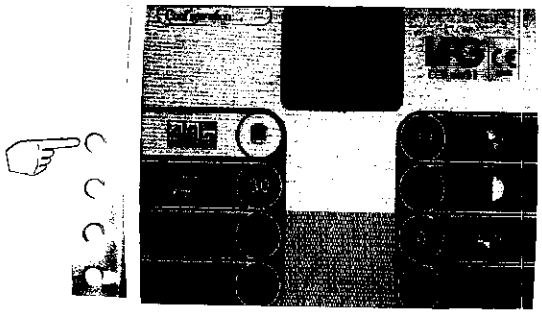
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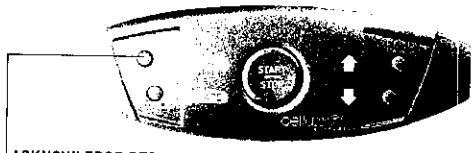

ACKNOWLEDGE REPLACEMENT BY PRESSING THE KEY FOR A LONG TIME

It is important to replace the filter cartridges one after the other, so that the correct cartridge is replaced in its housing. The Cellu M6® must be switched off before proceeding with a filter cartridge change. The unit must also be cold, so as to avoid any risk of burning.

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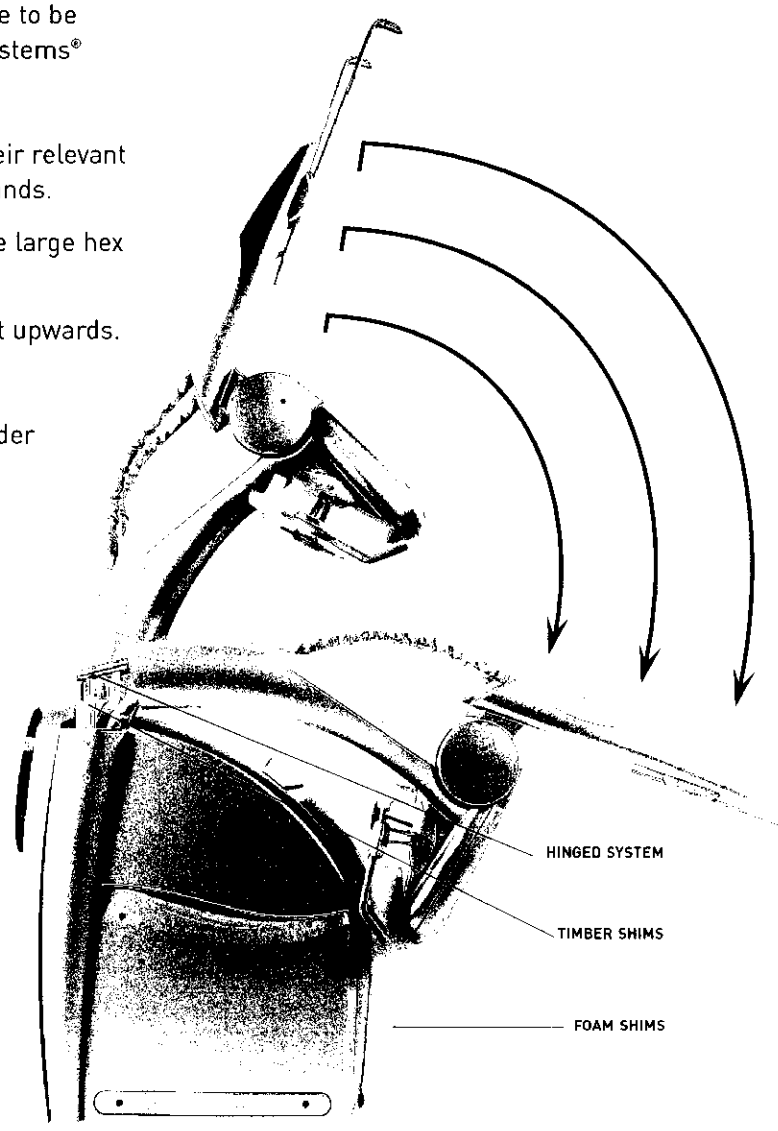
Transport/Storage

In the event of having to relocate the unit by professionals, it is essential to pack the unit in its original packaging.
Where the unit is only being moved a short distance or when stored for a short while in the folded position, it is essential to insert the two shims provided for this purpose

If you require any information on the packaging, shims and procedure to be adopted, please contact LPG Systems® Customer Service.

- Fix the treatment heads to their relevant support using large rubber bands.
- Loosen the 4 screws using the large hex key.
- Pull the top section of the unit upwards.
- Bend while holding the unit.
- Insert the various shims in order to protect the hoods.



LPG Systems® will not be liable for damage caused by transport or storage in the folded position, if the shims provided for this purpose, are not in place.

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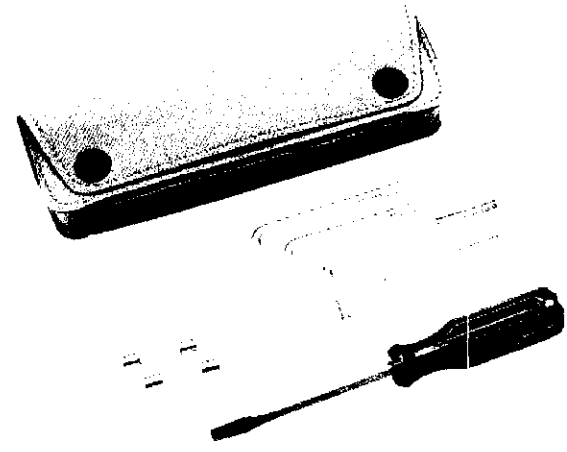
Maintenance kit

The tools supplied with the equipment in the tool box are sufficient to carry out the maintenance operations defined in this guide.

Contents of the maintenance kit:

- 4 hole covers
- 2 spare fuses
- 2 hex key (model No. 2.5 and 5)
- 1 torx T10 key
- 1 torx T30 key
- 1 screwdriver



Maintenance file

Replacement of the filter cartridge for the main head circuit ..... 40 hours
Replacement of the filter cartridge for the auxiliary head circuit ..... 40 hours
Overhaul of the main head ..... approx. every 1000 hours
Replacement of the vacuum generator filters ..... 1000 hours

DATE	NUMBER OF HOURS	OPERATIONS CARRIED OUT

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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A little problem! What should I do ?

If your unit is not working properly, proceed with the following checks before calling Customer Service of LPG Systems®:

- Is the unit properly connected to a main plug?
- Is the main plug live?
- Is the ON switch lit up?
- Are the fuses of the unit in good order?
- Are the filter cartridges clean and properly in place?
- Are the hoses free?
- Are the hoses properly connected to the mobile arms of the balancer?
- Are the sealing valves of the main head in their proper place, clean and moving?
- Is the Keymodule® of the main head correctly fitted?
- When switching on, the main head screen is blocked in the MAINTENANCE MENU. This means that there is a compatibility problem with the electronic boards of the T70 and Cellu M6® Keymodule ***i***. Please contact Customer Service of LPG Systems®.

Once these checks have been carried out and if the malfunction persists, please contact Customer Service of LPG Systems®, or the nearest authorized dealer,indicating the model of your unit, its serial number and operating time in hours (see pages 96 and 97 re access to the time meters).

Customer Service of LPG Systems®:
Tel.: +33(0)4 75 78 69 89
Fax : +33(0)4 75 78 69 88

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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General characteristics

Dimensions: Length x width x height .....60 x 46 x 210 cm
Net weight .....90 kg
Maximum set pression .....69 kPa (690 mbar)
Fuses .....Time-delay
.....Dimensions 6,3 x 32 mm
Cooling .....By way of mechanical ventilation incorporated in the pump
Protection index .....IP 20
Electrical protection class 1

Unit fitted with patented treatment heads.

The Cellu M6® Keymodule *i* is marked CE 0088 as a medical device by virtue of Annex V of regulation 93/42/EEC (standards 60601-1-1 and 60601-1-2)

Electrical properties

230V - 50Hz

Supply voltage .....230 V AC
Frequency .....50 Hz
Intensity consumed .....4 A
Power consumed .....920 Watts
Pump output .....18,5 m^3/h
Ceramic fuses T8A

230V - 60Hz

Supply voltage .....230 V AC
Frequency .....60 Hz
Intensity consumed .....4,8 A
Power consumed .....1100 Watts
Pump output .....20 m^3/h
Ceramic fuses T8A

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Electrical properties

115V - 60Hz

Supply voltage	115 V AC
Frequency	60 Hz
Intensity consumed	8,7 A
Power consumed	1000 Watts
Pump output	20 m^3/h
Ceramic fuses	T16A

127V - 60Hz

Supply voltage	127 V AC
Frequency	60 Hz
Intensity consumed	10 A
Power consumed	1200 Watts
Pump output	20 m^3/h
Ceramic fuses	T12.5A

100V – 50/60Hz

Supply voltage	100 V AC
Frequency	50/60 Hz
Intensity consumed	12,5 A
Power consumed	1250 VA (50Hz)/1250 W (60Hz)
Pump output	18,5 m^3/h at 50Hz
	20 m^3/h at 60Hz
Ceramic fuses	T20A

Please consult LPG Systems® Customer Service center regarding other voltages.

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TREATMENT HEAD

cellum6i KEYMODULE

Registered trademark

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9 DESCRIPTION OF KEYMODULE® . . . . . .P. 47

9 FUNCTIONS INCORPORATED IN THE MAIN HEAD . . . . . .P. 49

9 DESCRIPTION OF AUXILIARY HEADS . . . . . .P. 51

9 FUNCTIONS INCORPORATED IN THE AUXILIARY ADAPTER . . . .P. 53

9 MAINTENANCE . . . . . .P. 54

The manufacturer reserves the right to amend the product technical specifications without prior notice. Any reproduction, even in part, is prohibited. All the illustrations of this treatment head supplement are non-binding.

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Main head T70

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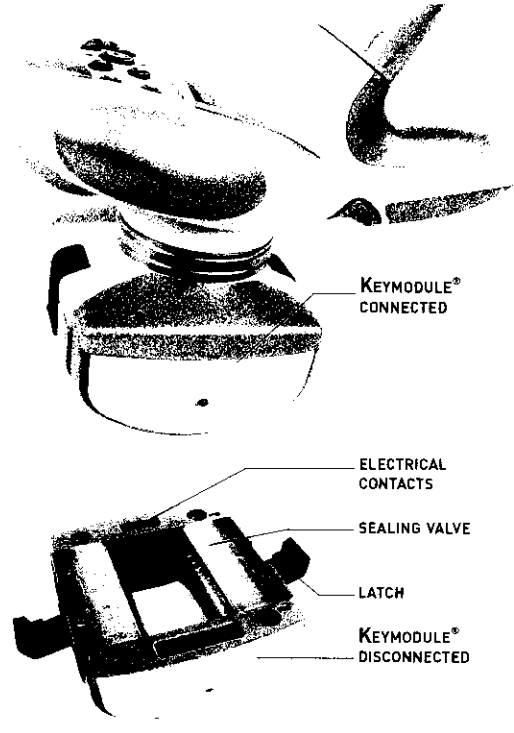
Keymodule®

8.

The Keymodule® is the bottom interchangeable section of the T70 main head. It comprises the motorised rollers and sealing valves.

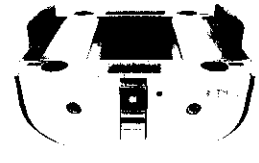
You have three Keymodule® the characteristics of which differ from the motorized rollers in several points:

- Diameter and texture of the rollers
- Rigidity of return springs



Keymodule® i2 :
This is recommended for the programs in the THERAPEUTICS and SPORT menus. It is characterized by the following points:

- Roller diameter: 24 mm
- Extra-soft springs
- Roller spacer stop (30 to 12 mm) to select the treatment depth



Movement and direction of rotation are visually displayed by LEDs for the Keymodule ™ treatment head.

Before running your unit for the first time, ensure that a Keymodule® was properly connected to the T70, because otherwise the screen will display an error message.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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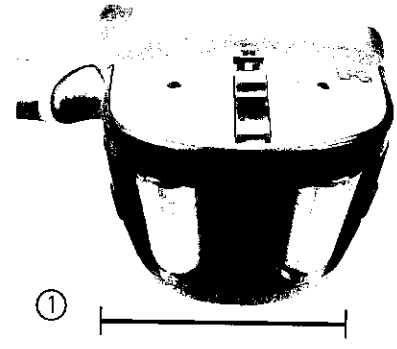
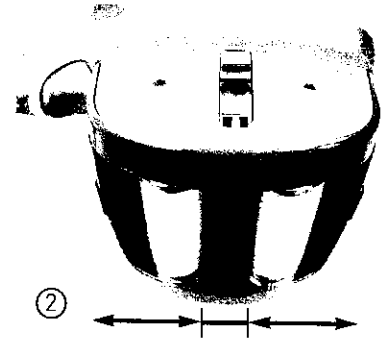
Setting the cursor of Keymodule® i2

The Keymodule® i2 has a cursor, which can be adjusted to 5 positions, thereby making it possible to adjust the spacing between the motorized rollers.

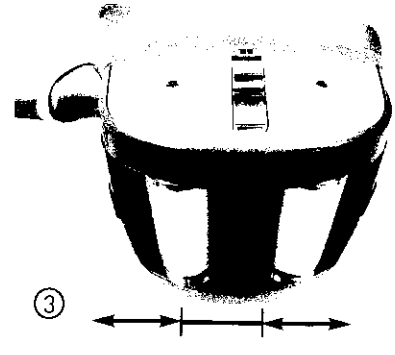
When the cursor is in the bottom position (figure 1) the distance between centres of the rollers is maximum and fixed, there is no roller mobility.



When the cursor is in the top position (figure 2) the distance between centres of the rollers is variable, from a maximum position to a minimum position, which ensures maximum mobility of the rollers.



When the cursor is in one of the 3 intermediate positions (figure 3) the distance between centres of the rollers, as well as their mobility, are variable.



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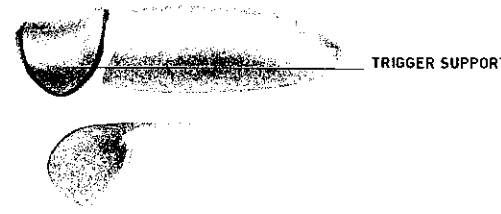
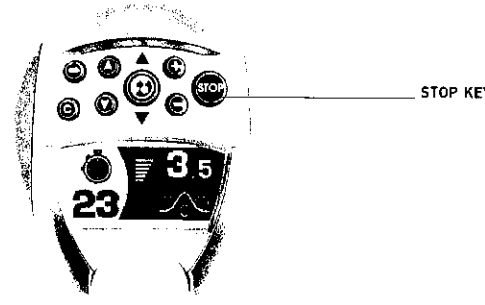
Functions incorporated in the main head

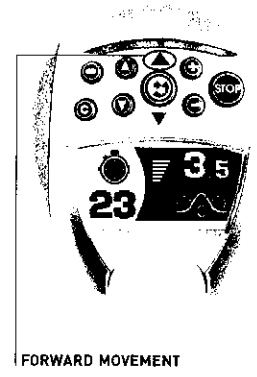
Apart from setting the treatment intensity, duty cycle, frequency or method of treatment, the main head also incorporates the start/stop and reverse functions and displays the direction of movement, as well as adjusting the volume and selecting the keyboard beep pitch.

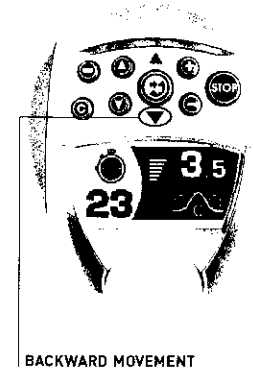


START/STOP function:
Once the pump has been switched on by the START button on the control panel keyboard, treatment start and stop are controlled by the main head.
To start treatment, press the trigger.
To stop treatment, press the STOP key.



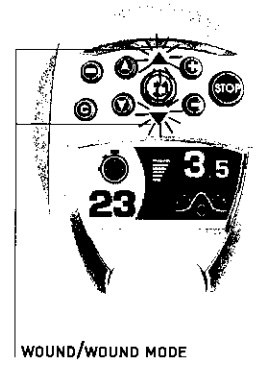
Indication of the direction of head movement (where the rollers move in the same direction):
Each time the trigger is pressed, this reverses the direction of head movement. The direction of movement of the main head is indicated throughout treatment by flashing lights.

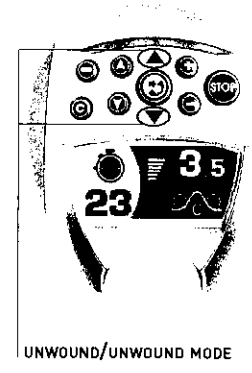




Reverse mode and LEDs:
When you are in reverse mode (the rollers are turning in the opposite direction), the flashing LEDs become specific:

- In wound/wound mode (where the 2 rollers wind the fold), the 2 diodes are lit and flashing
- In unwound/unwound mode (where the 2 rollers unwind the fold), the 2 diodes are lit and continuous.





These functions are only possible provided the main treatment head has been selected.

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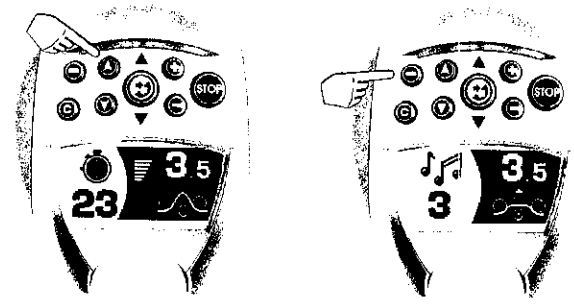
Functions incorporated in the main head

Adjusting the volume and selecting the keyboard beep pitch:
An audible beep is heard every time a key on the keyboard is pressed. The volume and pitch of the beep can be changed.
To regulate the volume of the keyboard beep (quiet, soft, average or loud), go to the RING MENU of the main head by pressing the key followed by pressing the key to gain access to the VOLUME parameter.

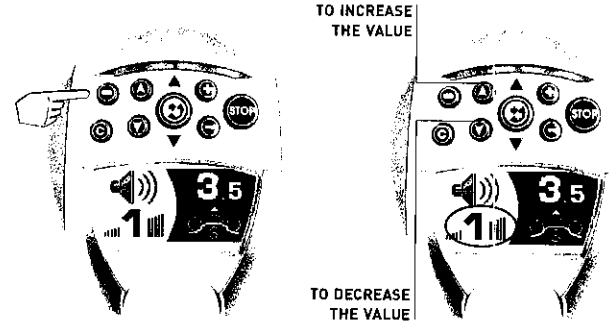


Validate the selection via the key the VOLUME value will start to flash.
Use the and keys to adjust this parameter to your requirements.

- 0: silent
- 1: soft
- 2: average
- 3: loud

Validate by pressing the key.

Use the key to return to the monitor screen.



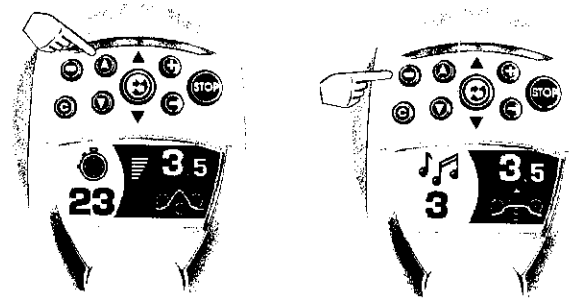
To regulate the pitch of the keyboard beep (low, medium or high) from the VOLUME parameter, press the key to gain access to the TONE parameter. Validate by pressing the key and the TONE value will start to flash.

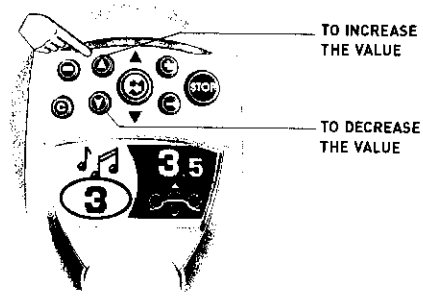
Use the and keys to adjust this parameter to your requirements.

- 1: high pitch
- 2: medium pitch
- 3: low pitch

Validate by pressing the key.

Use the key to return to the RING MENU and then to the monitor screen.





These functions are only possible provided the main head has been selected.

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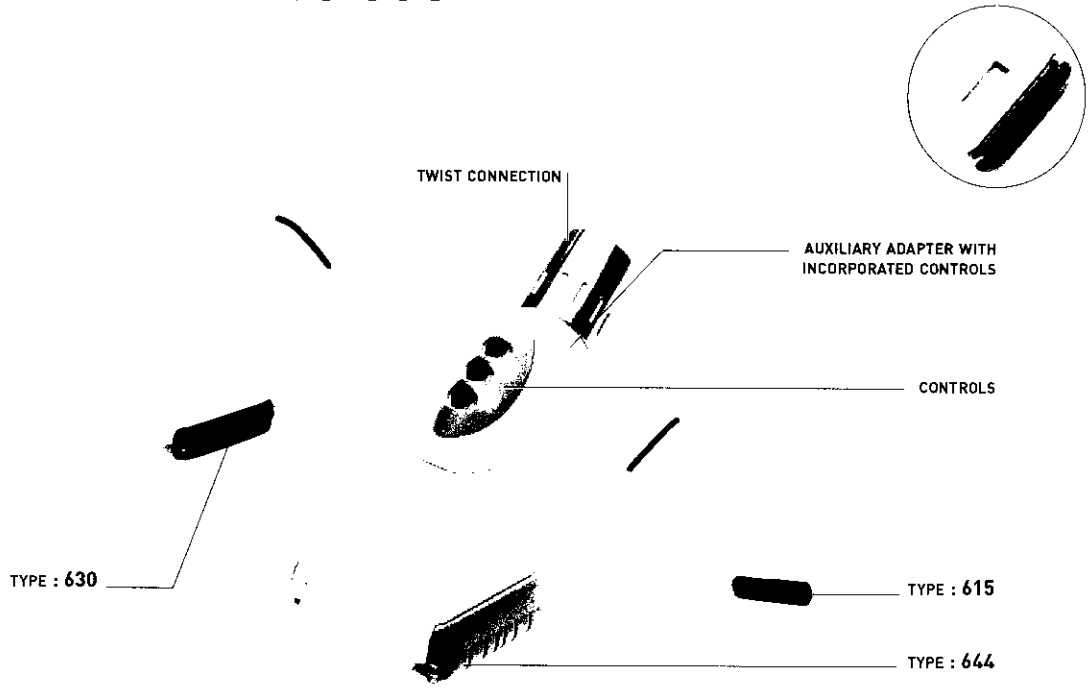
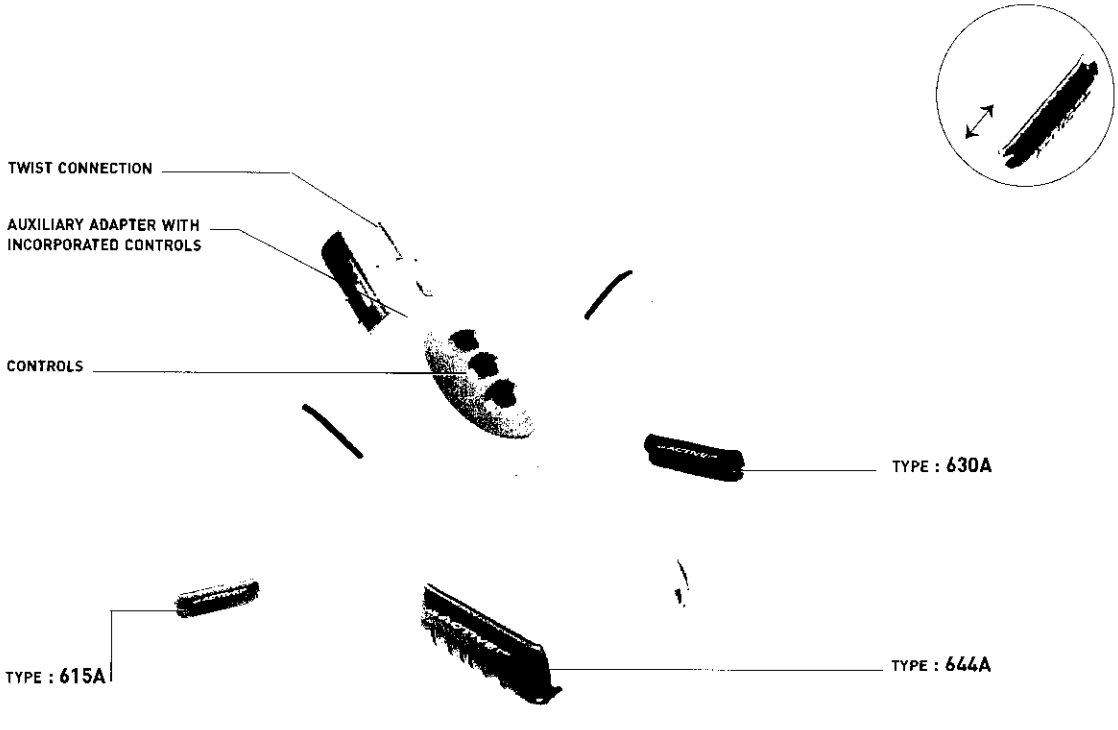
Auxiliary heads series 600



Auxiliary heads series 600 – active



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Page Not Used

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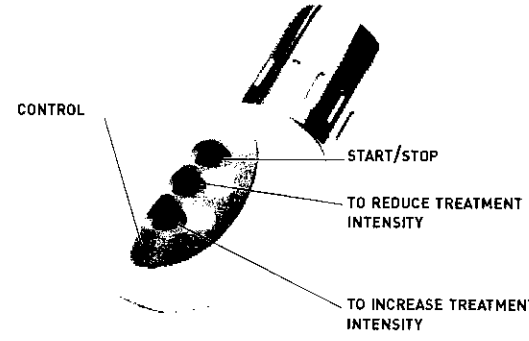
Functions incorporated in the auxiliary adapter

Because the control is incorporated in the auxiliary head connection, you can start or stop your treatment by operating the START/STOP switch and adjust the treatment intensity using the +/- keys without having to go to the control panel of your unit.



These functions are only possible provided the auxiliary treatment head has been selected.

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Index

CLEANING THE MAIN HEAD . . . . . .P. 55

CLEANING THE AUXILIARY HEADS . . . . . .P. 57

OVERHAUL OF THE KEYMODULE® . . . . . .P. 58

All the maintenance operations described in this section must be carried out with the unit switched off and the supply cable disconnected.

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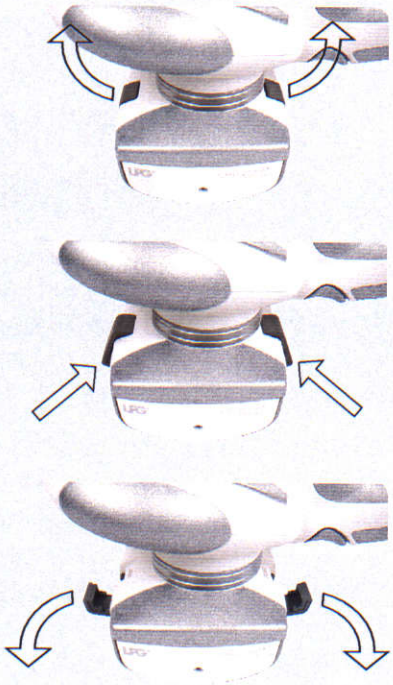
Cleaning the main head

For hygiene reasons, the treatment heads must be cleaned after each use, using antiseptic wipes with a bactericidal and fungicidal solution.

Special attention must be paid to those parts coming into contact with the patient.



Cleaning the tightness valves:

1) Release the Keymodule® as shown on the photos

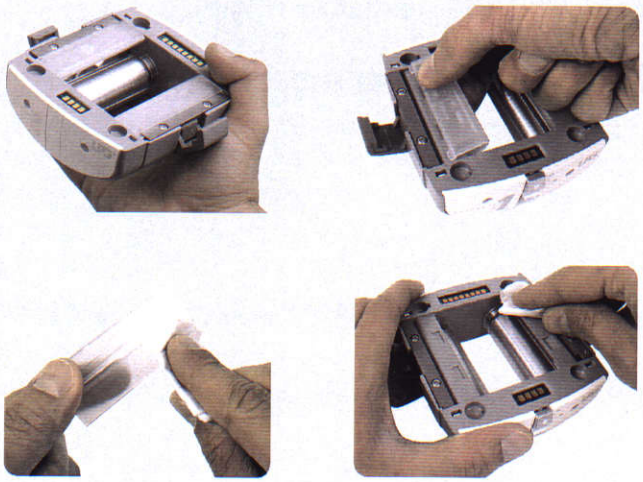
2) Make sure that the cursor is in the top position (see page 112)

3) Bring the roller to the center

4) Remove the corresponding sealing valve by handling it as shown on the photo. Repeat this operation for the other valve.

5) Then clean the valves and their location

Replace the valves after:
100 hours' operation.



Do not use aggressive products, such as acetone, trichloroethylene or alcohol at 90°, or abrasive sponges.

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Cleaning the main head

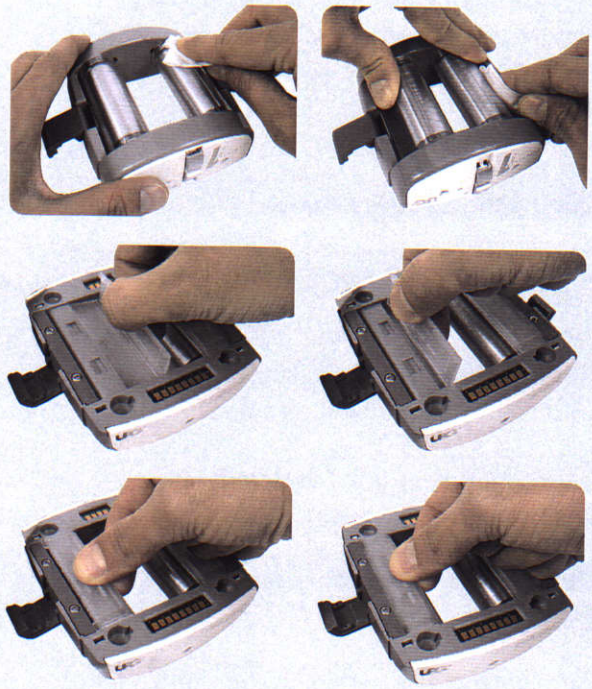
Cleaning the Keymodule® :

1) Turn the Keymodule® and clean the rollers on either side. Manually turn the rollers so as to gain access to the entire surface area.

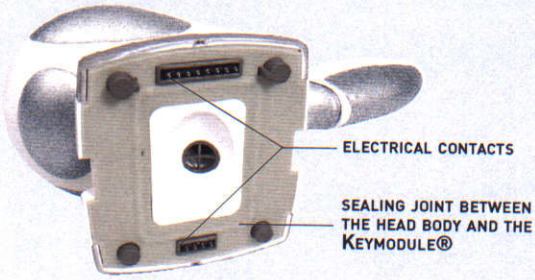
2) Turn the Keymodule® again and refit the sealing valves as shown on the photos.

3) Do not forget to clean the sealing joint between the Keymodule® and head body.

4) Check that the electrical contacts are clean and dry and proceed in the reverse sequence to refit the Keymodule® onto the main head.



Now check that the head is operating correctly.
To do this, operate the head in the palm of your hands to ensure the correct sealing of the treatment chamber and visually inspect the movement of the valves and that of the rollers.



WARNING: if the Keymodule® is not fitted to the main head, if it is incorrectly positioned or even faulty, the main head screen will display the icon alongside:

Check the assembly of the Keymodule®.

Do not use aggressive products, such as acetone, trichloroethylene or alcohol at 90°, or abrasive sponges.

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Cleaning the auxiliary heads

6.

For hygiene reasons, the treatment heads must be cleaned after each use, using wipes containing an antiseptic, bactericidal and fungicidal solution.

Cleaning the auxiliary heads:

- Disconnect the auxiliary head of the adapter for cleaning purposes.
- Remove the two head rollers to proceed with quick and efficient cleaning.
- Clean the rollers and the treatment chamber.
- Refit the rollers and check that they rotate freely.
- For cleaning, use cotton swabs containing the same solution.

Do not use aggressive products, such as acetone, trichloroethylene or alcohol at 90°, or abrasive sponges.

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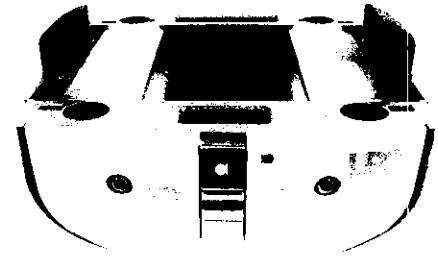
Overhaul of the Keymodule®

The Keymodule® is a high-technology unit comprising numerous mobile micro-mechanical parts. The unit must be returned to our Technical Support Center if certain wear items require replacing.



The head may start to lose some of its characteristics at around 1000 hours of operation.

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General warranty conditions

You have just purchased an LPG® unit. Purchasing this unit implies full legal acceptance of the present general conditions by the purchaser / professional operator. If the unit has been sold by an approved agent of LPG Systems®, the operator must refer to the general guarantee conditions of his supplier, which will not, under any circumstances, have the effect of increasing the manufacturer's commitment under the present warranty. This warranty can only be implemented and is only valid provided the guarantee slip has been duly filled in and returned to LPG Systems® within 15 days following delivery, irrespective of the country in question. All warranty slips that are only partially filled in will be rejected.

LPG Systems® guarantees this unit againt all manufacturing flaws or defects in the raw materials. The present warranty is valid for a period of one year with the first operator, without this exceeding 2000 hours of operation from the date of invoice. During this period, we undertake to exchange or repair, free of charge, any part acknowledged by ourselves as being faulty, without this necessarily entailing a complete replacement of the unit. Shipping costs and return forwarding costs of the unit or spares to/from our After Sales department, are not covered by this warranty.

Any replacements or repairs under the warranty, whether these cause an immobilization of the unit or not, will not have the effect of extending the period of cover, under any circumstances. The replaced parts become the property of LPG Systems®. No compensation will be awarded for inconvenience enjoyment. The purchaser is duty-bound to give us the necessary time and means to proceed with any repairs and replacement deliveries of spares. Failure to comply will absolve us from our obligation under the warranty.
It is expressly agreed that the company accepts no liability in the event of use exceeding the level of professional qualification of the operator or where the unit is used incorrectly.
The courts located within the jurisdiction of the registered office of LPG Systems® are alone competent in the event of disputes, despite any other clause, which may specify a different jurisdiction featuring on the commercial invoices of the contracting parties.

The warranty is also excluded in cases of:

- Damage that occurred during transport. This unit is forwarded at the risk and peril of the recipient. It is up to the latter to check that it is in a perfect state prior to delivery;
- Non-observation of the installation rules and the LPG Systems® operator's manual, failure to carry out maintenance of the unit and to clean the filter cartridges, connecting the unit to a faulty electric line or one which does not have an earth connection, or to a power supply whose voltage is different to the one indicated on the unit;
- Resale of the unit (except in the case of exemption and only with the express agreement of LPG Systems®;
- Modification, fitting accessories or dismantling the unit;

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General warranty conditions

- Any intervention work not scheduled in the LPG Systems® operator's manual and which was carried out on the unit by the operator or third party not approved by LPG Systems®;
- Using inappropriate consumables or parts not supplied by LPG Systems®;
- Blocage of the unit as a result of the aspiration of a foreign object or through the use of consumables other than those recommended and/or supplied by LPG Systems®;
- Wear to all parts of the unit as a result of normal use;
- The unit being dropped, in the event of impact, lightning, fire, force majeure, water damage and natural disasters.

Under no circumstances will this warranty give rise to any form of damages or compensation.

Limitation and exoneration of liability

Non-compliance with the general guarantee conditions during the term of the warranty and following expiry of the latter, may lead to LPG Systems® being exonerated of any liability in the event of damage attributed to the products supplied.

LPG Systems® will not be held liable with respect to equipment/material losses or physical accidents (i), following installation that does not comply with the statutory or regulatory provisions of the country where the unit is to be used or (ii) which could jeopardize a Cellu M6® Keymodule *i* unit, which was the subject of intervention work not scheduled in the LPG Systems® operator's manual and/or carried out by the operator or a third party not authorized by LPG Systems®.

LPG Systems® will be absolved of its liability in the event of use exceeding the level of professional competence/qualification of the operator or resulting from the incorrect use of the unit.

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To be filled in by the manufacturer

LPG
United States Customer Services & Training Offices
LPG - United States Customer Services
7060 W State Road 84, Davie, 33317

Tel: 888.730.0144 - Fax: 888.571.0040

Type of unit: Cellu M6® Keymodule *i*

To be completed and returned to LPG Systems®

Name: .....

Adress: .....

Country: .....

Tel.: .....

Type of establishment: .....

Profession: .....

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Type of unit: **Cellu M6® Keymodule *i***
Serial number: .....
Date: .....

To validate the warranty, detach this slip and return to the address below within 15 days following use of the unit:
LPG - United States Customer Services & Training Offices
7060 W State Road 84, Davie, 33317

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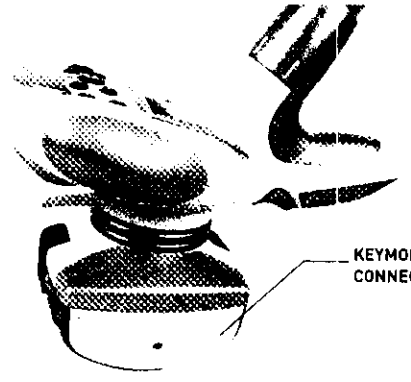
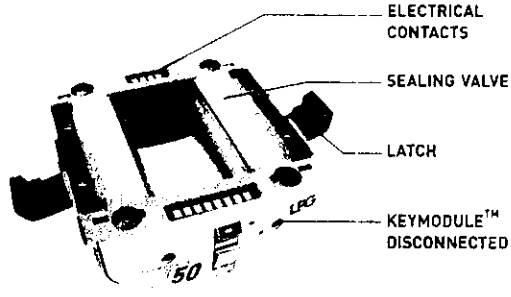
Description unit

The Keymodule *i* 50 is adaptable to the main head of the Cellu M6 Keymodule *i* T70. It consists of two motorised rollers and airtight valves.

It is characterized by the following points:

- Roller diameter: 26 mm
- Soft springs
- Roller spacer stop (28 to 10 mm) to select the treatment depth.





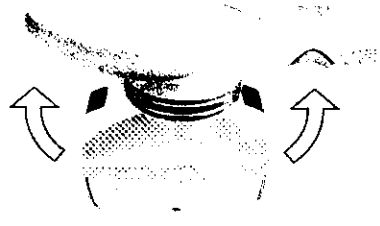
Installation

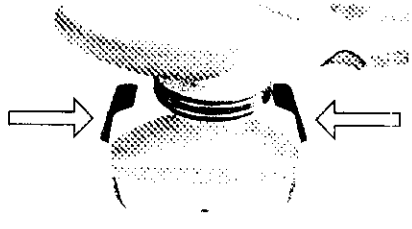
The Keymodule *i* 50 is designed to be compatible with the main head T70.

Attach the Keymodule to the main head as shown in the photos opposite.

To remove the Keymodule release the latches.

For Cellu M6 Keymodule i up to and including version 3.0, the picograph is displayed on the screen.





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Precautions

- The Keymodule *i* 50 must only be used with the main head T70 of the Cellu M6 Keymodule *i* machine.
- Do not use the Keymodule *i* 50 to treat the scalp.
- LPG Systems absolves itself from all responsibility in the case of any inappropriate use.
- All the usage precautions of the Cellu M6 Keymodule *i* also apply to the Keymodule *i* 50. Please refer to the operator's manual.

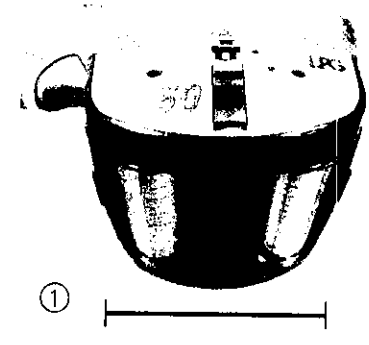
Adjustment of the cursor of the Keymodule™ *i* 50

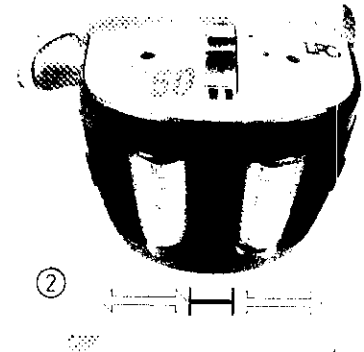
The Keymodule *i* 50 has a cursor which can be set in 5 different positions to adjust the distance between the motorised rollers.

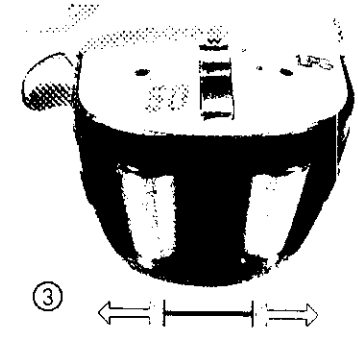
When the cursor is in the bottom position (figure 1) the distance between the rollers is maximum and fixed, there is no roller mobility.

When the cursor is in the top position (figure 2) the distance between the rollers is variable, from a maximum position to a minimum position, which ensures maximum mobility of the rollers.

When the cursor is in one of the 3 intermediate positions (figure 3) the distance between the rollers, as well as their mobility, are variable.







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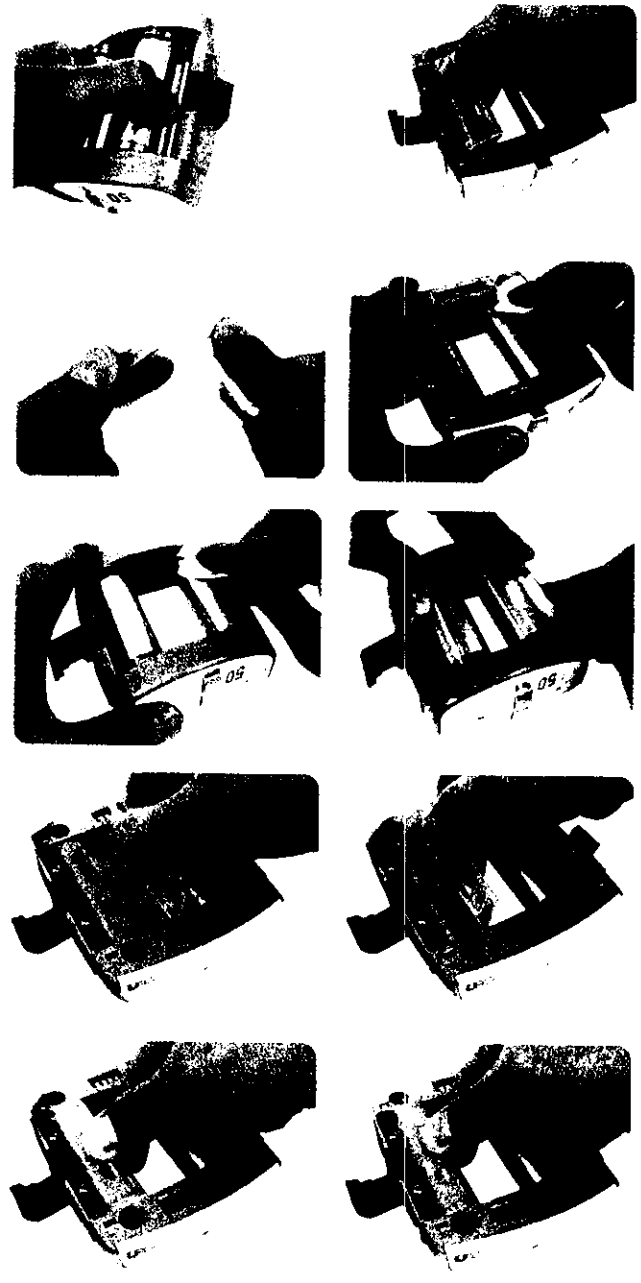
Maintenance

In order to guarantee optimum hygiene as well as the performance of your machine it is important to clean your Keymodule *i* 50 after each treatment session.



Cleaning the Keymodule™

- After removing the Keymodule ensure that the cursor is in the highest position.
- Bring the roller to the center.
- Remove the corresponding sealing valve by handling it as shown on the photo. Repeat this operation for the other valve.
- Then clean the valves and their chambers.
- Replace the valves after: 100 hours' operation.
- Turn the Keymodule and clean the rollers on either side. Manually turn the rollers so as to clean to the entire surface area.
- Turn the Keymodule again and refit the sealing valves as shown on the photos.
- Do not forget to clean the sealing joint between the Keymodule and the main head.
- Make sure that the electrical contacts are clean and dry, then reattach the Keymodule to the main head.

Overhaul of the Keymodule™ *i* 50

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- The Keymodule is a high-technology unit comprising of numerous mobile micro-mechanical parts. The unit must be returned to our Technical Support Center if certain parts require replacing.
- The head may start to lose some of its characteristics at around 1000 hours of operation.

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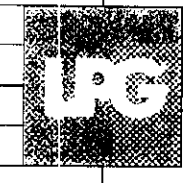
> LPG ONE, INC - Executive Office
701 Brickell Avenue • Miami • FL. 33131
Tel (305) 379 8800 Fax (305) 375 0903 Tel (800) 222 3911 • fax (800) 573 0063
> Training and Technical Center
7060 State Road 84 • Davie • FL. 33317
Tel (954) 476 7199 - Fax (954) 476 9795 - Tel (888) 730 0144 • fax (888) 571 0040 - www.lpgone.net



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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 02, 2006

LPG ONE, INC
C/O MANSOUR CONSULTING, LLC
845 ARONSON LAKE COURT
ROSWELL, GA 30075
ATTN: JAY MANSOUR

510(k) Number: K053225
Product: CELLU M6
KEYMODULE I

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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September 22, 2006

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER HFZ-401

K053225/S2

9200 CORPORATE BLVD
ROCKVILLE, MD 20850

ATTENTION: DR DORA VEGA, M.D., Ph.D
TEL 301-594-3090 X142
DIVISION OF GENERAL, RESTORATIVE AND NEUROLOGICAL DEVICES, HFZ-410

SUBJECT: 510K #K053225 SUPPLEMENT S2

Dear Dr Vega,

K.43

Our response is sent in two binders: one original, and one copy

VERY IMPORTANT: In order to locate the tabs that include the attachment numbers mentioned throughout this response letter, kindly refer to the EXPANDED table of contents on pages 12 and 13 of this response letter, which includes important explanations for each attachment, discussed in detail for your convenience.

VERY IMPORTANT: We authorize FDA to take as much time as necessary to fully and adequately review this supplement S2.

VERY IMPORTANT: If you require any clarification during the review process, we kindly ask/encourage you to call us prior to replying officially to the supplement, as we stand ready to PROMPTLY resolve any concerns with the least burdensome approach for us and for you, especially that this is Supplement S2.

VERY IMPORTANT: If a face-to-face meeting facilitates your review, we are ready to travel to your location on a short notice and meet you for a walk through, or even for a detailed scientific and clinical discussion, if so needed.

VERY IMPORTANT: We strongly believe that we provided you with all the required information that confirms safety and effectiveness of our device, for the indications for use claimed in this submission.

VERY IMPORTANT: (Historical Background for your consideration)
Dear Dr Vega, with the full understanding that you are the authority through which we are submitting this 510k, allow us to mention the following, for your kind consideration:
Before you took over the file, Dr Carlos Peña and Mr Ted Stevens agreed at an earlier stage of the negotiations that **we are allowed to compare our technological characteristics against one device[1], while we are allowed to compare our clinical effectiveness against another device[2]. The reason is that there is no predicate device with the same product code ISA for the same indications for use being submitted now**. It is really difficult and impractical to provide technological comparison between two devices having different technologies (although they have the same mode of action "wave action" and ultimately substantially equivalent performance). However, our other massager device ES1 device was cleared for us by FDA earlier, having very similar technology as Keymodule

[1] Refer to attachments 5a, 5b, 5c, 5d and 5e
[2] Refer to attachments 7, 8, 9, 10, 11a1, 11a2, 11a3, 11a4, 11b, 12, 13 and 14. Also refer to attachments 15 and 16.

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i. That is why -in order to substantiate our 510k for safety and effectiveness- we are using ES1 as one of our predicates[3], so that we don't have to compare our device technologically with the other predicates that we are using for the purpose of indications for use and for clinical comparison. Despite that, and going the extra mile, we made every attempt possible to provide as much information and details as possible, for all predicates devices.

[3] Refer to attachment 4 (Substantial Equivalence comparison table for predicate devices)

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MANSOUR CONSULTING

SUMMARY: the big picture

Going through the main original submission, supplement S1 and the preparation to submit supplement S2, including all letters, negotiations and conference calls, we believe that we provided you with all requested documents, and we revised our documents and labeling materials at each stage as required. We hope that you agree with the following main points, for you to kindly consider:

1- A class 1 massager is exempt from 510k requirements. But since we added new indications for use that go beyond the exemption status, we are required to submit a 510k notification application.

2- Adding the new indications for use necessitates that we provide clinical studies[4] to confirm safety and effectiveness for the new indications for use with a set of predicate devices having same indications for use, as well as provide technological comparison with our other massager ES1, being very similar in technology, and having been already cleared by FDA at an earlier stage via 510k #K990445. (K990445 was not exempt from 510k at that time, due to the inclusion of "burn rehabilitation" in the indications for use)

3- We did provide clinical studies, along with all the associated documents, confirming that the clinical studies were done in a controlled way, and documented in accordance with FDA requirements, and thus establishing confidence that the clinical studies (both of them) were real and indeed do validate our claims. These studies do confirm the safety and effectiveness of our device Keymodule i.

4- We went through a very lengthy and tedious process[5] to collect information from the marketplace, in order to provide you with the latest data about the technologies and parameters being used now in US. We provided you with lengthy discussions and other literature about the predicates, as well as the clinical studies associated with them.

5- We also provided you with a detailed discussion of the differences between our clinical studies and the ones of the predicates, showing you that our studies are more robust than the other ones. Our studies provide far more data and measurements than the clinical studies done on the predicate devices.

6- We also provided you with the reason why our device is truly substantially equivalent to the predicates, as far as the mode of action is concerned. For that, we added another predicate device –Flexitouch- that better illustrates the fact that our mode of action is actually the same as the other predicate devices. They all aim to **produce a wave action for fluid displacement**, as detailed in our detailed responses below.

7- In short, we went through great lengths in order to prove to you that our device is really safe and effective for the indications for use being claimed. Although the documentation associated with this submission has been substantial due to the very nature of the submission, **we kindly request that you take as much time as necessary in order to reach your own determination,** which we hope will be a clearance letter.

[4] Refer to appendix 2 of original submission (tab 24), as well as attachments 16, 17, 18, 19, 20, 21a, 21b, 22, 23 and 24 of Supplement S1 and attachments 8, 9, 10, 11a1, 11a2, 11a3, 11a4, 11b, 12, 13, 14 and 15 of this supplement S2

[5] Refer to tabs 26, 27 and 28 of original submission, as well as attachments 8, 9, 10a, 10b, 11, 15a and 15b of Supplement S1, and attachments 4, 14, 15 and 16 of this Supplement S2

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QUICK OVERVIEW OF OUR RESPONSES:

Please note the main points below, which follow the same numbering sequence as your letter dated June 15, 2006.

1- We changed our labeling to include the device's prescription statement on the first page of each device labeling.

2- We reduced our indications for use by canceling two of them: (a) Fibrotic induration and (b) Deep vein thrombosis.

3- We provided an explanation on the head attachments, including pictures and dimensions. They are i50, T615, T615-A, T630, T630-A, T644, and T644-A. No other head attachment applies for the indications for use mentioned in this submission. Also, the maximum negative pressure has been consolidated to (b) (4) mm Hg for the sole purpose of lymphedema treatment, as discussed elsewhere.

NOTE: To avoid misunderstandings and to standardize the wording, the terminology that we use is "Head Base" and "Head attachment". "Head base" pertains to either T70 (which is the end of the left hose), or "Auxiliary Head Base" (which is the end of the right hose). "Head attachments" are the removable attachments that are added to the head base for functioning purposes. i50 connects to T70, while T615, T615-A, T630, T630-A, T644, and T644-A connect to Auxiliary head base. The "attachment heads" are also referred to simply as "heads".

4- All tests related to the left hose -i.e., head base T70- have already been conducted using head attachment i50 (i50 being the ONLY attachment head that can connect to head base T70)

All tests related to the right hose –i.e., Auxiliary head base- have already been conducted using each of the 6 auxiliary head attachments (T615, T615-A, T630, T630-A, T644, and T644-A being the ONLY head attachments that can connect to Auxiliary Head base).

We provided you also a with a protocol addendum for Tab 12 of supplement S1, in order to better clarify what we documented for you earlier.

5- We discussed the "wave action" in details, showing that the mode of action and the end result for our device and the predicate devices –except ES1, of course- are really substantially equivalent, even if our device is a massager, and the predicate devices are not. This is due to the particular way our device works, versus other "standard" massager machines in the marketplace. So, other massagers cannot simply claim those indications for use and get FDA clearance, because (a) they will have to provide the same mode of action ("wave action"), as well as (b) prove safety and effectiveness **via clinical studies**.

6- There is a safety/emergency stop button, as shown in the user manual.

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DETAILED RESPONSES:

First, please note that the submission summary[6] is updated and included within this response.

In reference to your letter[7] dated June 15, 2006, our subsequent conference call, as well as to the Document Mail Center letter approving extension of time[8] till December 12, 2006, we respond below, following the same sequence and numbering as per your letter.

For your convenience, please note that a Q&A section has been added on page 10 of this response letter.

Second, our detailed responses are shown below, which –again- follow the same numbering sequence as your letter dated June 15, 2006:

1- The device's prescription statement has been added on the cover page and the following page of the brochure[9], on the first page of "directions for use"[10], and on the cover page and the following page of the manual[11]. This satisfies or exceeds your request to include the statement on the first page of each labeling. This statement is:
"Caution: Federal law restricts this device to sale by or on the order of a clinician licensed by the Law of the State where he/she practices to use or order the use of the device".

Note/historical: the statement was hand written on the fourth page of the brochure (attachment 25-1 of supplement 1, tab 31), handwritten on the first page of the directions for use (attachment 25-2 of supplement S1, tab 31), and typed on page 11 of the manual (attachment 25-3 of supplement S1, tab 31)

2- We choose to delete two indications for use from our list. Those two indications are the second and fifth from our earlier list. The second one was: reduction of lymphedematous fibrotic induration. The fifth one was: prevention of deep vein thrombosis (DVT). The remaining four indications for use that are submitted for clearance under this supplement S2 are:

(a) Reduction of secondary lymphedema of the arm (SLA) post mastectomy
(b) Improvement of primary and secondary lymphedema
(c) Prevention of venous stasis and venous insufficiency
(d) Improvement of lymphatic circulation in the treated area

The change in the indications for use is reflected in the new 510k summary[12] as well as in the revised indications for use form[13]. Also, we revised page A4 of attachment 25-1 (which is the brochure[14]) in Tab 31 of supplement S1 by removing the two indications for use already cancelled. Finally, those two indications for use have also been removed from the first page of the directions for use[15].

---

[6] Refer to attachment 2 (510k summary)
[7] Refer to attachment 1a (FDA deficiencies letter)
[8] Refer to attachment 1b (FDA extension of time letter)
[9] Refer to attachment 17 (Brochure)
[10] Refer to attachment 18 (Directions for use)
[11] Refer to attachment 19 (Manual)
[12] Refer to attachment 2 (510k summary)
[13] Refer to attachment 3 (Indications for use Form)
[14] Refer to attachment 17 (Brochure)
[15] Refer to attachment 18 (Directions for use)

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3- We confirm that the ONLY **head attachments** (also referred to sometimes simply as **heads**) submitted as part of this device are:

(a) i50. This head attachment is connected to main motorized head base T70, located at the end of the "left hose" of the machine Keymodule i.

(b) T615, T615-A, T630, T630-A, T644 and T644-A. These head attachments are connected to the Auxiliary head base located at the end of the "right hose" of the machine Keymodule i. These head attachments are either Active (T615-A, T630-A and T644-A), or non-active (T615, T630 and T644).

(Refer to page 6 of the manual to see left and right hoses)
(Refer to page 20 of manual to see main head base T70 and auxiliary head base, to which the head attachments are connected)

Head attachments have been used in our clinical studies, and proven to provide a safe and effective use of the device.

We removed head attachment i2 from our list of head attachments to be cleared in this submission, as i2 was not used in our clinical studies. Head attachments i1 and i3 have been already deleted from supplement S1, and remain deleted. So, **i1, i2 and i3 are deleted**.

We revised attachment 3a of supplement S1 accordingly. Note that attachment 3a relates to comparing our previously cleared device ES1 with the new Keymodule i for the purpose of providing technological comparison as explained at the beginning of this response letter (i.e., despite the fact that ES1 is a massager with different indications for use)

Note: Head attachments i1, i2 and i3 have been deleted, as they don't pertain to our indications for use. They used to connect to head base T70.

Photographs of the 7 different head attachments are included[16] elsewhere within this supplement S2, showing the length and width by including graduations with the photos. These photos show the head attachments from the bottom surface that comes in contact with the skin. To see a top view, refer to page 46 of the manual[17] for the combination of T70 head base and i50 head attachment, and to page 51 of the manual for the combination of Auxiliary head base and auxiliary head attachments.

We hope that the manual and the photos will allow for acceptable description of the head attachments.

Explanation on the head attachment sizes:

The auxiliary head attachments –whether Active or non Active- have the same dimensions (and external shape for that matter). So, T615 and T615-A have the same dimensions. T630 and T630-A have the same dimensions. T644 and T644-A have the same dimensions.

[16] Refer to attachment 11a4 (Treatment head dimensions)
[17] Refer to attachment 19 (Manual)

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The following was mentioned in attachment 3a of Supplement S1:

"... A large one (45mm x 18mm), a medium one (30mm x 14mm) and a small one (15mm x 10mm)".

The large one refers to T644 and T644-A. The medium one refers to T630 and T630-A. The small one refers to T615 and T615-A.

The dimensions mentioned above referred to the **nominal length** and **nominal opening** (i.e., clearance between the diameters of both rollers) of the actual head attachment. These **nominal dimensions** mentioned are still correct. Accordingly, the statement in italic *"... A large one (45mm x 18mm), a medium one (30mm x 14mm) and a small one (15mm x 10mm)"* and the table below DO NOT CONTRADICT EACH OTHERS.

Attachment 11a4 includes photographs defining the sizes of all head attachments, i50, as well as T615 and T615-A, T630 and T630-A, and T644 and T644-A.

In attachment 11a4, the dimensions are defined as follows:

1- "Width of head attachment" refers to the length of the individual roller
2- "Length of head attachment" refers to the distance from center of diameter of one roller to the center of the diameter of the other roller

While the length of the head attachment reflects the width of the curve formed due to the negative pressure applied between the rollers and positive pressure applied under the rollers[18], the width of the head attachment reflects the depth of the curve.

According to above, the following table defines the dimensions shown in attachment 11a4:

(As per definition above)	Length of head attachment	Width of head attachment
i50	(b)(4) [redacted]	
T615 and T615-A		
T630 and T630-A		
T644 and T644-A		

Explanation about the different pressures mentioned:

- The 550 mbar and 650 mbar pertain to ES1, which is our predicate device, being the massager. While 650mbar is the theoretical rating of the pump, (b)(4) [redacted] mbar is the actual maximum permissible pressure corresponding to power level 9. This can be verified by having a look at attachment 3b of supplement S1 (tab 4). It is important to note that attachment 3a of supplement S1 (Tab 3) includes information for ES1 (predicate) as well as our device Keymodule i. In that attachment, 650 mbar was indeed mentioned for ES1 as the maximum theoretical rating of the pump, while 700 mbar was mentioned for Keymodule i as the maximum theoretical rating of the pump.

[18] Refer to attachments 11a1, 11a2 and 11a3. Also, refer to attachment 11a4 mentioned earlier

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- As per our conference call, we confirm that since Keymodule i is used only at power levels 1 to 4 for our indications for use, power levels 5 and higher have been cancelled, leaving the user with the physical possibility of using only power levels 1 to 4. This means that the maximum pressure possible now is (b)(4), or (b)(4), instead of 700 mbar mentioned earlier in Supplement S1. All of our labeling material has been updated accordingly.

4- We confirm and certify that all tests pertaining to the left hose and head base T70 have been conducted while (b)(4) (b)(4)

We also confirm and certify that all tests pertaining to the right hose and Auxiliary head base have been conducted (b)(4) (b)(4)

We also confirm and certify that all other tests pertaining to all head attachments have been conducted when (b)(4) (b)(4)

We include a table[20] defining each test in relationship with the head attachment(s) connected during testing.

Additionally, and in order to provide you with more explanations of our software documentation presented earlier in Supplement S1, we also include[21] "protocol addendum" for our tab 12 of supplement S1.

Suitability for those head attachments is confirmed via our own clinical studies, as mentioned[22] elsewhere within this supplement S2. The 6 auxiliary head attachments (T615, T615-A, T630, T630-A, T644 and T644-A) have been used in (b)(4) clinical study, while all of the 7 head attachments (i50, T615, T615-A, T630, T630-A, T644 and T644-A) have been used in (b)(4) clinical study.

5- As we now reach a maximum of (b)(4), as explained earlier (canceling all power levels 5 and beyond), it is now comparable with the 150 mm Hg of Sequential Circulator, Model SC-3008.

In order to better visualize the substantially equivalent mode of action of our device with the technology of the predicate devices (and subsequently the effect and results of the mode of action), we add another predicate device (510k #K013061)[23].

Several self-explanatory attachments are included.

One attachment[24] shows conceptually how the wave action is created for our device and for the predicate Flexitouch (also known as Biotouch).

A second attachment[25] provides dimensional details of the curves created by our device.

---

[19] Refer PRIMARILY to attachment 5b (Cellu M6 ES1 vs. Keymodule i Technological comparison). To have a complete picture, also review attachments 5a (Description/Comparison of the device), 5c (Keymodule i components list), 5d (diagrams comparing ES1 and Keymodule i) and 5e (Mode of function)
[20] Refer to attachment 6 (Software information)
[21] Refer to attachment 6 (Software information)
[22] Refer to attachment 13 and the related explanations in the Expanded table of contents
[23] Refer to attachment 15 for a copy of the clinical study of Flexitouch, as well as for a copy of 510k information from FDA website
[24] Refer to attachment 10
[25] Refer to attachment 11a1

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A third attachment[26] provides dimensional/simulated details of the curves created by the predicate Flexitouch.

Whereas Flexitouch exerts positive pressure, our device exerts positive pressure under the rollers, and negative pressure between the rollers. But both allow the formation of a wave action for fluid displacement, and thus providing[27] substantially equivalent results.

While the volume of whole arm is reduced by 186.3 ml in (b)(4) clinical study, it is reduced by 210.5 ml in Flexitouch clinical study.

Also, while the volume of whole arm is reduced by 19% in (b)(4) clinical study, it is reduced by 7.6% in Flexitouch clinical study.

Important details are included in attachment 9.

6- Referring to our manual[28], an emergency stop button is provided as clarified on pages 8 and 49 for main head base T70, and on page 53 for auxiliary head base.

[26] Refer to attachment 11b
[27] Refer to attachments 8 and 9
[28] Refer to attachment 19

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QUESTIONS AND ANSWERS: Q&A

Q: Have you answered all questions and have you submitted all documents necessary to back up your responses.
A: Yes, to the best of our knowledge and ability

Q: Do you consider this supplement to be extensive, documentation-wise?
A: No, this supplement includes some information that needs a very careful review. We spent a great effort assembling or generating documents in order to reply to your questions in as much details as possible.

Q: Have you altered anything in the indications for use within this supplement #2?
A: Yes. Two out of 6 IFU have been deleted.

Q: Why are you discussing ES1 device?
A: The reason is to provide you with a device cleared by FDA **for us** having VERY similar technological characteristics as our KeyModule i device.

Q: Why did you add an additional predicate device?
A: The reason is that Flexitouch provides very similar dimensional characteristics which better explains the substantial equivalency of our device with the predicate devices, in terms of "wave action".

Q: Several changes occurred on supplement S2. Can you summarize those changes for our convenience?
A: Certainly.

- Tab 2 of Supplement S1 is superceded by Tab 3 of Supplement S2
- Tab 3 of Supplement S1 is superceded by Tab 6 of Supplement S2
- Tab 4 of Supplement S1 is superceded by Tab 7 of Supplement S2
- Tab 5 of Supplement S1 is the same as Tab 9 of Supplement S2
- Tab 6 of Supplement S1 is the same as Tab 10 of Supplement S2
- Tab 7 of Supplement S1 remains in effect, and not repeated in Supplement S2
- Tab 8 of Supplement S1 is superceded by Tab 8 of Supplement S2
- Tabs 9, 10 and 11 of Supplement S1 remain in effect, and not repeated in Supplement S2
- Tab 12 of Supplement S1 remains in effect, and supplemented by Tab 11 of Supplement S2
- Tab 13 of Supplement S1 remains in effect
- Tab 14 of Supplement S1 remains in effect, and supplemented by Tab 23 of Supplement S2
- Tabs 15, 16 and 17 of Supplement S1 remain in effect
- Tab 18 of Supplement S1 is superceded by Tab 12 of Supplement S2
- Part 1 of Tab 19 of Supplement S1 is deleted, Part 2 of Tab 19 of Supplement S1 is superceded by Tab 13 of Supplement S2
- Tab 20 of Supplement S1 is superceded by Tab 5 of Supplement S2
- Tabs 21, 22, 23, 24 and 25 remain in effect, and not repeated in Supplement S2
- Tab 26 of Supplement S1 is deleted
- Tabs 27, 28, 29 and 30 remain in effect, and not repeated in Supplement S2
- Part 1 of Tab 31 of Supplement S1 is superceded by Tab 26 of Supplement S2, part 2 of Tab 31 of Supplement S1 is superceded by Tab 27 of Supplement S2, and part 3 of Tab 31 of Supplement S1 is superceded by Tab 28 of Supplement S2

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We hope that you will find this supplement complete, accurate and to your satisfaction. In the meantime, we stand ready to reply promptly to any questions that may arise.

Best Regards,

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MANSOUR CONSULTING

EXPANDED TABLE OF CONTENTS

(including further explanations on the attachments included in this Supplement S2)

ATTACHMENT		TITLE/SUBJECT	EXPLANATION	TAB	PAGE
GENERAL	N/A	RESPONSE LETTER	RESPONSE LETTER ANSWERING YOUR LETTER DATED JUNE 15, 2006	N/A	1.1 to 1.13
	1a	FDA's Deficiencies letter of June 15	Against supplement S1	1	N/A
	1b	Extension of time	Extended until December 12, 2006	2	
	2	**510k summary**	Main reasons for revision: (1) description updated to include correct head attachments (2) Intended use updated to exclude 2 claims that are cancelled now	3	3.1 to 3.3
	3	**Indications for use form**	Revised by deleting two claims that are no longer wanted	4	4.1
ALL PREDICATE DEVICES	4	**Substantial Equivalence comparison table for predicate devices**	General table showing ALL predicate devices: 1- K990445 (Device ES1) is included for the purpose of technological comparison with our device 2- K912004, K914774, K974395, K043423 and K013061 are included as having same indications for use as our device	5	5.1
TECHNOLOGICAL COMPARISON WITH PREDICATE K990445	5a	Description/Comparison of the Device	PART 1: narration detailing the similarities and the (minor) differences between ES1 and Keymodule I (Attachment 3a of supplement S1 updated)	6	6.1 to 6.6
	5b	Cellu M6 ES1 vs. Cellu Keymodule i Technological comparison	PART 2: tabulated technological comparison between ES1 and Keymodule I (Attachment 3b of supplement S1 updated)	7	7.1
	5c	Cellu M6 Keymodule i- Components List	PART 3: List of main components of Keymodule i (Attachment 4 of Supplement S1 updated only for clarification)	8	8.1
	5d	Diagrams comparing ES1 and Keymodule i functionalities	PART 4: diagrammatical comparison between ES1 and Keymodule i (Attachments 3c and 3d of supplement S1 repeated for convenience, being identical to the ones of Supplement S1)	9	9.1 & 9.2
	5e	Mode of function	PART 5: graphical comparison of the aspiration cycles between ES1 and Keymodule i (Attachment 3e of supplement S1 repeated for convenience, being identical to the one of Supplement S1)	10	10.1
SOFTWARE	6	Software information	Addendum and explanation to attachment 7 of Supplement S1	11	11.1 to 11.3
CLINICAL COMPARISON WITH PREDICATES K912004, K914774, K974395, K043423 and K013061	7	**Indications for use and Directions for use table**	- Indications for use of our device as compared with other predicate devices. - Directions for use of our device referred for FDA reviewer's convenience Attachment 12 of Supplement S1 updated to include: 1- Additional predicate device K043423 2- Corrections for heads and their sizes	12	12.1
	8	**Clinical results comparison table**	Attachment 13 part 2 of Supplement S1 updated to include K043423, in addition to K013061 and K053225	13	13.1
	9	**Clinical studies analysis**	This analysis contains detailed discussion comparing the methods, techniques, clinical goals, interpretation, quality comparison for the clinical studies conducted by manufacturers of K053225 (both Piller I and Piller II), K013061 and K043423, confirming the concept of the wave action generated by these devices to achieve substantially similar results Also, refer to attachment 14 as an additional background.	14	14.1 to 14.7
	10	**Substantially Equivalent Action**	Graphical representation of the wave action concept	15	15.1

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	11a1	**Dimensions of Keymodule i curves generated by different head attachments at different settings**	As a background, refer to attachments 11a2, 11a3 and 11a4	16	16.1
	11a2	Graphic Representation with Dimensions of Skinfold created by i50 treatment head "chamber"	This is a conceptual representation for Keymodule i, using i50 head attachment as an example	17	17.1
	11a3	Endoscopic images of skinfold inside i50 "treatment chamber"	This is a photographic evidence of the shape of the curve using i50 at different settings (followed by a narration explaining the photos)	18	18.1 & 18.2
	11a4	Treatment head dimensions	Dimensions of the different head attachments are shown in enclosed photographs, noting that the "length" of the head attachment corresponds to the width of the curve as depicted in attachment 11a1, while the "width" of the head attachment corresponds to the depth of the curve. Contents: i50, T615 & T615-A, T630 & T630-A, and T644 & T644-A	19	19.1 to 19.4
	11b	Wave dimensions for Flexitouch	Several simulated curves at different stages during inflation and deflation of individual Flexitouch chambers	20	20.1 & 20.2
	12	Quality Analysis of Piller Studies	Checklist type of document reflecting that BOTH studies conducted in [redacted] (b)(4) re robust	21	21.1 to 21.8
	13	Flinders letters	(b)(4) [redacted] (b)(4) One letter is dated August 24, 2006, confirming that the auxiliary head attachments have all been used during the first clinical study (T615-A, T615, T630-A, T630, T644-A and T644) One letter is dated August 28, 2006, confirming that the settings (or power levels) during the first clinical study were restricted to 1, 2, 3 and 4 Note: for the second clinical study, it has been documented on page 2 of attachment 21a of Supplement S1 and throughout attachment 21b of Supplement S1 that i50 and all the auxiliary head attachments have been used, and that the power level was restricted to the range of 1 to 4	22	22.1 & 22.2
	14	Szuba study: decongestive lymphatic therapy for patients with breast carcinoma-associated lymphedema	(b)(4) [redacted] study is basically the same as th (b)(4) [redacted] study (weak abstract) submitted in S1 (same author) under attachment 9 (Tab 14). However, we were able to find a real full text study with statistics, and were accordingly able to compare a lot more data and to make our argument tighter. (Refer to attachment 9)	23	23.1 to 23.8
PREDICATE K013061 ADDED	15	Part 1: Clinical study	BMC Cancer- Research Article, 10 pages	24	24.1 to 24.10
			Calculation sheet, 2 pages		24.10X1, 24.10X2
		Part 2: 510k #K013061	Printout from FDA website		24.11 to 24.15
	16	Labeling	Directions for use	25	25.1 & 25.2
K053225	17	Brochure	Attachment 25a in Tab 31 of Supplement S1 updated	26	26.1 to 26.5
	18	Directions for use	Attachment 25b in Tab 31 of Supplement S1 updated	27	27.1 to 27.6
	19	Manual	Attachment 25c in Tab 31 of Supplement S1 updated	28	1 to 61 (pre-numbered)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ATTACHMENT 1A

LPG One, Inc.
% Mr. Jay Mansur
Mansur Consulting, LLC
845 Aronson Lake Court
Roswell, GA 30075

JUN 15 2006

Re: K053225/S001
Trade Name: Cellu M6 Keymodule I
Dated: May 9, 2006
Received: May 16, 2006

Dear Mr. Mansur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require you provide the following information:

Regarding your response to deficiency #1, in our fax dated January 13, 2006:

1. You confirmed your acceptance to change the device's prescription statement to be: "Caution: Federal law restricts this device to sale by or on the order of a clinician licensed by the Law of the State where she/he practices to use or order the use of the device." You also state that all of your labeling documents have been updated accordingly. However, the above statement was not included in the first page of the device labeling. Please revise your labeling to include the prescription label in the first page of the device labeling.

Regarding your response to deficiency #2, in our fax dated January 13, 2006:

2. Your response dated May 9, 2006 states that the device labeling has been updated to reflect only the specific indications for use as mentioned on page R (Tab 7) of the submission, and that these changes are: (a) Reduction of secondary lymphedema; (b) Reduction of lymphedematous fibrotic induration; (c) Improvement of primary and secondary lymphedema; (d) Prevention of venous stasis and venous insufficiency; (e) Prevention of deep vein thrombosis (DTV); and (f) Improvement of lymphatic circulation in the treated area. The predicate devices you identified do not have the specific indication for use of *fibrotic induration*, nor are we aware of any device for this specific indication. In addition, in "Selectivity," Therapeutic benefits, Attachment 31, page A4 in your response indicates *"deep vein thrombosis"* as a use for the device." Please provide medical/scientific rationale and supporting clinical performance data for the use of the device for these IFU and a discussion

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supporting equivalence with the predicates, which contraindicate the use of the device in deep vein thrombosis and thrombophlebitis. Otherwise, please remove these claims from your labeling.

Regarding your response to deficiency #5 in our fax dated January 13, 2006:

3. The response in your letter dated May 9, 2006 provides information that clarifies the technological specifications in the different types of the device heads (i.e., i1, i2, and i3.) However you mention that "there are three auxiliary heads intended for use for treatment of lymphedema in smaller areas of the body," (Attachment 3a and Attachment 31, page B1), which significantly differ (e.g., 45 mm x 18 mm; 30mm x 14mm; and 15mm x 10mm) from the physical dimensions reported for the heads i1, i2, and i3 reported above. In addition, the revised labeling of the device still has some apparent discrepancies in the device specifications (e.g., 500 mb, 650 mb and 700 mb maximum negative pressure in the device, Attachment 3a.) Please provide information that adequately clarifies the physical dimensions in the device heads as well as a discussion about the substantial equivalent performance of the varied dimensions in the device heads, and the vacuum.

Regarding your response to deficiency #7, in our fax dated January 13, 2006:

4. You report that the software components tested used the Stand-alone Cellu M6 Keymodule I with *various* heads attachments. It is unclear which specific device heads were tested for the intended use for the device. Please provide information that clarifies the device heads tested and a discussion about their suitability for the intended use for the device.

Regarding your response to deficiency #9, in our fax dated January 13, 2006:

5. The Sequential Circulator, Model SC-3008 that you identify as a new predicate for your device in your letter dated May 9, 2006 is an inflatable pneumatic sleeve, which exerts up to 150 mm Hg positive pressure at the treatment site. Your Cellu M6 Keymodule I differs in the mode of action because it operates by suction reaching a maximum vacuum (negative) pressure up to 500 mm Hg - 700 mm Hg. Despite the similar Indications for Use for the treatment of primary or adjunctive treatment of lymphedema, due to the device technological differences with the predicate Sequential Circulator, Model SC-3008 it is unclear how the clinical data submitted for the predicate can be used to support the safety and effectiveness of your device. Please provide valid scientific evidence supporting your claim for substantial clinical equivalence between your proposed Cellu M6 Keymodule I and the predicate Sequential Circulator, Model SC-3008.

6. Please revise the Operator's Manual to include instructions on what the user should do if the treatment head locks up on a patient's skin during treatment.

When using a standard to demonstrate equivalence, providing a declaration of conformity or a statement that the device will comply prior to marketing, may be provided in lieu of data. Please refer to our document, titled Use of Standards in Substantial Equivalence Determinations located at <http://www.fda.gov/cdrh/ode/guidance/1131.pdf> for additional guidance.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If you have any questions concerning the contents of the letter, please contact Dora Vega, M.D., Ph.D., at (301) 594-3090 x 142. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

for Mark N. Melkerson, M.S.
Director Division of General, Restorative
and Neurological Devices
Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

ATTACHMENT 1B

July 03, 2006

LPG ONE, INC
C/O MANSOUR CONSULTING, LLC
845 ARONSON LAKE COURT
ROSWELL, GA 30075
ATTN: JAY MANSOUR

510(k) Number: K053225
Device: CELLU M6
KEYMODULE I

Extended Until: 12-DEC-2006

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FINAL SSE

510(k) Summary
As Required by 21 section 807.92 (c)

1-Submitter Name: LPG One, Inc
2-Address: 801 Brickell Ave. Suite 850. Miami, FL 33131
3-Phone: (305) 379- 8800
4-Fax: (305) 375- 0903
5-Contact Person (Consultant): Jay Mansour of Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA
(678) 908-8180. Fax (678) 623-3765

6-Date summary prepared: September 16th, 2006
7-Device Trade or Proprietary Name: CELLU M6 KEYMODULE i
8-Device Common or usual name: Massager
9-Device Classification Name: Electrical Therapeutic Massager
10-Substantial Equivalency is claimed against the following devices:

1- LPG One (formerly LPG USA) ES1 Massager- 510k #K990445
2- Shepard Medical's Sport Pump- 510k #K912004
3- Progressive Medical's Multipulse Sequential Compression unit- 510k #K914774
4- Grad-Line's Atlant's- 510k #K974395
5- Model SC-3008 Sequential Circulator- 510k #K043423
6- Flexitouch (also known as Biotouch)- 510k #K013061

11-Description of the Device:

The Cellu M6 Keymodule i electrical therapeutic massager is comprised of a program console housing a vacuum pump and a regulation system. The main treatment head i50 consists of two parallel motorized rollers housed in a chamber which produces both negative pressure above the rollers and positive pressure below the rollers. This technology creates a skin fold between the two rollers in a suction chamber, thus mimicking the "rolled palpation" of manual massage techniques.

In addition to Head i50 which is meant primarily for the upper arm and for legs, auxiliary heads T615, T615-A, T630, T630-A, T644 and T644-A are also used, as they better suit smaller morphology (parts) of the body. Details are provided along the labeling provided.

This device has the capability to produce both constant and sequential aspiration. Constant aspiration provides a deeper massage, which also mobilizes the muscle fascia. With sequential aspiration, the suction power is cyclically interrupted to provide pulsation to the skin fold between the two rollers and a softer, gentler stroking action of the tissues.

The suction power ranges from 45 mm Hg to 180 mmHg, which is represented by a power level scale ranging from 1 to 4.

12-Intended use of the device: (refer to FDA form attached)

The intended uses of this device are:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Reduction of secondary lymphedema of the Arm (SLA) Post Mastectomy
Improvement of secondary lymphedema
Improvement of lymphatic circulation in the treated area

13-Safety and Effectiveness of the device:

This device is safe and effective as the predicate devices cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate devices. Refer to the explanations/details within the main submission.

FDA file reference number	510k # K912004, K914774, K974395, K043423 and K013061	510k #K990445
TECHNOLOGICAL CHARACTERISTICS	**Comparison result of this device with the predicate devices**	
Indications for use	Identical	Different
Target population	Identical	Different
Design	Similar in terms of mode of action	Very similar
Materials		
Performance		
Sterility	Not applicable	
Biocompatibility	Similar	
Mechanical safety		
Chemical safety	Not applicable	
Anatomical sites	Similar	Similar
Human factors		Similar
Energy used and/or delivered		Very similar
Compatibility with environment and other devices		Identical
Where used		Similar
Standards met		Very similar
Electrical safety		Very similar
Thermal safety	NOT APPLICABLE	
Radiation safety		

Refer to the submission for more details.

PAGE 3.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT 2

510(k) Summary
As Required by 21 section 807.92 (c)

Amended / revised. (see final version)

1-Submitter Name: LPG One, Inc
2-Address: 801 Brickell Ave. Suite 850. Miami, FL 33131
3-Phone: (305) 379- 8800
4-Fax: (305) 375- 0903
5-Contact Person (Consultant): Jay Mansour of Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA
(678) 908-8180. Fax (678) 623-3765
6-Date summary prepared: September 16th, 2006
7-Device Trade or Proprietary Name: CELLU M6 KEYMODULE i
8-Device Common or usual name: Massager
9-Device Classification Name: Electrical Therapeutic Massager
10-Substantial Equivalency is claimed against the following devices:

1- LPG One (formerly LPG USA) ES1 Massager- 510k #K990445
2- Shepard Medical's Sport Pump- 510k #K912004
3- Progressive Medical's Multipulse Sequential Compression unit- 510k #K914774
4- Grad-Line's Atlant's- 510k #K974395
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This device has the capability to produce both constant and sequential aspiration. Constant aspiration provides a deeper massage, which also mobilizes the muscle fascia. With sequential aspiration, the suction power is cyclically interrupted to provide pulsation to the skin fold between the two rollers and a softer, gentler stroking action of the tissues.

The suction power ranges from 45 mm Hg to 180 mmHg, which is represented by a power level scale ranging from 1 to 4.

12-Intended use of the device: (refer to FDA form attached)

The intended uses of this device are:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2013-1897; Released 9/15/14

Reduction of secondary lymphedema of the Arm (SLA) Post Mastectomy
Improvement of primary and secondary lymphedema
Prevention of venous stasis and venous insufficiency
Improvement of lymphatic circulation in the treated area

13-Safety and Effectiveness of the device:

This device is safe and effective as the predicate devices cited above. This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate devices. Refer to the explanations/details within the main submission.

FDA file reference number	510k # K912004, K914774, K974395, K043423 and K013061	510k #K990445
TECHNOLOGICAL CHARACTERISTICS	**Comparison result of this device with the predicate devices**	
Indications for use	Identical	Different
Target population	Identical	Different
Design	Similar in terms of mode of action	Very similar
Materials		
Performance		
Sterility	Not applicable	
Biocompatibility	Similar	
Mechanical safety		
Chemical safety	Not applicable	
Anatomical sites	Similar	Similar
Human factors		Similar
Energy used and/or delivered		Very similar
Compatibility with environment and other devices		Identical
Where used		Similar
Standards met		Very similar
Electrical safety		Very similar
Thermal safety	NOT APPLICABLE	
Radiation safety		

Refer to the submission for more details.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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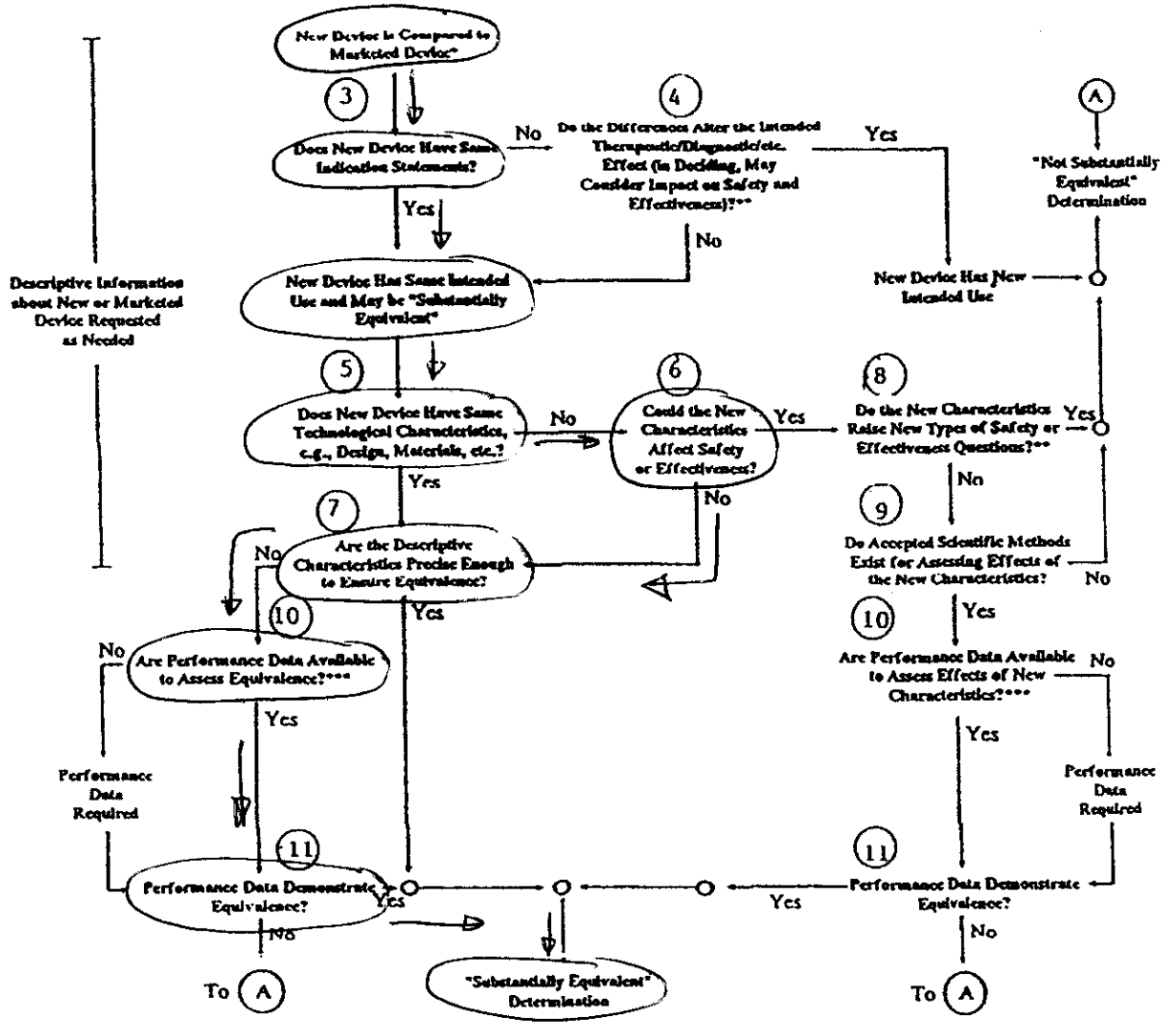
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FINAL

Indications for Use

510(k) Number (if known): K053225

Device Name: CelluM6 Keymodule i

Indications For Use:

Reduction of Secondary Lymphedema of the Arm (SLA) Post Mastectomy
Improvement of Secondary Lymphedema
Improvement of lymphatic circulation in the treated area

Prescription Use ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K053225

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

PAGE 4.1

510(k) Number_____

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT 3

Indications for Use

510(k) Number (if known): K053225

Device Name: CelluM6 Keymodule i

Indications For Use:

~~Reduction of secondary lymphedema of the Arm (SLA) Post Mastectomy~~
~~Improvement of primary and secondary lymphedema~~
~~Prevention of venous stasis and venous insufficiency~~
~~Improvement of lymphatic circulation in the treated area~~

Amended / revised. (see prior page.)

Prescription Use ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SUBSTANTIAL EQUIVALENCE COMPARISON TABLE FOR ALL PREDICATE DEVICES

K990445 included as having very similar technological characteristics as K053225

K912004, K914774, K974395, K043423 and K013061 included as having same indications for use as K053225

CRITERIA	CelluM6 Keymodule i	CelluM6 ES1 Therapeutic Massager	Sports Pump	Talley MultiPulse Sequential Compression	ATLANT'S	Sequential Circulator Model SC-3008	Predicate Added: FlexiTouch® (aka Biotouch)
510k Clearance	**K053225**	**K990445**	**K912004**	**K914774**	**K974395**	**K043423**	**K013061**
Manufacturer	LPG Systems	LPG Systems	Shepard Medical Products, Inc.	Progressive Medical Technology/ Talley Group, Ltd.	Grad-Line Corp.	Bio Compression Systems, Inc.	Tactile Systems Technologies, Inc.
Mechanical Action	Positive pressure against rollers + negative pressure between rollers (see Tab ___)	Positive pressure against rollers + negative pressure between rollers	Positive pressure	Positive pressure	Positive pressure	Positive pressure	Positive pressure
Net Action Result	Dynamic fluid displacement caused by wave action	<Cleared as massager>	Dynamic fluid displacement caused by wave action	Dynamic fluid displacement caused by wave action	Dynamic fluid displacement caused by wave action	Dynamic fluid displacement caused by wave action	Dynamic fluid displacement caused by wave action
Programmable Sequential Time	30-100 cycles per second (cyclically interrupted aspiration)	Not Applicable	15-220 seconds inflation time 15-175 seconds deflation time	30-120 seconds inflation time Auto-2 minutes deflation time	1-99 minutes inflation time	30 seconds inflation time 5 seconds deflation time	1-3 seconds inflation and deflation time
Sequential Action	Yes; a "rolling chamber" created by rollers contained in treatment head	Not Applicable	Yes; (chamber number not available)	Yes; 10 chambers sequentially filled	Yes; multi-chambers created by particle filled garment	Yes; 8 chambers sequentially filled (4 chambers used in study)	Yes; 32 chambers (combined trunk & limb) sequentially filled
Pressure Range for Lymphedema Treatment	45-180 mmHg	Not Applicable	0-185 mmHg	0-130 mmHg	10-100 mmHg	25-100 mmHg	30-40 mmHg
Maximum Pressure	180 mmHg	412 mmHg	185 mmHg	150 mmHg	100 mmHg	150 mmHg	60 mmHg
Weight	90 kg	79 kg	Not Available	11.2 kg	5.5 kg	17.6 kg	Not Available
Amperage	8.7 amp	8.7 amp	Not Available	5 amp	0.5 amp	5 amp	Not Available
Voltage	115V, 60 Hz	115V, 60 Hz	120V	200/250V, 50 Hz	110V, 60 Hz	120 V, 60 Hz	Not Available
Depth, width, height	60 x 46 x 210 cm	60 x 60 x 188 cm	Not Available	43 x 26 x 31 cm	Not Available	14 x 31.7 x 22.2 cm	Not Available

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ATTACHMENT 4

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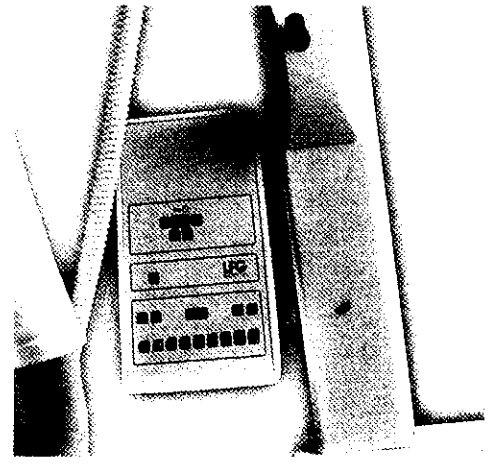
ATTACHMENT 5A

Description/Comparison of the Device

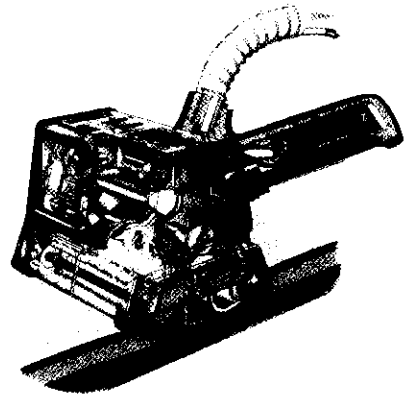
The original version of the LPG therapeutic massage device, the ES1, was classified and distributed in the United States as a Class 1 medical device exempted from pre-market notification[1], product codes 89 ISA and 89 IRO, panel physical medicine. The device name was listed as a Therapeutic Massager (21 CFR Section 890.5660), with a proprietary name of LPG Therapeutic Massager, Model ES1.

Cellu M6 ES1 Model



Analog Display

The treatment head of the ES1 model was patented under 4.729.368 US and contained more than (b)(4) [redacted] individual parts. Only 3 static auxiliary heads were available with this model. A front panel (analog) allowed the user to enter the parameters (time, power, main or auxiliary hose selection, cleaning mode.) The pump power of the ES1 reached a maximum negative pressure of 412 mmHg and had a treatment power level scale ranging from 1 to 9. (See comparison table Tab 7.)



Cellu M6 ES1 Main Treatment Head

[1] Cleared later on under 510k #K990445 in order to cover the indication for use related to burn rehabilitation, being prescription use

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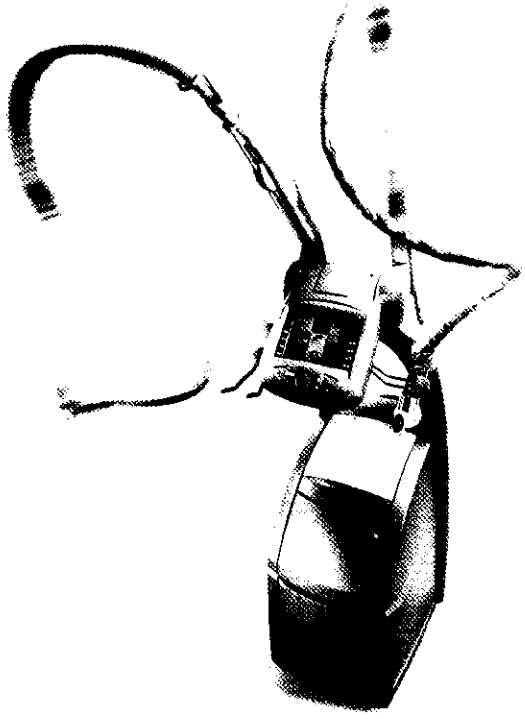
(b)(4)

[redacted]

The Cellu M6 Keymodule i is the latest version of the LPG professional machines with a state-of-the art design. Based on the company's internal evaluation system, the Cellu M6 Keymodule i is equivalent to the ES1. Both the ES1 and the Cellu M6 Keymodule i utilize constant aspiration in a closed loop process. However, one cycle of the ES1 is equivalent to 3 cycles of the Cellu M6 Keymodule I (3:1 ratio.) Or conversely, one cycle of the Cellu M6 Keymodule i is equivalent to less than one quarter of the ES1.

More simply put, the cycle time of the Keymodule is shorter, smoother and utilizes more consistent pressure than the ES1 model. The improvements to the operating principles of the Cellu M6 Keymodule i allow for increased sharpness of regulation (more consistent range of suction within a power level), a smaller functioning threshold and a shorter mechanic time delay resulting in quicker action. (See Mode of Function graph and schematic flowcharts for the ES1 and Keymodule Tab 9 & 10.)



Cellu M6 Keymodule i Model

Digital Display

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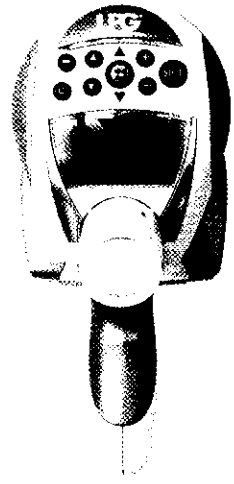
Like the ES1, the Cellu M6 Keymodule i therapeutic massager is comprised of a program console housing a vacuum pump and a regulation system. The improved design of the Cellu M6 Keymodule i updates the front panel to digital technology, providing the user with a menu of pre-set programs for specific treatments. The pump power can reach a maximum pressure of 180 mmHg, and has a treatment power level scale ranging from 1 to 4. (See comparison table Tab 7.)

A regulation bloc regulates the vacuum pressure according to the power selected by the user. This regulation bloc was piloted by a regulation board in the ES1 model and is regulated by a piloting board in the Cellu M6 Keymodule i. (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted] The mechanics of the regulation bloc have been improved with new technology, allowing for increased sensation to the client.

The main treatment head is protected by United States patent number 4.729.368 from the ES1 model, as well as by a new patent number of 4.883.047. As with the ES1 model, (b)(4) [redacted] (b)(4) [redacted] Both main treatment head and auxiliary heads have been re-designed for ease of use for the operator and greater efficiency for the client (i.e. lighter weight, swivel hose, adaptation of detachable i50 roller head, choice of spring-loaded or static auxiliary heads.)

As with the ES1, the Cellu M6 Keymodule i treatment contains (b)(4) [redacted] rollers housed in a chamber which produces both negative pressure above the rollers and positive pressure below the rollers. This technology creates a skinfold between the two rollers in the suction chamber, thus mimicking the "rolled palpation" of manual massage techniques. The updated design of the Cellu M6 Keymodule i has the capability to produce both (b)(4) [redacted] (b)(4) [redacted] aspiration in order to provide a pulsation to the skin and massage the tissues in various ways, including the specific wave-like movement for the lymphedema-related conditions indicated in this paper.



Cellu M6 Keymodule i Main Treatment Head (T70)

The LPG Technique: Applicable for both Cellu M6 Keymodule i and ES1

The LPG technique involves mobilization of the subcutaneous and cutaneous tissues accomplished with both versions: Keymodule and ES1. (b)(4) [redacted] The rollers come together or are drawn apart in relation to the parameters of the program selected (b)(4) [redacted] the roller width of the treatment head selected (main head for ES1, i50 head attachment head for Keymodule or auxiliary heads), the type of tissue encountered and the power level selected. (The Keymodule has 4 power levels for lymphedema treatment, while the ES1, being a general therapeutic massager, has 9 power levels. (b)(4) [redacted]

Vertical and horizontal maneuvers can be performed with both Keymodule and ES1 treatment heads, allowing them to displace fluids and reach specific tissue layers, respectively. (b)(4) [redacted] aspiration settings (only available with Keymodule) can be used to perform lighter, more superficial massage strokes (b)(4) [redacted] aspiration settings (available with both Keymodule and ES1) can be used to perform a more static massage and mobilize more blood flow to the skin's surface.

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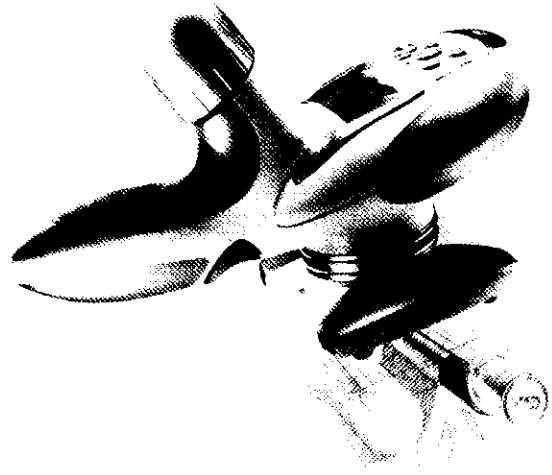
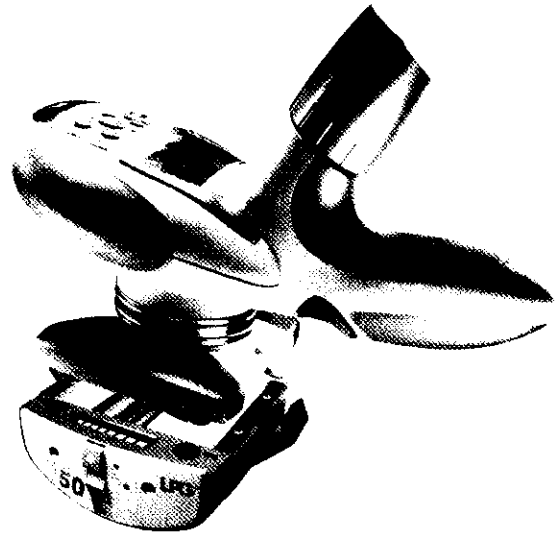
Main treatment head for treatment of lymphedema:

The Cellu M6 Keymodule i device has a detachable motorized roller treatment head (i50) which attaches to the main head base (T70) and connects to the main hose on the left.



Cellu M6 Keymodule i Main Treatment Head (T70)

The i50 attachment head is designed to be used for treatment of relatively small body surface areas. Its rollers measure 26 mm in diameter and 54 mm in length. The size of these rollers can be adapted more efficiently to body parts, such as the upper arms and the calves, which are common sites requiring lymphedema treatment.



Keymodule T70 Treatment Head with i50 Attachment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Auxiliary treatment heads for treatment of lymphedema:

The Cellu M6 Keymodule i also contains a set of 6 auxiliary heads: 3 (b)(4) [redacted] auxiliary heads called *Active* heads, and 3 static auxiliary heads called *Inactive* heads. These heads can be used for treating lymphedema in even smaller areas of the body, such as the axillary areas, forearms and wrists in *Secondary Lymphedema of the Arm Post-Mastectomy*, and ankles in lower extremity lymphedema.

The auxiliary heads are (b)(4) [redacted] and they are attached to a separate auxiliary hose on the right of the machine when used. There are three sizes of each *Active* and *Inactive* auxiliary heads: a large one (44 mm x 44 mm), a medium one (30 mm x 30 mm) and a small one (23 mm x 15 mm), which are used according to the morphology of the treated area when needed.

The function of the springs in the *Active* auxiliary heads allows for optimal movement of the rollers on the tissues when using the (b)(4) [redacted] aspiration (b)(4) [redacted]) programs designed for performing lighter, more superficial massage strokes and (b)(4) [redacted] The function of the *Inactive* auxiliary heads is to correspond to the static action of the (b)(4) [redacted] aspiration settings for more static massage and mobilizing more blood flow to the skin's surface.

Active (b)(4) [redacted] Auxiliary Head
and
Inactive (Static Rollers) Auxiliary Head

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ATTACHMENT 5B

CELLU M6 ES1 vs. CELLU M6 KEYMODUL
TECHNOLOGICAL COMPARISON

Technical Specifications	Cellu M6 ES1®	Cellu M6 Keymodule i®
Mechanism of action	Aspiration + rollers	Aspiration + rollers
Pump power	Maximum negative pressure : 412 mmHg	Maximum negative pressure : 180 mmHg
Length of rollers	Main head: 65 mm Aux heads: 44 mm, 30 mm, 23 mm	i50 head attachment: 54 mm Aux heads: 44 mm, 30 mm, 23 mm
Diameter of rollers	Main head : 24 mm Auxiliary heads: 18, 14, 10 mm	i50 head attachment: 26 mm Auxiliary heads: 18, 14, 10 mm
Motorization of rollers	Main head only (not auxiliary)	T70 head + i50 head attachment (not auxiliary)
Power scale	1 : 82 mmHg 2 : 97 mmHg 3 : 150 mmHg 4 : 187 mmHg 5 : 225 mmHg 6 : 244 mmHg 7 : 281 mmHg 8 : 319 mmHg 9 : 412 mmHg	1 : 45 mmHg 2 : 90 mmHg 3 : 135 mmHg 4 : 180 mmHg
Power used during clinical trials	Blood circulation (b) (6), (b) (4) 3-4 using main treatment head	Secondary lymphedema of the arm post-mastectomy (b) (4) : 1-4 using i50 treatment head attachment or auxiliary heads
Speed of motorized roller rotation	(b)(4)	(b)(4)
Power source	Power cord	Power cord
Parameters display	Control panel (analog)	Control panel (digital)
Treatment sites	Body and extremities	Body and extremities

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ATTACHMENT 5C

LPG

CELLU M6 KEYMODULE i- COMPONENTS LIST

(b)(4)

[redacted]

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ATTACHMENT 5D

(b)(4)

[redacted]

Cellu M6® ES1

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PG

(b)(4)

[redacted]

Cellu M6® Keymodule i

PAGE 9.2 51

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(b)(4)

[redacted]

Mode of Function

ATTACHMENT 5E

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ATTACHMENT 6

TABLE DETAILING WHICH HEAD(S) WERE USED DURING SOFTWARE TESTING, FOR EACH OF THE TESTS CONDUCTED [see mark √]

TEST CASE NUMBER	HEAD(S) USED IN THE TESTING						
Refer to pages 26 to 88 of Attachment 7 (Tab 12) in Supplement S1	i50	T615	T615-A	T630	T630-A	T644	T644-A
Page 27- test case	(b)(4) [redacted]						
Page 28- test case							
Page 29- test case							
Page 30- test case							
Page 31- test case							
Page 32- test case							
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Page 86- test case							
Page 87- test case							
Page 88- test case							

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

SOFTWARE PROTOCOL- Addendum

Objective: the objective of this protocol addendum is to provide further explanations on attachment 7 (Tab 12) of Supplement S1, as well as to the table included at the beginning of this Supplement S2 attachment 6, showing which tests were tested for which software testing.

Background: Keymodule i has 2 separate hoses (LEFT and RIGHT), each one ending with a different control head.

- HOSE #1 (LEFT): The first control head [redacted] (b)(4) the attachment [redacted] (b)(4) is connected. [redacted] (b)(4) are transferred from [redacted] (b)(4) into the attachment [redacted] (b)(4) for [redacted] (b)(4).
- Most of the test sheets conducted on the left hose are really independent of whether [redacted] (b)(4) head attachment is connected to Head base [redacted] (b)(4) or not. **Nevertheless, [redacted] (b)(4) was connected to [redacted] (b)(4) for all software testing applicable for the left hose.**

- HOSE #2 (RIGHT): The second control head is called [redacted] (b)(4) Head, to which one attachment out of 6 options may be connected. These 6 options are again divided into two sub-categories. The first sub-category is Active Auxiliary head attachment and includes ONLY T644-A, T630-A, and T615-A. The second sub-category is NON Active Auxiliary head attachment and includes ONLY T644, T630, and T615. The only difference between Active and Non Active attachments is that the Active attachments have the [redacted] (b)(4) [redacted] (b)(4)
- All 6 Auxiliary Head attachments (Active and Non Active) have no electrical and/or mechanical components that are [redacted] (b)(4). Therefore, the usage of any of these 6 attachments has [redacted] (b)(4) on software testing as well as its functionality. The controls are rather located at [redacted] (b)(4) [redacted] (b)(4) itself. **Nevertheless, each of [redacted] (b)(4) [redacted] (b)(4) was connected to [redacted] (b)(4) for all software testing applicable for the right hose.**

Certification:

Not withstanding the above, we confirm and certify that all tests submitted in Supplement S1 (Tab 12, Attachment 7) have been conducted while the head(s) applicable for each of the tests was (were) appropriately connected. The table entitled *"table detailing which head(s) were used during software testing, for each of the tests conducted"* (attached at the beginning of this tab) is explained below:

1- **Each check mark (√) identifies which head attachment(s) apply for each test**

2- **Each check mark (√) confirms that the identified head attachment(s) was (were) indeed connected during the testing**

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Document mapping for test sheets in Supplement S1, Tab 12:

Refer to last paragraph of page 21 **outlining** the different test sheet sections.

Refer to pages 22, 23 and 24 **detailing** the different Software Requirements Specifications (SRS).

As per pages 21 to 24, the following sections are identified:

SRS-G-xxx : Overall/general
SRS-HI-xxx : Human Interface
SRS-R-xxx : Regulation
SRS-PH-xxx : Principal Head
SRS-AH-xxx : Auxiliary Head
SRS-MP-xxx : Maintenance Programs

The same numbering system is used throughout test sheets to define the "Test Case Number" (i.e., being the first row in each test sheet)

Illustration/Example:
The test procedure numbers on the test sheets (i.e., (b)(4) [redacted]) are specified in the SRS (i.e., page 24, prog 61). They both have the same reference numbers, i.e., (b)(4) [redacted].

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510(K) MEMORANDUM

11/2/06

TO: K053225/S002

FROM: Dora Vega, M.D., Ph.D.,
ODE / DGRND
Restorative Devices Branch (HFZ-410)

DATE: October 27, 2006

SUBJ: Cellu M6 Keymodule i Massager

CONTACT: Jay Mansur
C/o Mansur Consulting, LLC
845 Aronson Lake Court
Roswell,
GA 30075
Ph: (770) 777-4146. Fax: (678) 623-3765

Procode: ISA
Class: I
Regulation Number: 21 CFR 890.5660 – Therapeutic Massager
Regulation Name: Physical Medicine

Recommendation: Review of the information in this application allows determine SE between Cellu M6 Keymodule i massager and the predicates.

Reason for this submission: To provide response to the FDA's request for additional information to obtain the clearance of the Cellu M6 Keymodule i, which is proposed to be substantially equivalent to the currently marketed SportMed Pump, K912004, (Sheppard Medical); Multipulse Sequencial Compression Unit, K914774, (Progressive Medical); Atlant's, K974395, (Grad-Line), and Flexitouch, Biotouch, K013061.

Reviewer's Comments: The reason of this S002 submission is to provide response to the FDA's request for AI, letter dated June 15, 2006.

In Supplement S001 the sponsor's provides adequate response to the review concerns issued in fax dated January 13, 2006. However additional information/clarification was necessary in order to

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determine device equivalence with the predicates, (see listing of deficiencies in this memo.)

REVIEW:

Device Description: The proposed Cellu M6 Keymodule i is a powered suction massager that operates in conjunction with head treatment rollers and is intended for use for "Reduction of secondary lymphedema of the arm (SLA) post-mastectomy; improvement of primary and secondary lymphedema; prevention of venous stasis; and improvement of lymphatic circulation in the treated area."
LPG One, Inc., claims that the proposed device is SE to the inflatable Shepard Medical Sport Pump, K912004; Progressive Medical Multipulse Sequential Compression Unit, K914774; Grad-Line's Atlant's, K974395, and Flexitouch, Biotouch, K013061 (an additional predicate provided in the current supplemental submission, S002.)

1. **Comparison of the Intended Use/Indications of the Subject Device and Predicate(s)**

Subject Device
The Cellu M6 Keymodule I was originally intended for the following Indications for Use:

- "Reduction of secondary lymphedema of the arm (SLA) post-mastectomy.
- *Reduction of lymphedematous fibrotic induration (*)*
- Improvement *of primary* and secondary lymphedema *(**)*
- *Prevention of venous stasis (**)*
- *Prevention of deep venous thrombosis (*)*
- Improvement of lymphatic circulation in the treated area."

At the FDA's request, LPG One elected to remove two of the originally intended Indications for Use for the device (*) in S002. However, at the FDA during review of this supplemental S002 submission, LPG One removed two additional original claims (**) at the FDA's request, (see section "Deficiencies" in this Memo.)

Predicate device(s)
The IFU for the predicates Shepard Medical Sport Pump, K912004; Progressive Medical Multipulse Sequential Compression Unit, K914774; and Grad-Line's Atlant's, K974395 are:

- Shepard Medical Sport Pump, K912004: "Is indicated for acute care of the arm and leg swelling; treatment of chronic edema; treatment of lymphedema, including post-traumatic and rheumatic edema and chronic venous insufficiency and venous stasis ulcers"

- Progressive Medical Multipulse Sequential Compression Unit, K914774: "Is indicated for primary lymphedema; post-mastectomy edema; leg ulcers; edema following trauma and sport injuries; post-immobilization edema; prophylaxis of deep vein thrombosis; and venous insufficiencies due to muscle inactivity."

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- Grad-Line's Atlant's, K974395: "Is indicated for treatment of chronic venous insufficiency; lymphedema; edema of venous origin; post-amputation; lymphatic obstruction; wound healing; and contusion."

In Supplement S002 the sponsor provides the additional predicate Flexitouch, Biotouch, K013061, which is intended for the following IFU, (IMAGE system):

- Primary lymphedema,
- Post-mastectomy edema
- Leg ulcers
- Edema following trauma and sport injuries
- Post-immobilization edema,
- Venous insufficiencies, and
- Lymphedema.

Discussion of whether the intended use/indications are the same.
The proposed Indications for Use except "reduction of lymphedematous fibrotic induration," were found SE to the intended use of the predicates. At the FDA's requests the specific indication for use for *"reduction of lymphedematous fibrotic induration,"* has been removed from the device IFU statement in S001, (* above.) However, given that the device has different technology (i.e., operates under suction / vacuum pressure compared with compression pressure in the predicates, safety concerns are raised for the specific use of the device for *"prevention of deep venous thrombosis" and "prevention of venous stasis."*

2. **<u>Comparison of the Technological Characteristics (Design, Materials, Sizes, Shapes, etc.) of the Subject Device</u>**
The Cellu M6 Keymodule I represents the last version of the LPG – ES1 therapeutic massager exempted from pre-market notification by 21 CFR Section 890.5660. The proposed Cellu M6 Keymodule device has changes in the design, materials, and performance specifications compared to the previously cleared ES1 device.

✓ The device power suction ranges between 50-500 mmHg and is scaled from level 1 to 10. The device can produce both, (b)(4) [redacted] aspiration to produce the massaging action on tissues. The device is comprised of a program console housing the vacuum pump and a regulation system. The device treatment head consists of (b)(4) [redacted] rollers placed inside a chamber, which produces negative pressure above the rollers and positive pressure below the rollers creating a skin fold between the two rollers in the suction chamber mimicking a manual rolling massage technique (i.e. suction skin fold) where roller A folds up the tissues and roller B unfolds them down. The Cellu M6 device has the capability to move the rollers forward, backward, inward, or in the outward direction -independently or together-, which enables the operator to massage the skin in a variety of skin folds shape, depth and thickness (e.g., roll-in, roll-out and roll-up.) Also the variable aspiration setting allows perform a deeper or more superficial massage to tissues.

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Predicate Device(s)
Briefly, the technological characteristics of the predicates are as follow:

- Shepard Medical Sport Pump, K912004. Is a powered two –interior and exterior- inflatable bladder massager cleared as Class II device. The interior bladder is longitudinally compartmentalized in cells, and the exterior bladder allows a single cell intermittent compression or sequential compression. The device consists in a triple wall sheath designed to wrap/encase the arm or leg. A positive pressure exerted by the liquid or air in the bladders forces the tissue fluids be moved / drained into the underlying lymphatic vessels.

- Progressive Medical Multi-pulse Sequential Compression Unit, K914774. It consists in a 10 individual inflatable chambers with adjustable pressure control and readout gauge. Three of the 10 chamber are inflated at a time to allow the therapist to adjust the pressure within the range of the patient's comfort. The device has multi-pulse setting, which consists in the alternative inflation and deflation of the chambers provide sequential wave of compression up the limb (i.e., "milking" action.) It also has a multi-port garment attachment. It is a typical compression device.

- Grad-Line's Atlant's, K974395. It consists in inflatable boots or sleeves massagers which creates a linear and dynamic pressure gradient over the limbs. It has three different pressure curves, which can be operated at three different speeds: slow, medium and fast. The device is made from micro-porous foam encapsulated between two layers of neoprene. When the device is turned-on the air is forced into the distal part of the device and creates a positive pressure, which decreases as air diffuses following a linear gradient of pressure.

- Biotouch, K013061 consists in a pneumatic compression device controlled by a microprocessor. The pressure is sequentially exerted on tissues (i.e., leg, arm, trunk, and/or chest to decrease accumulation of tissue interstitial fluids and facilitate fluid absorption.

Discussion of whether the subject device has a significant change in technological characteristics.
Cellu M6 Keymodule I represents the last version of the LPG – ES1 therapeutic massager exempted from pre-market notification by 21 CFR Section 890.5660. It has slight changes in design, materials, and performance specifications compared to the previously cleared ES1 device.
Briefly, Cellu M6 Keymodule I is a cyclic and discontinuous aspiration / suction pump that produces a "tissue wave" massaging action on tissues, and ultimately facilitates circulation of interstitial fluids. For the device specific intended use in the submission, the variable roller settings will operate with vacuum forces up to ~180 mm Hg pressure.
The predicates are compression inflatable devices (i.e., boots, sleeves), which exert local

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increased pressure at the site to mechanically produce a similar "tissue wave" movement that facilitates circulation / absorption of tissue interstitial fluids.
Therefore, the main difference in technology between the proposed and the predicate devices is that the predicates' source of mechanical massage is the device air or fluid compression exerted on tissues, while in the Cellu M6 device the vacuum suction between both rollers is the source of the mechanic pulsation forces to the tissues to allow drainage of interstitial fluids. But, in both cases, the mode of action of these devices is to increase the local interstitial circulation of fluids but generating equivalent pressure forces in tissues for the same IFU (i.e., reduction of lymphedema.

Note that the previously cleared LPG – ES1 -owned by the sponsor- is also a suction therapeutic massager that was exempted from pre-market notification by 21 CFR Section 890.5660, Pro-code 89 ISA and 89 IRO, Physical Medicine panel. The proposed Cellu M6 Keymodule i device operates also using the *same mode of action –i.e., suction/vacuum pressure* to facilitate mechanical movement of accumulated interstitial tissue fluids (i.e., drainage). In this submission, the Cellu M6 massager proposes a new intended use (i.e., treatment of lymphedema), which falls under 21 CFR 890.9 - Limitations of exemptions from section 890.5660, but this IFU is identical to that of the predicates, and the device technological specifications such as device vacuum pressure has been reduced to show equivalence with the predicates.

Comparative Data: Safety (in vitro, animal and/or clinical) – Effectiveness Data

Subject Device
LPG One, Inc. states that the material specifications and biocompatibility are the same that those in the LPG Massage Vibrator cleared in K990445.
In addition, the sponsor provides the report of a clinical study on pneumatic compression devices in 10 subjects (original application, Appendix 20) and 45 subjects (original application, Appendix 24), and scientific literature to support the device safety and effectiveness (Attachment 9, 10a, and 15a, S001.)

Predicate Device(s)
The predicate in this application have provided biocompatibility data to comply with safety issues for all body-contacting materials for clearance purposes.

A listing of the original review concerns regarding the device safety and effectiveness was issued to the sponsor on January 1, 2006, (fax dated January 1, 2006), and in additional letter S001, (AI letter dated June 15, 2006.)
The current submission consists in the LPG's response to the FDA's request for AI, Supplemental submission S002, which is discussed below:

Deficiencies

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Deficiency #1: You confirmed your acceptance to change the device's prescription statement to be: "Caution: Federal law restricts this device to sale by or on the order of a clinician licensed by the Law of the State where she/he practices to use or order the use of the device."
All or our labeling documents have been updated accordingly." However, it was not included in the first page of the device labeling. Please revise your labeling to include the prescription label in the first page of the device labeling.

Sponsor's response to Def. #1: *LPG One states that:*

- *The device's prescription statement "Caution: Federal law restricts this device to sale by or on the order of a clinician licensed by the Law of the State where she/he practices to use or order the use of the device," has been added on the cover page and the following page on the brochure, on the first page of "Directions for Use."*

Reviewer's comments/recommendation: - Def. #1: Adequate
Comments: The sponsor's response is self-explanatory, and satisfies the FDA's request.

Deficiency #2: Your response dated May 9, 2006 states that the device labeling has been updated to reflect only their specific indications for use as mentioned on page R (Tab 7) or the submission, and that these changes are: (a) Reduction of secondary lymphedema; (b) Reduction of lymphedematous fibrotic induration; (c) Improvement of primary and secondary lymphedema; (d) Prevention of venous stasis and venous insufficiency; (e) Prevention of deep vein thrombosis (DVT); and (f) Improvement of lymphatic circulation in the treated area. The use of your device for *fibrotic induration* is not substantial equivalent to the Indications for Use for the predicates. Also, section "Selectivity," Therapeutic benefits, Attachment 31, page A4 in your response indicates *"deep vein thrombosis as therapeutic use* for the device." Please provide medical scientific rationale and supporting clinical performance data for the use of the device for these IFU and a discussion on why you claim substantial equivalence with the predicates, which contraindicate the use of the device in deep vein thrombosis and thrombophlebitis. Otherwise, please remove these claims for the device labeling.

Sponsor's response to Def. #2: *LPG states that:*

- *The company elects to remove two Indications for Use from the original list:*
  a. Reduction of lymphedematous fibrotic induration, and
  b. Prevention of Deep Vein Thrombosis (DVT)

- *The remaining four indications for use intended by the sponsor for clearance in this submission are:*
  - ✓ *Reduction of secondary lymphedema;*
  - ✓ *Improvement of primary and secondary lymphedema;*
  - ✓ *Prevention of venous stasis and venous insufficiency; and*
  - ✓ *Improvement of lymphatic circulation in the treated area.*

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Reviewer's comments/recommendation: - Def. #2: Adequatel requested
Comments: The IFU the sponsor intends the clearance of:

- ✓ Reduction of secondary lymphedema of the arm (SLA) post-mastectomy;
- ✓ Improvement *of primary* and secondary *lymphedema*;
- ✓ *Prevention of venous stasis and venous insufficiency;* and
- ✓ Improvement of lymphatic circulation in the treated area.

Note that the sponsor deems unnecessary clinical data to support differences in technology with the predicates based on a statement that *"Dr. Carlos Pena and Mr. Ted Stevens agreed at an earlier stage of the negotiations that we [the company] were allowed to compare our technological characteristics against one device, while we are allowed to compare our clinical effectiveness against another device. The reason is that there is no predicate device with the same product code ISA for the same indications for use being submitted now."*
The sponsor's assertion was consulted with Dr. Pena, who provided the sponsor's consultant e-mail and the FDA internal discussion and conclusion that the sponsor *"should be comparing his new device to the inflatable tube massager,"* to demonstrate device equivalence in technology for the intended use, (see e-mail dated February 27, 2006 enclosed in the file.)

Although the Indications for Use for the device in this submission are equivalent to those for the predicates, the proposed CelluM6 Keymodule device differs in technology with the predicates, (i.e., CelluM6 Keymodule operates under *vacumm/succion negative pressure* instead of *only inflatable/fluid positive pressure as in the predicates),* which requires clinical performance data to demonstrate equivalence in device performance.

In addition, the sponsor's intended clearance of the primary lymphedema is found not equivalent to secondary lymphedema of the arm. The etiology of primary and secondary lymphedema is not necessarily similar. Use of the device for lymphedema of varied etiology raises safety concerns for device performance, which require clinical performance data. The clinical study report regarding the predicate Flexitouch supports the device safety and effectiveness for the specific predicate's inflatable-pressure technology, but not necessarily reflects equivalent device performance for the CelluM6 device, which differs in technology. The FDA requests to provide clinical performance data to demonstrate similar device performance in primary lymphedema of the arm, or remove this statement from the device proposed claims.

Venous stasis and venous insufficiency also are medically considered predisposing factors for appearance of DVT, and comprised under "*Prevention of Deep Vein Thrombosis (DVT),"* which the sponsor elected to remove from the IFU statement at the FDA's request. No clinical performance data that demonstrate device safety for the intended use for prevention of DVT / Thrombophebitis have been provided. Accordingly, the FDA requests to remove the specific device IFU *"Prevention of venous stasis and venous insufficiency"* as in case of the claim for use of the device in *"Prevention of DVT"* given that there is no clinical data to support equivalence in device performance with the predicates.

In summary the FDA requests LPG One remove the device IFU for "*primary lymphedema*", and

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"*prevention of venous stasis and venous insufficiency*"; or provides clinical performance data that support equivalence the clinical device performance for these specific intended uses.

On October 31, 2006, I requested Mr. Mansur, Consulting, LPG One, to remove the following additional claims for the device: "Improvement *of primary lymphedema*"; and "*Prevention of venous stasis and venous insufficiency*" based on the reasons explained in section "Reviewer Comments / Recommendation," above. The sponsor agreed to remove both claims for the device, which satisfies the FDA's request.

Deficiency #3: Your response, letter May 9, 2006 provides information that clarifies the technological specifications in the different types of the device heads (i.e., i1, i2, and i3.) However you mention that "there are three auxiliary heads intended for use for treatment of lymphedema in smaller areas of the body," (Attachment 3a and Attachment 31, page B1), which significantly differ (e.g., 45 mm x 18 mm; 30mm x 14mm; and 15mm x 10mm) from the physical dimensions reported for the heads i1, i2, and i3 reported above. In addition, the revised labeling of the device still has some apparent discrepancies in the device specifications (e.g., 500 mb, 650 mb and 700 mb maximum negative pressure in the device, Attachment 3a.) Please provide information that adequately clarifies the physical dimensions in the device heads as well as a discussion about the substantial equivalent performance of the varied dimensions in the device heads, and the vacuum.

Sponsor's response to Def. #3: *The sponsor states that:*

- *They confirm that the only head attachments in the application refer to the:*
  (a) i50 head, which is connected to the (b)(4) [redacted] *head base located at the end of the left hose of the Keymodule i, and*
  (b) T615, T615-A, T630, T630-A, T644, and T644-A, which are connected to the (b)(4) [redacted] *head base located at the right hose of the Keymodule i. These head attachments are either Active (T615-A, T630-A and T644-A) or non-active (T615, T630 and T644), Device Manual, page 6.)*
- *These head attachment have been used in clinical studies to support the device safety and effectiveness.*
- *The company has removed head attachments i1, i2, and i3 from the original listing of device head attachments proposed in this submission.*
- *Attachment 3a of the supplemental submission has been revised accordingly to the changes reported above.*
- *An explanation on the head attachments sizes and different pressures exerted by the head attachments has been provided in pages 1.6 and 1.7 in the supplemental submission S002.*
- *The head attachment dimension referred as nominal length correlates with the nominal opening (i.e., clearance between the diameter of both rollers) in table on page 1.7.*
- *Regarding the different device pressures, the 550 mbar and 650 mbar pertain to the predicate ES1. The 550 mbar is the max pressure at power 9, while 650 mbar is the theoretical rating of the pump in the predicate.*
- *Despite that the maximum theoretical rating of the pump in Cellu M6 is 700 mbar, the*

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company confirms that for the proposed indications for use, the Keymodule i is recommended to be used only at power levels 1 to 4 (i.e., maximum pressure 240 mbar or 180 mm Hg), and power 5 and above have been cancelled.

Reviewer's comments/recommendation: - Def. #3: Adequate
Comments: LPG One provides:

- ✓ Adequate clarification regarding the specific device head attachments intended for use with the device. Briefly, the sponsor mentions the model i50 which is connected to the device main (left) hose; and the T615, T615-A, T630, T630-A, T644, and T644-A head attachments, which are connected to the (b)(4) head base located at the right hose of the device. Detailed information regarding the roller treatment head i50 which attaches to (b)(4) head base is provided in Device Manual, page 6.5. Similarly information that describes the proposed auxiliary (i.e., active and inactive) treatment heads is provided in page 6.6.
- ✓ A statement that confirms that head attachments i1, i2 and i3 have been removed from the current submission and that Attachment 3a has been accordingly revised.
- ✓ Adequate explanation about the head attachments sizes (i.e., nominal length and nominal opening) and pressures.
- ✓ A statement that confirms that the device will be only used at power levels 1 to 4 (i.e., 240 mbar or 180 mm Hg), and no power level above 5 will be used for the current indications for use for the device.

Deficiency #4: You report that the software components tested has used the Stand-alone Cellu M6 Keymodule I with *various* heads attachments. However it is unclear the specific device heads tested for the intended use for the device. Please provide information that clarifies the device heads tested and a discussion about their suitability for the intended use for the device.

Sponsor's response to Def. #4: LPG One states that:

- *They confirm that all tests pertaining to the left hose and head (b)(4) base referred in the submission have been performed with the head attachment i50.*
- *Also the sponsor confirms that all tests pertaining the right hose and (b)(4) head base have been conducted when each and every one of the auxiliary head attachments were connected to the head base and individually tested.*
- *The company certifies that all other tests pertaining to all referred head attachments (i.e., i50 and auxiliary heads) have been conducted when they were connected to the corresponding head base.*
- *Table 20 describes the relationship between the device and the head attachment connected during testing.*
- *Suitability for the referred head attachment is confirmed by the previous clinical studies for ES1, which used the same head attachments proposed in this submission. (i.e., (b)(4) studies.)*

Reviewer's comments/recommendation: - Def. #4: Adequate
Comments: The sponsor's response is self-explanatory, and satisfies the FDA's concern regarding

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the device head treatment used during testing for the intended use. The clinical study reports provided in S002 support the use of the specific device head attachments and their suitability for the intended use secondary lymphedema of the arm after post-mastectomy, (Attachment 12.)

Deficiency #5: The newly introduced predicate Sequential Circulator, Model SC-3008 for your device, your letter dated May 9, 2006 is an inflatable –pneumatic- sleeve, which exerts up to 150 mm Hg pressure at the treatment site. Your Cellu M6 Keymodule I differs in the mode of action because it operates by suction reaching a maximum vacuum pressure up to 500 mm Hg - 700 mm Hg. Despite of the similar Indications for Use for the treatment of primary or adjunctive treatment of lymphedema, due to the device technological differences with the predicate Sequential Circulator, Model SC-3008 it is unclear why you claim that the clinical data submitted for the predicate can be used to support the safety and effectiveness of your device. Please provide valid scientific evidence supporting your claim for substantial clinical equivalence between your proposed Cellu M6 Keymodule I and the predicate Sequential Circulator, Model SC-3008.

Sponsor's response to Def. #5: *LPG One states that:*

- *As per the change in the device setting pressure to maximum 180 mm Hg, now the device pressure feature is comparable to 150 mmHg in the predicate Sequential Circulator, Model SC-3008.*
- *To better illustrate device equivalence with the predicates for the mode of action, they include the Biotouch, K013061 as an additional predicate. Additional attachments show conceptually the tissue wave generated by the proposed device and the predicate Biotouch and dimensional details of the tissue waves created by the proposed Cellu M6 device and this predicate.*
- *The volume of the patient's arm is reduced 186.3 ml in the Piller's II study, and by 210.5 ml in the Biotouch study.*
- *Additional information including a comparative table for clinical assessment of lymphatic drainage supporting the proposed and the predicate devices is provided in Attachment 9 in the submission.*

Reviewer's comments/recommendation: - Def. #5: Adequate

Comments:

- ✓ Given that the sponsor elects to reduce the device maximum pressure power to 4 and cancel the levels above (i.e., 5 to 9), the resulting device maximum pressure is now reduced to 180 mmHg, which is seems equivalent to the 150 mm Hg in the predicate Biotouch. Although the predicate mode of action is positive pneumatic pressure, and the forces exerted by Cellu M6 device is given by negative suction, the maximum pressure exerted on tissues by both devices (i.e., 180 mm Hg and 150 mm Hg) supports device equivalence for device tissue pressure with the predicate.
- ✓ Minor comment: Although reduction of the lymphedema is reported numerically similar (i.e., 186.3 ml in the Cellu M6 study vs. 210.5 ml in Biotouch), no conclusions can be reached regarding equivalence in device performance because the methods of assessment in these studies significantly differed, (Attachment 9.)

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Deficiency #6: Please revise the Operator's Manual to include instructions on what the user should do if the treatment head locks-up on a patient's skin during treatment.

Sponsor's response to Def. #6: *LPG One provides a revised Operator's Manual, (pages 8 and 49 – main head base T70, and o page 53 for the auxiliary head base.*

Reviewer's comments/recommendation: - Def. #6: Adequate
Comments: LPG One provides a revised Operator's Manual, which is self-explanatory and satisfies the FDA's request about the stop button that has to be pressed to release the system (Operator's Manual, pages, 8, 49 and 53.)

Don J

Dora Vega., M.D., Ph.D.
Medical Officer
Division of General, Restorative,
and Neurological Devices
Plastic and Reconstructive Surgery Devices Branch

Date: October 27, 2006.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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URGENT

TOTAL # OF PAGES INCLUDING THIS : 6

October 31, 2006

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DOCUMENT MAIL CENTER HFZ-401

9200 CORPORATE BLVD
ROCKVILLE, MD 20850

ATTENTION: DR DORA VEGA, M.D., Ph.D
TEL (NEW) 240 276 3602. ~~FAX~~ (NEW) 240 276 3609
fax phone

SUBJECT: 510K #K053225

Dear Dr Vega,

Upon your request, we agree to cancel some of the indications for use submitted earlier under this 510k.

The revised and final indications for use list is shown below:

1- Reduction of Secondary Lymphedema of the Arm (SLA) Post Mastectomy
2- Improvement of Secondary Lymphedema
3- Improvement of lymphatic circulation in the treated area

The indications for use that we agree to withdraw from our submission are:

1- Improvement of Primary Lymphedema
2- Prevention of venous stasis and venous insufficiency

Accordingly, we include –along with this letter- a revised summary and a revised indications for use form.

Our labeling will be updated accordingly in the next few days. A copy of this letter, a copy of the summary, a copy of the indications for use form, and a revised set of labeling will be sent to you in duplicate at Doc mail center HFZ-401 shortly.

For the record, we list below the labeling that will change:

Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA
Phone: 1-678-908-8180
Fax: 1-678-623-3765
info@mansourconsulting.com
www.mansourconsulting.com

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Attachment 17 (Tab 26): page 26.3 will exclude the indications for use that we agree to cancel, and will mention only the ones that we are keeping.

Attachment 18 (Tab 27):

- page 27.1 will also be revised to reflect only the new indications for use
- page 27.4 will be revised by canceling the primary lymphedema claim
- page 27.5 will be deleted

We believe that we covered all the labeling issues associated with change in indications for use. However, if you require any other changes, kindly let us know and we will change anything else promptly.

Thank you very much for the continued support. We very much appreciate your cooperation and assistance for the benefit of the healthcare sector, mainly the patients.

We look forward to receiving your final positive determination for our 510k submission.

Best Regards,

Jay Mansour, MSQA, BE, RAC, LA
President, Mansour Consulting LLC
For LPG One, Inc
845 Aronson Lake Court
Roswell, GA 30075 USA

Tel 678-908-8180. Fax 678-623-3765. Email jay@mansourconsulting.com

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Indications for Use

FINAL IFU. (Revised)

510(k) Number (if known): K053225

Device Name: CelluM6 Keymodule i

Indications For Use:

Reduction of Secondary Lymphedema of the Arm (SLA) Post Mastectomy
Improvement of Secondary Lymphedema
Improvement of lymphatic circulation in the treated area

Prescription Use ✔ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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FINAL SSE
(i.e., revised).

510(k) Summary
As Required by 21 section 807.92 (c)

1-Submitter Name: LPG One, Inc
2-Address: 801 Brickell Ave. Suite 850. Miami, FL 33131
3-Phone: (305) 379- 8800
4-Fax: (305) 375- 0903
5-Contact Person (Consultant): Jay Mansour of Mansour Consulting LLC
845 Aronson Lake Court
Roswell, GA 30075 USA
(678) 908-8180. Fax (678) 623-3765
6-Date summary prepared: September 16th, 2006
7-Device Trade or Proprietary Name: CELLU M6 KEYMODULE i
8-Device Common or usual name: Massager
9-Device Classification Name: Electrical Therapeutic Massager
10-Substantial Equivalency is claimed against the following devices:

1- LPG One (formerly LPG USA) ES1 Massager- 510k #K990445
2- Shepard Medical's Sport Pump- 510k #K912004
3- Progressive Medical's Multipulse Sequential Compression unit- 510k #K914774
4- Grad-Line's Atlant's- 510k #K974395
5- Model SC-3008 Sequential Circulator- 510k #K043423
6- Flexitouch (also known as Biotouch)- 510k #K013061

11-Description of the Device:

The Cellu M6 Keymodule i electrical therapeutic massager is comprised of a program console housing a vacuum pump and a regulation system. The main treatment head i50 consists of two parallel motorized rollers housed in a chamber which produces both negative pressure above the rollers and positive pressure below the rollers. This technology creates a skin fold between the two rollers in a suction chamber, thus mimicking the "rolled palpation" of manual massage techniques.

In addition to Head i50 which is meant primarily for the upper arm and for legs, auxiliary heads T615, T615-A, T630, T630-A, T644 and T644-A are also used, as they better suit smaller morphology (parts) of the body. Details are provided along the labeling provided.

This device has the capability to produce both constant and sequential aspiration. Constant aspiration provides a deeper massage, which also mobilizes the muscle fascia. With sequential aspiration, the suction power is cyclically interrupted to provide pulsation to the skin fold between the two rollers and a softer, gentler stroking action of the tissues.

The suction power ranges from 45 mm Hg to 180 mmHg, which is represented by a power level scale ranging from 1 to 4.

12-Intended use of the device: (refer to FDA form attached)

The intended uses of this device are:

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Reduction of secondary lymphedema of the Arm (SLA) Post Mastectomy
Improvement of secondary lymphedema
Improvement of lymphatic circulation in the treated area

13-Safety and Effectiveness of the device:

This device is safe and effective as the predicate devices cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate devices. Refer to the explanations/details within the main submission.

FDA file reference number	510k # K912004, K914774, K974395, K043423 and K013061	510k #K990445
TECHNOLOGICAL CHARACTERISTICS	Comparison result of this device with the predicate devices	
Indications for use	Identical	Different
Target population	Identical	Different
Design	Similar in terms of mode of action	Very similar
Materials		
Performance		
Sterility	Not applicable	
Biocompatibility	Similar	
Mechanical safety		
Chemical safety	Not applicable	
Anatomical sites	Similar	Similar
Human factors		Similar
Energy used and/or delivered		Very similar
Compatibility with environment and other devices		Identical
Where used		Similar
Standards met		Very similar
Electrical safety		Very similar
Thermal safety	NOT APPLICABLE	
Radiation safety		

Refer to the submission for more details.

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From: Schroeder, Marie
Sent: Monday, February 27, 2006 11:06 AM
To: 'jay@mansourconsulting.com'; Pena, Carlos L
Cc: Courtney, Michael
Subject: RE: 510(k) Device Inquiry Regarding Predicate Device Comparisons

Carlos,
This response is troublesome. We do need a comparison of technologies regardless of how similar or different. Additionally, While some clinical studies do not compare a device to another device, when appropriate, as in this case, Mr. Mansour should be comparing his new device to the inflatable tube massager, and he needs to demonstrate that his device is at least as safe and as effective. Please let Mr. Mansour know that his conclusions are not correct. Thanks.
Marie

From: Jay Mansour [mailto:jay@mansourconsulting.com]
Sent: Monday, February 27, 2006 12:33 AM
To: Pena, Carlos L
Cc: Schroeder, Marie; Courtney, Michael
Subject: RE: 510(k) Device Inquiry Regarding Predicate Device Comparisons
Importance: High

Dear Dr Pena,

Thanks for responding to me on a Saturday. I appreciate it.

I refer to our previous phone call that occurred after me sending you the email shown below.

I understand from your email that if we have a predicate device with the same intended use but different technology, we won't need to provide a technological comparison between our device and the predicate, because such a comparison cannot be as comprehensive as when we have a predicate device with the same (or similar) technology (and of course, same intended use).

And the above holds true only if we provide clinical study of our device confirming its safety and effectiveness, without the need to specifically provide clinical study involving direct comparison between our device and the predicate device (which has different technology).

I appreciate your continuous support and involvement in order to allow for the 510k submission to be completed. We gathered most of the information so far, and we should complete our documentation in 1 or 2 weeks time, pending your confirmation to this email.

As a final remark, please note that PMA's are typically submitted without the need for predicate devices, relying on clinical studies of the product itself to confirm safety and effectiveness. In our current 510k, we are in fact (almost) matching the level of a class III device in our submission, despite the fact that our device is not class III device, and this should work in our favor for the purpose of completing this 510k, without the need to have technological comparison with a predicate device which has a different technology.

I look forward to receiving your comments/determination/ruling to the above.

Best Regards,

Jay Mansour, MSQA, BE, RAC, LA
Mansour Consulting LLC

845 Aronson Lake Court
Roswell, GA 30075

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tel 678-908-8180. Fax 678-623-3765
jay@mansourconsulting.com
www.mansourconsulting.com

-----Original Message-----
From: Pena, Carlos L [mailto:carlos.pena@fda.hhs.gov]
Sent: Sat, February 25, 2006 11:37 PM
To: 'Jay Mansour'
Cc: Schroeder, Marie; Courtney, Michael
Subject: 510(k) Device Inquiry Regarding Predicate Device Comparisons

Dear Mr. Mansour, I have discussed your inquiry with Mr. Ted Stevens re whether one product can serve as a predicate device for technology, while a second product can serve as a predicate device for intended use. A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, performance, safety, effectiveness, labeling, biocompatibility, standards, and other applicable characteristics. Detailed information on how FDA determines substantial equivalence can be found in the Premarket Notification Review Program 6/30/86 (K86-3) blue book memorandum. However, please be advised that additional clinical performance data may be needed if you plan to employ one product as a predicate device based on technology, while a second product will be employed as a predicate device for intended use. Please let me know if you have any additional questions or concerns.

Sincerely,

Carlos Peña, PhD, MS
Acting Branch Chief
Restorative Devices Branch
Division of General, Restorative and Neurological Devices
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Boulevard, HFZ-410
Rockville, MD 20850
carlos.pena@fda.hhs.gov

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From: Jay Mansour [mailto:jay@mansourconsulting.com]
Sent: Tuesday, February 07, 2006 9:18 PM
To: Schroeder, Marie
Cc: Courtney, Michael; Pena, Carlos L
Subject: RE: 510k #K053225

Dear Captain Schroeder, Dear Mr Courtney, Dear Mr Pena,

In order to speed up the process and avoid idle time, I took the liberty of emailing the agenda of two points to all parties involved, including Mr Courtney.

AGENDA:

1- The introduction of an additional predicate device and the related clinical studies that was

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reviewed and cleared by FDA, which is 510k #K043423. (Two clinical studies are available to us as conducted on this predicate device, which allow us to provide a performance comparison summary reflecting substantial equivalency)

2- The link established between our device and the new predicate, and your acceptance -in principle- that the link is indeed established.

During our conference call, we intend to clear up those two issues mentioned above, so that we can concentrate separately on the documentation that you requested in your previous fax.

We are available for the conference call on Friday February 10. Please specify your preferred time anytime between 11am and 4pm.

In the meantime, in order to reach me quickly, please feel free to call me at 678-908-8180.

Best Regards,

Jay Mansour, MSQA, BE, RAC, LA
Mansour Consulting LLC
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Roswell, GA 30075 USA
CELL 678-908-8180
Tel 770-777-4146. Fax 678-623-3765
jay@mansourconsulting.com
www.mansourconsulting.com

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From: Schroeder, Marie
Sent: Monday, February 27, 2006 11:06 AM
To: 'jay@mansourconsulting.com'; Pena, Carlos L
Cc: Courtney, Michael
Subject: RE: 510(k) Device Inquiry Regarding Predicate Device Comparisons

Carlos,
This response is troublesome. We do need a comparison of technologies regardless of how similar or different. Additionally, While some clinical studies do not compare a device to another device, when appropriate, as in this case, Mr. Mansour should be comparing his new device to the inflatable tube massager, and he needs to demonstrate that his device is at least as safe and as effective. Please let Mr. Mansour know that his conclusions are not correct. Thanks.
Marie

From: Jay Mansour [mailto:jay@mansourconsulting.com]
Sent: Monday, February 27, 2006 12:33 AM
To: Pena, Carlos L
Cc: Schroeder, Marie; Courtney, Michael
Subject: RE: 510(k) Device Inquiry Regarding Predicate Device Comparisons
Importance: High

Dear Dr Pena,

Thanks for responding to me on a Saturday. I appreciate it.

I refer to our previous phone call that occurred after me sending you the email shown below.

I understand from your email that if we have a predicate device with the same intended use but different technology, we won't need to provide a technological comparison between our device and the predicate, because such a comparison cannot be as comprehensive as when we have a predicate device with the same (or similar) technology (and of course, same intended use).

And the above holds true only if we provide clinical study of our device confirming its safety and effectiveness, without the need to specifically provide clinical study involving direct comparison between our device and the predicate device (which has different technology).

I appreciate your continuous support and involvement in order to allow for the 510k submission to be completed. We gathered most of the information so far, and we should complete our documentation in 1 or 2 weeks time, pending your confirmation to this email.

As a final remark, please note that PMA's are typically submitted without the need for predicate devices, relying on clinical studies of the product itself to confirm safety and effectiveness. In our current 510k, we are in fact (almost) matching the level of a class III device in our submission, despite the fact that our device is not class III device, and this should work in our favor for the purpose of completing this 510k, without the need to have technological comparison with a predicate device which has a different technology.

I look forward to receiving your comments/determination/ruling to the above.

Best Regards,

Jay Mansour, MSQA, BE, RAC, LA
Mansour Consulting LLC

845 Aronson Lake Court
Roswell, GA 30075

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Addit.
Predicate : BIOTOUCH

K013061

September 6, 2001

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

RE: 510(k) Premarket Notification
biotouch™ Massage Therapy System

To Whom It May Concern:

The enclosed 510(k) Notification (provided in duplicate in accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act and in conformance with 21 CFR 807) requests clearance for Tactile Systems Technology, Inc. to introduce the ***biotouch***™ Massage Therapy System into interstate commerce for commercial distribution.

The ***biotouch***™ Massage Therapy System is substantially equivalent to the Progressive Medical Technology, Inc., Multipulse Sequential Compression Unit (K914774, cleared 02/11/92). The ***biotouch***™ Massage Therapy System is substantially equivalent in design, size, construction, materials and intended use to the predicate device.

This premarket notification is organized following the recommendations contained in the CDRH Manual titled *Premarket Notification 510(k): Regulatory Requirements for Medical Devices* (August 1995). The Truthful and Accurate Statement and the separate Indications for Use are located on the following pages.

This submission contains confidential commercial and trade secret information; we respectfully request that you give it the maximum protection provided by law. If you require further information or clarification of the information provided, please feel free to contact me at the numbers below.

Sincerely,
Tactile Systems Technology, Inc.

Eric McKee

Eric McKee
President and CEO

Tel: (763) 434-2888
Fax: (763) 434-4161

RM/II

SK 141

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as President of Tactile Systems Technology, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Eric McKee
President and CEO
Tactile Systems Technology, Inc.
September 6, 2001

Premarket Notification 510(k) Number

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use Statement

The ***biotouch***™ device is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as:

- Primary lymphedema
- Post mastectomy edema
- Leg ulcers
- Edema following trauma and sport injuries
- Post immobilization edema
- Venous insufficiencies
- Lymphedema.

September 6, 2001

120

80

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Concurrence of CDRH, Office of Device Evaluation (ODE)

September 6, 2001

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ATTACHMENT A - PROPOSED LABELING

ATTACHMENT B - DEVICE DRAWINGS

ATTACHMENT C – PREDICATE DEVICE INFORMATION

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 1 - General Information

General information regarding the Tactile Systems Technology, Inc., ***biotouch***™ Massage Therapy System is contained in the following table.

Table 1: General Information

Trade Name	***biotouch***™ Massage Therapy System
Common Name	Massage Therapy System
Classification Name	Massager, Powered Inflatable Tube
Establishment Registration Number	TSTI has not yet received an Establishment Registration Number, but plans to once FDA marketing approval is obtained.
Contact Person	Eric McKee Tel: (763) 434-2888 Fax: (763) 434-4161 E-mail: emckee@tactilesystems.com
Manufacturer	Tactile Systems Technology, Inc. 1074 Legion Street Shakopee, MN 55379 Tel: (952) 445-7578 Fax: (952) 445-1864
Classification	This device has been classified by the Division of Physical Medicine into Class II (21 CFR 890.5650) as a Massager, Powered Inflatable Tube
Reason for Premarket Notification	TSTI intends to introduce the TSTI ***biotouch***™ device into interstate commerce for commercial distribution.
Identification of Equivalent Devices	Progressive Medical Technology, Inc. (representing Talley Group Ltd.) Multipulse Sequential Compression Unit cleared under K914774.
Performance Standards and Compliance with special controls	**Special Controls:** No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. Voluntary standards were used throughout the development, testing and manufacturing processes (See section 9 Standards and Guidelines).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 2 - 510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

1. *Submitter's Name / Contact Person*

Eric McKee
Tel: (763) 434-2888
Fax: (763) 434-4161

Tactile Systems Technology, Inc.
1074 Legion Street
Shakopee, MN 55379
Tel: (952) 445-7578
Fax: (952) 445-1864

2. *General Information*

Trade Name: *biotouch*™ Massage Therapy System

Classification Name: Massager, Powered Inflatable Tube

Classification: This device has been classified by the Division of Physical Medicine into Class II (21 CFR 890.5650) as a Massager, Powered Inflatable Tube

3. *Device Description*

The TSTI *biotouch*™ device is a microprocessor controlled pneumatic compression device that applies calibrated sequentially graduated pressure to the arm, leg, trunk, and/or chest. The device consists of two major components:

- lightweight, portable pneumatic controller, and
- extremity garments composed of 4 to 16 chambers.

The controller is pre-programmed with thirteen separate treatment programs, which consists of pre-determined sequences and inflation times and should be used under medical supervision. The device is provided to the end-user in individual cartons to ensure safe shipping and arrival of the device. (See Attachment B for device drawings.)

4. *Intended Use*

The *biotouch*™ device is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as:

- Primary lymphedema
- Post mastectomy edema
- Leg ulcers
- Edema following trauma and sport injuries
- Post immobilization edema
- Venous insufficiencies
- Lymphedema.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5. *Substantial Equivalence Comparison*

The ***biotouch***™ device is substantially equivalent to the following devices with respect to intended use, design, materials and construction:

- (Progressive Medical Technology, Inc., Multipulse Sequential Compression Unit (K914774))

No new safety and/or effectiveness issues are raised.

6. *Summary of Studies*

Performance testing was completed to verify the design specifications necessary for the ***biotouch***™ device. Test results support the safety and performance of the ***biotouch***™ device for its intended use.

7. *Conclusion (statement of equivalence)*

The data and information provided in this submission supports a substantial equivalence determination, and, therefore, 510(k) premarket notification clearance of the ***biotouch***™ device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 3 - Proposed Labeling

Representative package labeling and "Instructions for Use" for the *biotouch*™ device are included in ATTACHMENT A - Proposed Labeling.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 4 - Substantial Equivalence Comparison

Table 2 contains a comparison of the ***biotouch***™ device design features to the predicate device to which it is substantially equivalent. The ***biotouch***™ device is substantially equivalent to the Progressive Medical Technology, Inc., Multipulse Sequential Compression Unit (K914774). The predicate device is cleared for commercial distribution in the US. (See Attachment C for predicate device information.)

The ***biotouch***™ device design is intended and indicated for the same uses as the Multipulse Sequential Compression Unit (MSCU). The devices are basically identical with the exception of: (1) metallic enclosure verses plastic enclosure, (2) nominal applied pressures used, (3) total number of chambers, (4) inflation cycle times, (5) garment material differences, (6) number of anatomical sites treated, and (7) configuration of the wraps used to connect the wrapping.

The ***biotouch***™ device has the following major differences:

(1) off-the-shelf metallic enclosure that is designed for medical, or other, tabletop instrumentation versus plastic enclosure,
(2) lower pressures than the predicate device for more comfort for the patient,
(3) up to 32 chambers versus 10 chambers for the predicate device providing smaller treatment area per chamber,
(4) inflation times of 1 to 3 seconds per chamber versus 3 to 12 seconds,
(5) nylon outer layer with polyurethane inner layers verses nylon re-enforced polyurethane garments,
(6) treats the trunk and/or chest regions, and
(7) more connections due to increased number of chambers and additional areas treated.

Questions of equivalence that could be raised by these technological differences are the effectiveness of the lower pressure coupled with the decreased inflation time and the safety and effectiveness of treating the groin and shoulder areas. The lower pressures used by the ***biotouch***™ are still within the lower range of the pressures offered by the predicate device and are near the pressures typically used in a clinical setting. The decreased inflation times cause compression on the lymphatic and venous vessels in similar time frames as what occurs when a person is walking or exercising their arms. The groin and shoulder areas are typically problems areas for patients with lymphedema due to the removal of lymph nodes and limited lymph flow in these regions. The ***biotouch***™ trunk and shoulder garments gently massage the hips, groin and shoulder areas to assist the body in moving the fluid past these regions.

These are not *new* questions of safety or effectiveness of therapy for patients with lymphedema and other vascular related problems. Results of verification and therapy efficacy testing demonstrate that, despite the technological differences, the ***biotouch***™ device will provide an effective therapy for patients and raises no new safety concerns. (see Section 7 for details).

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Table 2: Substantial Equivalence Comparison

Device Name / Manufacturer	Progressive Medical Technology (Talley Group, Ltd) Multipulse Sequential Compression Unit	***biotouch***™ Massage Therapy System
510(k) Number	K914774	*To be assigned*
Intended Use	primary lymphedema, post mastectomy edema, leg ulcers, edema following trauma and sports injuries, post immobilization edema, venous insufficiencies, lymphedema	primary lymphedema, post mastectomy edema, leg ulcers, edema following trauma and sports injuries, post immobilization edema, venous insufficiencies, lymphedema
Indications for Use	primary lymphedema, post mastectomy edema, leg ulcers, edema following trauma and sports injuries, post immobilization edema, venous insufficiencies, lymphedema	primary lymphedema, post mastectomy edema, leg ulcers, edema following trauma and sports injuries, post immobilization edema, venous insufficiencies, lymphedema
Design/Physical Characteristics	all plastic construction 10" x 14" x 4" (250mm x 360mm x 100mm) 10 lbs. (6 kgs.) All input voltages available 3-12 second per chamber 40-140 mmHg pressure adjustable total therapy time power on/off switch 10 chamber capability	metal enclosure with plastic handle 10.4" x 9.8" x 4.7" (263mm x 250mm x 120mm) 11 lbs. (5 kgs.) All input voltages available 1-3 second per chamber 25-75 mmHg pressures adjustable total therapy time power on/off switch 32 chamber capability
Materials	controller unit is plastic enclosure, garments are nylon re-enforced polyurethane	controller unit is metal enclosure with plastic handle, garments are nylon outer layer with inner layer of polyurethane

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Device Name / Manufacturer	Progressive Medical Technology (Talley Group, Ltd) Multipulse Sequential Compression Unit	***biotouch***™ Massage Therapy System
Performance	Peristaltic gradient sequential compression Stimulates circulation and reduces swelling Mimics the body's own natural functions by peristaltic action See Section 7 – Performance Data below	Peristaltic gradient sequential compression Stimulates circulation and reduces swelling Mimics the body's own natural functions by peristaltic action See Section 7 - Performance Data below
Sterility	non-sterile product	non-sterile product
Biocompatibility	nylon reinforced polyurethane	nylon outer layer garments with inner layers of polyurethane
Mechanical Safety	rigid plastic enclosure used for controller air tubes easily disconnected from extremity garment garments are zippered and are extremely difficult to remove when inflated maximum rated pressure of 150 mmHg tourniquet effect avoided by porous nylon liner of garments with pressure loss over 1 to 2 minutes	rigid metal enclosure used for controller strong force needed to cause disconnection of tubing from garment garments applied by fabric hook and loop system, garments are very easy to remove when inflated maximum rated pressure of 75 mmHg tourniquet effect avoided since all chambers automatically deflate unless actively inflating, in the event of power loss to controller all chambers will be evacuated, deflation occurs in normal operating time frame of just a few seconds
Anatomical Sites	treats foot, calf, thigh, hand, forearm, bicep regions	treats foot, calf, thigh, hand, forearm, bicep, trunk and shoulder regions
Human Factors	user operation through operator panel and extremity wrap	user operation through operator panel and extremity wrap

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Device Name / Manufacturer	Progressive Medical Technology (Talley Group, Ltd) Multipulse Sequential Compression Unit	***biotouch***™ Massage Therapy System
Energy used and/or delivered	electrical power source for controller; compression energy delivered to body	electrical power source for controller; compression energy delivered to body
Compatibility with the environment and other devices	no known adverse conditions have occurred	no known adverse conditions have occurred, EMC (EN60601) and UL (UL2601) testing was successfully completed
Where Used	hospitals, clinics, homes	hospitals, clinics, homes
Standards Met	Unknown	voluntary standards: EN 60601, UL2601
Electrical Safety	no electrical connections to patient	no electrical connections to patient, successfully tested controller to UL2601 safety standards
Sterilization	Non sterile product	Non sterile product

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 5 - Device Description

The TSTI ***biotouch***™ device is a microprocessor controlled pneumatic compression device that applies calibrated sequentially graduated pressure to the arm, leg, trunk, and/or chest. The device consists of two major components:

- lightweight, portable pneumatic controller, and
- extremity garments composed of 4 to 16 chambers.

The controller is pre-programmed with thirteen separate treatment programs, which consist of pre-determined sequences and inflation times and should be used under medical supervision. The device is provided to the end-user in individual cartons to ensure safe shipping and arrival of the device. (See Attachment B for device drawings.)

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Section 6 – Intended Use

The ***biotouch***™ device is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as:

- Primary lymphedema,
- Post mastectomy edema,
- Leg ulcers,
- Edema following trauma and sport injuries,
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- Venous insufficiencies, and
- Lymphedema.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 7 - Performance Data Demonstrating Safety and Effectiveness

The ***biotouch***™ device was subjected to testing to verify the design specifications. Test results from the design verification tests demonstrate the safety and performance of the ***biotouch***™ device; no new questions of safety and effectiveness were raised. A summary of the design verification and therapy efficacy testing is provided in this section.

Design Verification

The objectives of the Design Verification Testing (DVT) were to ensure that the ***biotouch***™ would be a safe and effective product and would not present any hazards to operators, users or other equipment. Testing consisted of six (6) different groups of tests. Test articles used were manufactured according to established manufacturing methods.

In-house verification testing was performed to ensure that the product worked according to the product specification. These included shipping, temperature cycling, maximum pressure, extremity pressure, software and hardware verification tests. Design reviews were held to confirm that the wraps, tubing harness, enclosure, operator interface, software, and electronic hardware designs met the requirements of the product and hardware specifications. Additional testing was conducted on the electronic hardware to confirm that variability in electronic components would not effect the operation of the device. Also, sixteen (16) test protocols were written and performed on the ***biotouch***™ device to thoroughly test the software and its operation. The user selectable options and each of the thirteen (13) therapy programs were confirmed to operate according to the product specification. These tested the inflation sequencing of the air chambers for each therapy program, the operator interface operation, and the application pressure of the wraps.

A summary of the objective, method and result for each group of tests is detailed below.

1. Shipping Tests

Objective

The objectives of these tests were to ensure that the device could be safely shipped to the end-user with no damage.

Test Method

After being individually packaged in a cardboard shipping carton surrounded by bubble wrap and packing peanuts, the ***biotouch***™ devices were dropped according to the manual handling requirements of the ASTM D 4169 - 99 standard and shipped via ground transportation for an approximate 18 hour trip. Then, the units were again dropped according to the manual handling requirements of the ASTM D 4169 - 99 standard. The units were visually inspected and functionally tested.

Test Results

All three (3) ***biotouch***™ devices tested met the specifications.

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2. Temperature Cycling Tests

Objective

The objectives of these tests were to ensure that the device would operate safely and function normally after being subjected to extreme temperatures.

Test Method

Three (3) devices were placed in an approximate 0°F environment for two (2) hours, then ambient for two (2) hours, then an approximate120°F environment for two (2) hours. After sitting in ambient for two (2) hours, this cycle was repeated. The devices were allowed to sit in ambient temperature overnight before they were visually inspected and functionally tested.

Test Results

All three (3) ***biotouch***™ devices tested met the specifications.

3. Maximum Pressure Tests

Objective

The objectives of these tests were to ensure that the wraps and tubing harness could withstand the maximum pressure provided by the compressor.

Test Method

Five (5) different tubing harnesses that were attached to five (5) different wraps were used. The tubing harnesses were individually connected to the controller unit and the controller was put into a special test mode so that the pressurization time and selected pressurized chamber could be individually selected. All wrap chambers were subjected to at least 15 seconds of pressurization via the controller unit's compressor to ensure that the selected tubing, tubing connections and wrap chamber received maximum pressure for an extended period of time. The components were monitored for visual signs of damage and air leakage as detected by audible hissing.

Test Results

All five (5) ***biotouch***™ wraps and associated tubing harnesses tested met the specifications.

4. Extremity Pressure Tests

Objective

The objectives of these tests were to ensure that the average maximum pressure applied to each body region was obtained in the time specified.

Test Method

A pressure data acquisition system was utilized to monitor the pressure applied by each chamber of every ***biotouch***™ wrap. The wraps were applied in a manner similar to that used in a typical therapy session. Data was collected for each chamber for a minimum of five (5) inflation sequence cycles. This data was analyzed and the average maximum applied pressure was determined for each body region, which includes the hand, wrist, forearm, bicep, chest, trunk, thigh, calf, and foot regions.

Test Results

The applied pressure for all of the ***biotouch***™ wrap chambers tested met the specifications.

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5. Software Verification Tests

Objective

The objectives of these tests were to ensure that the operator interface functions and therapy programs of the controller unit operated as specified.

Test Method

Fourteen (14) test protocols were utilized to test every pre-programmed program and the operator interface. The operation of the operator interface was verified to function as specified. The chamber inflation sequencing and program length of the thirteen (13) selectable programs were tested.

Test Results

All ***biotouch***™ operator interface functions and selectable therapy programs tested met the specifications.

6. Hardware Verification Tests

Objective

The objectives of these tests were to ensure that the electronics of the controller unit would properly control the valves over the manufacturing component variability range.

Test Method

A resistive load representing the worst-case valve loading condition was attached to four (4) different valve control drivers on three (3) different controller units. The voltage sourced by the drivers was monitored.

Test Results

All twelve (12) ***biotouch***™ valve control drivers tested met the specifications.

In addition to in-house verification test, the product was tested at International Certification Services, Glencoe, MN to ensure that the ***biotouch***™ device complied with international electromagnetic compatibility requirements, such as radiated and conducted emissions and immunity. The ***biotouch***™ device was found to comply with the standard EN60601-1-2 , May 1993 Medical Electrical Equipment Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility Requirements and Tests. Electromagnetic compatibility testing was performed in accordance with the EN60601-1-2, EN61000-4-2, -3, -4, -5, -6, -8 and -11 and IEC1000-4-3 per the requirements of the EMC Directive. These tests confirmed that the device could withstand electrostatic discharges, electrical fast transients, surge, power frequency magnetic fields, voltage dips, short interruptions, voltage variations and that it was immune to radiated and conducted electromagnetic radiation. In addition, both radiated and conducted electromagnetic emissions tests were performed according to the procedures in the ANSI C63.4-1992 standard. These tests confirm that the ***biotouch***™ device has been found in compliance with the EN55011 Class B standard.

The ***biotouch***™ device was also tested by Underwriters Laboratory, Inc.® and was found to comply with the UL2601-1 and CSA 22.2 No. 601.1 standards. These tests include the following:

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- Marking Durability,
- Voltage Limitation,
- Earthing and Potential Equalization,
- Leakage Current,
- Dielectric Voltage Withstand,
- Mechanical Strength,
- Stability and Transportation,
- Temperature,
- Humidity Preconditioning Treatment,
- Impairment of Cooling,
- Overflow, Spillage, Leakage, Cleaning, Sterilization and Disinfection, Harmful Ingress of Liquids, and
- Abnormal Operation and Fault Conditions.

Therapy Efficacy

In addition to bench and performance verification testing, TSTI also conducted a pilot clinical study per an IRB that was approved at the Mayo clinic (Rochester, MN) in which several subjects tried the device to evaluate its performance. Results show that the device is effective.

1. Human Study

Objective

The objective of this study was to determine whether treatments by the ***biotouch***™ device could be tolerated and whether patients who have difficulty maintaining reduction in their limbs could maintain limb reduction.

Test Method

A few, highly selected patients were observed and educated on the use of the ***biotouch***™ device. Once it was determined that these patients responded to treatment and tolerated the treatment, they were allowed to take the device home and use it.

Test Results

Patients that used the ***biotouch***™ device experienced comfortable therapy that resulted in immediate and long-term reductions in the size of their limbs. A summary of the clinical notes on three patients has been provided below.

Patient #1 - Lymphedema of Left Leg

Patient #1 has lymphedema of the left leg and was scheduled to receive 4-6 weeks of MLD therapy. However, the patient was given the ***biotouch***™ device and was sent home with the massage therapy system on the third day because the results were so good. This patient saw a reduction in circumference of the limb for one-day treatment from 0.5 cm to 6.4 cm along the length of the entire leg.

Patient #2 - Lymphedema of Left Arm

Patient #2 has lymphedema of the left arm as a result of treatment for breast cancer. On a follow-up visit to the clinic the doctor noted that most of her dimensions

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had shrunk over one centimeter in circumference during a four-week period. The skin of her left arm was softer and less swollen. The report states that the patient has obtained a very satisfactory result from the use of the ***biotouch***™ device.

Patient #3 - Venous Insufficiency

Patient # 3 had venous insufficiency in both legs. The clinical notes indicate that this patient obtained the lowest measurements ever seen and there was absolutely no edema in the extremities. The edema was "extremely well controlled on her extremities." During the first four month period after starting to use the ***biotouch***™ device, this patient saw dramatic reduction, as indicated in the following table.

		Circumference (inches) Day One	**Circumference (inches) 4 months later**
Right Leg	Ankle	10	8.75
	Calf	14	12
Left Leg	Ankle	10	8.5
	Calf	14	12.5

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Section 8 - Biocompatibility Assessment

The device is not an implant nor requires direct contact with the body. However, indirectly the ***biotouch***™ device's wraps contain a nylon material that if in direct contact with the body could potentially cause skin irritation or a rash with certain people. However, the ***biotouch***™ device's IFU (see Attachment A) instructs the user to ensure another material, such as cotton clothing, is worn at all times while wearing the ***biotouch***™ garments. The IFU also states that the skin that could be in contact with the trunk and chest wraps should be covered.

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Section 9 - Standards and Guidelines

1. Performance Standards

No special standards or guidelines exist for Massage Therapy Systems.

2. Voluntary Standards

Table 3 below shows that the Tactile Systems Technology ***biotouch***™ devices were developed, tested, and/or manufactured using the standards listed in the table.

Table 3: Voluntary Standards

Standard No.	Description
EN60601-1-2	Medical Electrical Equipment Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility Requirements and Tests
EN61000-4-2	Part 2: Electrostatic Discharge Requirements
IEC1000-4-3	Part 3: Radiated Electromagnetic Field Requirements
EN61000-4-4	Part 4: Electrical Fast Transient/Burst Requirements
EN61000-4-5	Part 5: Surge Requirements
EN61000-4-6	Part 6: Conducted Immunity Requirements
EN61000-4-8	Part 8: Power Frequency Magnetic Field Requirements
EN61000-4-11	Part 11: Voltage dips, short interruptions, and voltage variations immunity tests
UL 2601-1	UL Standard for Safety of Medical Electrical Equipment – Part 1: General Requirements for Safety
CSA 22.2 No. 601.1	Medical Electrical Equipment – Part 1: General Requirements for Safety
EN 980	Terminology, symbols and information provided with medical devices – Graphic symbols for use in labeling of medical devices.
EN 1041	Information supplied by manufacturer with medical devices.
EN 1441	Medical Devices – Risk Analysis, dated November 1994
ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems
HIBC	Supplier labeling standard

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ATTACHMENT A - Proposed Labeling

The following labeling items for the ***biotouch***™ device are included in this attachment:

- Controller UL label
- Wrap cover labels
- Instructions for use

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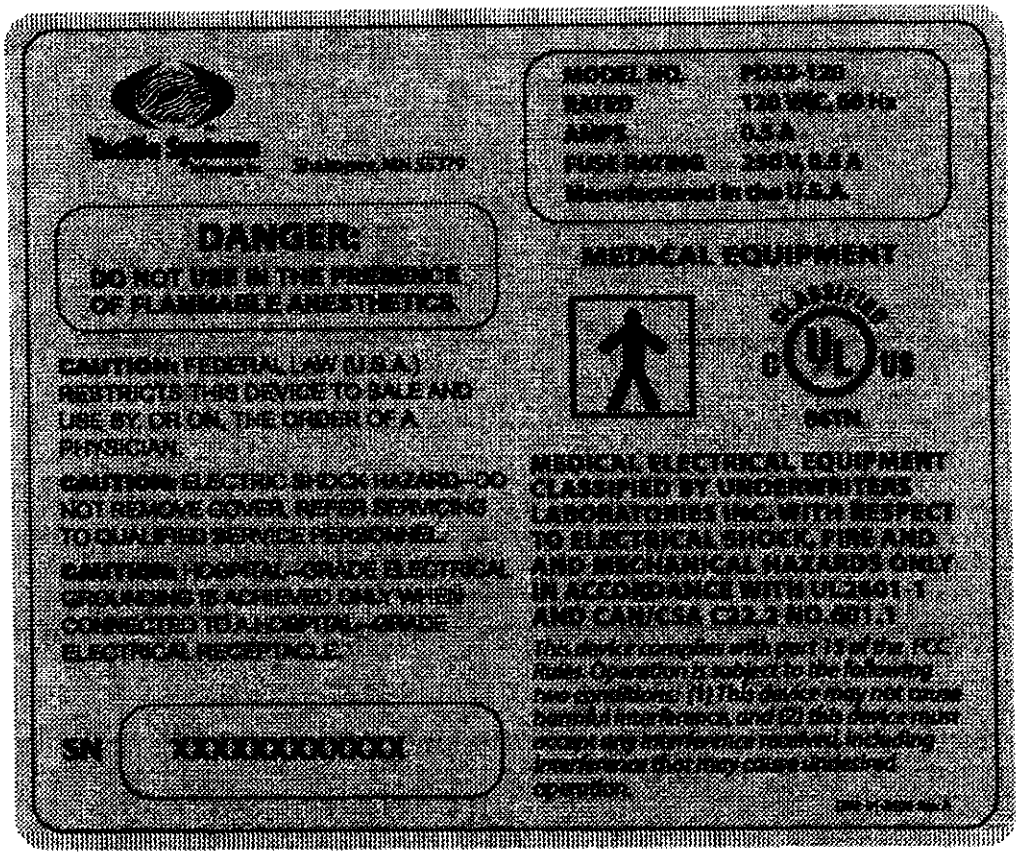

biotouch UL Controller Label
D/N: 01-2100 Rev A
Date: 09/06/01

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biotouch™

Massage Therapy System

D/N 01-2167 Rev A

biotouch Massage Therapy System
Logo Wrap Cover Label
D/N: 01-2167 Rev A
Date: 09/06/01

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Individual Wrap Labels

TRUNK-THIGH LE
(PATENTED, PATENTS-PENDING)
LONG
LEFT EXTREMITY
ORDER NO. LE32T18L
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2150 Rev A

TRUNK-THIGH LE
(PATENTED, PATENTS-PENDING)
REGULAR/SHORT
LEFT EXTREMITY
ORDER NO. LE32T14L
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2152 Rev A

TRUNK-THIGH UE
(PATENTED, PATENTS-PENDING)
LEFT EXTREMITY
ORDER NO. LE32T09L
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2154 Rev A

CALF-FOOT
(PATENTS-PENDING)
LEFT EXTREMITY
ORDER NO. LE32C00L
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2156 Rev A

TRUNK-THIGH LE
(PATENTED, PATENTS-PENDING)
LONG
RIGHT EXTREMITY
ORDER NO. LE32T18R
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2151 Rev A

TRUNK-THIGH LE
(PATENTED, PATENTS-PENDING)
REGULAR/SHORT
RIGHT EXTREMITY
ORDER NO. LE32T14R
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2153 Rev A

TRUNK-THIGH UE
(PATENTED, PATENTS-PENDING)
RIGHT EXTREMITY
ORDER NO. LE32T09R
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2155 Rev A

CALF-FOOT
(PATENTS-PENDING)
RIGHT EXTREMITY
ORDER NO. LE32C00R
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2157 Rev A

ARM
(PATENTS-PENDING)
REGULAR/SHORT
LEFT EXTREMITY
ORDER NO. LE32A26L
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2160 Rev A

ARM
(PATENTS-PENDING)
LONG
LEFT EXTREMITY
ORDER NO. LE32A30L
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2158 Rev A

CHEST
(PATENTED, PATENTS-PENDING)
LEFT EXTREMITY
ORDER NO. LE32C00L
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2162 Rev A

WAIST EXTENDER
LEFT EXTREMITY
ORDER NO. WE16L
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2165 Rev A

ARM
(PATENTS-PENDING)
REGULAR/SHORT
RIGHT EXTREMITY
ORDER NO. LE32A26R
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2161 Rev A

ARM
(PATENTS-PENDING)
LONG
RIGHT EXTREMITY
ORDER NO. LE32A30R
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2159 Rev A

CHEST
(PATENTED, PATENTS-PENDING)
RIGHT EXTREMITY
ORDER NO. LE32C00L
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2163 Rev A

WAIST EXTENDER
RIGHT EXTREMITY
ORDER NO. WE16R
SERIAL NO. XXXXXXX
OUTER LAYER: 100% NYLON
TACTILE SYSTEMS TECHNOLOGY, INC
MANUFACTURED IN THE U.S.A
D/N 01-2166 Rev A

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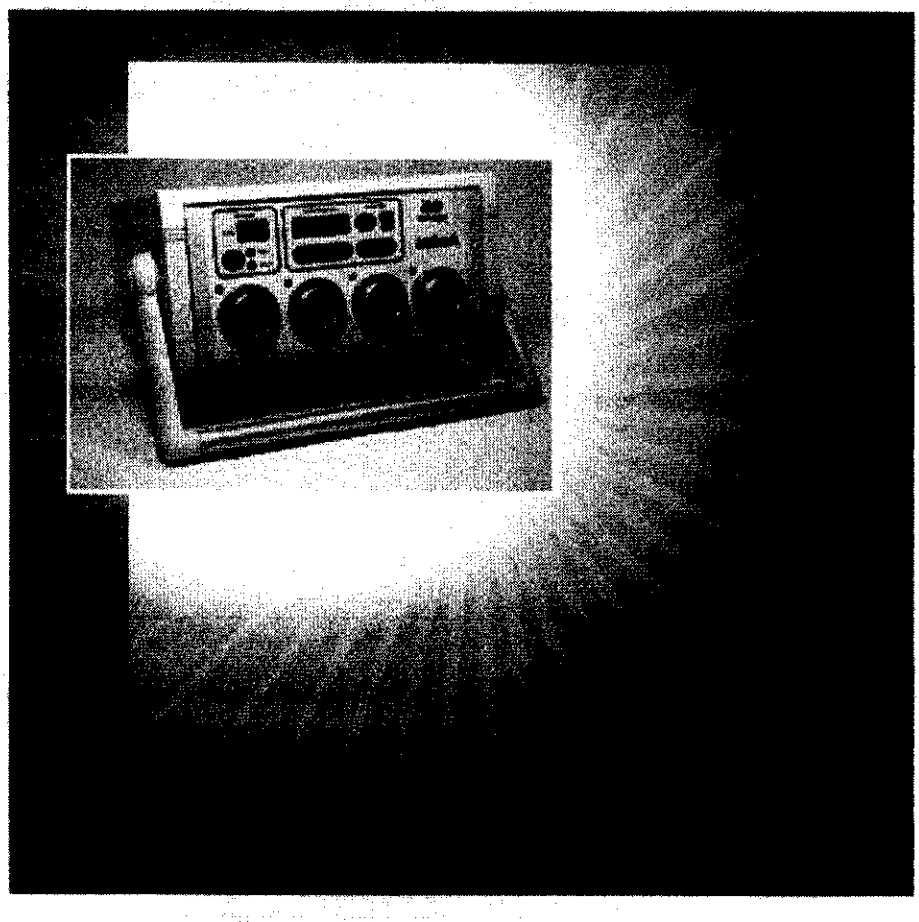
Tactile Systems Technology, Inc.

Massage Therapy System



biotouch™

INSTRUCTIONS FOR USE

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Cautions and Warnings.

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Intended use.

8 **Contraindications**
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8 **Controller Set Up**
How to set up the controller unit for use.

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How to apply the upper and lower extremity garments.

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21 **Storage Instructions**
How to store wraps and controller unit when not in use.

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Important

READ ALL INSTRUCTIONS BEFORE USING

Before attempting to connect, operate or use this product, please follow these instructions completely. Keep this manual handy for further reference.

Safety/Precautions

This product must be used under medical supervision only. Consult your physician for detailed instructions regarding proper use, therapy program, treatment cycles and/or duration of treatment. Use this product only at the settings prescribed by your physician.

Federal law (USA) restricts this device to sale and use on the order of a physician trained and/or experienced in the use of this device.

THE CONTROLLER UNIT IS NOT EXPLOSION PROOF AND CONSTITUTES AN EXPLOSION HAZARD IF USED IN THE PRESENCE OF FLAMMABLE GASES.

CAUTION ⇨ **To reduce the risk of electrocution:**

- To prevent electric shock hazard - do not open control unit.
- Do not attempt to service the unit yourself. Such attempts could result in injury to you, damage the product, and will void any warranty.
- Hospital-grade electrical grounding is achieved only when connected to a hospital-grade electrical receptacle.
- Always unplug your controller unit immediately after using.
- Do not use your controller unit while bathing or near water.
- To prevent fire or shock hazards, do not expose unit to water.
- Do not place your controller unit where it can fall or be pulled into water.
- Do not reach for your controller unit if it falls into water, unplug the unit at the electrical outlet immediately.

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WARNING ⇨ To reduce the risk of personal injury or fire:

- Keep garments away from flames.
- Do not smoke near the unit or while using the unit.
- The following items should not be used on or near the garments: sharp objects, such as pins, scissors, clasps, or hot devices such as irons or blow-dryers.
- Close supervision is necessary when your controller unit is used by, on, or near children or invalids.
- Your controller unit should never be left unattended while plugged in.
- Use your controller unit only for its intended purpose, as directed in this manual. Do not use any attachments not recommended by Tactile Systems Technology, Inc.
- Never operate the controller unit if the cord or plug is not working properly, if it has been damaged, or if it has been dropped into water. Return it to Tactile Systems Technology, Inc. for inspection or repair. Do not modify the cord or plug.
- Keep the power cord away from heated surfaces.
- Never operate the controller unit where the cord or tubing harness will present a fall hazard to the persons in the immediate area.
- Never block the ventilation area openings on the back or the sides of the unit.
- Never use the controller unit by placing it on a soft surface, such as a bed, couch, or pillow, where the ventilation openings may be blocked. Keep the ventilation openings free of lint, hair, etc.
- Never drop or insert any object into any opening on the controller unit.

Description and Operating Principle

❋❋❋

The ***biotouch***™ device is a massage therapy device designed to assist in directing and moving excess bodily fluid (i.e. lymph) from the legs, or arms, into the trunk region. The device works by applying dynamic low pressure compression to the affected trunk and extremities using a gentle, rhythmic, pumping, massage action. Extremity garments, or wraps, with built-in air chambers are placed around the affected trunk and limb, either the leg or the arm, and are connected to the controller by a tubing harness. The controller

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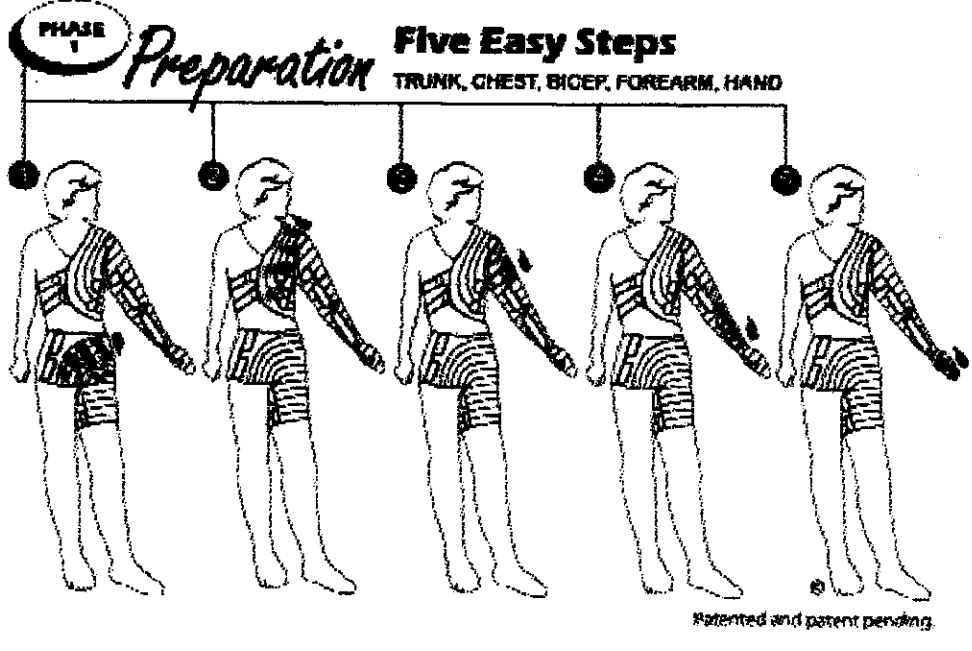
inflates and deflates the air chambers within the garments in a predetermined pattern to assist the lymphatics in moving the fluid into adjacent lymph node regions of the trunk.

The ***biotouch***™ device consists of a controller unit, trunk garment and limb garments, either an arm garment or a leg garment. The controller, which contains a pneumatic pump, provides individual chamber inflation cycles that are approximately 1 to 3 seconds in length.

Along with the controller, the specially designed extremity wraps "stimulate and prepare" lymph nodes and lymph vessels for "drainage" of the lymph fluid. This involves a two-step process: first, the main lymph nodes and vessels in the trunk and limbs are prepared and second, the extremities are drained. This is performed using a proprietary Lymph Preparation & Drainage™ treatment method.

The preparation phase treats the affected body extremity in sections. For instance, trunk, thigh, calf, and foot for lower extremity treatment and trunk, chest, bicep, forearm, and hand for upper extremity treatment. Within each body section the inflation sequence is in the distal to proximal direction, except when performing upper extremity treatment of the trunk. The drainage phase treats the trunk and limb regions in one sequence, starting with the most distal segment. The following figures show the order and direction in which each of the body sections are treated for both treatment phases.

TREATING THE UPPER EXTREMITY ⇨ **Figure 1**



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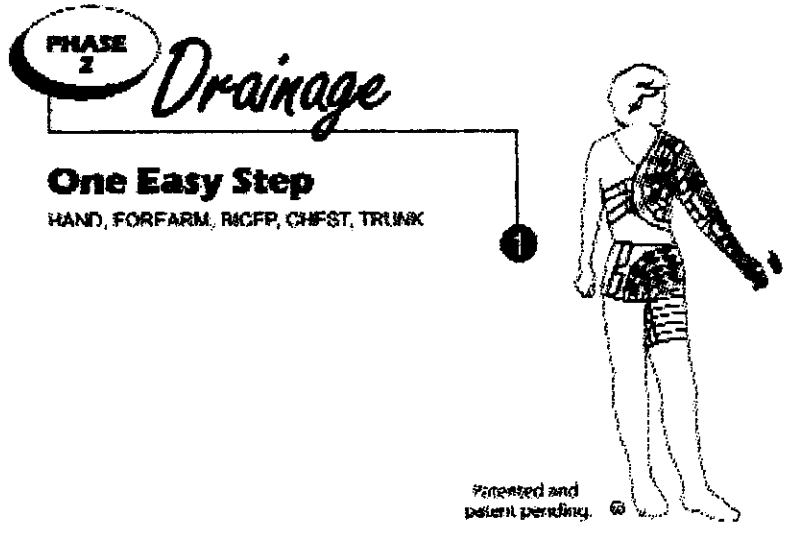
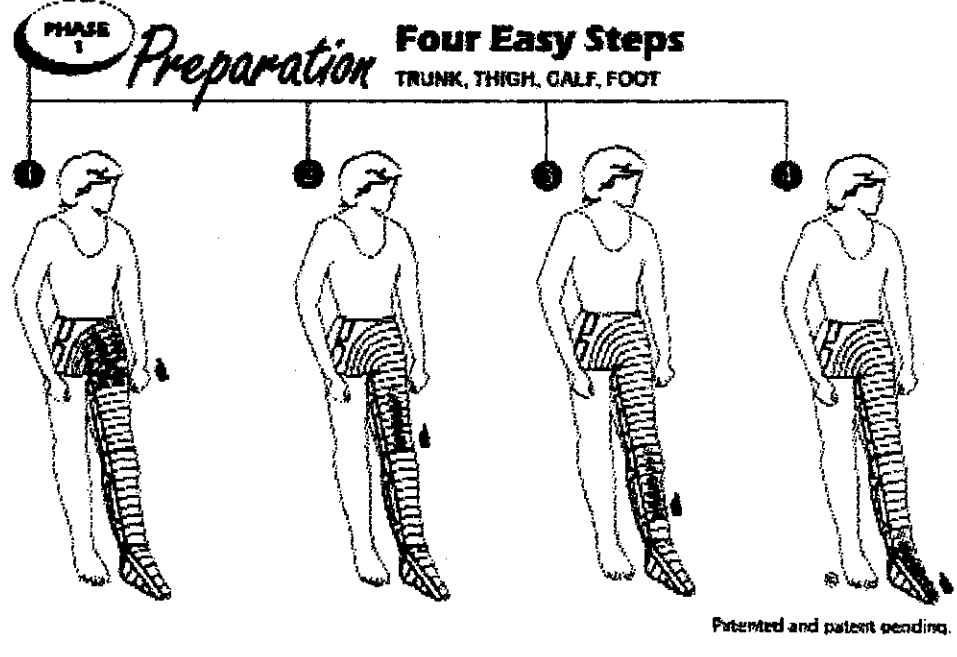
TREATING THE UPPER EXTREMITY ⇨ **Figure 1 Continued**



TREATING THE LOWER EXTREMITY ⇨ **Figure 2**



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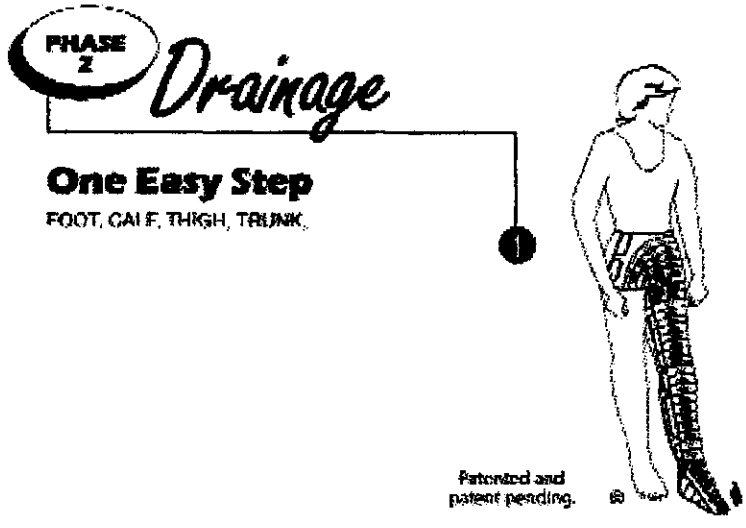
TREATING THE LOWER EXTREMITY ⇨ **Figure 2 Continued**



The ***biotouch***™ has thirteen different treatment programs so that individualized therapy can be performed as required by each patient's specific needs. All programs, except for LE01, utilize the specialized Lymph Preparation & Drainage™ treatment method.

The following table illustrates the body regions that are treated with each program and the order in which they are treated. During the preparation phase of treatment, the body sections are treated in the listed order from left to right. During the drainage phase, the body is treated in the reverse order, starting with the most distal segment. For example, program UE01 will begin by preparing the trunk, then the chest, the bicep, the forearm, and the hand in that order. Then, the prepared extremity is ready for drainage, starting at the fingertips. (see the "Treating the Upper Extremity" illustration.) In addition, the table provides the approximate time required to complete the selected program.

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Program Name	Body Regions Treated	Time (min)
UE01	trunk, chest, bicep, forearm, hand	60
UE02	trunk	12
UE03	trunk, chest	24
UE04	bicep, forearm, hand	36
UE05	forearm, hand	24
UE06	hand	12
LE01	trunk, thigh, calf, foot	60
LE02	trunk	15
LE03	trunk, thigh	30
LE04	thigh, calf, foot	45
LE05	calf, foot	30
LE06	foot	15
LE07	calf, foot (Drainage Phase Only)	30

The ***biotouch***™ device provides calibrated gradient sequential compression to the extremities using programmed pressure levels for each of the air chambers. These levels are pre-selected to provide optimal treatment outcomes. The following tables list the approximate pressure levels obtained in each air chamber within the selected body region based upon proper application of the extremity garments. The ***biotouch***™ device allows for manual selection of the applied pressure in the foot and hand regions, as required. As indicated, the difference between the Standard pressure setting and the Intense pressure setting is in the hand and foot regions.

The pressures listed are the average maximum pressures applied to each body region, based on wrapping the garments as recommended. The pressures are very comfortable due to the proprietary dynamic inflation and deflation cycles, the small width of each chamber and the soft touch of the extremity garments. In addition, these pressures are only obtained at the end of each inflation cycle and are not held for any period of time. That is, the pressure in each chamber increases up to the maximum value over the course of the inflation cycle, which only lasts from 1 to 3 seconds.

Upper Extremity Maximum Pressures

Body Section	Standard (mmHg)	Intense (mmHg)
Trunk	45	45
Chest	50	50
Bicep	55	55
Forearm	60	60
Hand	65	75

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Lower Extremity Maximum Pressures

Body Section	Standard (mmHg)	Intense (mmHg)
Trunk	45	45
Thigh	50	50
Calf	55	55
Foot	65	75

Indications for Use

The ***biotouch***™ device is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as:

- Primary lymphedema
- Post mastectomy edema
- Leg ulcers
- Edema following trauma and sport injuries
- Post immobilization edema
- Venous insufficiencies
- Lymphedema

Contraindications

The ***biotouch***™ device should not be used in the following cases:

- Pulmonary edema
- Thrombophlebitis
- Congestive heart failure
- Deep vein thrombosis
- Episodes of pulmonary embolism
- Infections and inflammations
- Acute cancer
- Where increased venous and lymphatic return is undesirable

The ***biotouch***™ Trunk-Thigh wraps should not be used during pregnancy.

Controller Set Up

The ***biotouch***™ system uses either a lower trunk and leg garments, or an upper trunk and arm garments. Care must be taken in connecting the garment's tubing harnesses. Please read and follow the instructions carefully. If the

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garment tubing harnesses are not correctly connected to the controller, according to manufacturers instructions, undesirable treatment may result and is not recommended.

Follow these steps to set up the controller for the therapy session:

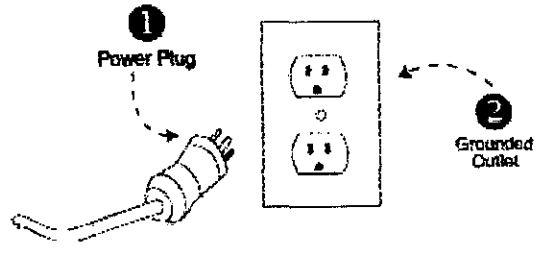
NOTE: Before following the set up instructions, please read through the entire user manual. There are illustrations to show you how to operate and hook up the wraps for easy set up.

1. **Preparing to set up the controller unit.**
   Place the controller unit on a sturdy, flat surface near a grounded electrical outlet. The carrying handle may be turned upward, or downward, by simultaneously pushing in on both handle release buttons, which are located on the sides of the controller handle, and rotating the handle.

2. **Connecting the power cord to a grounded AC outlet.**
   Set the power switch to the OFF position (i.e. "o" is depressed). Plug the female end of the power cord into the input power module in the back of the controller unit and the three-pronged male plug into a three-hole grounded AC electrical outlet.

   CAUTION ⇨ **To reduce the risk of electrocution:**
   To avoid potential shock hazard, be sure to plug the power cord into the controller unit before plugging the power cord into the electrical outlet.

   GROUNDED AC OUTLET ⇨ **Figure 3**



WARNING ⇨ This equipment is intended to be electrically grounded and is supplied with a hospital-grade power cord that contains a three-pronged plug–a plug with a grounding pin. This plug is designed to be used only with grounded AC outlets. Do not use any other power cord with your unit.

DO NOT ATTEMPT TO CUT OFF, BEND, OR REMOVE THE GROUND CONNECTION OR ALTER THE PLUG IN ANY WAY AS THIS MAY RESULT IN AN ELECTRICAL HAZARD.

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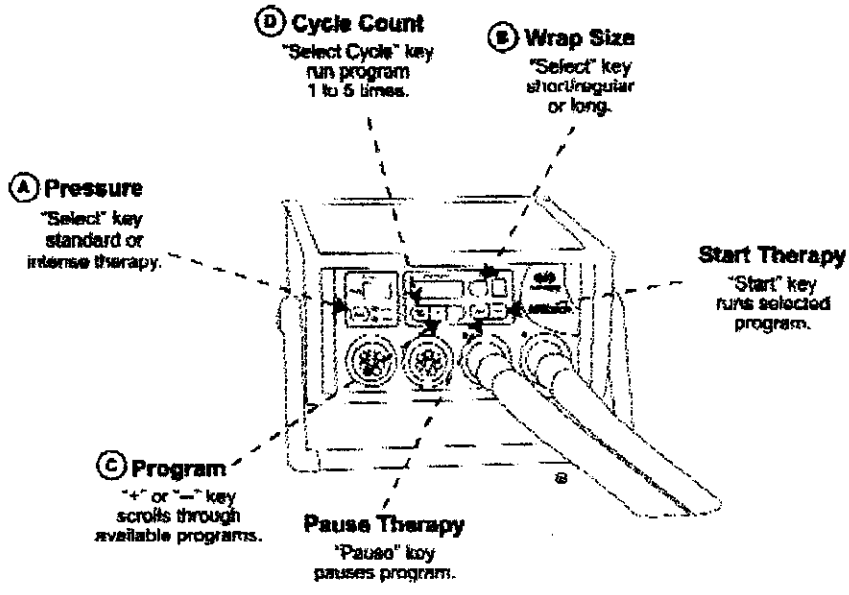
3. **Turn ON the controller unit.**
   Turn the controller unit ON (i.e. "I" is depressed) by using the switch located in the power input module on the back of the controller unit.

4. **Selecting the treatment pressure, wrap size, program, and cycle count.**
   Select the settings prescribed by your physician. The controller unit will remember the settings used for the last therapy session and will automatically default to these values. Therefore, in most situations these parameters will not need to be modified.

CONTROLLER UNIT DISPLAY ⇨ **Figure 4**



a. **Select prescribed pressure.**
   As explained in the "Description and Operating Principle" section, the intense pressure setting provides higher pressure application on the hand or foot regions, as appropriate. Press the Pressure "Select" key to toggle between Standard and Intense therapy.

b. **Select the wrap size.**
   Press the Wrap Size "Select" key to toggle between "S" (short/regular size wrap, or garment) or "L" (long size wrap, or garment).

c. **Select the program.**
   Press the "+" and "–" key to scroll through the list of possible programs, as provided in the "Description and Operating Principle" section of this manual. Locate the program your physician prescribed.

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d. Select the cycle count.
Press the "Select Cycles" key and notice that the Select Program display shows the currently selected cycle count ("CC x", where x is the number of times the selected therapy program will run). The controller allows the user to run the selected program from 1 to 5 times without interruption or restarting the controller. Each subsequent press of the "Select Cycles" key will increment the count until 5 is reached and then the next key press will cause the cycle count to return to 1.

NOTE: The Select Program display will automatically return to display the selected program after approximately 2 seconds have passed since the last time you pressed the "Select Cycle" key.

NOTE: See the front panel display illustration for details and follow the steps provided for selecting the appropriate controller settings.

5. Suggested Treatment Program

CAUTION ⇨ Always follow the treatment regimen prescribed by your doctor.

Recommended treatment programs for the ***biotouch***™ massage therapy system:

Condition	Program	Cycles	Pressure
Arm Lymphedema	UE01	1	Standard
Leg Lymphedema	LE01	1	Standard
Lower Leg Venous Insufficiency	LE07	1	Standard

6. Connecting the connectors to the controller unit (Figure 5)
Connect tubing harness located on each garment to the controller unit. The harness connector labeled "1" is attached to controller unit connector labeled "1". Likewise, the same is true for connectors labeled "2", "3", and "4". Locate the connector key on the face of the garment tubing harness connector (It is located between the two notches and on the same side as the connector number). Place this key in the notch of the corresponding connector on the controller unit. Firmly screw the ring onto the controller connector assuring that proper alignment has occurred. (Gently and slightly rocking the connector may assist in proper alignment.) Repeat for all required connections.

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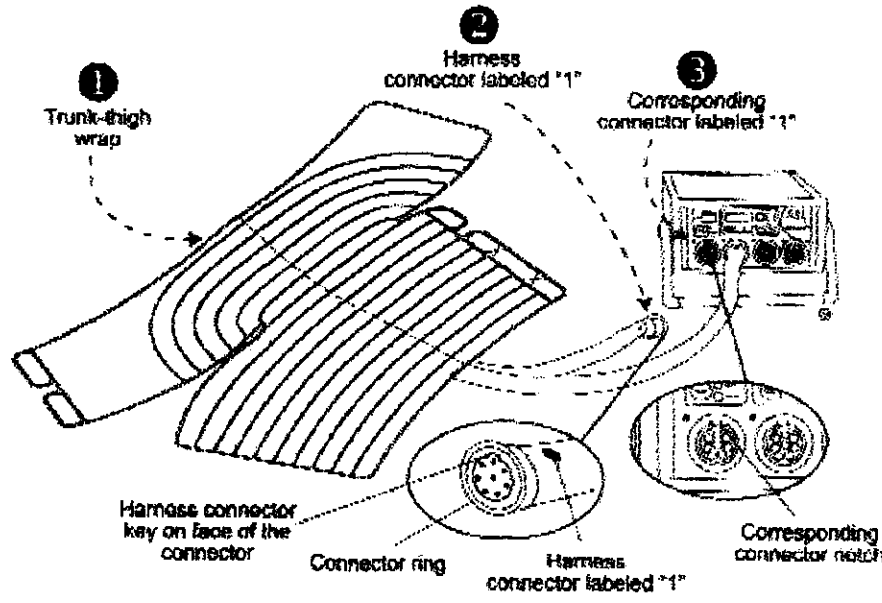
CONNECTING THE CONNECTORS ⇨ **Figure 5**



Applying the Garments

* * *

CAUTION: COTTON CLOTHING, SUCH AS A STOCKINETTE, SHOULD BE WORN AT ALL TIMES WHILE WEARING THE ***biotouch***™ GARMENTS. SKIN THAT WILL BE IN CONTACT WITH THE TRUNK AND EXTREMITY GARMENTS SHOULD BE COVERED. PROLONGED EXPOSURE OF THE SKIN TO THE GARMENTS MAY LEAD TO SKIN IRRITATION AND/OR A RASH. IF SKIN PROBLEMS APPEAR, CONSULT WITH YOUR DOCTOR.

Follow the instructions below for either the leg garment or arm garment, as appropriate.

Applying Leg Garments

* * *

1. **Initially applying the Trunk-Thigh LE garment (Figure 6)**
   Apply a white stockinette over your leg and foot to help keep the product clean and avoid any possible skin irritation. Place the Trunk-Thigh LE wrap on your bed and position it so that when you sit on the garment the center seam of the wrap will be along the side of your leg. In addition, make sure the top of the thigh area of the wrap (next to the cut out) is close to the groin area and can be lifted between your legs. If needed for your waist, attach a waist extender to the hook fasteners of the trunk section. A waist extender is available, if needed.

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INDICATIONS FOR USE AND DIRECTIONS FOR USE

CELLUM6 KEYMODULE i 510(k) #K053225			CROSS REFERENCE OF OUR INDICATIONS FOR USE TERMINOLOGY WITH PREDICATE DEVICES				
Treatment Head and Dimensions (length x width)		Indications for use	*Predicate:* Shepard K912004	*Predicate:* Progressive K914774	*Predicate:* Atlant's K974395	*Predicate:* Bio Compression K043423	*Added Predicate:* Flexitouch® (aka Biotouch) K013061
Keymodule i50 54 mm x 54 mm *Auxiliary heads for smaller surface areas:* T 644 or T 644-A 44 mm x 44 mm T 630 or T 630-A 30 mm x 30 mm T 615 or T615-A 23 mm x 15 mm	18 27.2 ~~K~~27.3	Reduction of secondary lymphedema of the arm (SLA) post mastectomy	Acute care of arm and leg swelling	Post mastectomy edema	Lymphedema	1.Primary or adjunctive treatment of primary or secondary lymphedema 2. General treatment of swelling in the extremities	Post mastectomy edema
	18 27.4						
	18 27.5	Prevention of venous stasis and venous insufficiency	Treatment of **lymphedema**, including post traumatic and rheumatic edema and chronic venous insufficiency and venous stasis ulcers	1. Post immobilization edema 2. Venous insufficiencies due to muscle activity	1. Chronic venous insufficiency 2. Edema of venous origin	Additional or alternate treatment of venous insufficiency and chronic venous stasis ulcers associated with venous insufficiency	1. Post immobilization edema 2. Venous insufficiencies
	18 27.2 to 27.5	Improvement of lymphatic circulation in the treated areas	Treatment of chronic edema	Not Applicable	Lymphedema	Not Applicable	Lymphedema

ATTACHMENT 7

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CLINICAL RESULTS COMPARISON TABLE WITH PREDICATES K013061 & K043423 vs. MLD

Clinical Study	Piller study of LPG® Technique			Wilburn study of Flexitouch®		Szuba study of BioCompression®	
Clearance Information	#K053225			#K013061		#K043423	
	Manual Lymphatic Drainage (MLD)	LPG Therapeutic Massager - Cellu M6 KMi 2004-5 Study	LPG Therapeutic Massager – Cellu M6 KMi 2006 Study	Manual Lymphatic Drainage (MLD)	Flexitouch® Compression Device	Decongestive Lymphatic Therapy (DLT = MLD + bandaging + exercise)	DLT + Bio Compression Intermittent Pneumatic Compression Pump
Treatment Time Period	4 weeks (4x each week) 16 sessions			14 consecutive days 14 sessions		2 weeks (5x each week) 10 sessions	
Volume Whole Arm Reduction (ml)	142.7 ml *Tab 24/Page 10 of original submission (See table)*	133.6 ml *Tab 24/Page 9 of original submission (See table 1A)*	186.3 ml *Tab 27/Page 17 of supplement S1 (Attachment 21a)*	- 52.7 ml*	210.5 ml*	Not Available	Not Available
Volume Whole Arm Reduction (%)	21.3 % *Tab 24/Page 10 of original submission (See table)*	18.2 % *Tab 24/Page9 of original submission (See table 1A)*	19% *Tab 27/Page 17 of supplement S1 (Attachment 21a)*	- 1.6 %*	6.6%*	26 % *Tab14/Page 1 of supplement S1 (Attachment 9) & Tab23/Page 23.1 of supplement S2 (Attachment 14)*	45.3 % *Tab14/Page 1 of supplement S1 (Attachment 9) & Tab23/Page 23.1 of supplement S2 (Attachment 14)*
Volume Forearm Reduction (ml)	129 ml *Tab 24/Page13 of original submission (See table)*	101.1 ml *Tab 24/Page12 of original submission (See table)*	137.7 ml *Tab 27/Page 17 of supplement S1 (Attachment 21a)*	Not Available	Not Available	Not Available	Not Available
Volume Forearm Reduction (%)	19.1% *Tab 24/Page14 of original submission (See summary)*	19.4% *Tab 24/Page14 of original submission (See summary)*	14% *Tab 27/Page 17 of supplement S1 (Attachment 21a)*	Not Available	Not Available	Not Available	Not Available
Volume Upper Arm Reduction (ml)	34 ml *Tab 24/Page16 of original submission (See figure 3B and table 3B)*	33.5 ml *Tab 24/Page15 of original submission (See figure 3A and table 3A)*	48.4 ml *Tab 27/Page 17 of supplement S1 (Attachment 21a)*	Not Available	Not Available	Not Available	Not Available
Volume Upper Arm Reduction (%)	Not Available	Not Available	4.9 % *Tab 27/Page 17 of supplement S1 (Attachment 21a)*	Not Available	Not Available	Not Available	Not Available

** Refer to pages 24.10X1 and 24.10X2 of attachment 15 of Supplement S2

ATTACHMENT 8

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ATTACHMENT 9

Lymphedema Clinical Studies Analysis

Cellu M6 Keymodule i (b)(4) [redacted]
vs.
Flexitouch (Wilburn, et al., 2006)
BioCompression (Szuba, et al., 2002)

Fluid Reduction Evaluation	(b)(4) Studies (I & II)	Wilburn Study	Szuba Study
Equipment Evaluated	Cellu M6 Keymodule i	Flexitouch Pneumatic Compression Device	BioCompression Pneumatic Compression Device + Decongestive Lymphatic Therapy (DLT)
Comparator	Manual Lymphatic Drainage (MLD)	Manual Lymphatic Drainage (MLD)	Decongestive Lymphatic Therapy (DLT = MLD + bandaging + exercise)
Fluid Reduction Measurement Methods	Perometry (b)(4) [redacted], ultrasound, lymphoscintigraphy, clinical photography	Formula calculation: $\frac{\text{Volume lymphedema}}{\text{Volume normal}} \times 100\%$	Water displacement volumetry

Evaluation methods of the 3 studies

In the Szuba BioCompression study, serial measurement of volume by water displacement was used to quantify limb volume for clinical evaluation. The response to therapeutic intervention (DLT and IPC vs. IPC alone) was quantified as the percent reduction.

In the Wilburn Flexitouch study, limb volume was calculated by an indirect volume measurement that utilizes surface measurements and a simplified formula derived from the formula for a frustum (truncated cone). The authors claim that this approach has been demonstrated to have excellent intra- and inter-observer reliability and to yield results that are statistically indistinguishable from the water displacement method, which is accepted by many as the "gold standard." The response to therapeutic intervention (IPC vs. MLD) was quantified as a percent reduction as well as a milliliter reduction in limb volume.

In the (b)(4) [redacted] Keymodule studies, limb volume was calculated by perometry (device using optoelectronics to measure arm circumference at every 3 mm), (b)(4) [redacted].

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ultrasound, lymphoscintigraphy and clinical photography. The (b)(4) studies used several methods to verify their data, whereas the Szuba and Wilbur studies used only one method each. (Only percent reduction and milliliter volume reduction were reported in our submission in order to comparably measure the data with the two predicate studies.) The response to therapeutic intervention (LPG vs. MLD) was quantified as a percent reduction as well as a milliliter reduction in limb volume.

Treatment techniques deployed by the different devices

1. BioCompression®
   The BioCompression Sequential Circulator treated secondary lymphedema of the arm by way of a four-chamber pneumatic sleeve and a gradient-sequential pneumatic pump. Patients received 30 minutes of IPC treatment per day at the designated pressure setting (40-50 mmHg), a total of 10 sessions in 2 weeks. **The action of the BioCompression device utilized positive pressure in a sequential gradient to move the fluid in the anatomical direction (distal to proximal) for lymphatic drainage.**

2. Flexitouch®
   The Flexitouch device contained a two-phase preparation and drainage program. Its garment utilized a composite of laminated materials that delivered variable stretch during inflation. This stretch was designed to simulate the therapist's hand movements during manual lymphatic drainage (MLD). The curved chambers of the Flexitouch garment help to optimize the redirection of fluid flow by lying perpendicular to the lymphatic pathways. This directed lymph fluid to follow anatomical pathways away from the affected limb toward unaffected lymph node regions. Each individual chamber was a narrow 1.5 inches (3.75 cm) wide, based on research indicating that chambers should be as narrow as possible to maximize flow from regions that have been compressed.[1]

   The Flexitouch delivered brief applications of mild pressure (amount not specified) for 1-3 seconds in a continuously moving, rhythmic work-and-release action that was repetitively applied in each section. No two chambers were ever fully inflated at the same time. Patients received IPC treatment for 1 hour daily for 14 consecutive days, a total of 14 sessions. **The action of the Flexitouch device utilized positive pressure in a sequential gradient to move the fluid in the anatomical direction (distal to proximal) for lymphatic drainage.**

3. Cellu M6 Keymodule® i
   The LPG device (Cellu M6 Keymodule i) treated lymphedema by way of a mechanical skin rolling technique facilitated by 2 rollers and vacuum aspiration that was sequentially programmed to create a (b)(4) stimulation to the skin and to simulate the therapist's hand movements during manual lymphatic drainage (MLD). (See Tab 3, Attachment 3a in Supplement S1 for a detailed description.) This provided both positive pressure (exerted by the 2

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rollers against the tissue) and negative pressure (on the skinfold drawn up by the vacuum aspiration) to the treated area. **The negative pressure exerted by the vacuum aspiration is incorporated into the LPG technology in order to facilitate the grasping of the skin into the treatment chamber. However, it is the** (b)(4) [redacted] (b)(4) [redacted] **hat provides displacement of fluid in the treatment of lymphedema.**

The dimensions of the treated area created by the motorized i50 treatment head were (b)(4) [redacted]. The 2 rollers housed in the treatment head created "rolling chambers". Patients received LPG treatment 4 times per week over the course of 4 weeks (16 sessions total) for 25 minutes in (b)(4) [redacted] and 30 minutes in (b)(4) [redacted] **The action of the LPG device utilized positive and negative pressure to grasp the tissue in conjunction with rollers to move the fluid in a sequential gradient following the anatomical direction (distal to proximal) for lymphatic drainage.**

Clinical goal/outcome sought by the devices

The predicate devices utilize positive pressure alone, whereas the LPG device utilizes both positive and negative pressure. **Regardless of the direction of the pressure, a** (b)(4) [redacted] (b)(4) [redacted] (Refer to Tab 15 in this supplement for more details and illustrative diagrams of this concept.)

Both the LPG device and the predicate devices stimulate the lymphatic system to move fluid through vessels with one-way valves. Between each one-way valve and the next is a lymphangion. The lymphangions have a layer of smooth muscle that spirals around them. Angion (meaning heart) is the "pump" that pushes the lymph. Each lymphangion has an internal stretch sensor. The walls of the lymphangion stretch when they fill up with lymph, which signals the stretch sensor to contract the muscle. The spiraling muscle contracts squeezing the lymph into the next chamber. This in turn causes the next lymphangion to swell and then contract, pushing the fluid down the line. **At the same time the lymphangion is pushing the lymph forward, it also is creating a vacuum behind it. It is partly because of this vacuum effect that the lymph gets pulled into the initial lymphatic vessel in the first place.**[2]

Once the lymphangions begin contracting, they cause a chain reaction, or a wave of contractions that start to push and pull the lymph through the body. In this way stimulating lymph flow in one area can increase lymph flow in another. Other factors that can assist the movement of the lymph are skeletal muscle contractions, breathing, the pulsing of arteries, as well the ability of the angions to contract independently of the stretch receptors. The effectiveness of the LPG and pneumatic compression devices (as well as manual lymphatic drainage) lies in their ability to (b)(4) [redacted]

(b)(4) [redacted] which significantly increases the pulsation rate of the lymphangions, increasing lymph flow through the vessels.

Specifically in the case of pneumatic compression, the action is performed through sequential compression of chambers using a (b)(4) [redacted]" action to move fluids in the proper direction for lymphatic drainage. The Cellu M6 Keymodule i treatment head is used in a similar fashion with (b)(4) [redacted] aspiration to move fluids in the same anatomical direction for proper lymphatic drainage.

(b)(4) [redacted]

Post-Mastectomy Arm Treatment: MLD Comparison to Flexitouch and LPG		
MLD	**Flexitouch**	**LPG**
Trunk area is decongested first	Preparation phase starts at the trunk.	Preparation phase of anastomosis on upper back
Each stroke stretches the skin to manipulate capillaries and smooth musculature of the lymph angions	Variable stretch is delivered against the skin during inflation using patented garment structure and proprietary materials.	Vacuum aspiration provides a mild stretch to the skin
The working phase of each stroke lasts about 1 second and is repeated	Repeatedly delivers applications of mild pressure	Repeatedly delivers applications of mild pressure
Moves lymph fluid from an affected trunk and limb to functional adjacent lymph node groups	Garments use up to 32 curved chambers to redirect fluid from the congested area to the functional adjacent lymph node groups	Treatment head creates the "rolling chambers" to move lymph fluid from an affected trunk and limb to functional adjacent lymph node groups
Prepares and drains the trunk and affected extremity	Uses 2 phases: Preparation and Drainage	Uses 4 phases: Preparation, Mobilization, Drain 1 and Drain 2

Comparative results

(See Clinical Results Comparison Table, Tab 13.)

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Interpretation of clinical studies table

Due to lack of statistical information provided by the Szuba and Wilburn studies, only whole arm percentage volume reduction can be compared across the board for all 3 studies.

The Szuba study achieved the highest value of volume reduction at 45.3%. However, this pneumatic compression device was not studied independently, but treatment was combined with all other lymphedema management treatments (massage, bandaging and exercise). Likewise, the MLD component of their study was also not studied independently, but rather, used in combination with bandaging and exercise. (Note: Bandaging was used as a constant treatment therapy for all 3 studies in both the device and MLD components.)

The Wilburn study achieved the lowest volume reduction value with isolated analysis of the Flexitouch device. The MLD component of their study reached a negative number. Due to lack of clear statistical analysis in this study, both of these values had to be extrapolated from the graphs provided. Therefore, to account for some margin of error, these reported values are approximated.

The (b)(4) studies achieved statistically significant volume reduction values as well as volume reduction percentages. This is further substantiated by significant reduction values of both the upper arm and forearm segments of the whole arm. All of these values were derived from isolated analysis of the Cellu M6 Keymodule i device, as well as isolated analysis of MLD.

Quality comparison of clinical studies

Per specific request, a detailed report was compiled to analyze the quality of the LPG studies conducted by (b) (6) . (See Tab 21.) In addition to this detailed report, the following is quality comparative information of the 3 clinical studies.

Both the Szuba and Wilburn studies were carried out at the Stanford Center for Lymphatic and Venous Disorders at Stanford University School of Medicine. This facility offers an extensive clinical research program with ongoing clinical trials making it unique among the few other U.S. programs that offer therapy for lymphedema. Though he was not the principle investigator, Stanley G. Rockson, M.D., director of the center, chair of the Scientific Advisory Board of the Lymphatic Research Foundation and member of the trans-NIH Coordinating Committee for Lymphatic Research, co-authored both studies.

The LPG study was carried out at (b)(4) , which has established a reputation as a leading research institution with an acclaimed devotion to innovation. It is a member of (b)(4) and ranks among the leading (b)(4) The principle investigator of this study, (b) (6) is

a lymphologist and the team leader of the (b)(4) [redacted] (b)(4) [redacted] He specializes in clinical and experimental research on primary and secondary lymphedema, along with its assessment, treatment and management.

Of the three clinical studies presented in this second supplement submission, the LPG studies conducted by (b)(6) [redacted] clearly are the most detailed. The initial treatment phases were carried out for the longest period of time (16 sessions, as opposed to 14 and 10 sessions). LPG used a truly valid comparator: manual lymphatic drainage (MLD), as did the Wilburn study of Flexitouch. The Szuba also used MLD as a comparator, but as a sub-component of Decongestive Lymphatic Therapy (DLT), which combines MLD, bandaging and specific exercises. **However, only the LPG study compared MLD performed by a trained Vodder[3] therapist. The other 2 predicate devices compared self-administered MLD, a method of therapy that is less consistent and would produce much less accurate results for good clinical analysis.**

Self-administered manual lymphatic drainage (MLD) is advocated as a standard technique in the management of chronic lymphedema, with a demonstrated capacity to sustain at least a major component of the benefits derived from the active therapeutic interventions undertaken with a trained physiotherapist. **However, the delicate massage technique designed to stimulate lymph vessels to contract more frequently, directing and channeling fluid toward adjacent functioning lymph basins, can be more effective and accurately measured when applied by a trained therapist than when self-administered.**

The LPG study clearly produced the greatest amount of statistical data. It reported whole volume reduction as well as upper and forearm volume, whereas the predicate studies only reported whole arm reduction. The Szuba BioCompression study only reported the percentage values. The Wilburn Flexitouch study did not actually report milliliter volumes or percentages at all, but demonstrated results in the form of a bar graph, from which numerical values had to be extrapolated for comparison. Lastly, the Wilburn study of the Flexitouch device only weakly concluded that the short-term evaluation "suggests" that the device "may" provide better maintenance edema control than the self-administered massage in breast cancer-associated lymphedema. The authors suggested that further broad-scale testing is warranted.

Conclusion

In conclusion, (b)(4) [redacted] studies conducted with the Cellu M6 Keymodule i clearly demonstrate good clinical practice and are "robust" in detail. All of the values showing reduction of Secondary Lymphedema of the Arm Post-Mastectomy were derived by evaluating the LPG device independently of other treatments and comparing those values to a valid comparator (manual lymphatic drainage [MLD]) with statistically significant results. Further, (b)(4) [redacted] studies used the same comparator (MLD) as was used by the FDA-cleared Flexitouch device in their Wilburn study.

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To the best of our knowledge and based on our good faith, we affirm that both of our clinical studies were well-controlled and conducted by qualified experts. (See attached quality analysis report Tab 21.) Our device provided safe and effective treatment of Secondary Lymphedema of the Arm Post-Mastectomy. The predicate devices (Flexitouch and BioCompression) did not provide as much robust clinical data, according to their published studies and our best efforts to research information on them. However, from the clinical data that was provided regarding reduction of arm fluid volume, our device, the Cellu M6 Keymodule i, provided results that are substantially equivalent to those results derived from the predicate devices.

The Cellu M6 Keymodule i, BioCompression and Flexitouch devices all utilize pressure (positive and/or negative) to simulate (b)(4) [redacted], necessary for horizontal fluid displacement, similar to that created by the action of the therapist's hands during manual lymphatic drainage (MLD). The end result is equivalent: reduction of lymphedema.

---

[1]Kelly D. *A primer on lymphedema*. Upper Saddle River, NJ:Prentice Hall, 2002:103.

[2]Kasseroller R. *Compendium of Dr. Vodder's Manual Lymph Drainage*, Haug, Heidelberg, 1998

[3]The Dr. Vodder method of MLD stimulates the contraction of lymph vessels through the pumping and stretching effect on the lymph vessels, helping to move the lymph forward and drain the connective tissue. Scientific research in Europe by Hutzschenreuter, Mislin, Földi, et al. has made this a well researched therapeutic technique.

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(b)(4)

[redacted]

ATTACHMENT 10

Substantially Equivalent Action

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(b)(4)

[redacted]

ATTACHMENT 11A1

KEYMODULE i

(b)(4)

[redacted]

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ATTACHMENT 11A2

(b)(4)

[redacted]

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ATTACHMENT 11A3

Endoscopic Images of Skinfold Inside i.50 Treatment Chamber

(skinfold created at power levels 1 -4)

(b)(4)

[redacted]

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Protocol for Endoscopic Visualization of Skinfold Images Inside i.50 Treatment Head Chamber

June 2006

Location: (b)(4) [redacted]

Objective: To visualize the different skinfolds generated in the i.50 treatment head at power levels 1, 2, 3 and 4.

Equipment: (b)(4) [redacted]

Subject: 49-year-old female with secondary lymphedema of the arm post mastectomy.

Treatment site: Upper arm.

Method: Through endoscopic photography, LPG was able to demonstrate the dimensions of the skinfold portion (b)(4) [redacted] of fluid displacement at power levels 1 through 4 (45 to 180 mmHg).

(b)(4) [redacted]

Measurements were obtained using millimeter-scaled graph paper applied to the internal side of the i.50 treatment. Each tiny gray box on the graph paper represents 1 mm. The diameter of each roller is 26 mm. Skinfold measurements can therefore be calculated as:

08 mm at power level setting 1
10 mm at power level setting 2
13 mm at power level setting 3
16 mm at power level setting 4

(b) (6), (b) (4) [redacted]

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ATTACHMENT 11A4

i.50 Treatment Head Dimensions

(b)(4)

[redacted]

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T615 and T615-A Auxiliary Treatment Head Dimensions

(b)(4)

[redacted]

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(b)(4)

[redacted]

T630 and T630-A Auxiliary Treatment Head Dimensions

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(b)(4)

[redacted]

T644 and T644-A Auxiliary Treatment Head Dimensions

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ATTACHMENT 11B

CROSS-SECTION OF 2 ADJACENT FLEXITOUCH CHAMBERS

(b)(4)

[redacted]

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CROSS-SECTION OF 2 ADJACENT FLEXITOUCH CHAMBERS

(b)(4)

[redacted]

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ATTACHMENT 12

QUALITY ANALYSIS OF (b)(4) STUDIES
(b)(4)

LPG Study: Secondary Lymphedema of the Arm Post-Mastectomy
Principal Investigator: (b) (6)

Task: Determine if the steps taken to initiate, conduct and terminate (b)(4) studies were completed according to appropriate international standards for conducting clinical trials for FDA clearance with attention to "study robustness".

In general, the steps taken when initiating, conducting and terminating both (b)(4) studies (b)(4) were done according to ICH GCP and the (b)(4). The following pages will discuss what components were present showing that both studies were "robust."

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I. Introduction

According to the *E6 Good Clinical Practice: Consolidated Guidance for Industry*, good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and wellbeing of trial subjects are protected and that the clinical trial data are credible.

The objective of this ICH GCP guidance is to provide a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

The guidance was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of AUSTRALIA, Canada, the Nordic countries, and the World Health Organization (WHO).

This guidance should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities. The principles established in this guidance may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

II. Question: Were (b)(4) studies "robust"?

Yes. In response to the potential issues related to the studies' robustness, the following addresses key points showing the studies' robustness.

A. "Robust" criteria related to International Standards of conducting clinical research:

1. With regard to (b)(4) studies, it should firstly be noted that the studies were conducted at the (b)(4), in English-speaking (b)(4), which is one of the countries from where the ICH GCP guidelines were developed.

2. (b)(4) studies were carried out and conducted according to the Good Clinical Practice (GCP) guidelines developed by the International Conference on Harmonization (ICH).

3. (b)(4) studies' protocols (b)(4) the guidleines for how a clinical trial is conducted and reviewed by external regulatory agencies according to the principles contained in the (b)(4) (b)(4) (b)(4) is located in (b)(4) where it is required that all protocols

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are considered by relevant ethical review committees whose jurisdictions cover the sites where studies will take place.

4. (b)(4) studies were carried out according to 21 Code of Federal Regulation 50 & 56, as the IRB approval was obtained by a related ethics committee in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans (June 1999) (b)(4). The informed consents were also approved and obtained for each medical record of each participant.

5. (b)(4) studies were carried out under Good Clinical Practice, as all documents were present in file; i.e. informed consent, IRB approval, study protocol, CRF, statistical report, etc.

B. "Robust" criteria related to specific study design related to therapy and disease selection when conducting clinical research:

6. (b)(4) study's choice of the correct selection of duration and frequency of the LPG device is based on previous studies.

7. The target validation and/or biological activity of the clinical study are/is validated methods of measurements such as arm volume, lymphoscintigraphy, ultrasound and subjective patient report.

8. Lymphedema was chosen as the appropriate choice of disease, given the lack of response from conventional therapies such as MLD and garments. Secondary lymphedema of the arm post-mastectomy affects some 25-30% of women. It may remain latent for 3.5 years and often the arm swells 150-200% of its normal limb volume. The burden of disease caused by secondary lymphedema certainly merits observation and further research to identify a therapy that would improve the patient's health.

C. Introduction to (b)(4) studies (b)(4)

(b)(4) 52 women are recruited of which 45 complete. The participants are randomized into control group (MLD, 45 mins 4x/wk for 4 weeks with 1 month follow up) and experimental group (LPG, 25 mins, 4x/wk for 4 weeks with 1 month follow up). Measurements are taken at Day 0, Day 1, Day 7, Day 10, Day 14, Day 17, Day 21, Day 23, Day 30 and Day 60 (follow up). Measurements include: medical history, lymphedema history, previous lymphedema treatment, perometry (whole arm volume, affected forearm volume, affected upper arm volume), (b)(4) (affected arm fluid, truncal fluid), body weight, fat mass and body fat, (b)(4) (posterior and anterior thorax, forearm, upper arm), blood pressure (systolic, diastolic, pulse), subjective symptoms and voluntary tests (ultrasound and lymphoscintigraphy).

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In both studies, the objectives were:

- Reduce size and volume of chronic lymphedema limb
- Reduce level of extracellular fluid in lymphedema limb
- Reduce amount and extent of fibrotically tissue in limb
- Improve lymphatic transport capacity
- Improve arm range of motion
- Improve patient subjective indicators

From the previous study (b)(4) [redacted], the results (using auxiliary treatment heads T644, T630 and T615 according to the morphology of the treated areas) were positive for the LPG group on the swollen arm and other parts of the body. There was a significant drop of subjective symptoms, softening of anterior thorax and tissue in lymphatic territories of forearm and upper arm. Recommendations followed for (b)(4) [redacted] study and were based on the assumption that better reduction of fluid in the affected limb (reduction of size and volume of the affected limb) could be gained by a slightly longer LPG treatment with greater concentration of clearance across the anterior and, particularly, the posterior watersheds and lateral upper arm, in addition to the use of a larger motorized treatment head (i.50).

Therefore, in (b)(4) [redacted], 10 women with post mastectomy arm lymphedema were enrolled. The main difference between (b)(4) [redacted] and (b)(4) [redacted] was the increased treatment time from 25 minutes to 30 minutes, and the use of a larger motorized treatment head (i.50). (See Results Comparison Table Tab 13.)

D. (b)(4) [redacted] study

The following were a list of documents provided for review:

1. Institutional Review Board (IRB) approval
2. Informed Consent
3. Study Protocol
4. Case Report Form
5. Final Report

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Criteria	Contents/ Information	More Information	Checklist Yes or No
Ethics Committee Approval Obtained	On August 5, 2003, the study was approved by (b)(4) (b)(4) (b)(4).	(b)(4) (b)(4) is constituted and operated in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans (June 1999) (b)(4).	Yes
		Items covered: IRB approval, progress reports annually provided to IRB, I.C. signed as part of participant's medical record, IRB must approve advertisement, IRB must be notified of any changes to protocol, AND the duty of the Principal Investigator to inform the IRB of any adverse or unforeseen events and change in the base for the decision made by the Committee.	Yes
Ethics Committee Approval Obtained	On (b)(4), the study is approved for the following 12 months.		Yes
Research Program Clearly Delineated	All components present: Background, Progression of lymphedema, LPG device, Manual Lymphatic Drainage, Objectives, Methods, Matched Pair, Duration of treatment/ study, Subject inclusion criteria, Measurements		Yes
Participant Informed Consent (I.C.) Provided	All components present: Background, Study Plan, Benefits/ Risks, Measurements, Confidentiality, Contact information of P.I., Right to withdraw and Signature page		Yes

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Maps to Study Sites provided	Directions with illustrated map provided to patient		Yes
Case Report Form provided for each patient	All components present: Background History, Lymphedema Onset, Logs for documenting MLD and LPG drainage, bandaging, Questions pre-massage sessions, BioData, Subjective Symptoms, Log for Compression Bandaging		Yes
Final Report with Statistical Results Provided May 2005	All components present: Background, MLD, LPG technique, Aim, Methods (Study Plan, Inclusion/ exclusion criteria, Measurements and their validations, Analysis, Results with tables and concluding summaries, Overall summary, and Recommendation for improvement of outcomes	Overall, both treatment regimes resulted in similar reductions in arm volume, arm fluid, truncal fluid and body weight. Both regimes also resulted in lymphatic territory softening and improvement in subjective symptoms. It is of interest to note that the majority of parameters although they increased at one month follow-up, they did not return to baseline values.	Yes Conclusive Final Report

E. (b)(4) [redacted] study

The following were a list of documents provided for review:

6. Institutional Review Board (IRB) approval
7. Agreement with LPG System for the Provision of Contract Research Services
8. Informed Consent
9. Research Program/ Study Protocol
10. Case Report Form
11. LPG Treatment Protocol
12. Final Report (b)(4)
13. Certification: Financial Interests and Arrangements of Clinical Investigators

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Criteria	Contents/ Information	More Information	Checklist Yes or No
Ethics Committee Approval Obtained	Ethics Committee's involvement continues with the study as "letter dated (b)(4) [redacted] amendment to original protocol was received, noted approved."	Principal Investigator continues close relationship with IRB	Yes
Ethics Committee Approval Obtained	On (b)(4) [redacted], the study is approved for the following 12 months. (b)(4) [redacted]	Extension is received to continue into (b)(4) [redacted]	Yes
Agreement with LPG System for the Provision of Contract Research Services	Delineating the Role and Responsibility of Researcher and Client And it was dated on (b)(4) [redacted]		Yes
Research Program Clearly Delineated	All components present: Background, Objectives, Methods, Matched Pair, Duration of treatment/ study, Subject inclusion criteria, Measurements, Budget are included		Yes
Participant Informed Consent (I.C.) Provided	All components present: Background, Study Plan, Benefits/ Risks, Measurements, Confidentiality, Contact information of P.I., Compensation, Right to withdraw and Signature page		Yes
LPG Treatment Protocol	Two documents provided: Three page illustrated document describing 30 minute LPG session AND Cellu M6 Keymodule i/ Therapeutic Application Sheet		Yes

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Case Report Form provided for each patient	All components present: Background History, Lymphedema Onset, Logs for documenting MLD and LPG drainage, bandaging, Questions pre-massage sessions, BioData, Subjective Symptoms, Log for Compression Bandaging		Yes
Final Report with Statistical Results Provided 2006	All components present: Introduction, Results with tables and concluding summaries, Overall summary, and Recommendation for improvement of outcomes	Overall this new protocol resulted in truncal fluid, arm fluid, and volume reductions and improvements in (b)(4) reading and subjective symptoms. The new treatment compared to 2004 protocol appears to be advantageous in that the additional drainage time negates an increase in upper arm volume and softens tissue in the posterior thorax territory.	Yes Conclusive Final Report

Concluding Remarks:

Both (b)(4) studies appear to be robust. The studies were developed to address secondary lymphedema of the arm post-mastectomy whose burden of disease is much greater than the medical options available to patients. Both (b)(4) studies (b)(4) were designed, conducted, recorded, and reported in accordance with the international standards of how to conduct clinical studies (i.e., IRB approval, study protocol, CRF, IC, data collection, and statistical analysis) involving the participation of human subjects according to GCP ICH guidelines, 21 CFR 50 & 56, and the principles contained in (b)(4).

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(b)(4)

ATTACHMENT 13

(b)(4)

(b) (6)

LPG One Inc
801 Brickell Avenue Ste. 850
Miami, Florida 33131

(b)(4)

Dear (b) (6)

Re: LPG Clinical Trial, Phase One

As per your recent request to us regarding the model of the treatment head used during the clinical trial of the effectiveness of manual lymphatic massage (MLD) and machine based massage (LPG) on post mastectomy arm lymphoedema, we confirm that the following treatment heads were used for the study.

We confirm that, during the clinical trial, the Auxiliary head T644 was used on the upper arm. The Auxiliary heads T630 and T615 were also used throughout the trial predominantly on the forearm and wrist.

We also confirm that the ACTIVE heads were used for steps 1 and 3 of (b) (6) trial and the INACTIVE heads was used for step 2.

(b) (6) protocol included the following steps:

1. To Prepare the anastomosis - (b)(4) program
2. To Mobilise the fibrosis - (b)(4) t suction program
3. To Drain the upper limb - (b)(4) program

(b) (6)

(b)(4)

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(b)(4)

(b)(4)

(b) (6)

LPG One Inc
801 Brickell Avenue Ste. 850
Miami, Florida 33131

Dear (b) (6)

Re: LPG Clinical Trial, Phase One

As per your follow up request to us regarding the power levels used during the clinical trial on post mastectomy arm lymphoedema, we confirm the following.

As stated in (b) (6) original trial protocol the following power levels were applied. At no time did the trial go over power level 4, in fact on most cases the power level was kept to level 2 and 3. The level used was dependent on the fibrosis in the lymphatic territories

The power levels indicated relate to:

- Power 1 - 45 mmHg
- Power 2 - 90 mmHg
- Power 3 - 135 mmHg
- Power 4 - 180 mmHg

I hope this clarifies your queries. If you have any further requests, please don't hesitate to contact me.

Kind Regards

(b) (6)

(b)(4)

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ATTACHMENT 14

Decongestive Lymphatic Therapy for Patients with Breast Carcinoma-Associated Lymphedema

A Randomized, Prospective Study of a Role for Adjunctive Intermittent Pneumatic Compression

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BACKGROUND. Disruption of the lymphatic circulation through breast carcinoma-associated axillary lymph node dissection, with or without radiation therapy, reportedly is the most common cause of lymphedema in developed countries. There is no cure for breast carcinoma-associated lymphedema. Although intermittent pneumatic compression (IPC) has been acknowledged as a potential component of the multidisciplinary therapeutic strategy in the treatment of patients with breast carcinoma-associated lymphedema, prospective study of its adjunctive safety and efficacy is required.

METHODS. IPC was assessed as a component of the initial therapeutic regimen for newly treated patients with breast carcinoma-associated lymphedema. Twenty-three patients who had not previously been treated for lymphedema were randomized to receive either decongestive lymphatic therapy (DLT) alone or DLT with daily adjunctive IPC. Patients with stable, treated, breast carcinoma-associated lymphedema also were assessed in the maintenance phase of therapy. Twenty-seven patients were randomized either to DLT alone or to DLT coupled with daily IPC. In both studies, objective assessment included serial measurement of volume by water displacement, tissue tonometry to assess elasticity of the skin, and goniometry to measure joint mobility.

RESULTS. During initial treatment, the addition of IPC to standard DLT yielded an additional mean volume reduction (45.3% vs. 26%; $P < 0.05$). During maintenance DLT alone, there was a mean increase in volume (32.7 ± 115.2 mL); with DLT and IPC, there was a mean volume reduction (89.5 ± 195.5 mL; $P < 0.05$). In both studies, IPC was tolerated well without detectable adverse effects on skin elasticity or joint range of motion.

CONCLUSIONS. When IPC is used adjunctively with other, established elements of DLT, it provides an enhancement of the therapeutic response. IPC is well tolerated and remarkably free of complications. ***Cancer* 2002;95:2260–7.**

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DOI 10.1002/cncr.10976

KEYWORDS: lymphedema, edema, breast carcinoma, biocompression.

Lymphedema can be defined as the generalized or regional accumulation of protein-rich interstitial fluid that occurs primarily as a consequence of malformation, underdevelopment, or acquired disruption of the lymphatic circulation. With chronic impairments in lymphatic drainage, the ensuing edematous state is characterized over time by the secondary proliferation of fibroblasts, keratinocytes, and adipocytes; the accumulation of collagen; and the destruction of elastin fibers within the skin.

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Edema of the arm after axillary lymph node dissection reportedly is the most common cause of lymphedema in developed countries.[1] In general, without regard to the individual surgical approach or the elapsed time since treatment, approximately one in four women develops arm edema after treatment for breast carcinoma.[2] Once it is established, lymphedema has an inexorable tendency to progress.[3] Although the risk of developing lymphedema after therapy for breast carcinoma has been associated with anatomic risk factors, such as the extent of axillary lymph node dissection and the patient's exposure to axillary radiation, this awareness has reduced, but not eliminated, the problem of breast carcinoma-associated lymphedema.[2] The advent of upper extremity edema has a distinct detrimental effect on the perceived quality of life for breast carcinoma survivors.[4] Patients with arm edema secondary to breast carcinoma therapy experience a substantial degree of functional impairment, psychological morbidity, and diminished quality of life.[4–7]

With the remarkable advances that have accrued both in the early detection of breast carcinoma and in the successful application of effective adjuvant therapies, it is increasingly imperative that suitable treatment measures be developed for the sequelae of breast carcinoma therapy, like lymphedema, that impair patients' functional status or perceived quality of life.

There is no cure for breast carcinoma-associated lymphedema. A variety of physiotherapeutic interventions have been proposed for the control of symptoms and to minimize complications. In 1998, the American Cancer Society conducted an international conference to address the need to prioritize diagnostic and treatment strategies for patients with breast carcinoma-associated lymphedema.[8] The resulting recommendations emphasized the aggressive use of a variety of physiotherapeutic interventions to control lymphedema symptoms and to minimize complications.[8] Since that time, prospective investigation of the standard elements of decongestive lymphatic therapy (DLT), including manual lymphatic massage, multilayer compressive bandaging, and the use of compressive garments, has validated the utility of these interventions for the control of acquired lymphedema.[9,10]

Although intermittent pneumatic compression (IPC) has been acknowledged as a potential component of the multidisciplinary, therapeutic approach to treating patients with breast carcinoma-associated lymphedema,[8] conclusive, prospective documentation of the beneficial role of this modality has not been provided.[11] Accordingly, we undertook a prospective, randomized study to investigate the safety and relative efficacy of pneumatic compression therapy for the treatment of patients with breast carcinoma-associated upper extremity lymphedema when used adjunctively with compression bandaging and manual lymphatic massage.

MATERIALS AND METHODS

Design of the Trial

The prospective evaluation of pneumatic compression therapy in patients with breast carcinoma-associated lymphedema was undertaken in two phases. In the first phase (Study 1), adjunctive IPC was assessed for its role as a component of the initial decongestive therapy prescribed for patients with previously untreated lymphedema. This was a 10-day, randomized study with a 30-day follow-up. In the second phase (Study 2), a prospective study was performed to evaluate the adjunctive benefit of IPC for maintenance therapy in patients with stable, chronic, breast carcinoma-associated lymphedema. This study was conducted with a randomized, 2-month, cross-over design and included a 6-month follow-up.

Patients

Study 1 (initial therapy)

Patients with lymphedema of the upper extremity after surgical and/or radiotherapeutic interventions for breast carcinoma were eligible for enrollment. Recruitment was undertaken from the population of patients who presented to the Stanford Center for Lymphatic and Venous Disorders for prospective evaluation of upper extremity edema in the setting of therapy for breast carcinoma. The patient characteristics are shown in Table 1.

Inclusion and exclusion criteria for Study 1

Patients were eligible for inclusion if they presented with breast carcinoma-associated lymphedema, which was defined as the presence of an increase $\geq$ 20% in the volume of the swollen limb compared with the volume of the contralateral, normal arm. For this reason, patients with bilateral disease were excluded. Volume was assessed by water-displacement volumetry, as described below. Patients were required to have an interval of at least 12 weeks from the completion of breast carcinoma therapy (either surgery, or radiotherapy, or both) prior to enrollment in the trial. Evidence of bilateral lymphedema; breast carcinoma recurrence; active clinical infection; or clinically evident, concomitant venous occlusion constituted the exclusion criteria for Study 1.

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TABLE 1
Demographics by Patient Group in Study 1

Variable	Group I	Group II
No. of patients	12	11
Age (yrs)		
Mean ± SD	68.8 ± 9.11	65 ± 10.8
Range	56–81	47–81
Duration of edema (mo)		
Mean ± SD	41.1 ± 62.3	35.6 ± 21.6
Range	3–180	3–72
Excess limb volume (%)		
Mean ± SD	41 ± 32.9	43.8 ± 24.3
Range	11–104	16.5–86
Axillary dissection alone (no.)	2	5
History of radiation therapy (no.)	10	6
History of recurrent cellulitis (no.)	4	3
History of hypertension (no.)	5	4
Reduced joint mobility (no.)	8	3

SD: standard deviation.

Study 2 (maintenance therapy)

Patients with stable, treated, breast carcinoma-associated lymphedema of the upper extremity were eligible for randomization into Study 2.

Inclusion and exclusion criteria for Study 2

Patients were eligible for inclusion in Study 2 if they demonstrated chronic lymphedema of a single extremity as a consequence of prior therapy for breast carcinoma and had completed the initial course of intensive DLT at least 1 month and less than 1 year prior to the time of enrollment in the study. Exclusion criteria included the presence of recurrent malignancy, active infection, clinical evidence of venous obstruction, or bilateral lymphedema of the upper extremity.

For both studies, informed consent was obtained from all participants. The study was performed under the auspices of the Institutional Review Board of Stanford University.

Treatment Methods

Decongestive lymphatic therapy (DLT) was performed as described previously.[10] In summary, DLT is a multidisciplinary, physiotherapeutic approach to improve lymphatic flow and reduce the excess limb volume of lymphedema. All patients received their outpatient therapy at the Stanford Center for Lymphatic and Venous Disorders. Each session of therapy included manual lymphatic drainage (MLD; from 30 minutes to 1 hour, as required), compressive wrapping of the limb with minimally elastic bandages, and decongestive exercises. MLD was performed according to the technique advocated by the Vodder School.[12] At each treatment session, massage was followed by decongestive exercises and multilayered, low-stretch compressive bandaging (Comprilan®; Beiersdorf, Germany). Bandages were left in place for the interval spanning successive daily manipulations. Each patient received 10 days of daily DLT.

When IPC was used, it was applied to the treated arm with a four-chamber pneumatic sleeve and a gradient-sequential pneumatic pump (Sequential Circulator 2004; BioCompression Systems Inc.). A standard pressure setting of 40–50 mmHg was used. In Study 1, for the patients who were randomized to this treatment arm, IPC was performed daily for 30 minutes at the designated pressure settings. In Study 2, IPC was prescribed as a daily, self-administered session of 60 minutes at the same pressure settings.

Treatment Regimens

Study 1

Patients were randomized to one of two treatment groups. In Group I, IPC (30 minutes at 40–50 mm Hg) was performed daily after MLD and before compression bandaging. Patients in Group II received standard, initial, decongestive therapy without the adjunctive IPC. After completion of the initial intervention, all patients were fitted with a Class II compression garment (MEDI USA) to be worn on a daily basis. Patients were instructed in the techniques of self-applied manual lymphatic massage, which was continued on a daily basis at home after completion of the initial decongestive intervention. Assessments of limb volume, tissue elasticity, and joint mobility were performed at the time of enrollment and subsequently on Days 10 and 40 (follow-up, Day 30) of the study.

Study 2

After an initial objective assessment of limb volume and skin tonometry, patients were randomized to one of two arms of the study. In the first arm of the study, the patients were instructed simply to continue maintenance measures for lymphedema (daily, self-administered, manual lymphatic massage and the Class II compression garment). In the second arm of the study, these maintenance techniques were supplemented with 1 hour of IPC. Each patient was supplied with a gradient-sequential pneumatic pump (Sequential Circulator 2004; BioCompression Systems Inc.) for their home use. All patients were reassessed after 1 month of therapy and, thereafter, cross-over to the alternate arm was undertaken during the second month, and this was followed by a complete, objective reevaluation.

Quantitative assessments were performed at the

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time of enrollment and at the completion of each arm of the study. Upon completion of both arms of this study, each patient was given the opportunity to maintain the adjunctive home use of pneumatic compression therapy. All such patients were reassessed objectively after a period of 6–12 months of continuous therapy. Compliance with the therapy was assessed through an exit interview of the patient at the completion of the study.

Measurements and Assessments

Tank volumetry

Water-displacement volumetry was used to quantitate limb volume prior to randomization and at each subsequent clinical evaluation. Each limb was immersed sequentially in a water-filled tank. The displaced fluid was collected and measured. The patient rested the immersed hand on a plastic bar positioned within the tank to ensure consistency in the depth of immersion with repetitive, sequential volume determinations.

The response to the therapeutic intervention (DLT and IPC vs. DLT alone) was quantified as the percent reduction in limb volume (Study 1) or as the absolute reduction in limb volume (Study 2), as follows: $Vpre_A$: volume of the affected arm prior to treatment; $Vpre_N$: volume of the nonaffected arm prior to treatment; $Vpost_A$: volume of the affected arm after treatment; $Vpost_N$: volume of the nonaffected arm after treatment; Δpre arm volume difference prior to treatment ($Vpre_A - Vpre_N$); Δpost arm volume difference prior to treatment ($Vpost_A - Vpost_N$); absolute arm volume reduction: Δpre − Δpost and % volume reduction: [(Δpre − Δpost) / Δpre] × 100.

Skin tonometry

Skin tonometry measurements were performed as described previously.[13,14] We used a mechanical tonometer with a base diameter of 1 cm and a probe weight of 60 g. The probe was applied to the skin of the forearm for 1 minute before the quantitative recording of the depth of the probe descent as a measure of tissue elasticity.

Goniometry

The range of motion of the shoulder, elbow, and wrist joints was quantitated with the standard techniques of goniometry.[15] The quantitation of range of motion was performed prior to randomization. For all patients with impaired range of motion at baseline, the effect of therapeutic randomization on joint range of motion was reassessed at each subsequent clinical reevaluation.

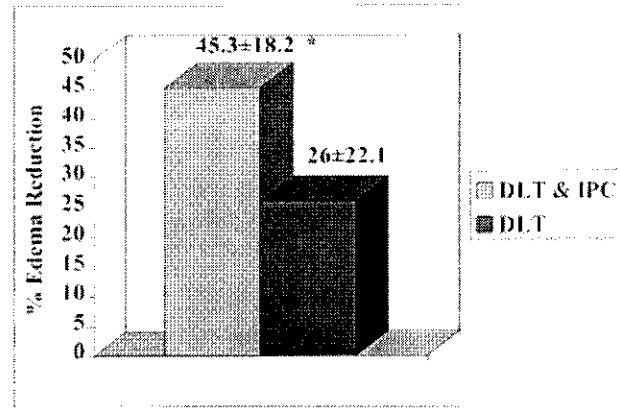

FIGURE 1. The effect of adjunctive, intermittent pneumatic compression (IPC) on initial decongestive lymphatic therapy (DLT) in patients with breast carcinoma-associated lymphedema. The data depict the percent reduction in volume of the limb attained after 10 days of daily therapy with either 1) DLT plus IPC or 2) DLT alone. The data are provided as the mean ± standard deviation for each group. The asterisk denotes a statistically significant difference ($P < 0.05$, unpaired t-test).

Data Analysis

Data were assessed using both paired and unpaired t-test and analyses of variance.

RESULTS

Study 1

Demographics

Twenty-three women with arm lymphedema were recruited into the study. The mean patient age was 66.9 years (range, 47–81 years), and the average duration of untreated arm lymphedema was 48.3 months (range, 3–180 months). For these patients, the average time elapsed from breast carcinoma therapy was 144.1 months (range, 11–408 months). Sixteen of 23 patients had undergone adjunctive radiation therapy. Seven patients had a history of recurrent cellulitis, and eight patients had a history of hypertension.

Clinical responses

Twelve patients were randomized to Group I (DLT plus IPC), and 11 patients were randomized to Group II (DLT alone). After 2 weeks of treatment, the mean percent reduction in volume of the edematous arm was 45.3% for Group I and 26% for Group II ($P < 0.05$, Fig. 1). The therapeutic benefits were durable: after the completion of intensive therapy, at Day 40, the mean % volume reduction was 30.3% (range, − 13% to 83%) for Group 1 and 27.1% (range, − 23% to 59.5%) for Group 2. These results were not significantly different compared with the outcomes noted at Day 10. For each treatment group, the serial tonometry mea-

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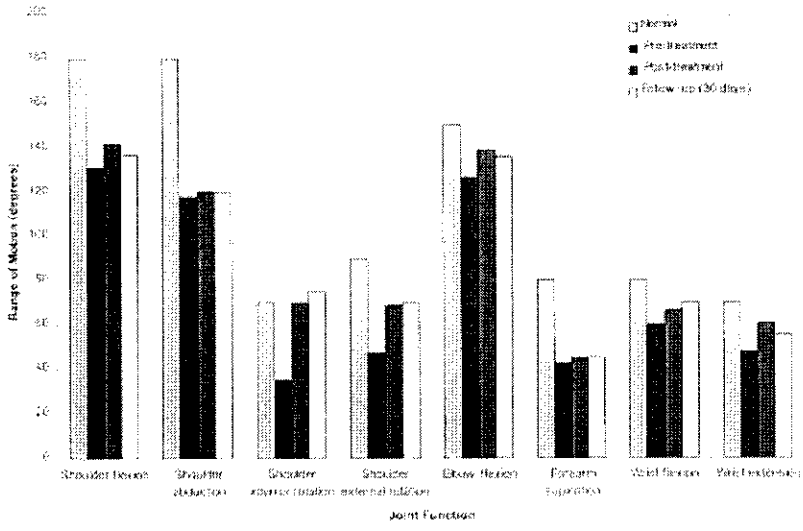

FIGURE 2. The effect of therapeutic choices on joint mobility after initial decongestive therapy and after 30 days of follow-up. All range-of-motion determinations were obtained by standard goniometry. The graph depicts the data derived from those patients who presented with an initial pretreatment impairment of joint mobility. Because the number of patients from Group II with preexisting mobility problems was small (see Table 1), the data represent the aggregate measurements from patients in both Group I and Group II. The patients who presented without an initial impairment of joint mobility did not change during or after therapy and are not shown.

surements of skin elasticity revealed no significant differences between the pretreatment values and posttreatment values (paired *t*-test). Furthermore, a comparison between DLT plus IPC (2.4 mm ± 0.7 mm) and DLT alone (2.3 mm ± 5.7 mm) revealed no significant difference (unpaired *t*-test).

Adverse effects

The addition of IPC to standard DLT techniques was well tolerated almost universally. In one instance, a patient from Group II repetitively experienced headache and modest increases blood pressure during pneumatic compression pump therapy.

Goniometry

To examine the potential for adverse consequences of IPC on joint mobility, we examined the effect of the adjunctive therapy on the subgroup of individuals who presented with impaired upper extremity range of motion at the time of randomization. Shoulders, elbows, and wrists were evaluated by goniometry along with forearm supination. Eleven of 23 patients in Study I (48%) had objective evidence of impaired range of motion at baseline. Of these, eight patients were randomized to receive DLT plus IPC therapy (Group I), and three patients received DLT only (Group II).

After patients received therapy for initial volume reduction, joint mobility improved uniformly ($P = 0.011$; baseline compared with posttreatment), without regard to treatment group (Fig. 2). There were no significant differences among the changes observed at the conclusion of treatment (Day 10) and at Day 40.

Study 2

Demographics

Twenty-seven patients were recruited for the study, with a mean age of 65.9 years (range, 43–81 years). The average duration of lymphedema was 60 months (range, 3–480 months), and the average time from surgery was 113.7 months. Twenty-five of 27 patients completed the study. Two patients voluntarily withdrew.

Clinical responses

During the month of self-administered maintenance therapy with DLT alone, there was a mean ± standard deviation increase in volume of the treated limb of 32.7 ± 115.2 mL. There was no apparent effect of treatment order. Conversely, during the month of therapy that included self-administered, adjunctive IPC, without a perceptible effect of treatment order, there was a mean volume reduction of 89.5 ±195.5 mL ($P < 0.05$; Fig. 3). Tonometry performed at the conclusion of Study II revealed no significant difference between the group that was randomized to receive IPC first (2.2 mm ± 0.6 mm) and the group that was randomized to receive DLT first (1.9 mm ± 0.8 mm; unpaired *t*-test). There were no adverse responses observed to maintenance IPC.

Follow-up study

Of 25 patients who completed Study 2, 20 patients elected to continue the use of the pump as an adjunct to their daily maintenance DLT. One patient died during the follow-up study; the remaining 24 patients were available for follow-up reassessment at 6 months. Nineteen of those 24 patients continued to

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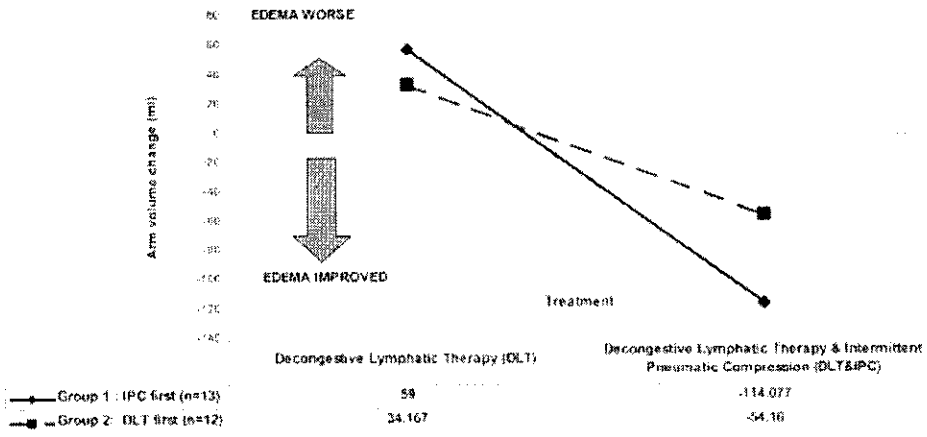

FIGURE 3. The effect of therapeutic choices on edema volume after chronic maintenance therapy in patients with breast carcinoma-associated lymphedema. The two therapeutic regimens were assessed in a 1-month, cross-over design. For decongestive lymphatic physiotherapy (DLT) alone, without an effect of treatment order, the patients in both randomized groups experienced a slight mean increase in edema volume, as detected by water displacement volumetry. In contrast, DLT combined with intermittent pneumatic compression, without regard to the treatment order, yielded a mean additional decrease in edema volume. The data are provided as the mean ± standard deviation for each group. The asterisk denotes a statistically significant difference ($P < 0.05$; paired t-test).

use the pump at the time of reevaluation, with an average reported frequency of 4 times per week.

In these 19 patients, there was a subsequent, additional average arm reduction of 29.1 mL compared with the documented limb volume at the conclusion of Study 2: In the 5 patients who elected to discontinue IPC, there was average increase in arm volume of 35 mL. No adverse consequences of IPC were reported.

Range of motion was evaluated at the beginning of the study and at follow-up. Seventeen patients with a pretreatment impairment were available for follow-up analysis. Fifteen of those 17 patients continued IPC at home. All 17 patients continued standard DLT, including self-administered massage and application of the compression garment. Joint mobility improved over time in all patients.

DISCUSSION

Lymphedema of the upper extremity is a common occurrence after patients receive therapeutic interventions for breast carcinoma. Current estimates suggest that secondary lymphedema affects approximately 26% of women who undergo treatment for breast carcinoma.[2] It has been estimated that, currently, approximately 400,000 patients in the United States are afflicted with lymphedema of the upper extremity.[2] This number may represent an underestimate: The definition of lymphedema in some studies often relies on either subjective criteria or objective documentation of lymphedema in the absence of well-defined or widely accepted criteria, and the majority of the available studies on patients with breast carcinoma-associated lymphedema are retrospective. In addition, current prognostic estimates predict an increase in the incidence of breast carcinoma in the United States, from 185,000 per year to 420,000 per year, over the next 20 years.[16] The increasing incidence of breast carcinoma may produce an increase in the incidence of secondary lymphedema despite the developments in breast-conserving surgery and sentinel lymph node biopsy. The increasingly popular approach of sentinel lymph node biopsy is intended to eliminate the necessity for axillary lymph node dissection. However, with 28–46% of eligible patients manifesting a positive sentinel lymph node,[16,17] this approach will not render lymphedema obsolete. Axillary lymph node dissection correlates positively with 10-year survival in breast carcinoma patients[18] and continues to be employed for the majority of patients with early-stage disease.[18]

DLT currently is the most popular treatment for patients with lymphedema. DLT includes MLD and compressive bandaging, which is intended to stimulate cutaneous lymphatic transport, along with decongestive exercises and meticulous skin care.

The physiologic basis for the accentuation of lymphatic flow with IPC has been well established.[19] Similarly, early studies demonstrated an ameliorative effect on lymphatic protein transport.[20] Historically, the pneumatic compression pump often was used as stand-alone therapy for patients with lymphedema and, in all likelihood, was the most frequently prescribed treatment modality for lymphedema in the

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United States. The incorporation of IPC into a multidisciplinary, therapeutic approach long has been advocated empirically by some physiotherapeutic schools.[21,22] Numerous early studies purported to demonstrate the efficacy of pumps as a sole therapeutic intervention for patients with lymphedema;[23–27] nevertheless, individual reports of complications and lack of efficacy[28–30] have tended to dampen enthusiasm for the use of IPC. It was to address these unresolved questions that the current study was undertaken.

The results of our investigation suggest that IPC, when it is used as an adjunct to the other established elements of DLT, provides an enhancement of the therapeutic response both in the initial, decongestive phase of therapy as well as in the maintenance of volume reduction. The therapy is well tolerated and remarkably free of complications. The tolerability of this therapy is supported indirectly by the sustained, elective use of IPC among many of the patients who completed our study protocol.

It has been alleged that IPC may contribute both to inappropriate tissue retention of interstitial protein, leading to an excess of cutaneous fibrosis, and to a reduction in joint mobility. Thus, we elected to observe the patients in this investigation for changes in tissue elasticity (as detected by serial tonometry) and for range of motion (by serial goniometry of the large joints of the upper extremity). In neither case was there any evidence of deterioration that might be ascribed to the addition of IPC to the therapeutic regimen.

The results of this investigation support the observation, reported in previous studies,[23–27] that pneumatic compression pumps can be used safely and effectively for the treatment of patients with breast carcinoma-associated lymphedema. Conversely, we were unable to validate published claims that IPC has a deleterious effect on patients who receive prior treatment for lymphedema.[28,29]

The current investigation suggests that the use of IPC can be used effectively in the therapeutic approach to patients with breast carcinoma-associated lymphedema. In view of the important psychosocial ramifications of breast carcinoma-associated lymphedema,[4] the ease of application of IPC as a long-term therapeutic intervention suggests that it may warrant more widespread use in this patient population.

The apparent efficacy and tolerability of IPC warrants additional evaluation of its role in the therapeutic approach to chronic, secondary lymphedema. Certainly, it should be possible to extrapolate our observations obtained in patients with breast carcinoma-associated lymphedema to individuals with other iatrogenic types of acquired lymphedema, including lymphedema as a result of other neoplastic diseases, such as malignant melanoma, lymphoma, and urologic and gynecologic malignancies, among others. In addition, more formal evaluations of the impact on quality of life and the cost of care should be undertaken. Additional limitations of the current studies include the relatively small and clinically diverse sample population. Further study will permit correction for these features and, ideally, will serve to confirm the broader applicability of our observations.

The current study was not designed as a formal evaluation of the cost-effectiveness of IPC, although certain inferences can be drawn. In the initial phases of lymphedema therapy, the addition of IPC to the regimen can be expected to increase slightly the cost of the therapy (although the fixed utilization costs may be offset in part by reductions in the time spent by therapists with the patient). IPC may be expected to have its greatest economic impact in the chronic phase of therapy, during which the device may help to maintain the therapeutic effect in patients who no longer are receiving active interventions by therapists. This, in turn, may translate into a reduction in office visits and, plausibly, reduced use of resources for the evaluation and treatment of recurrent cellulitis. These benefits may be realized best by older or disabled patients who have difficulty with self-bandaging or application of gradient elastic garments. Most third-party payers, including Medicare, currently reimburse patients with breast carcinoma-related lymphedema for pneumatic compression pumps. Clearly, further investigation of the economic implications of this treatment is warranted.

The current study adds an important dimension to the existing literature on therapeutic approaches to the treatment of patients with breast carcinoma-associated lymphedema. Historically, to date, there has been a bias against the use of intermittent pneumatic therapy. The results of our study contradict this bias. In fact, given the availability and ease of use of the pneumatic devices, the documentation of a salutary therapeutic response constitutes a suitable stimulus for further study that may help to confirm the results of our investigation within a larger population of patients. Additional prospective observations may help to identify subpopulations of patients who may benefit most from combination physiotherapy. It will be important to study patient groups with both primary and secondary lymphedema, the latter in relation to a much broader array of malignant diseases.

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REFERENCES

1. Segerstrom K, Bjerle P, Graffman S, Nystrom A. Factors that influence the incidence of brachial oedema after treatment of breast cancer. *Scand J Plast Reconstr Surg Hand Surg.* 1992;26:223–227.
2. Erickson V, Pearson M, Ganz P, Adams J, Kahn K. Arm edema in breast cancer patients. *J Natl Cancer Inst.* 2001;93: 96–111.
3. Pecking A, Lasry S, Boudinet A, Floiras J, Rambert P, Guérin P. Postsurgical physiotherapeutic treatment: interest in secondary upper limb lymphedemas prevention. In: Partsch H, editor. Progress in lymphology-proceedings of the XIth Congress in Vienna, 1987. Amsterdam: Elsevier Science, 1988: 561–564.
4. Velanovich V, Szymanski W. Quality of life of breast cancer patients with lymphedema [see discussion]. *Am J Surg.* 1999; 177:184–188.
5. Woods M, Tobin M, Mortimer P. The psychosocial morbidity of breast cancer patients with lymphoedema. *Cancer Nurs.* 1995;18:467–471.
6. Maunsell E, Brisson J, Deschenes L. Arm problems and psychological distress after surgery for breast cancer. *Can J Surg.* 1993;36:315–320.
7. Passik S, Newman M, Brennan M, Holland J. Psychiatric consultation for women undergoing rehabilitation for upper-extremity lymphedema following breast cancer treatment. *J Pain Symptom Manage.* 1993;8:226–233.
8. Rockson SG, Miller LT, Senie R, et al. American Cancer Society Lymphedema Workshop. Workgroup III: diagnosis and management of lymphedema. *Cancer.* 1998;83(Suppl): 2882–2885.
9. Badger CM, Peacock JL, Mortimer PS. A randomized, controlled, parallel-group clinical trial comparing multilayer bandaging followed by hosiery versus hosiery alone in the treatment of patients with lymphedema of the limb. *Cancer.* 2000;88:2832–8327.
10. Szuba A, Cooke JP, Yousuf S, Rockson SG. Decongestive lymphatic therapy for patients with cancer-related or primary lymphedema. *Am J Med.* 2000;109:296–300.
11. Dini D, Del Mastro L, Gozza A, et al. The role of pneumatic compression in the treatment of postmastectomy lymphedema. A randomized Phase III study. *Ann Oncol.* 1998;9:187–190.
12. Kasseroller RG. The Vodder School: the Vodder method. *Cancer.* 1998;83(Suppl):2840–2842.
13. Clodius L, Deak L, Piller NB. A new instrument for the evaluation of tissue tonicity in lymphoedema. *Lymphology.* 1976;9:1–5.
14. Liu NF, Olszewski W. Use of tonometry to assess lower extremity lymphedema. *Lymphology.* 1992;25:155–158.
15. Gajdosik RL, Bohannon RW. Clinical measurement of range of motion. Review of goniometry emphasizing reliability and validity. *Phys Ther.* 1987;67:1867–1872.
16. Cox C, Bass S, McCann C, et al. Lymphatic mapping and sentinel lymph node biopsy in patients with breast cancer. *Annu Rev Med.* 2000;51:525–542.
17. Giuliano AE, Haigh PI, Brennan MB, et al. Prospective observational study of sentinel lymphadenectomy without further axillary dissection in patients with sentinel node-negative breast cancer. *J Clin Oncol.* 2000;18:2553–2559.
18. Bland KI, Scott-Conner CE, Menck H, Winchester DP. Axillary dissection in breast-conserving surgery for Stage I and II breast cancer: a National Cancer data base study of patterns of omission and implications for survival [see discussion]. *J Am Coll Surg.* 1999;188:586–596.
19. McGeown JG, McHale NG, Thornbury KD. Effects of varying patterns of external compression on lymph flow in the hindlimb of the anaesthetized sheep. *J Physiol.* 1988;397:449–457.
20. Zelikovski A, Manoach M, Giler S, Urca I. Lympha-press A new pneumatic device for the treatment of lymphedema of the limbs. *Lymphology.* 1980;13:68–73.
21. Leduc O, Leduc A, Bourgeois P, Belgrado JP. The physical treatment of upper limb edema. *Cancer.* 1998;83(Suppl): 2835–2839.
22. Brennan MJ, Miller LT. Overview of treatment options and review of the current role and use of compression garments, intermittent pumps, and exercise in the management of lymphedema. *Cancer.* 1998;83(Suppl):2821–2827.
23. Zanolla R, Monzeglio C, Balzarini A, Martino G. Evaluation of the results of three different methods of postmastectomy lymphedema treatment. *J Surg Oncol.* 1984;26: 210–213.
24. Richmand DM, O'Donnell TF Jr., Zelikovski A. Sequential pneumatic compression for lymphedema. A controlled trial. *Arch Surg.* 1985;120:1116–1119.
25. Kim-Sing C, Basco VE. Postmastectomy lymphedema treated with the Wright linear pump. *Can J Surg.* 1987;30: 368–370.
26. Klein MJ, Alexander MA, Wright JM, Redmond CK, LeGasse AA. Treatment of adult lower extremity lymphedema with the Wright linear pump: statistical analysis of a clinical trial. *Arch Phys Med Rehabil.* 1988;69(3 Pt 1):202–206.
27. Pappas CJ, O'Donnell TF Jr. Long-term results of compression treatment for lymphedema [see discussion]. *J Vasc Surg.* 1992;16:555–556,562–564.
28. Foeldi E, Foeldi M, Clodius I. The lymphedema chaos: a lancet. *Ann Plast Surg.* 1989;22:505–515.
29. Casley-Smith JR. Modern treatment of lymphoedema. I. Complex physical therapy: the first 200 Australian limbs. *Australas J Dermatol.* 1992;33:61–68.
30. Boris M, Weindorf S, Lasinski BB. The risk of genital edema after external pump compression for lower limb lymphedema. *Lymphology.* 1998;31:15–20.

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BMC Cancer

ATTACHMENT 15
PART 1

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Research article

A pilot, prospective evaluation of a novel alternative for maintenance therapy of breast cancer-associated lymphedema [ISRCTN76522412]

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Abstract

Background: Prospective investigations of complete decongestive lymphatic physiotherapy (CDPT), including manual lymphatic drainage (MLD), have validated the efficacy of these interventions for the initial reduction of edema and long-term maintenance of limb volume in lymphedema. However, CDPT demands substantial time and effort from patients to maintain these benefits; the treatments are not always well-accepted, and patients may suffer from a deterioration in quality-of-life or a time-dependent loss of initial treatment benefits. A new device designed for home use by the patient, the Flexitouch™, has been developed to mechanically simulate MLD. We have undertaken a prospective, randomized, crossover study of the efficacy of the Flexitouch™, when compared to massage, in the self-administered maintenance therapy of lymphedema.

Methods: A prospective, randomized, crossover study of maintenance therapy was performed in 10 patients with unilateral breast cancer-associated lymphedema of the arm. Each observation phase included self-administered treatment with the Flexitouch™ or massage, 1 hour daily for 14 days, respectively, followed by crossover to the alternate treatment phase. Each treatment phase was preceded by a 1 week treatment washout, with use of garment only. The sequence of treatment was randomly assigned. The potential impact of treatment modality on quality of life was assessed with serial administration of the SF-36.

Results: Statistical analysis disclosed that the order of treatment had no outcome influence, permitting 10 comparisons within each treatment group. Post-treatment arm volume reduced significantly after the Flexitouch™, but not after self-administered massage. The patients' mean weight decreased significantly with Flexitouch™ use, but not with massage. The Flexitouch™ device was apparently well-tolerated and accepted by patients. Serial SF-36 administration showed no deterioration in physical or psychosocial scores compared to baseline measurements; there were no statistical differences in scores when the two treatment modalities were compared.

Conclusion: This short-term prospective evaluation of the Flexitouch™ suggests that the device may provide better maintenance edema control than self-adiminstered massage in breast cancer-associated lymphedema. The apparent ease of use and reliability of response to the device suggest that further broad-scale testing is warranted.

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Background

Acquired disruption of the lymphatic circulation can lead to either regional or generalized accumulation of interstitial fluid, known as lymphedema [1]. Among the predicted 200,000 patients who develop breast cancer annually [2], conservative estimates dictate that 15–20% will ultimately develop secondary lymphedema of the upper extremity [3,4]. The cumulative incidence of lymphedema appears to increase with each year after surgery [5]. The advent of arm lymphedema after breast cancer therapies engenders severe psychological and physical morbidity [6-8]. Lymphedema affects social relations, and undermines body image and self-esteem [9].

Complete decongestive physiotherapy (CDPT), a combined treatment program that incorporates manual lymph drainage, multi-layer short-stretch bandaging, exercise and skin care, has been recommended by a consensus panel of experts [10] and is considered to be the standard approach to lymphedema management [11-13]. Various of the elements of CDPT, while costly and labor-intensive [14], have demonstrable efficacy, with reported initial reductions of the measured excess limb volume that approximate 50% [15,16]. Nevertheless, despite the documented efficacy of initial, intensive CDPT in the hands of the trained therapist, it has been observed that the most important factor to influence the long-term impact of lymphedema interventions is the patient's subjective response to the management variables [17,18]. The time-consuming, labor-intensive, and repetitive nature of the treatment strategies pose difficulty and set the stage for poor, or incomplete, patient compliance [19]. Thus, the chronic response to physiotherapeutic lymphedema interventions, once patient self-management supervenes, is often characterized by a time-dependent loss, to varying degrees, of the beneficial effects of the short-term intensive interventions undertaken by medical personnel [15,16]. This treatment recidivism likely reflects the combined influences of patient inefficiency with the demanding techniques of manual lymphatic drainage and bandaging, and diminished compliance with self-management strategies.

Optimal management may have the capacity to slow the inexorable tendency of chronic lymphedema to progress, and may forestall or eliminate many of the recognized complications of the disorder, including recurrent soft-tissue infection and chronic fibrosis [10]. To this end, we have prospectively evaluated the potential benefit of a

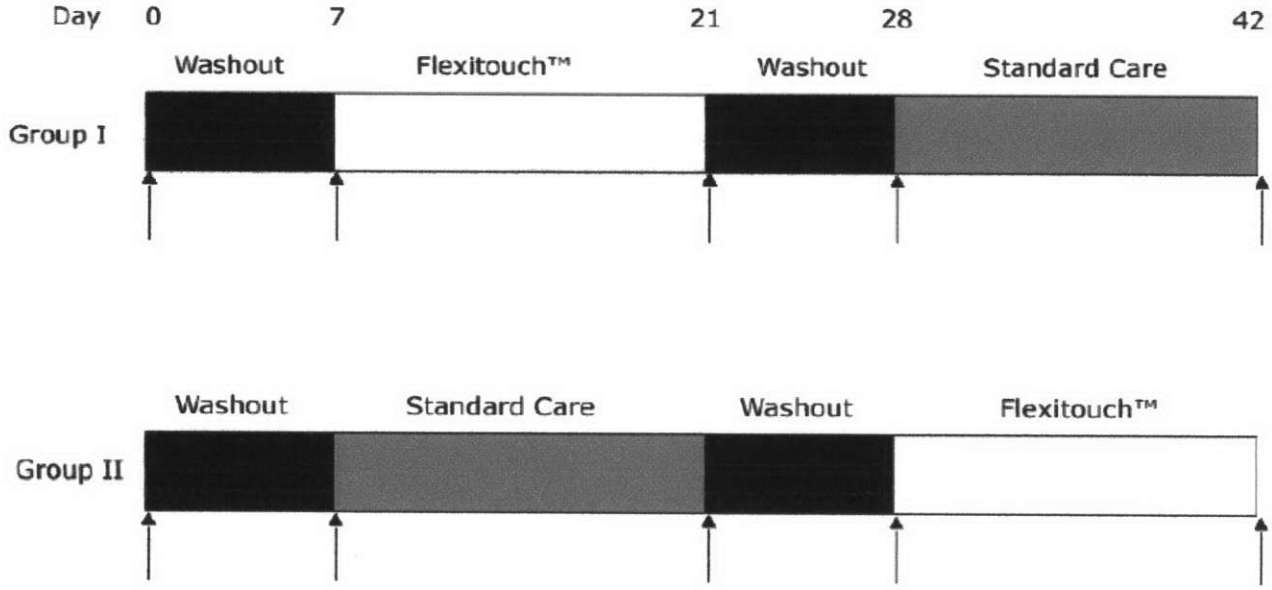

Figure 1
Schematic of the study protocol. There was a randomized assignment to Group I or II. During the washout periods, treatment was limited to the daily use of a compressive garment, with manual lymphatic drainage or other intervention. The vertical arrows indicate the times at which volumetry was performed by circumferential measurements of the limbs. The SF-36 was administered before and after each of the 14 day treatment phases.

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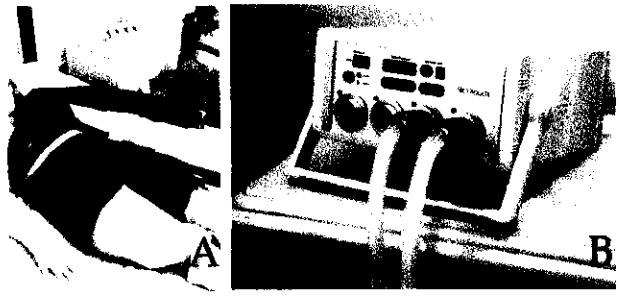

Figure 2
The figure depicts the unilateral Flexitouch™ garment as it is applied to the patient (A). The controller unit and connecting hoses are seen in panel B.

new approach to the maintenance phase of self-management in breast cancer-associated lymphedema.

The Flexitouch™ is a lightweight, portable device for home use that has been bio-engineered to closely simulate the effects of optimally performed manual lymphatic drainage. The device has been commercially available in the United States since June of 2002, when the Flexitouch™ system received 510 K clearance from the Food and Drug Administration. The current investigation was designed to evaluate the relative efficacy of the Flexitouch™, when compared to standard measures, in the maintenance self-management of breast cancer-associated lymphedema.

Methods

Design of the trial

A prospective evaluation of the Flexitouch™ in the maintenance management of breast cancer-associated lymphedema was undertaken in a prospective, randomized, crossover study. The investigation was undertaken from December 2003 through June 2004 and was approved by the Institutional Review Board of Stanford University. The study design is schematized in Figure 1.

Patients

Patients with lymphedema of the upper extremity after surgical and/or radiotherapeutic interventions for breast carcinoma were eligible for enrollment. Recruitment was undertaken from the population of patients who presented to the Stanford Center for Lymphatic and Venous Disorders. Written informed consent was obtained from all participants.

Inclusion and exclusion criteria

To be eligible for enrollment, a subject was required to have evidence of unilateral, breast cancer-associated lymphedema, with an increase of at least 10% in the measured volume of the affected arm when compared with the contralateral, normal limb. All subjects were required to have completed an initial treatment phase of limb volume reduction through intensive decongestive physiotherapy administered by a trained physiotherapist. A minimum of 30 days must have elapsed following the completion of initial treatment, which was required to include instruction in self-administered, maintenance simple manual lymphatic massage and the subsequent use of a properly fitted compression garment.

Exclusion criteria included the presence of any of the following: bilateral lymphedema of the upper extremity; active cancer; active infection; clinical evidence of venous obstruction or active thrombophlebitis; pulmonary edema; congestive heart failure; a history of pulmonary embolism; or the presence of any other relative contraindication to the use of the lymphedema treatment modalities employed in this investigation.

Treatment allocation

Once enrolled in the study, subjects were allocated randomly, in equal numbers, to begin treatment with either the experimental approach (daily use of the Flexitouch™) or with use of standard treatment measures (compression garment plus daily self-administered massage). Crossover to the alternate arm of therapy occurred in each enrolled patient after the designated observations and interval treatment washout had been completed. All study personnel responsible for patient observations and for data analysis were blinded to the subjects' treatment status, and patients were specifically instructed to refrain from discussing the particulars of their interval treatment status with the study personnel.

Treatment methods

Patients were instructed in the standard, self-administered use of the Flexitouch™. The device provides 1–3 seconds of mild pressure that moves continuously through the device during an individual treatment. In theory, the device design should, by analogy to the purported mechanisms of manual lymphatic drainage, encourage excess interstitial fluid to follow existing pathways of lymph efflux from the trunk to regain access to the central circulation,. The device features a two-phase preparation and drainage program. The Flexitouch™ is comprised of an electronic controller unit, utilized in concert with specialized garments worn on the trunk and the affected upper extremity (Figure 2).

The patented garments include separate trunk and limb components that, when combined, consist of up to 32 separate chambers. The Flexitouch garment utilizes a proprietary composite of laminated materials that deliver variable stretch during inflation. This stretch is designed to simulate a therapist's hand movements during manual

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lymphatic drainage. The device delivers brief applications (1–3 seconds) of mild pressure in a continuously moving, rhythmic work-and release-action that is repetitively applied in each section. No two chambers are ever fully inflated at the same time.

The inflatable chambers of the garment, constructed of distensible fabric, connect to the controller unit by tubing harnesses. In the initial, lymph preparation phase, a modest gradient of pressure is applied to the trunk to prepare for, and direct, the augmented flux of lymph; thereafter, lymph drainage of the affected extremity is accomplished by concerted cycles of pressure applied sequentially to the limb and the trunk.

For the conventional treatment phase of the trial, self-administered massage and use of elastic compression garments was undertaken as patients had been previously instructed during the initiation phase of CDPT [16], prior to enrollment in this trial. Self-administered massage is advocated as a standard technique in the maintenance management of chronic lymphedema, with a demonstrated capacity to sustain at least a major component of the benefits derived from the active therapeutic interventions undertaken with a trained physiotherapist [16]. The use of any additional management strategies was prohibited during active participation in the trial.

Treatment regimens

The active treatment phases were comprised of maintenance therapy with the Flexitouch™ alone or with self-administered massage alone, respectively, as an adjunct to the daily use of the compression garment. Each treatment modality was utilized for one hour daily during 14 consecutive days of treatment. Each phase of active treatment was preceded by a 1 week treatment washout, with use of the garment alone (no self-administered massage). The sequence of treatment was randomly assigned; the initial modality of therapy was followed, after a second washout phase, by crossover to the alternate treatment modality.

Measurements and assessments

All outcomes measure and assessments were accomplished by medical personnel trained and experienced in the objective assessment and treatment of lymphedema.

Limb volume measurements

Limb volume was calculated by a validated, indirect volume measurement that utilizes surface measurements and a simplified formula derived from the formula for a frustum (truncated cone) [20]. This approach has been demonstrated to have excellent intra- and inter-observer reliability, and to yield results that are statistically indistinguishable from the water displacement method, accepted by many, but not all, as the 'gold standard' [21]. Both arms were measured at each time point. Serial measurements were performed using gauged tape to ensure a uniform stretching force. Limb circumferences were measured at axial intervals of 4 cm, beginning with an initial measurement at the radial styloid. For each patient, absolute limb volume was expressed in milliliters (ml). In addition, the volume of the edematous arm was expressed as a ratio to the volume of the contralateral, normal arm ($Volume_{Lymphedema}/Volume_{Normal} \times 100\%$).

Quality of life assessment

The SF-36 was serially administered to each enrolled patient, before and after each phase of active treatment. The SF-36 is a validated, generic instrument to assess, in broad terms, the impact of disease and its management upon various categories of psychosocial function [22]. This instrument has previously, successfully been applied to study of breast cancer-associated lymphedema [23].

Data analysis

In this study, continuous variables were statistically compared using analysis of variance, paired and unpaired *t*-test analysis ($\alpha = 0.05$) and multiple regression analysis. For the sample size of the cohorts in this study and the primary endpoint of volume response, the statistical analysis had a power of 0.95 for an alpha = 0.01.

Results

Patient characteristics

Eleven (11) patients were approached for potential inclusion in this study. Consecutively presenting breast cancer survivors with unilateral upper extremity lymphedema were informed of the study at the time of their presentation to the Stanford Center for Lymphatic and Venous Disorders. Ten of these patients, all female, were enrolled in this prospective investigation.

The patient ages ranged from 54 to 78 years (60 ± 7 [mean ± SD]. For these patients, the duration since initial cancer therapy ranged from 36–288 months (103 ± 87 months). Onset of unilateral arm swelling was noted at 34 ± 34 months prior to enrollment in the study (range, 1–99 months). Initial cancer staging data was available for 8 of the 10 subjects: 2 initially presented with Stage I disease, 2 with Stage II and 3 with Stage III. Seven of the 10 subjects had undergone adjunctive radiotherapy.

There was an identical incidence of right- and left-sided involvement (5 subjects each) in this cohort. The mean pre-treatment body weight was 75 ± 12 kg (range, 58–83 kg). Hypertension (both systolic and diastolic) was prevalent in among the enrolled patients: the mean systolic pressure was 139 ± 14 mm Hg (120–167 mm Hg) and the mean diastolic pressure was 86 ± 7 mm Hg (80–95 mm Hg).

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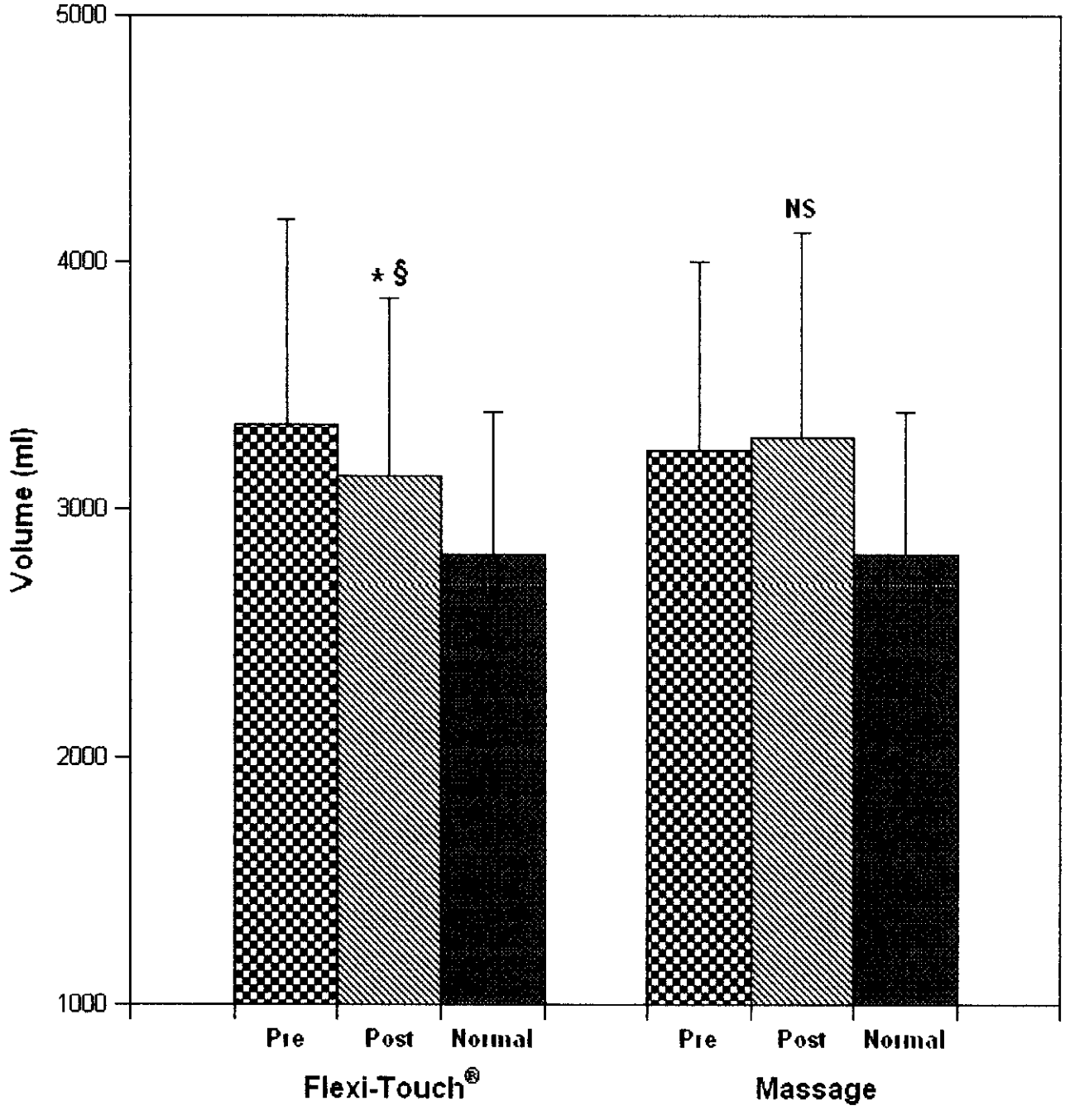

Figure 3
The effect of treatment modality on limb volume. Panels A and B depict the measured volume of the affected limb for each patient before and after Flexitouch™ and MLD therapy, respectively. Panel C illustrates the grouped data for each treatment phase (mean ± S.D.; * P = 0.002 when compared to pretreatment volume; § P = 0.007 when compared to the response to MLD). By multiple regression analysis, treatment status (Flexitouch™ *versus* massage) was predictive of volume change (P < 0.02). When controlled for the pre-treatment body weight, the results were unchanged; however, pretreatment arm volume was predictive of treatment response (P = 0.008).

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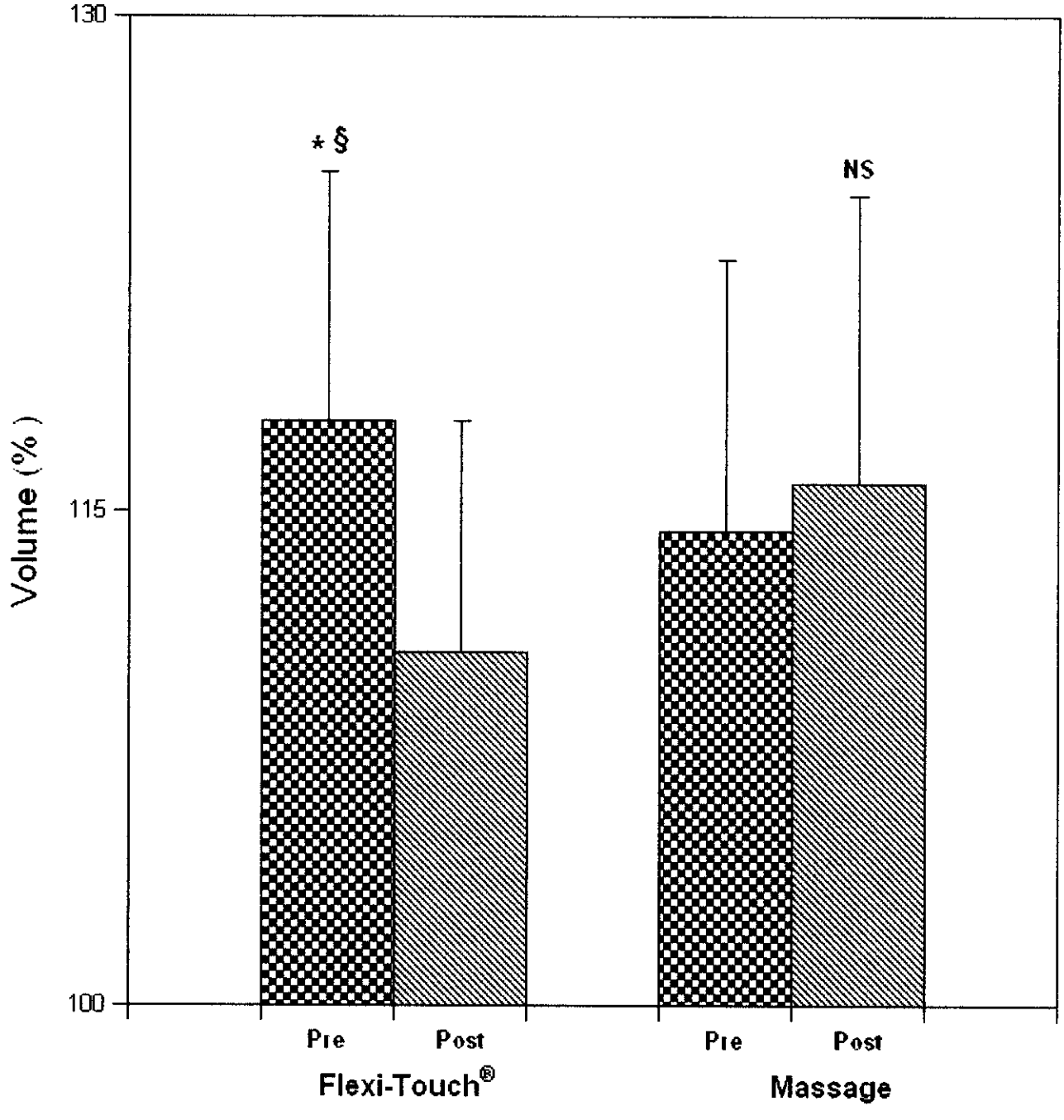

Figure 4
Excess volume of the affected arm, expressed as a percentage of the volume of the contralateral, normal arm. The effect of treatment on the % excess volume, when compared to the contra-lateral arm, was significant for Flexitouch™ but not for MLD (mean ± S.D.; *P = 0.0005 when compared to the pretreatment value; § P = 0.003 when compared to response to MLD).

Clinical responses

Five patients initiated the clinical evaluation with the Flexitouch™ treatment phase and 5 with self-administered massage, respectively. Statistical analysis disclosed no outcome influence of the order of treatment, permitting 10 comparisons within each treatment group. Arm volume

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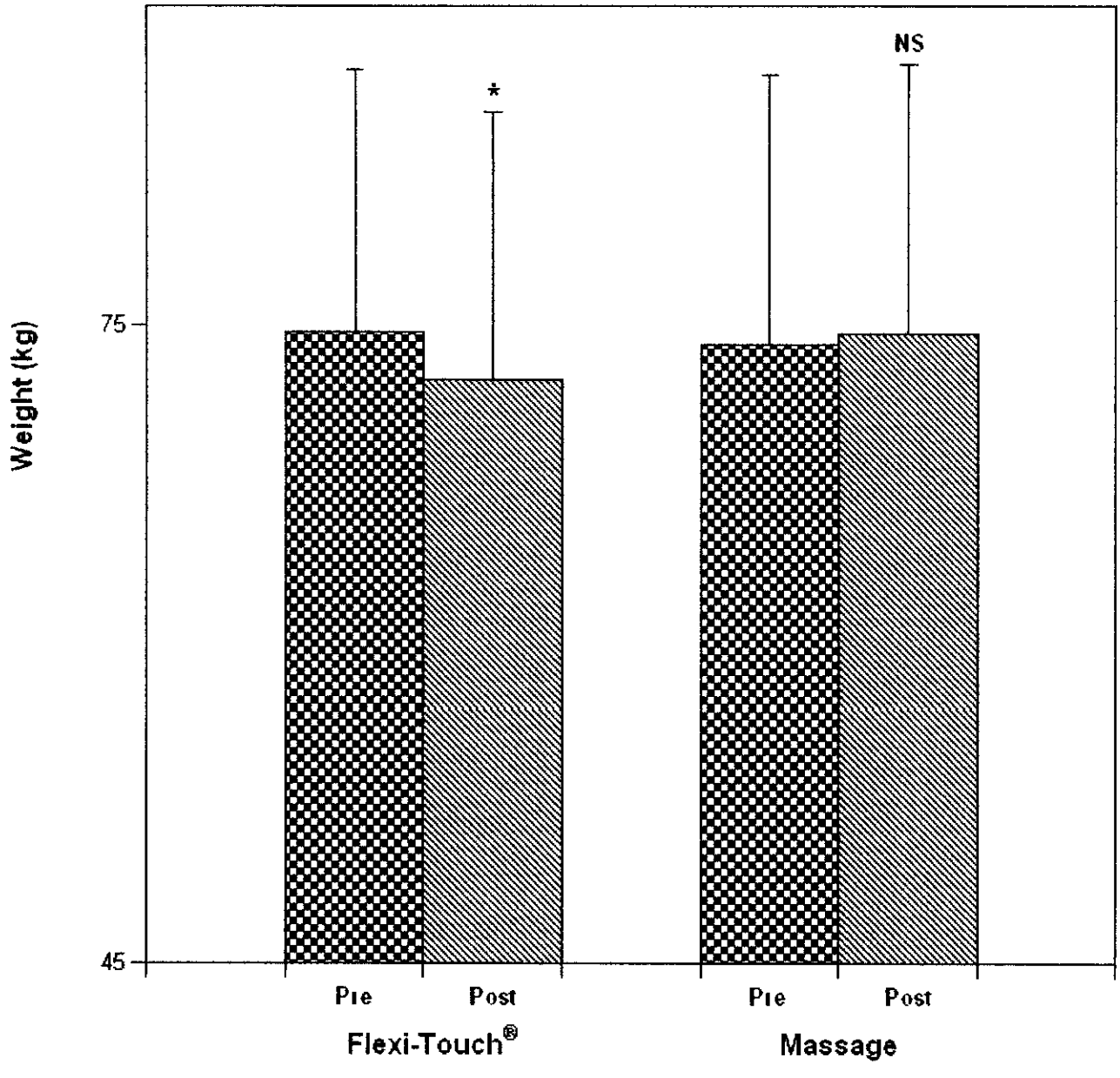

Figure 5
The effect of treatment strategy on body weight (mean ± S.D.; *P = 0.0002).

reduced significantly from pre-treatment (Figure 3) after the Flexitouch™ (mean change, -208 ± 157 ml, P = 0.002) but not after self-administered massage (+52 ± 106 ml, NS); when the absolute volume differences following Flexitouch™ treatment were compared to those following self-administered massage, the reduction in volume attained with the device was statistically significant (P = 0.007). The effect of treatment on the % excess volume, when compared to the contralateral arm, was significant for Flexitouch™ (pretreatment, 15 ± 7% *vs.* post-treatment, 12 ± 6%, P = 0.0005) but not for self-administered massage (pre- and post-treatment, 14 ± 7%, NS) [Figure 4]. As a corollary effect of partial edema resolution, the patients' mean weight decreased significantly after Flexitouch™ (-2.3 ± 1.3 kg, P = 0.0002) but not after self-administered massage (+0.5 ± 0.9 kg, NS) [Figure 5]. For the sample size employed in this study and the primary endpoint of volume response, the statistical analysis had a power of 0.95 for an alpha = 0.01.

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By multiple regression analysis, treatment status (Flexitouch™ versus massage) was predictive of volume change ($P < 0.02$). When controlled for the pre-treatment body weight, the results were unchanged; however, pretreatment arm volume was predictive of treatment response ($P = 0.008$). The change in limb volume with treatment was poorly correlated to the change in body weight ($r = 0.3$).

Quality of life indicators

Serial administration of the SF-36 demonstrated neither deterioration nor improvement in physical or psychosocial scores when compared to baseline or to those referable to standard therapy with self-administered massage. The total scores for the SF-36 were 132 ± 34 (baseline), 133 ± 33 (Flexitouch™), and 131 ± 37 (massage), respectively. Analysis of variance disclosed no statistical differences.

In addition to the serial administration of the SF-36, subjects were directly queried about their experiences with the device. The Flexitouch™ treatment phase was, by patient report, universally well-tolerated and -accepted. No adverse experiences were reported at the time of follow-up, or thereafter.

Discussion

With chronic obstructive derangement in the regional lymphatic circulation, an edematous state ensues that is characterized, over time, by chronic architectural alterations in the skin and supporting tissues [1,24]. Lymphedematous tissues are conceptualized to have a lower oxygen content, a greater distance between lymph vessels induced by the interstitial fluid accumulation, impaired lymphatic clearance, and depressed macrophage function, endowing these patients with an increased risk of soft tissue infection [25]. Once established, lymphedema has an inexorable tendency to progress. The concerted effects of increased interstitial fluid volume and chronic fibrotic changes expose these patients to substantial functional impairment, coupled with the psychosocial dysfunction that emanates from the chronic disease state and the associated impairment in body image and self-esteem [26-28].

Although the deleterious consequences of chronic lymphedema can be substantially reduced by effective physical management [10,15], the long-term impact of chronic decongestive physiotherapy upon lymphedema has not yet been optimized. While initial, intensive physiotherapeutic interventions can effectively minimize volume changes in the edematous limb, concerted self-management is required to maintain therapeutic benefits. Patients can effectively be taught to self-administer manual lymphatic drainage, but a gradual diminution in the magnitude of the initial therapeutic benefit is predictable [16]. It is likely that this phenomenon is related to some combined effect of patient inefficiency and a time-dependent reduction in patient compliance with self-management techniques. Adjunctive therapies, like intermittent pneumatic compression, have proven benefit [29], but may compound patient difficulty with compliance, since, of necessity, these adjunctive treatment measures lengthen the daily requirement for self-management.

In an attempt to improve the impact of maintenance self-management strategies on chronic lymphedema, we have undertaken the current study to investigate the relative efficacy of the Flexitouch™ when compared with a standard treatment approach (self-administered massage). The biodesign of the device and its impact on the disease state confer some distinct theoretical advantages. Because the Flexitouch™ is bioengineered to closely simulate the effects of correctly performed simple manual lymphatic massage, it should theoretically minimize the effect of improper or inadequate technique upon the treatment outcome. Furthermore, because the device emphasizes comfort and minimizes the active participation of the patient, it should, in principle, optimize compliance.

Indeed, our observations suggest that, even in short-term use, the device confers therapeutic benefit over that which can be attained through standard therapy. In addition to the demonstrable small, but significant, improvement in edema volume, the statistically significant reduction in body weight that accompanies the use of the Flexitouch™ serves as an independent confirmation of the added efficacy of this approach for the reduction of edema volume. While the magnitude of weight loss cannot be entirely explained by the quantitative reduction in limb edema volume, the concurrent changes seem to validate the beneficial impact of the Flexitouch™. The phenomenon of weight loss certainly bears additional investigation in larger numbers of patients. The current study was not designed to specifically address this response and, therefore, additional study with control of relevant variables during the treatment phase, such as fluid intake, diet, exercise, and medications, will be required to validate the observed phenomenon and to address the potential mechanisms of the therapeutic benefit.

The current, pilot study is limited chiefly by the small sample size and short duration of the therapeutic intervention. The positive results suggest that further investigation will be useful. When observed in larger cohorts of patients, with treatment phases sustained over longer intervals, it can be anticipated that even more substantial volume benefits might be demonstrable. In addition, quality-life-indicators should theoretically have the capacity to detect any favorable impact of streamlined therapy upon perceptions of the disease state. Finally, it will be desirable to attempt to demonstrate the theoretical favo-

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rable impact of this intervention upon tissue architecture and other chronic structural consequences of lymphedema. It is well-recognized that lymphedema, with chronicity, occasions the secondary proliferation of fibroblasts, keratinocytes, and adipocytes, the accumulation of collagen, and the destruction of elastin fibers within the skin [30]. It has been hypothesized that effective physiotherapy of lymphedema can diminish or eliminate these otherwise inexorable consequences. It is relevant that, in a recent study of the effect of therapeutic intervention upon lymphatic filariasis, the institution of even simple measures to reduce edema possessed the capacity to ameliorate the histopathological manifestations of chronic inflammation and fibrosis in punch biopsies of the skin [31]. While such direct histological confirmation may not be as readily derived from a breast cancer-associated lymphedema population, future, more extensive studies of the therapeutic potential of the Flexitouch™ might realistically incorporate other, more indirect attempts to document an ameliorative effect upon tissue architecture. Furthermore, evaluation of patients during more protracted use of the device, if it indeed enhances treatment outcome while minimizing the incursion of self-management upon the activities of daily living, would be predicted to disclose an improvement in perceptions of psychosocial and physical well-being. The aggregate benefits to be derived from this device will then require consideration in relationship to the retail cost of this device as it is currently marketed (unilateral garment, US $10,800; bilateral garment, US $12,400).

Conclusion

Short-term prospective evaluation of the Flexitouch™ device suggests that it may provide better maintenance control of edema volume than simple manual lymphatic drainage in patients with breast cancer-associated lymphedema. The ease of use and reliability of response to the device suggest that further broad-scale testing is warranted. Economic implications of the treatment choices will ultimately also be required to assess its relative merits within the scope of maintenance lymphedema care.

Abbreviations

CDPT: Complete decongestive lymphatic therapy

MLD: Manual lymphatic drainage

SD: Standard deviation

Competing interests

Tactile Systems, Inc., the manufacturer of the Flexitouch™, generously made available, on loan, the Flexitouch™ devices utilized in the current study. The authors have no financial ties to the company. Tactile Systems had no role in the design, execution, analysis, or communication of this investigation.

Authors' contributions

OW participated in the study design, completed data collection, and participated in the drafting of the manuscript; PW participated in data collection and analysis; SGR conceived of the study, participated in its design and coordination, assisted in statistical analysis and drafted the manuscript. All authors read and approved the final manuscript.

Acknowledgements

Tactile Systems, Inc. generously made available, on loan, the Flexitouch™ devices utilized in the current study.

References

1. Rockson SG: **Lymphedema.** *Am J Med* 2001, **110**:288-295.
2. American Cancer Society: *Cancer Facts and Figures – 2003* Atlanta, Ga: American Cancer Society; 2004.
3. Mortimer P, Bates D, Brassington H, Stanton A, Strachan D, Levick J: **The prevalence of arm oedema following treatment for breast cancer.** *Q J Med* 1996, **89**:377-380.
4. Petrek JA, Heelan MC: **Incidence of breast carcinoma-related lymphedema.** *Cancer* 1998, **83**:2776-2781.
5. Petrek JA, Senie RT, Peters M, Rosen PP: **Lymphedema in a cohort of breast carcinoma survivors 20 years after diagnosis.** *Cancer* 2001, **92**:1368-1377.
6. Tobin MB, Lacey HJ, Meyer L, Mortimer PS: **The psychological morbidity of breast cancer-related arm swelling. Psychological morbidity of lymphoedema.** *Cancer* 1993, **72**:3248-3252.
7. Hull M: **Functional and psychosocial aspects of lymphedema in women treated for breast cancer.** *Breast Cancer Care* 1998, **3**:97-100.
8. Ververs JM, Roumen RM, Vingerhoets AJ, Vreugdenhil G, Coebergh JW, Crommelin MA, Luiten EJ, Repelaer van Driel OJ, Schijven M, Wissing JC, Voogd AC: **Risk, severity and predictors of physical and psychological morbidity after axillary lymph node dissection for breast cancer.** *Eur J Cancer* 2001, **37**:991-999.
9. Paskett ED, Stark N: **Lymphedema: Knowledge, Treatment, and Impact Among Breast Cancer Survivors.** *Breast J* 2000, **6**:373-378.
10. Rockson SG, Miller LT, Senie R, Brennan MJ, Casley-Smith JR, Foldi E, Foldi M, Gamble GL, Kasseroller RG, Leduc A, Lerner R, Mortimer PS, Norman SA, Plotkin CL, Rinehart-Ayres ME, Walder AL: **American Cancer Society Lymphedema Workshop. Workgroup III: Diagnosis and management of lymphedema.** *Cancer* 1998, **83**:2882-2885.
11. Casley-Smith JR: **Modern treatment of lymphoedema. I. Complex physical therapy: the first 200 Australian limbs.** *Australas J Dermatol* 1992, **33**:61-68.
12. Ko DS, Lerner R, Klose G, Cosimi AB: **Effective treatment of lymphedema of the extremities.** *Arch Surg* 1998, **133**:452-458.
13. Szuba A, Rockson S: **Lymphedema: A review of diagnostic of techniques and therapeutic options.** *Vascular Medicine* 1998, **3**:145-156.
14. McNeely ML, Magee DJ, Lees AW, Bagnall KM, Haykowsky M, Hanson J: **The addition of manual lymph drainage to compression therapy for breast cancer related lymphedema: a randomized controlled trial.** *Breast Cancer Res Treat* 2004, **86**:95-106.
15. Foeldi E, Foeldi M, Clodius I: **The lymphedema chaos: A lancet.** *Ann Plast Surg* 1989, **22**:505-515.
16. Szuba A, Cooke JP, Yousuf S, Rockson SG: **Decongestive lymphatic therapy for patients with cancer-related or primary lymphedema.** *Am J Med* 2000, **109**:296-300.
17. Rose K, Taylor H, Twycross R: **Long-term compliance with treatment in obstructive arm lymphedema in cancer.** *Palliat Med* 1991:52-55.
18. Petrek JA, Pressman PI, Smith RA: **Lymphedema: current issues in research and management.** *Cancer J Clin* 2000, **50**:292-307.

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19. Goffman TE, Laronga C, Wilson L, Elkins D: **Lymphedema of the arm and breast in irradiated breast cancer patients: risks in an era of dramatically changing axillary surgery.** *Breast J* 2004, **10**:405-411.
20. Sitzia J: **Volume measurement in lymphoedema treatment: examination of formulae.** *Eur J Cancer Care (Engl)* 1995, **4**:11-16.
21. Meijer RS, Rietman JS, Geertzen JH, Bosmans JC, Dijkstra PU: **Validity and intra- and interobserver reliability of an indirect volume measurements in patients with upper extremity lymphedema.** *Lymphology* 2004, **37**:127-133.
22. Velanovich V: **Using quality-of-life instruments to assess surgical outcomes.** *Surgery* 1999, **126**:1-4.
23. Velanovich V, Szymanski W: **Quality of life of breast cancer patients with lymphedema.** *Am J Surg* 1999, **177**:184-187. discussion 188
24. Szuba A, Rockson S: **Lymphedema: anatomy, physiology and pathogenesis.** *Vascular Medicine* 1997, **2**:321-326.
25. Sieggreen MY, Kline RA: **Current concepts in lymphedema management.** *Adv Skin Wound Care* 2004, **17**:174-178.
26. Passik S, Newman M, Brennan M, Holland J: **Psychiatric consultation for women undergoing rehabilitation for upper-extremity lymphedema following breast cancer treatment.** *J Pain Symptom Manage* 1993, **8**:226-233.
27. Passik S, Newman M, Brennan M, Tunkel R: **Predictors of psychological distress, sexual dysfunction and physical functioning among women with upper extremity lymphedema related to breast cancer.** *Psycho-Oncology* 1995, **4**:255-263.
28. Carter BJ: **Women's experiences of lymphedema.** *Oncol Nurs Forum* 1997, **24**:875-882.
29. Szuba A, Achalu R, Rockson SG: **Decongestive lymphatic therapy for patients with breast carcinoma-associated lymphedema. A randomized, prospective study of a role for adjunctive intermittent pneumatic compression.** *Cancer* 2002, **95**:2260-2267.
30. Daroczy J: **Pathology of lymphedema.** *Clin Dermatol* 1995, **13**:433-444.
31. Wilson SF: **Histopathologic improvement with lymphedema management, leogane, haiti.** *Emerg Infect Dis* 2004, **10**:1938-1946.

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Mathematical Calculations for Wilburn Flexitouch Study

Wilburn O, Wilburn P, Rockson S. A pilot, prospective evaluation of a novel alternative for maintenance therapy of breast cancer-associated lymphedema BMC Cancer 2006, 6:84.

Since no measurement numbers were reported in this study, we had to scale the result graphs and mathematically calculate numbers for volume and percentage arm fluid reductions to be able to display in our clinical results comparison table.

(b)(4)

[redacted]

MLD: 3210.5 ml – 3263.2 ml = **- 52.7 ml Volume Whole Arm Reduction**

(b)(4)

[redacted]

Flexitouch: 3315.8 ml – 3105.3 ml = **210.5 ml Volume Whole Arm Reduction**

165

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From Graph on Page 6 – Figure 4:

(b)(4)

[redacted]

MLD: 14.3% - 15.9% = - **1.6% Volume Whole Arm Reduction**

(b)(4)

[redacted]

Flexitouch: 17.5% - 10.9% = **6.6% Volume Whole Arm Reduction**

166

PAGE 24.10 X 2

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JUL 1 2002 K013061

Section 2 - 510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

ATTACHMENT 15 PART 2

1. *Submitter's Name / Contact Person*

Eric McKee
Tel: (763) 434-2888
Fax: (763) 434-4161

Tactile Systems Technology, Inc.
1074 Legion Street
Shakopee, MN 55379
Tel: (952) 445-7578
Fax: (952) 445-1864

2. *General Information*

Trade Name: *biotouch*™ Massage Therapy System

Classification Name: Massager, Powered Inflatable Tube

Classification: This device has been classified by the Division of Physical Medicine into Class II (21 CFR 890.5650) as a Massager, Powered Inflatable Tube

3. *Device Description*

The TSTI *biotouch*™ device is a microprocessor controlled pneumatic compression device that applies calibrated sequentially graduated pressure to the arm, leg, trunk, and/or chest. The device consists of two major components:

- lightweight, portable pneumatic controller, and
- extremity garments composed of 4 to 16 chambers.

The controller is pre-programmed with thirteen separate treatment programs, which consists of pre-determined sequences and inflation times and should be used under medical supervision. The device is provided to the end-user in individual cartons to ensure safe shipping and arrival of the device. (See Attachment B for device drawings.)

4. *Intended Use*

The *biotouch*™ device is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as:

- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sport injuries
- Post immobilization edema
- Venous insufficiencies
- Lymphedema.

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5. *Substantial Equivalence Comparison*

The ***biotouch***™ device is substantially equivalent to the following devices with respect to intended use, design, materials and construction:

- (Progressive Medical Technology, Inc., Multipulse Sequential Compression Unit (K914774))

No new safety and/or effectiveness issues are raised.

6. *Summary of Studies*

Performance testing was completed to verify the design specifications necessary for the ***biotouch***™ device. Test results support the safety and performance of the ***biotouch***™ device for its intended use.

7. *Conclusion (statement of equivalence)*

The data and information provided in this submission supports a substantial equivalence determination, and, therefore, 510(k) premarket notification clearance of the ***biotouch***™ device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Mr. Eric McKee
President
Tactile Systems Technology, Inc.
1074 Legion Street
Shakopee, MN 55379

Re: K013061
Trade/Device Name: biotouch™ Massage Therapy System
Regulation Number: 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: II
Product Code: IRP
Dated: April 12, 2002
Received: April 15, 2002

Dear Mr. McKee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use Statement

The ***biotouch***™ device is intended for use by medical professionals and patients at home, who are under medical supervision, in treating many conditions, such as:

- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sport injuries
- Post immobilization edema
- Venous insufficiencies
- Lymphedema.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013061

January 4, 2002

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ATTACHMENT 16

How the flexitouch arm and trunk treatment works.

The Flexitouch® lymphedema system features a 2-phase Lymph Preparation and Drainage™ program. It applies a light pressure to the trunk and affected limb using inflatable chambers and fabric that ***stretches*** in four ways. Light pressure is used because it is known to stimulate the lymphatics and help evacuate these areas.

In addition, the curved design of the trunk garments allows lymph fluid to follow along existing pathways, providing the proper evacuation of the trunk.

For the arm, the preparation phase begins by applying a 1 to 3 second soft, tactile pressure to the trunk area (see 1). Starting at the waist, the first chamber inflates then quickly deflates as the next chamber starts deflates as the next chamber starts to inflate and so on down past the inguinal nodes. This cycle is repeated for about 6 minutes.

Next, the chamber closest to the axilla area inflates and deflates (see 2) and so on across the chest and down toward the inguinal nodes. After that, the chambers in the elbow area inflate and deflate to the shoulder and so on down to the fingers (see 3-4-5). The total preparation time is about 30 minutes.

The Drainage phase is different from the Preparation phase in that it begins the cycle at the fingers and moves all the way up past the chest and into the trunk before recycling again (see 6). This cycle repeats for about 30 minutes and then automatically shuts off.

The Flexitouch® offers a standard treatment program for the trunk and upper limb. There are additional programs to repeat therapy for specific problematic body sections.

Features include:

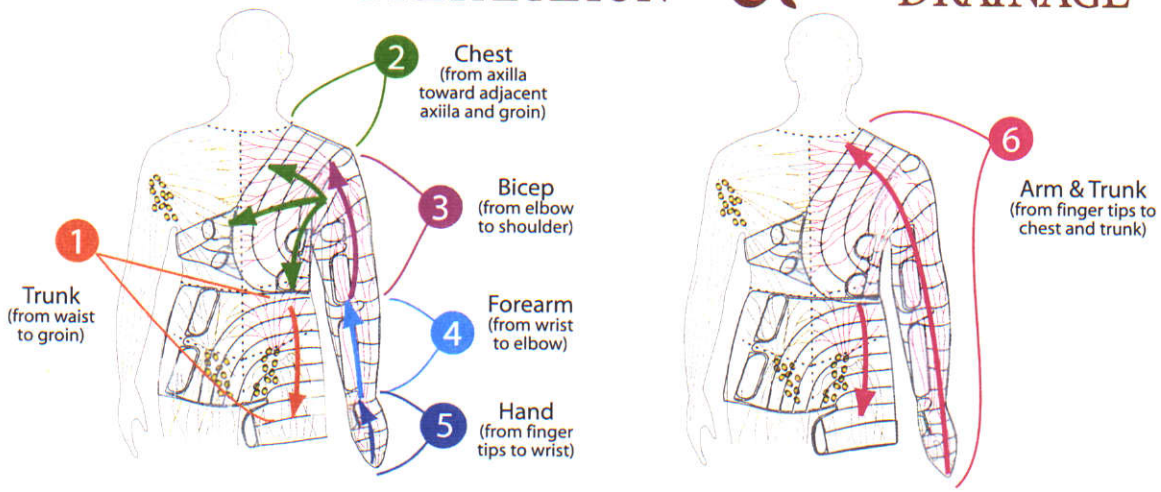
- 32 chambers approximately 1-1/2 inches wide.
- 7 individual programs for treating specific body regions.
- Adjustable garments utilize hook and loop closures for contoured fit.

Patented design allows lymph fluid to follow along existing pathways.

PHASE I (30 Minutes)
PREPARATION

&

PHASE II (30 Minutes)
DRAINAGE



Tactile Systems, 4824 Park Glen Road, Minneapolis, MN 55416
www. tactilesystems.com
866-4FLEXITOUCH toll-free
866-435-3948
952-224-4060 main
952-224-4061 fax

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flexitouch
extending MLD

D/N:01-2113 10/04 Rev. E

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How the flexitouch leg and trunk treatment works.

The Flexitouch® lymphedema system features a 2-phase Lymph Preparation and Drainage™ program. It applies a light pressure to the trunk and affected limb using inflatable chambers and fabric that ***stretches*** in four ways. Light pressure is used because it is known to stimulate the lymphatics and help evacuate these areas.

In addition, the curved design of the trunk garments allows lymph fluid to follow along existing pathways, providing the proper evacuation of the trunk.

For the leg, the preparation phase begins by applying a 1 to 3 second soft, tactile pressure to the trunk area (see 1). Starting at the inguinal nodes, the first chamber inflates then quickly deflates as the next chamber starts to inflate and so on up to the waist area. This cycle is repeated for about 6 minutes.

Next, the chamber closest to the knee inflates and deflates (see 2) and so on up to the inguinal nodes. After that, the chambers in the ankle area inflate and deflate to the knee and so on to the toes (see 3-4). The total preparation time is about 30 minutes.

The Drainage phase is different from the Preparation phase in that it begins the cycle at the toes and moves all the way up past the inguinal nodes and into the trunk before recycling again (see 5). This cycle repeats for about 30 minutes.

The Flexitouch® offers a standard treatment program for the trunk and lower limb. There are additional programs to repeat therapy for specific problematic body sections.

Features include:

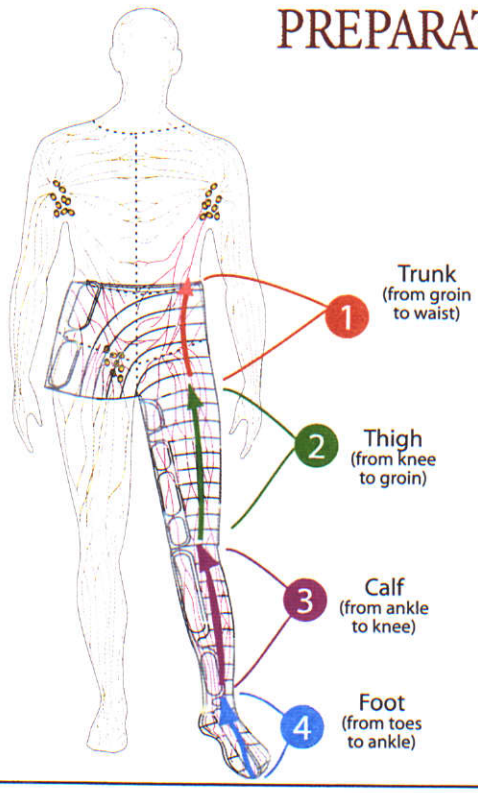
- 32 chambers approximately 1-1/2 inches wide.
- 7 individual programs for treating specific body regions.
- Adjustable garments utilize hook and loop closures for contoured fit.

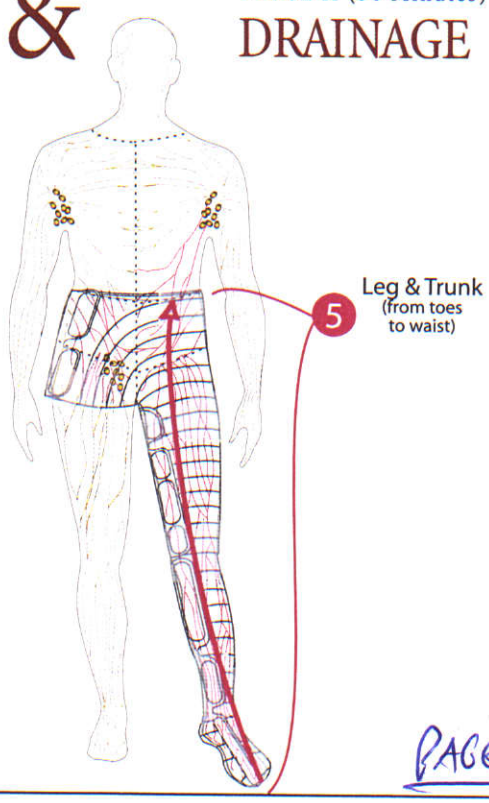
Patented design allows lymph fluid to follow along existing pathways.

PHASE I (30 Minutes)
PREPARATION

&

PHASE II (30 Minutes)
DRAINAGE





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D/N:01-2113 10/04 Rev. E

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ATTACHMENT 17

CELLU M6® KEYMODULE *i*

LPG

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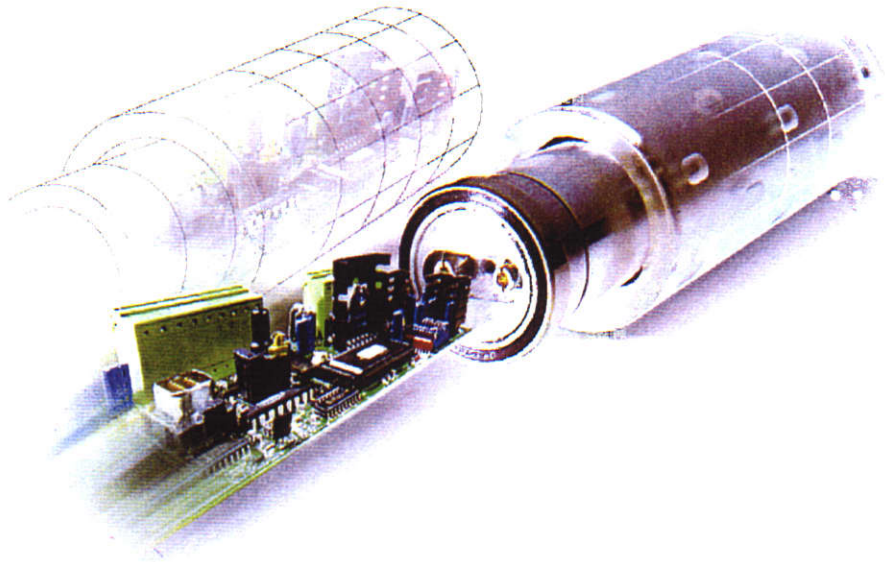
CAUTION: Federal law restricts this device to sale by or on the order of a clinician licensed by the law of the state where he/she practices to use or order the use of the device

MOBILITY

TISSUE TREATMENT IN ALL ITS DIMENSIONS

Each roller incorporates a miniaturized high-technology motor, allowing for optimal mobilization of the tissues.



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SELECTIVITY

THERAPEUTIC BENEFITS

- Venous stasis
- Venous insufficiency
- Primary lymphedema
- Secondary lymphedema of the arm post-mastectomy
- Secondary lymphedema

A NEW INTELLIGENT INTERFACE

The ***Cellu M6 Keymodule i*** is your gateway to the field of therapeutics. Fast and intuitive navigation will enable you to achieve your goal: targeted results that will satisfy your patients.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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www.lpgone.com

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Use of the Keymodule device is contraindicated for:

The CelluM6 Keymodule i should not be used on certain areas or under certain conditions.

1. This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.

2. Do not treat wounds, infected areas, skin tumors, open sores, scars form recent surgery, the eyes, intra-cavity areas, mucous membranes, the genitals or directly over nipples.

3. Do not treat patients with infectious progressive illnesses.

4. Do not treat patients with active cancer or a growing tumor. (Consult with the doctor if the patient has had a case history of tumors or is in remission.)

5. This device is contraindicated for skin cancer, tumors and other cancerous lesions in the area to be treated.

6. Do not treat patients suffering from inexplicable and persistent pain without seeking medical advice or without training in the LPG technique in this particular area.

7. Do not treat patients following invasive medical treatment without seeking the medical advice of the doctor or surgeon who performed this operation, or without training in the LPG technique in this particular area.

8. Not recommended for anyone under medical care for circulatory conditions without first consulting a physician.

9. Not recommended for pregnant women.

10. Stop treatment immediately if patient experiences any pain and consult the physician.

11. Avoid possible bruising. Use caution when determining a patient's sensitivity level.

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ATTACHMENT 18

Directions for Use

Cellu M6 Keymodule i
(Refer to Operator's Manual)

Caution: Federal law restricts this device to sale by or on the order of a clinician licensed by the law of the state where he/she practices to use or order the use of the device.

This device is indicated for use for the following:

- Reduction of secondary lymphedema of the arm (SLA) post mastectomy
- Improvement of primary and secondary lymphedema
- Prevention of venous stasis and venous insufficiency
- Improvement of lymphatic circulation in the treated areas

Directions for Use

The directions for use for this device are illustrated in this section over the following pages. For maximum efficiency, the treatment heads should be chosen according to the morphology of the treated area as illustrated below:

Motorized Heads:

i50	for the upper arm in the treatment of SLA; for legs in the treatment of lymphedema

Auxiliary Heads (*Active* and *Inactive*):

T644-A/T644	(as needed for small morphology)
T630-A/T630	(as needed for smaller morphology)
T615-A/T615	(as needed for smallest morphology)

Active auxiliary heads are loaded with springs behind the rollers. The function of the springs in the *Active* auxiliary heads is to allow for optimal movement of the rollers on the tissues when using sequential aspiration (or pulsating) programs designed to create the pump or wave-like action when treating lymphedema-related conditions.

Inactive heads do not have springs behind the rollers, and are meant to be used with constant suction settings for more static and deeper actions.

In addition to the directions for use for each program, all of the protocols are also recommended for the improvement of lymphatic circulation in the treated areas. Therefore, there is no specific direction for use for this claim, as it is implied by all the others.

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i50

Secondary Lymphedema of the Arm Post-Mastectomy

To prepare: 7 min.

EVALUATION ■ OEDEMA

OBJECTIVE ■ TO PREPARE THE ANASTOMOSIS

MANŒUVER ■ DIRECT LINE

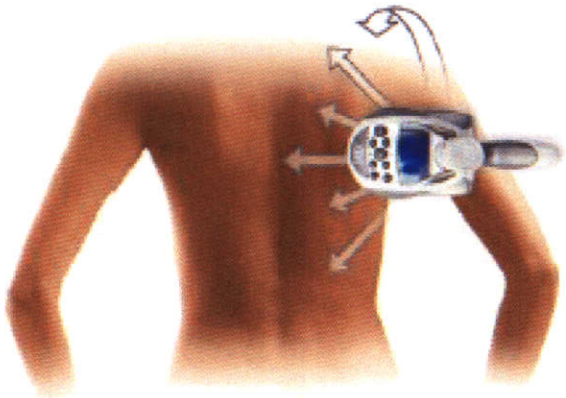
CYCLE: 30

FREQUENCY: 80

V1: 60

V2: 40

POWER: 1-3



> Direction is toward unaffected lymph node areas on trunk.

To mobilize: 12 min.

EVALUATION ■ ŒDEMA,

OBJECTIVE ■ TO MOBILIZE

MANŒUVERS ■ ARM, FOREARM, HAND TRANSVERSAL, LONGITUDINAL ASCENDING DIRECT LINE

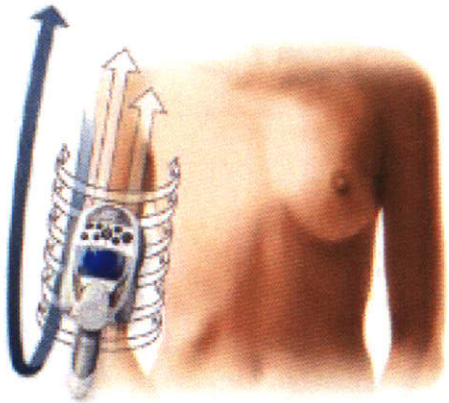
CYCLE: 100

FREQUENCY: 0

V1: 80

V2: 40

POWER: 1-3



The treatment head is chosen according to the morphology of the treated area (i50 ; auxiliary heads).

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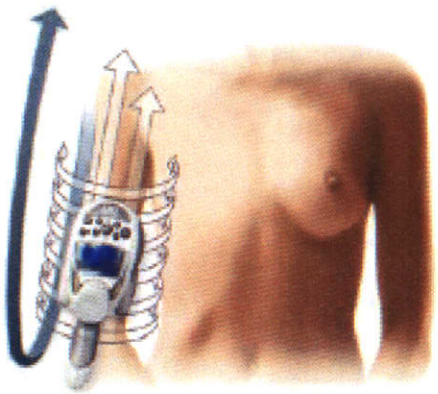
i50

Secondary Lymphedema of the Arm Post-Mastectomy

To drain - phase 1: 5 min.

EVALUATION ■ ŒDEMA
OBJECTIVE ■ TO DRAIN LYMPH
MANŒUVERS ■ TRANSVERSAL,
ARM, FOREARM, HAND
LONGITUDINAL ASCENDING
DIRECT LINE

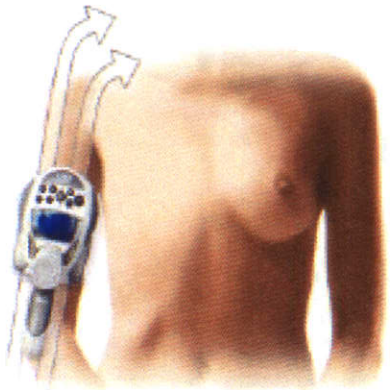
CYCLE: 40
FREQUENCY: 75
V1: 60
V2: 40
POWER: 2-4



To drain - phase 2: 6 min.

EVALUATION ■ ŒDEMA
OBJECTIVE ■ TO DRAIN LYMPH
MANŒUVERS ■ HAND, FOREARM, ARM
LONGITUDINAL ASCENDING
DIRECT LINE

CYCLE: 40
FREQUENCY: 75
V1: 60
V2: 40
POWER: 2-4



The treatment head is chosen according to the morphology of the treated area (i50 ; auxiliary heads).

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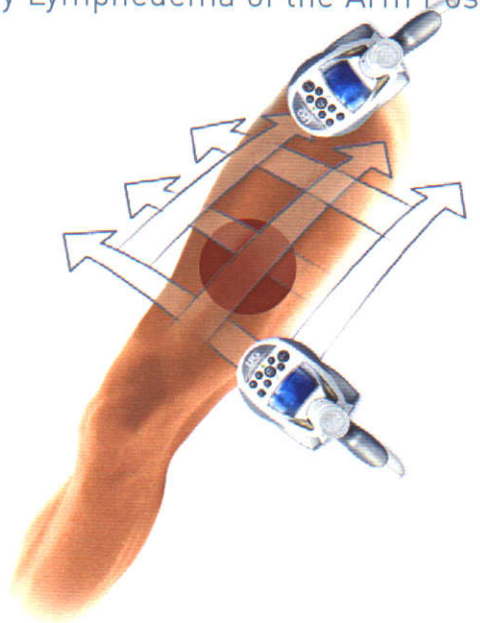
Primary and Secondary Lymphedema

(other than Secondary Lymphedema of the Arm Post-Mastectomy)

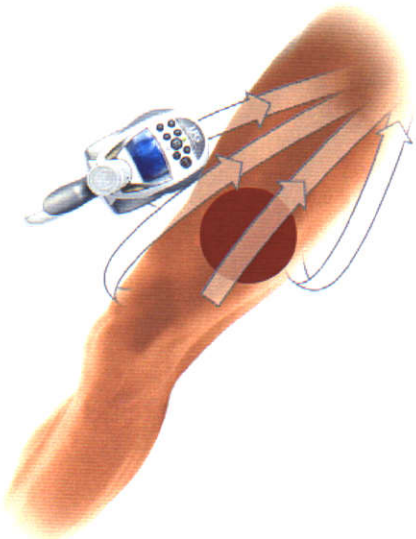
to collect

EVALUATION: EDEMA
OBJECTIVE: TO COLLECT
MANŒUVERS: **GRID**
DIRECT LINE
CYCLE: 40
FREQUENCY: 80
POWER: 3.0 +



to drain

EVALUATION: EDEMA
OBJECTIVE: TO DRAIN
MANŒUVERS: **LYMPHATIC PATHWAY**
DIRECT LINE
CYCLE: 40
FREQUENCY: 4
POWER: 2.0 +



- All indicated protocols are also recommended for the improvement of lymphatic circulation in the treated areas.
- The treatment head is chosen according to the morphology of the treated area (i50 ; auxiliary heads).

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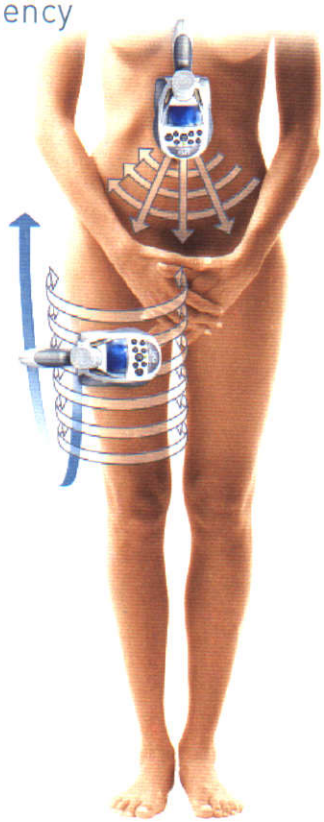
Venous Stasis and Venous Insufficiency

to drain

EVALUATION	EDEMA, HEAVY LEGS	CYCLE: 40
OBJECTIVE	TO DRAIN	FREQUENCY: 75
MANŒUVERS	TRANSVERSAL	V1: 80
	DIRECT LINE	V2: 60
		POWER: 2.0 +

to mobilize

OBJECTIVE	TO MOBILIZE	
MANŒUVERS	TRANSVERSAL	CYCLE: 100
	DIRECT LINE	FREQUENCY: 0
	BOUNCING	V1: 80
		V2: 60
		POWER: 2.0 +

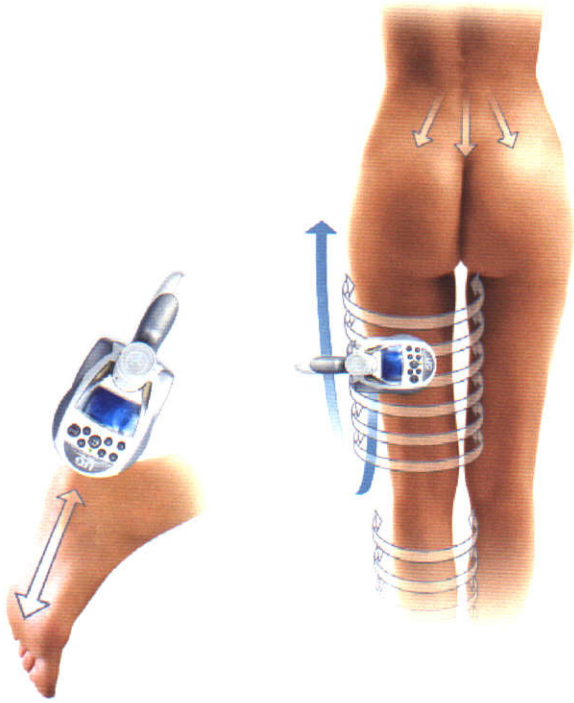


to drain

EVALUATION	EDEMA, HEAVY LEGS	CYCLE: 40
OBJECTIVE	TO DRAIN	FREQUENCY: 75
MANŒUVERS	TRANSVERSAL	V1: 80
	DIRECT LINE	V2: 60
		POWER: 2.0 +

to mobilize

OBJECTIVE	TO MOBILIZE	CYCLE: 100
MANŒUVERS	TRANSVERSAL	FREQUENCY: 0
	BOUNCING	V1: 80
	DIRECT LINE	V2: 60
		POWER: 2.0 +



➜ + Foot sole.

- All indicated protocols are also recommended for the improvement of lymphatic circulation in the treated areas.
- The treatment head is chosen according to the morphology of the treated area (i50 ; auxiliary heads).

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The CelluM6 Keymodule i should not be used on certain areas or under certain conditions.

1. This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.

2. Do not treat wounds, infected areas, skin tumors, open sores, scars form recent surgery, the eyes, intra-cavity areas, mucous membranes, the genitals or directly over nipples.

3. Do not treat patients with infectious progressive illnesses.

4. Do not treat patients with active cancer or a growing tumor. (Consult with the doctor if the patient has had a case history of tumors or is in remission.)

5. This device is contraindicated for skin cancer, tumors and other cancerous lesions in the area to be treated.

6. Do not treat patients suffering from inexplicable and persistent pain without seeking medical advice or without training in the LPG technique in this particular area.

7. Do not treat patients following invasive medical treatment without seeking the medical advice of the doctor or surgeon who performed this operation, or without training in the LPG technique in this particular area.

8. Not recommended for anyone under medical care for circulatory conditions without first consulting a physician.

9. Not recommended for pregnant women.

10. Stop treatment immediately if patient experiences any pain and consult the physician.

11. Avoid possible bruising. Use caution when determining a patient's sensitivity level.

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ATTACHMENT 19

OPERATOR'S MANUAL

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cellum6®
KEYMODULE

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Registered trademark

OPERATOR'S MANUAL

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Please read the complete manual carefully before using your equipment.

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GU 2-250

Edition B dated 01/01/05

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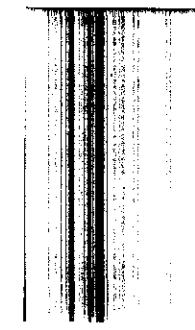

LPG®

Congratulations on the purchase of your Cellu M6® Keymodule ***i***. This model represents the fruits of numerous years of experience in the design and production of sub-cutaneous and cutaneous tissue treatment systems. You will experience fully the technical perfection and reliability of LPG Systems®, the leader in this sector. This operator's manual contains the operating description, directives basic maintenance information and safety instructions. If you have any doubts whatsoever concerning the operation or maintenance of your equipment, please do not hesitate to contact LPG Systems® Customer Service Center:

Tel: 888.730.0144
Fax: 888.571.0040

In order to respond better to customer requirements or expectations, LPG Systems® is continuously researching ways of improving the design and quality of its products. This will explain the few minor differences between your equipment and the item described in this guide.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Package contents

- One Cellu M6® Keymodule *i* unit
- One main T70 head
- Keymodule® Treatment Head
- One supply cable
- A set of auxiliary heads
- One operator's manual
- One maintenance kit
- Supplies kit

Please do not discard unpacking instructions.

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8 TECHNICAL SPECIFICATIONS ..... P. 42

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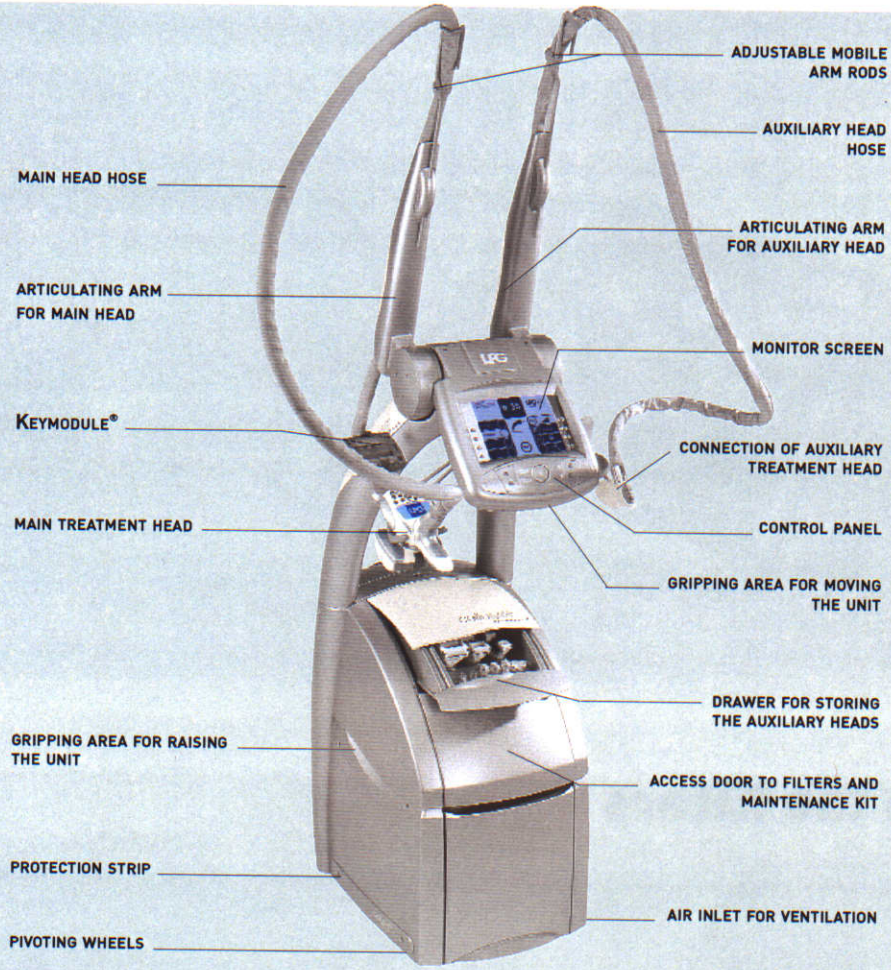
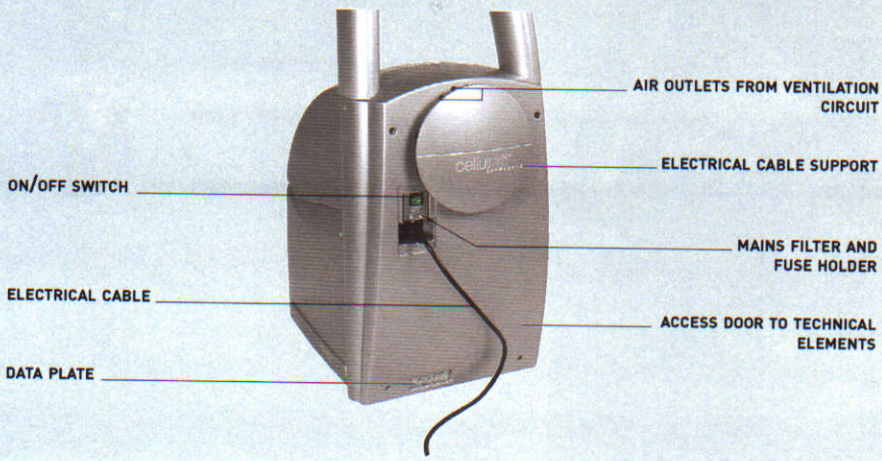
Cellu M6® Keymodule *i*



BEFORE USE MAKE SURE THAT THE SUPPLY CABLE IS COMPLETELY UNWOUND



The unit can only operate if it is connected to the mains by its supply cable and provided the on switch has been actuated and the green voltage light is on. When the unit is switched on, the pump starts to run automatically for about ten seconds for priming.

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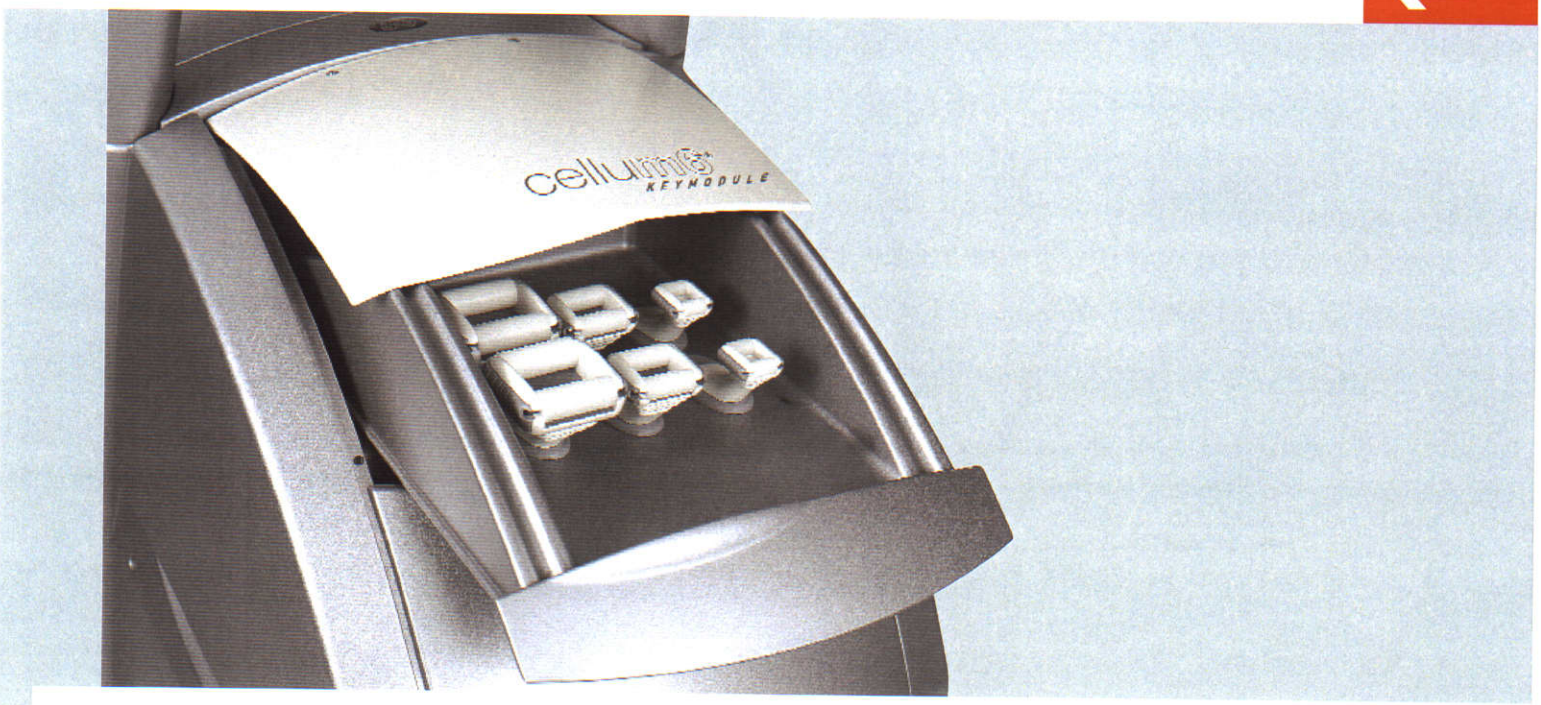
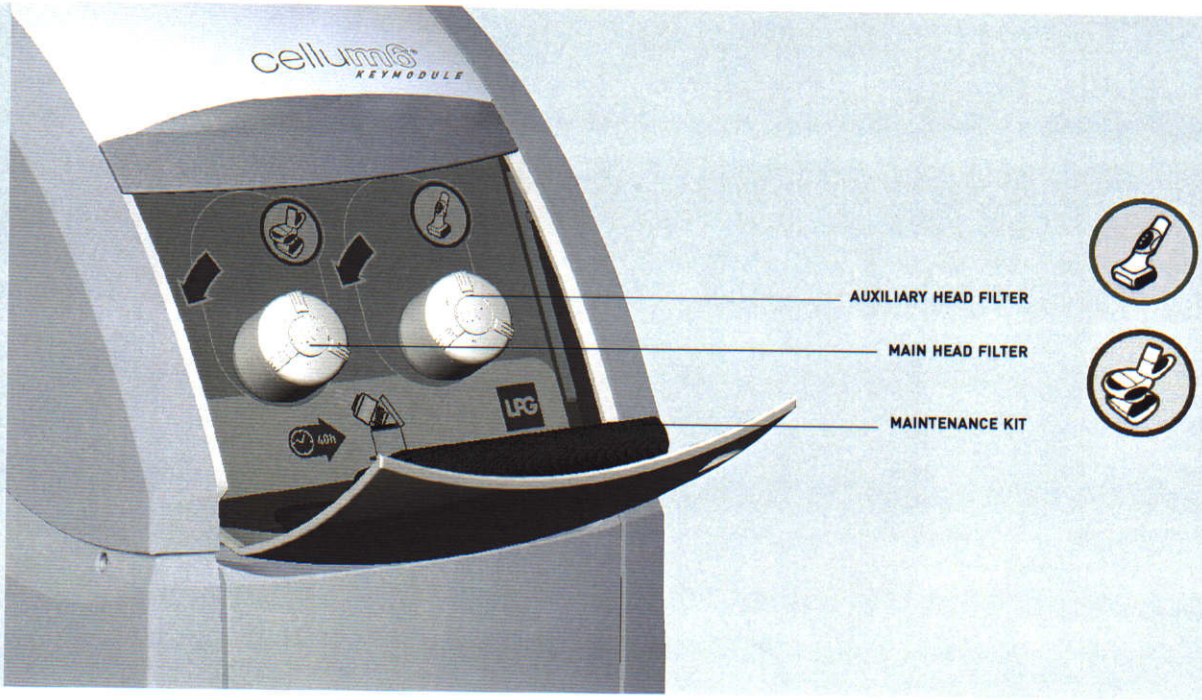
Drawer for storing the series 600 auxiliary heads



Access to the filters



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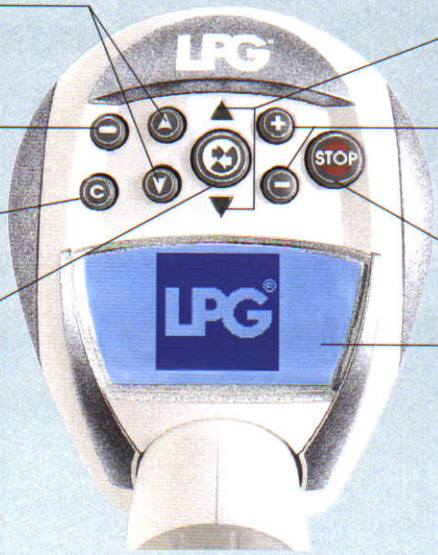
Control panel

Main head



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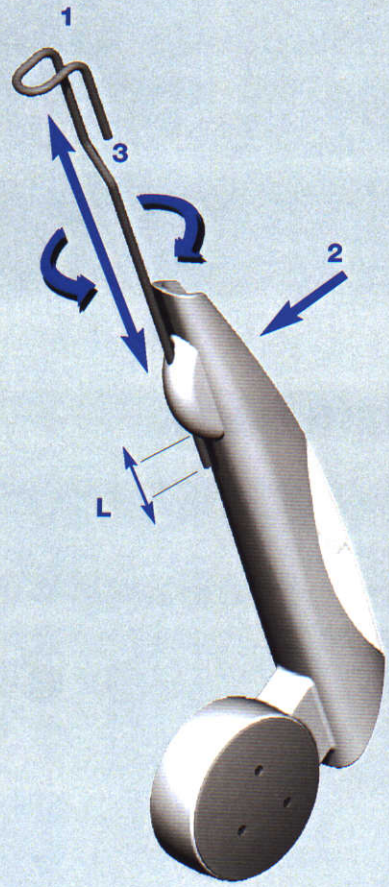
Adjusting the articulating arm rods

It is possible to personalize the position of the 2 articulating arm rods (depending on size and working position of the operator) so as to obtain even greater freedom of movement.

- Remove the hose from its housing on the articulating arm rod by pulling on the self-grip collar (**1**)
- Loosen the locking screws using the large hexagonal spanner (**2**)
- Adjust the rod to the length required position (**3**)
  (recommended length L=10 to 20 mm)
- Retighten the screw (**2**)
- Repeat the same operation for the second arm.



Fully unwind the electrical cable from its support, to ensure good ventilation of the unit.

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Precautions

- Check that the supply voltage of the unit indicated on the data plate complies with the mains voltage.
- The unit must be connected to a grounded outlet in accordance with current electrical standards.
- Never use the unit on a dusty, uneven floor, or in a moist atmosphere.
- Check that the inlet to the ventilation circuit is always unobstructed.
- Avoid operating the unit in a room where the ambient temperature exceeds 40° C.
- Fully unwind the electrical cable from its support to ensure good ventilation of the unit.
- Switch the unit off if it is not going to be used for a long period. In this case, operate the machine for a 1/2 an hour approximately every 8 weeks.
- Do not allow solid debris or liquid to be sucked into the unit, as these could cause damage.
- Never use the auxiliary adapter as a treatment head or allow it to come into direct contact with the skin.
- Do not use the main head to carry out treatment of the scalp.
- Only use the treatment heads supplied with your unit or recommended by LPG®.
- Only use LPG Systems® treatment garments.
- Never use the unit for purposes other than those recommended by LPG Systems®.
- LPG Systems® will not be liable for any inappropriate use of the equipment.
- With respect to treated tissue, some parameters may cause pain or tissue lesions. The operator must be particularly attentive to the sensations felt by the person undergoing treatment when :
  - the intensity is greater than 4 in continuous or sequential mode (for frequencies less than 4 Hz).
  - the system has changed to reverse mode (rollers rotating in opposite direction).
- The operator must ensure that the parameters (intensity, sequentiality, differential, ...) are always adapted to the cutaneous tissue being treated.

! *Where the unit has not been used for a long time, it is possible that marks may form on the ground where the wheels are. This phenomenon is the result of a chemical reaction between the components of some floorings and those of the wheels of the Cellu M6® Keymodule **i**.*

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Contraindications

The CelluM6® Keymodule i should not be used on certain areas or under certain conditions.

- This device should not be used over swollen or inflamed areas or skin eruptions. Do not use in the presence of unexplained calf pain. Consult a physician.
- Do not treat wounds, infected areas, skin tumors, open sores, scars form recent surgery, the eyes, intra-cavity areas, mucous membranes, the genitals or directly over nipples.
- Do not treat patients with infectious progressive illnesses.
- Do not treat patients with active cancer or a growing tumor. (Consult with the doctor if the patient has had a case history of tumors or is in remission.)
- This device is contraindicated for skin cancer, tumors and other cancerous lesions in the area to be treated.
- Do not treat patients suffering from inexplicable and persistent pain without seeking medical advice or without training in the LPG technique in this particular area.
- Do not treat patients following invasive medical treatment without seeking the medical advice of the doctor or surgeon who performed this operation, or without training in the LPG technique in this particular area.
- Not recommended for anyone under medical care for circulatory conditions without first consulting a physician.
- Not recommended for pregnant women.
- Stop treatment immediately if patient experiences any pain and consult the physician. Avoid possible bruising. Use caution when determining a patient's sensitivity level.

This unit contains programs to help the operator obtain the best anticipated results for each case undergoing treatment. Under no circumstances may these programs be construed as a guarantee of successful treatment, which varies, depending on the morphology, physiology and eating behavior of each patient.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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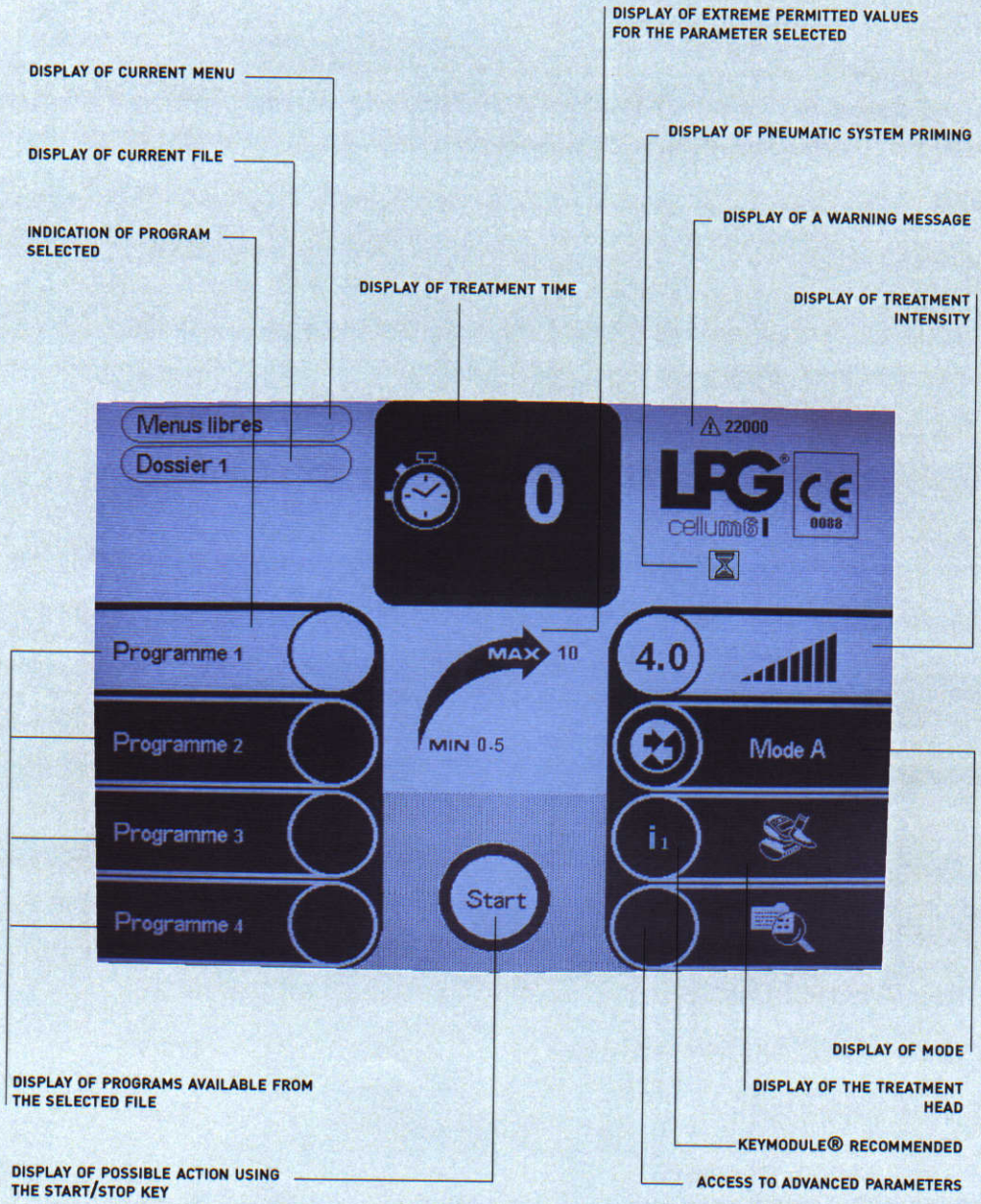
Monitor screen



The parameter selected is a reverse video.

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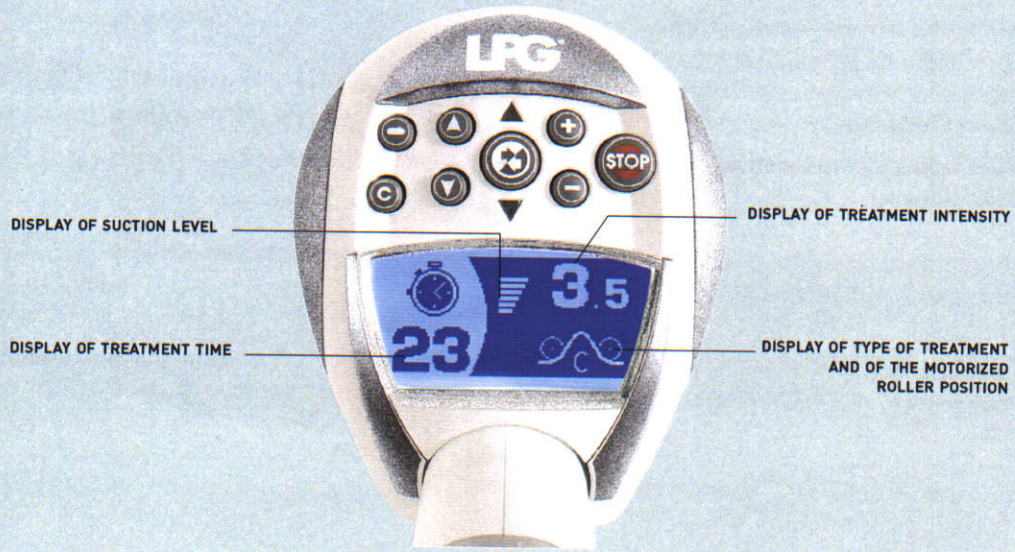
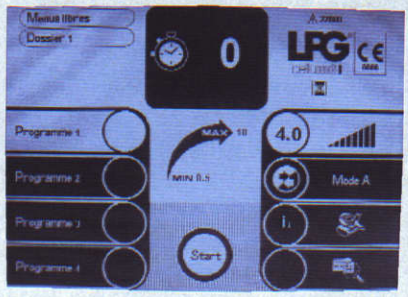
Main head screen



Power (on/off controls)

Treatment is started by pressing the START/STOP key once the icon is displayed.
Treatment is stopped by pressing the same key once the icon is displayed.
When starting up the pump, pressing the VALID key for a long time initiates the treatment time to the default value, according to the field of application.
On starting and stopping the pump, a priming phase automatically sets in for a few seconds.
This is displayed by a flashing icon or by simultaneous audible beeps. The user can proceed with no action during this period.



The unit can only be started when it is switched on. If the equipment is not used, it will automatically go to standby mode after 3 minutes. Press any key on the control panel to reactivate the unit.

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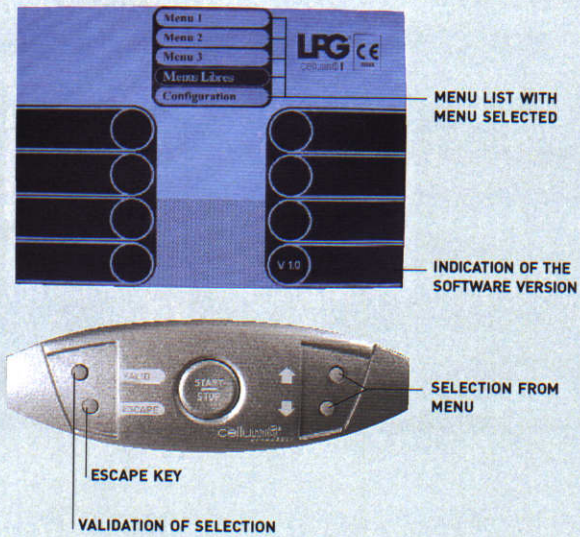
Menu screen

Use the navigation keys to select the required menu and reverse contrast, then confirm your choice by pressing the VALID key.

Use the ESCAPE key in the event of error or to exit from a menu.



Configuration screen

The CONFIGURATION menu will allow you to select the language of use, adjust the contrast, select and adjust the keyboard beep and to consult the TIME METER and other maintenance functions.

A menu is selected when it is in reverse video.

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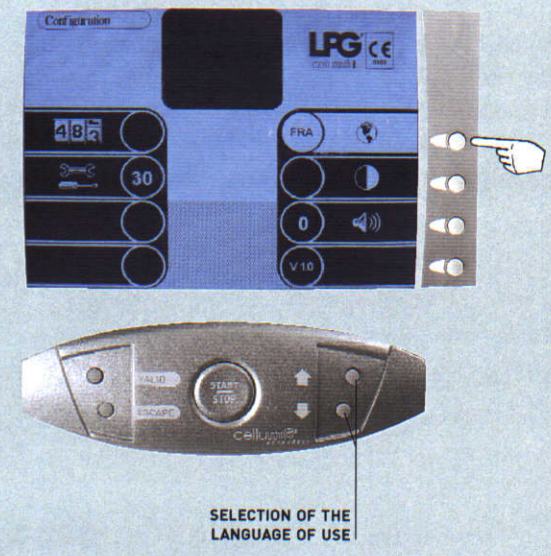
Language selection

To choose the language of use for your equipment, select the icon by pressing the appropriate key and then use the nagivation keys to scroll down the various programmed languages.

Once the language of use has been decided upon, press the ESCAPE key to return to the MENU screen or, if you want to proceed with another setting, press the key corresponding to the parameter you wish to change.

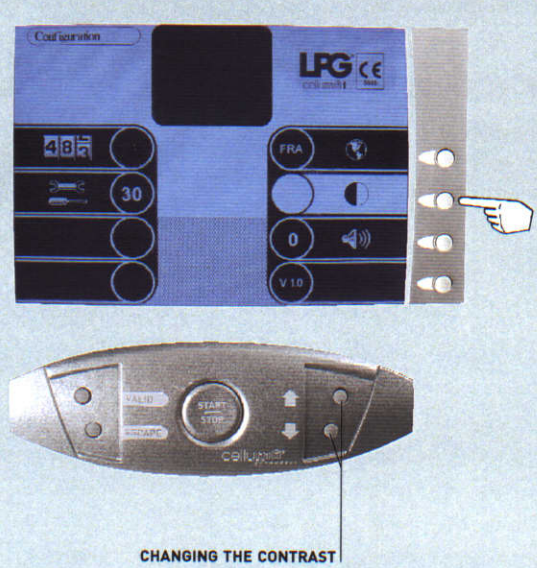


Adjusting the screen contrast

The screen brightness is pre-set at the factory so as to provide optimum contrast for an ambient temperature of 22° C. However, this parameter may be changed.

To adjust the screen contrast from the control panel, select the icon by pressing the appropriate key and then use the navigation keys to change the contrast.

Once the contrast has been adjusted, press the ESCAPE key to return to the MENU screen or, if you want to proceed with another adjustment, press the key corresponding to the parameter you want to change.



Sudden changes in temperature will affect the screen contrast. In such cases, wait for the brightness to stabilize before proceeding with any adjustment.

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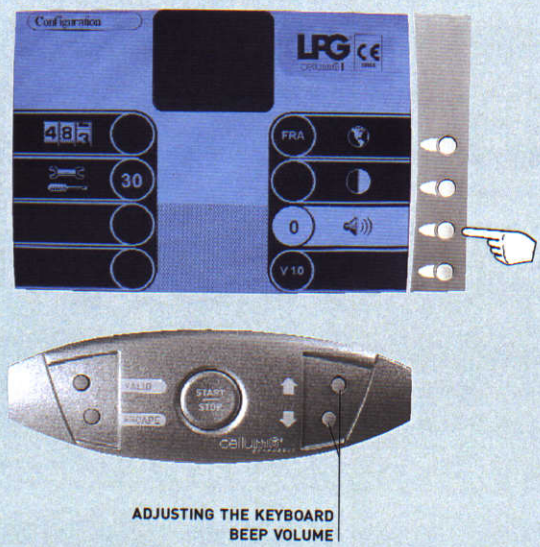
Selection/adjustment of the keyboard beep and control panel

Each time one of the keys of the control panel of your Cellu M6® Keymodule *i* is pressed, a beep will sound. The volume and pitch can be adjusted.

Adjusting the keyboard beep volume:

This adjustment is made via the CONFIGURATION screen. Select the icon by pressing the appropriate key and by using the navigation keys to adjust the keyboard beep volume:

- 0: silent
- 1: weak
- 2: average
- 3: loud

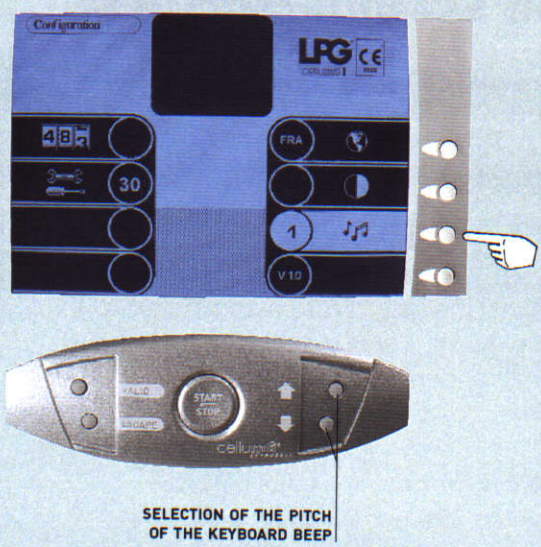


ADJUSTING THE KEYBOARD BEEP VOLUME

Selecting the keyboard beep pitch:

This selection is made via the CONFIGURATION screen. Select the icon by pressing the appropriate key and by using the navigation keys to change the pitch of the keyboard beep:

- 1: a high pitch
- 2: medium pitch
- 3: low pitch



SELECTION OF THE PITCH OF THE KEYBOARD BEEP

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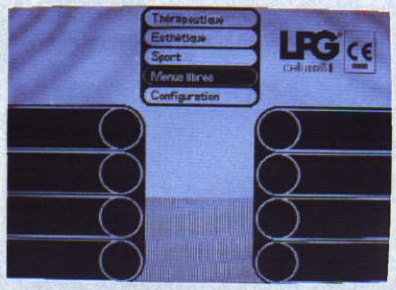
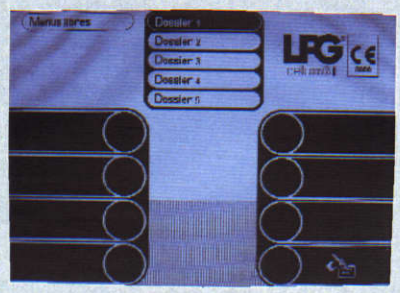
Selecting a program

When you are at the root menu, you can select from the areas of aesthetics, therapeutics or sport.

At any time during program selection, you can return to the previous menu by pressing ESCAPE.

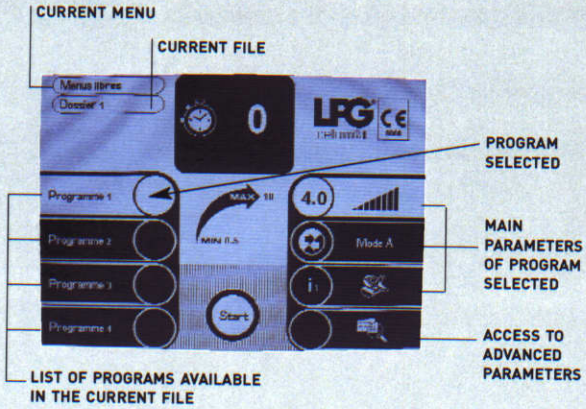
Select the appropriate area and then press VALID. You will now access the FILES.





Now select the appropriate FILE by pressing VALID. You now get to PROGRAM MENU.

You can now select the program you require and change the treatment intensity values, the mode and treatment head.



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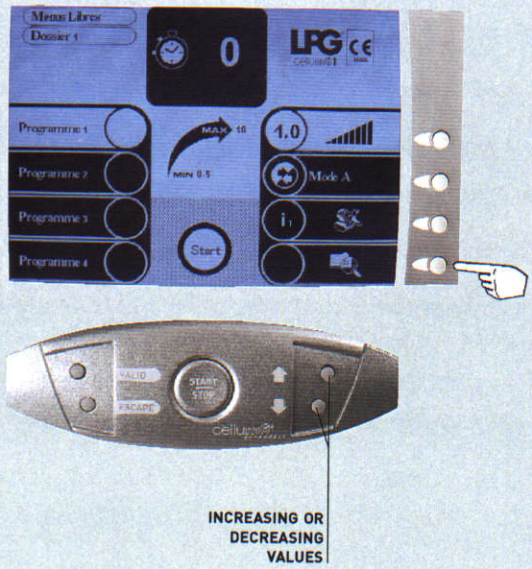
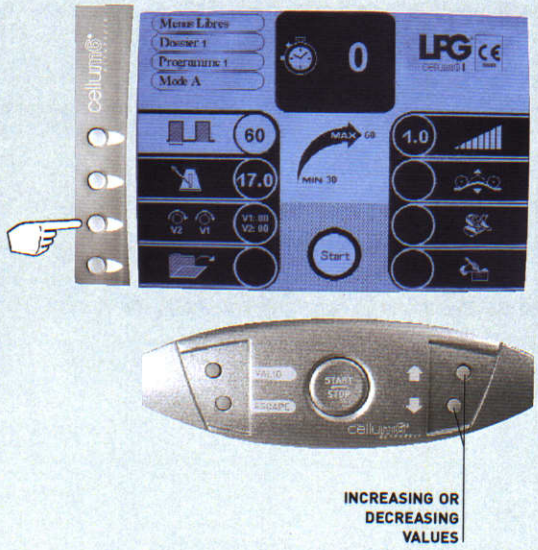
Selecting a program

Once you are in the program, you can gain access to the advanced parameters to see the pre-programmed parameter values by clicking on the icon. Increase or decrease the values using the arrows. The screen will tell you if you are in continuous or sequential mode via the icon.



You can also have access to the roller parameters (differential with respect to direction and speed) in order to amend the other parameters in the same way.

Press Start/Stop to start the treatment.



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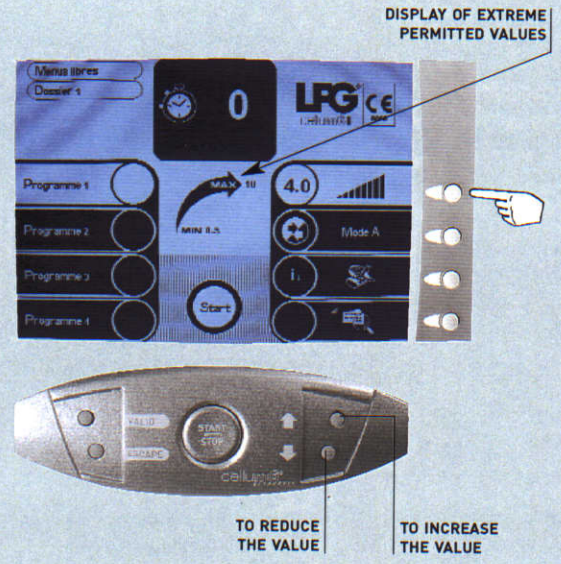
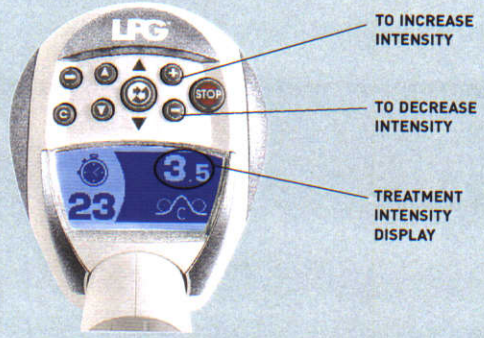
Adjusting the treatment intensity

1) From the control panel,
select the treatment INTENSITY adjustment parameter by pressing the appropriate key; the parameter is displayed as a reverse video.

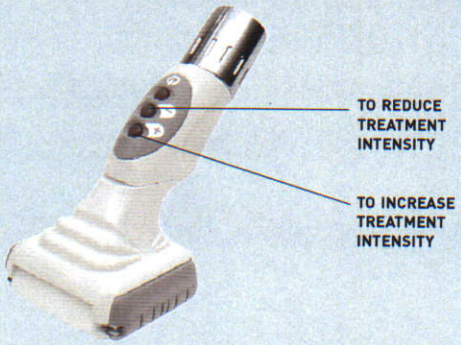
Now use the navigation keys to increase or decrease the treatment INTENSITY within the limits of the extreme permitted values.



2) From the main head, BASE
set or adjust the required treatment INTENSITY by pressing the keys ⊕ or ⊖.



3) From the auxiliary head, BASE
set or adjust the required treatment INTENSITY by pressing the keys ⊕ or ⊖ from the auxiliary head control.



! *The treatment intensity selected is continuously checked by an electronic vacuum sensor. However, too high a treatment intensity or a badly adjusted treatment intensity may lead to pain and traumatize the cutaneous tissue, thereby encouraging the onset of bruising.*

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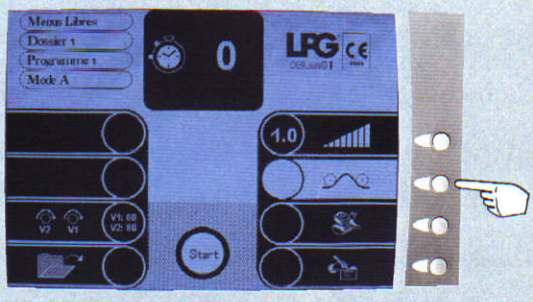
Selecting continuous or sequential treatment

ONLY FROM A FREE MENU

You can select the type of treatment (CONTINUOUS or SEQUENTIAL) you require from all the programs in the FREE MENU.



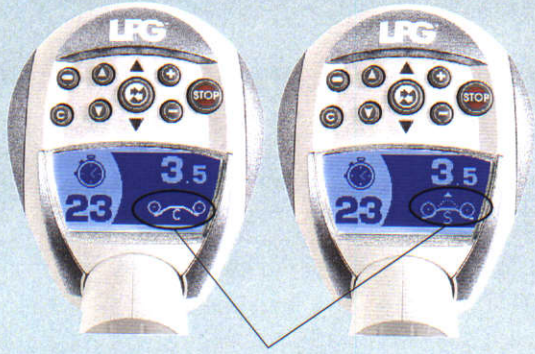
CONTINUOUS TYPE TREATMENT

To do this, go to the ADVANCED PARAMETERS screen of the FREE PROGRAM you selected and successively press the key, corresponding to the type of treatment.

SEQUENTIAL TYPE TREATMENT

At all times, the type of treatment you programmed will be displayed on the screen of the main head.

When you use a PARAMETERIZED PROGRAM, the type of treatment is defined by the program and cannot be changed; however, the screen of the main head will inform you of the type of treatment.



DISPLAY OF TYPE OF TREATMENT

If you work with continuous suction, the sequence-forming parameters (cycle and frequency ratio) will not be accessible.

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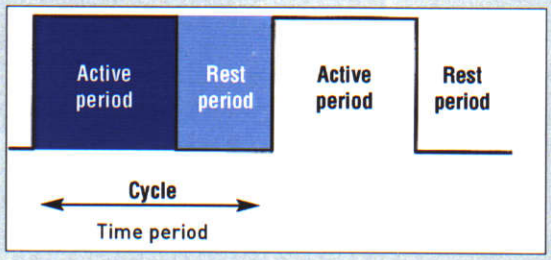
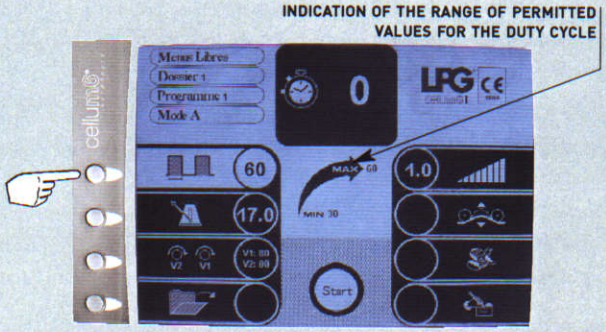
Setting the duty cycle

FOR SEQUENTIAL TYPE TREATMENT ONLY

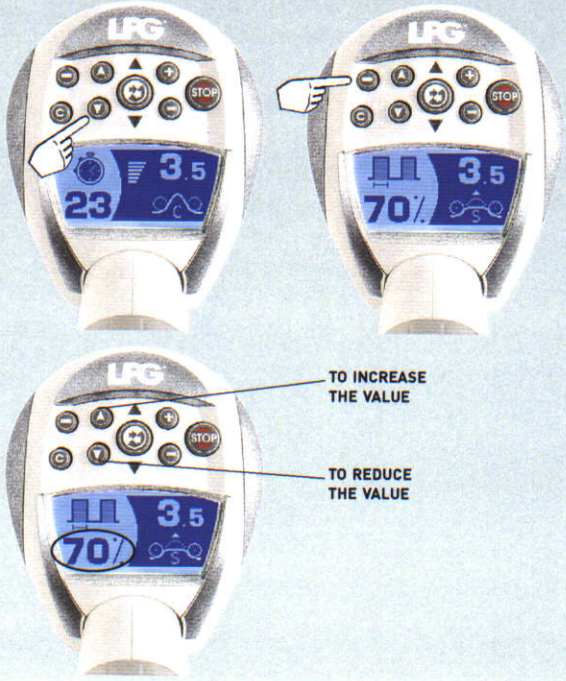
The sequential mode can be compared with the throbbing of a tissular seizure; this throbbing is characterized by two parameters – frequency and the duty cycle. The frequency corresponds to the number of beats over a given period of time (cycle). The duty cycle corresponds to a time of activity over a given period of time (cycle). The sequentiality can therefore be shown as follows:
When setting the frequency, the cycle time is increased or decreased. When setting the duty cycle, the phase of activity over one cycle is increased or decreased.





1) From the control panel,
to proceed with setting the DUTY CYCLE, first go into ADVANCED PARAMETERS of the program selected. To do this, press the KEY corresponding to ADVANCED PARAMETERS. Now select the DUTY CYCLE parameter by pressing the corresponding key.
Then use the nagivation keys to adjust the DUTY CYCLE within the range of permitted values.

2) From the main head,
press a ▼ key to display the value of the DUTY CYCLE parameter. Validate by pressing the ⊖ key, and the DUTY CYCLE value will start to flash. Now use the ▲ or ▼ keys to set this parameter to your convenience. Validate with the ⊖ key. Use the C key to return to the monitor screen.



Certain value combinations between the duty cycle and the frequency are invalid. This is to prevent improper treatment configurations.

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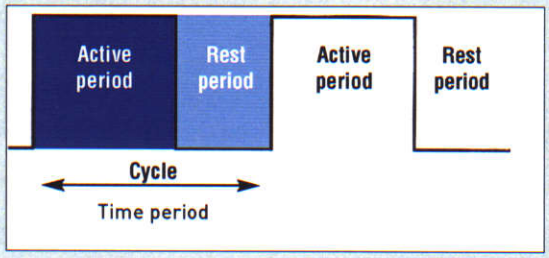
Setting the frequency

FOR SEQUENTIAL TYPE TREATMENT ONLY

The sequential mode can be compared with the throbbing of a tissular seizure; this throbbing is characterized by two parameters – frequency and the duty cycle. The frequency corresponds to the number of beats over a given period of time (cycle). The duty cycle corresponds to a time of activity over a given period of time (cycle).
The sequentiality can therefore be shown as follows:

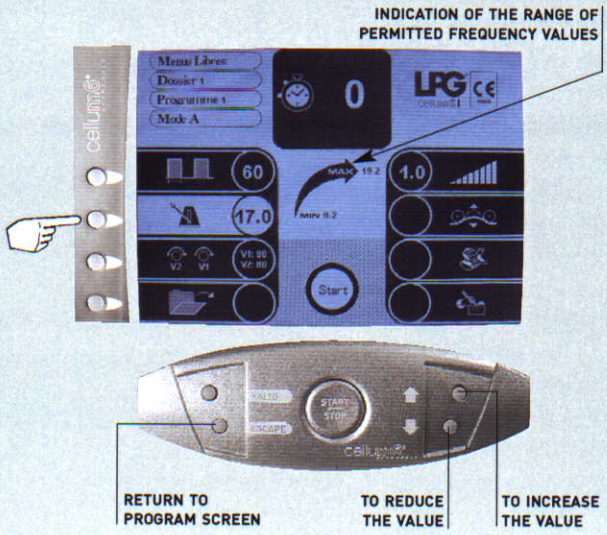
- when setting the frequency, the cycle time is increased or decreased
- when setting the duty cycle, the phase of activity over one cycle is increased or decreased.



1) From the control panel,
to proceed with setting the FREQUENCY, first go into ADVANCED PARAMETERS of the program selected. To do this, press the KEY corresponding to ADVANCED PARAMETERS.

Now select the FREQUENCY parameter by pressing on the corresponding key.

Then use the nagivation keys to adjust the FREQUENCY within the range of permitted values.



Certain value combinations between the duty cycle and the frequency are impossible. This is to prevent absurd treatment configurations.

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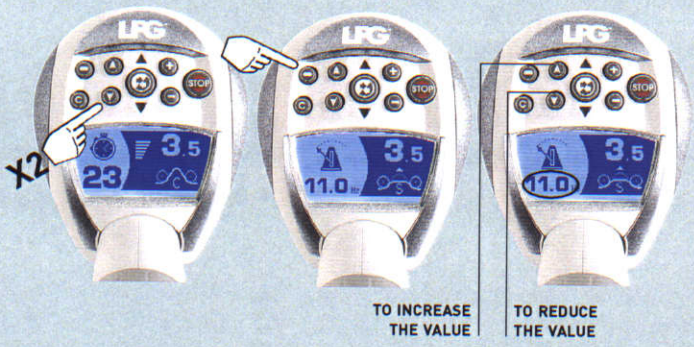
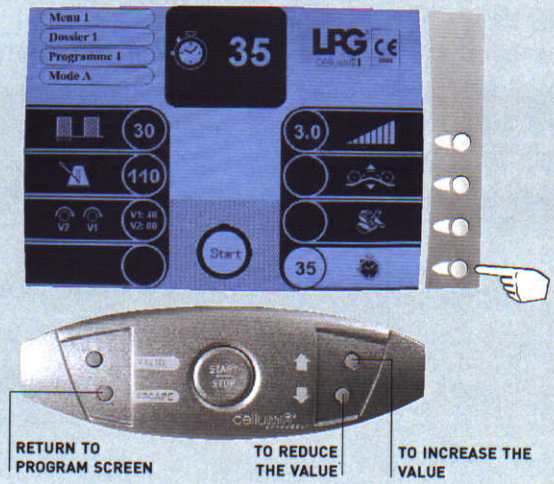
Setting the frequency

2) From the main head,
press a key twice in succession to display the value of the FREQUENCY parameter.
Validate by pressing the key , and the FREQUENCY value will start to flash. Now use the and keys to set this parameter to your convenience.
Validate with the key.
Use the key to return to the monitor screen.



Setting the treatment time

Setting the treatment time is only possible for those programs already offering a treatment time.
In such cases, time starts to decrease, minute by minute and at all times shows the remaining treatment time; once the time reaches 0, the machine will automatically stop.
Where no time is suggested, as in the FREE MENU, the time starts to increase minute by minute and at all times shows the time lapsed since the start of the session; you decide to stop the machine once the time you recommended has been reached.
It is consequently impossible and useless to proceed with any modification to this parameter.
In order to set the treatment TIME, first go the ADVANCED PARAMETERS of the program selected. To do this, press the key corresponding to the ADVANCED PARAMETERS.



Select the treatment TIME by pressing the appropriate key and use the navigation keys to increase or decrease the treatment TIME from 0 to 99 minutes.
A short press corresponds to one minute.
A long press corresponds to ten minutes.

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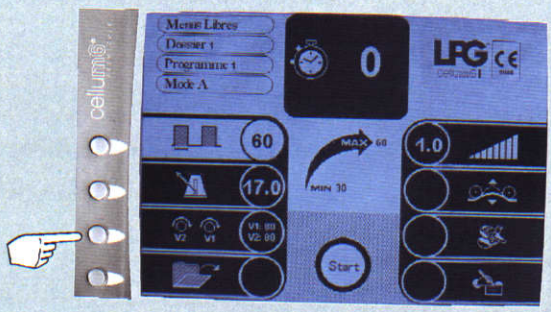
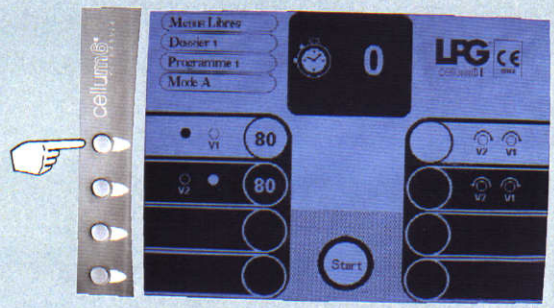
Setting the speed and direction of rotation of the rollers of the main head

The ROLLER SPEED AND DIRECTION OF ROTATION of the main head can be adjusted independently for each of the two rollers. To proceed with adjusting these parameters, go to ADVANCED PARAMETERS. To do this, press the key corresponding to ADVANCED PARAMETERS.

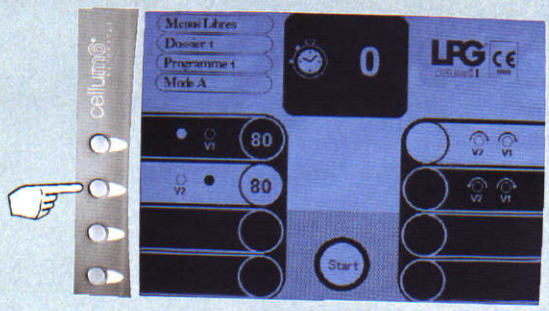


Then select the ROLLER SPEED AND DIRECTION OF ROTATION parameter by pressing the corresponding key.



Select the parameter for adjusting the front roller V1 (in relation to the direction of head movement), by pressing the corresponding key. Set the speed of rotation of roller V1 from 0 to 100% by using the navigation keys. The settings go in 10s.

Select the parameter for adjusting the rear roller V2 (in relation to the direction of head movement), by pressing the corresponding key.
Set the speed of rotation of roller V2 from 0 to 100% by using the navigation keys.
The settings go in 10s.



Warning: Setting the roller speed is only possible if the main head is selected.

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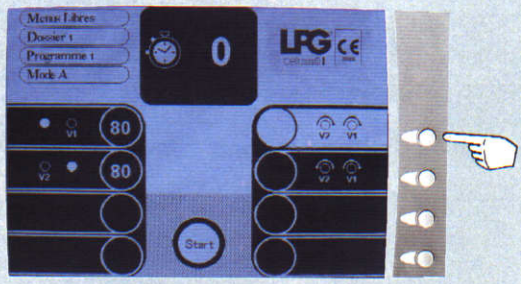
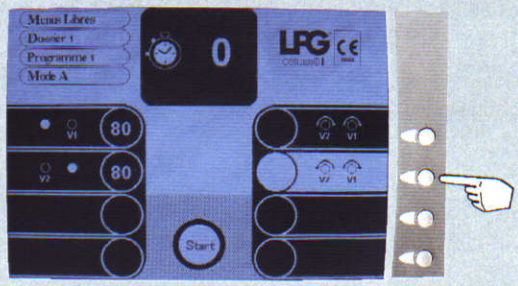
Setting the speed and direction of rotation of the rollers of the main head

If you want the two rollers of the main head to turn in the same direction, select parameter V1 and V2 to run in the same direction by pressing the corresponding key.



If you want the two rollers of the main head to turn in the opposite direction, select parameter V1 and V2 to run in the opposite direction by pressing the corresponding key.



Selecting the treatment mode

For some programs, the Cellu M6® Keymodule *i* offers you the option to select from two treatment modes, which entails different settings of certain parameters, for the same program.

1) From the control panel,
Successively press the selection key corresponding to the mode, so that you can change from one mode to the other.

Ensure that the parameters are always adapted to the cutaneous tissue undergoing treatment.

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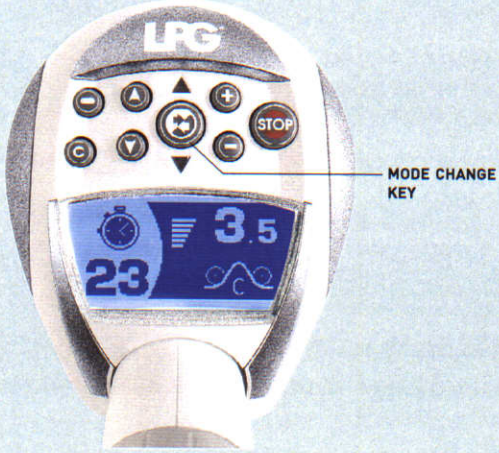
Selecting the treatment mode

2) From the main head, use the central key to go from one mode to the other.



Selecting the type of treatment head

The choice governing the type of head is based on the treatment to be carried out and the type of area being treated.

Select the type of head required by successively pressing the appropriate selection key.

Direct selection by pressing a key of the selected head when suction is not efficient.

Comment: when the auxiliary head type is selected, it is not possible to access "*setting the roller speed and direction of rotation*" for the main head.

SELECTING THE MAIN HEAD

SELECTING THE AUXILIARY HEAD

Never proceed with this setting when the treatment head is in contact with the cutaneous tissue.

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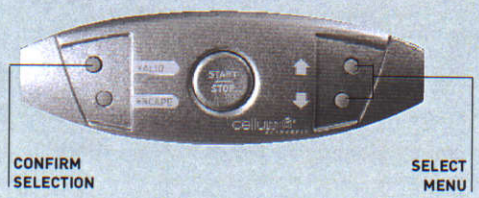
Programming a free menu

Select a MENU by using the navigation keys and then confirm by pressing the VALID key.

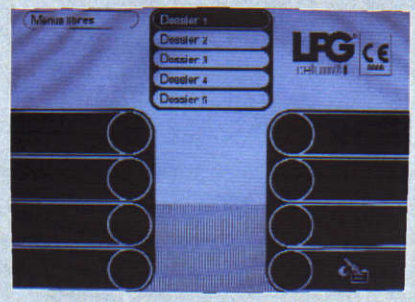
Then, in the same way, select a FILE and confirm by pressing the VALID key.

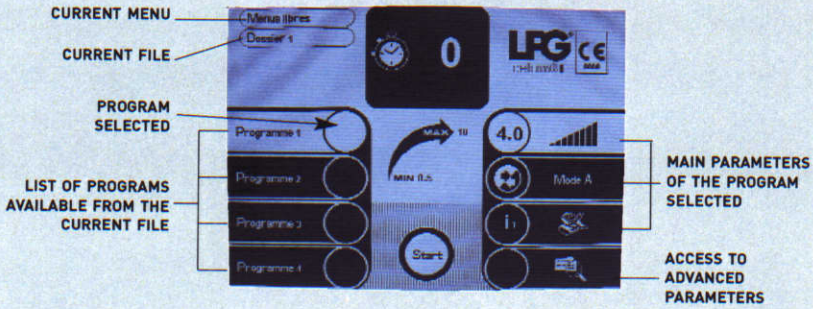
The PROGRAM, at the top left, is selected by default and its main parameters can be seen on the right side of the screen.



Then, referring to the relevant sections, set the different parameters of the selected PROGRAM :

- Treatment intensity
- Duty cycle (for sequential type treatment)
- Frequency (for sequential type treatment)
- Motorized roller speed and direction of rotation (for treatment with the main head)





Each program contains adjustments specific to a treatment, originating from our research and assessment center. However, the parameters that characterize these programs may be modified at any time during treatment by the operator. Once the unit is shut down or the program window comes on, all these settings will revert to the factory configuration.

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Creating a free program based on a parameterized program

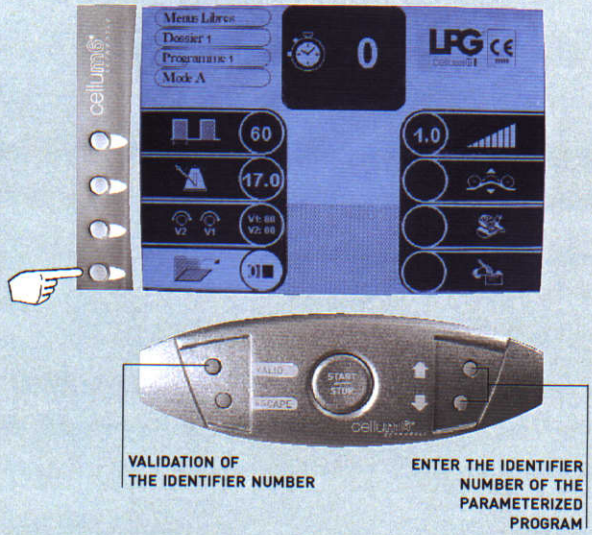
This function allows you to create a FREE PROGRAM on the basis of a PARAMETERIZED PROGRAM.
From the ADVANCED PARAMETERS screen of a FREE PROGRAM, select the icon by pressing the relevant key.

Now go to the PROGRAM LIST in order to identify the program number to recall the parameters.

Use the navigation keys to enter the number you identified and then validate. The parameters of your FREE PROGRAM are now copied to the PARAMETERIZED PROGRAM you selected. Now finalize your FREE PROGRAM by adapting the various treatment parameters you want to carry out.

Make sure that the parameters of your program are adapted to the cutaneous tissue undergoing treatment.

Programming and the use of a free menu is at the operator's option and is his responsibility alone.



The adjustments made to the free program parameters are automatically stored and can be reused at a later stage.

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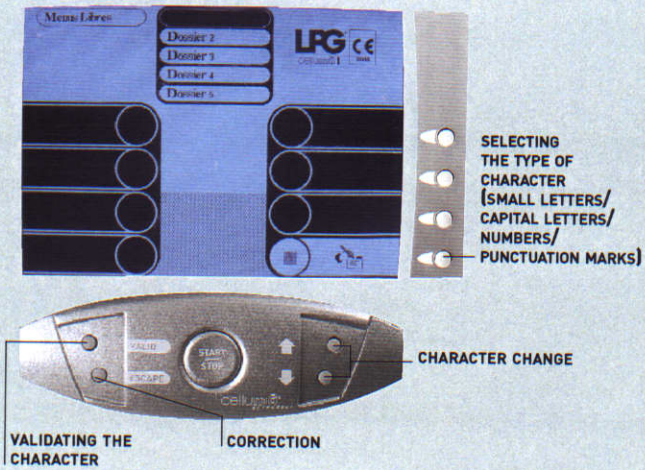
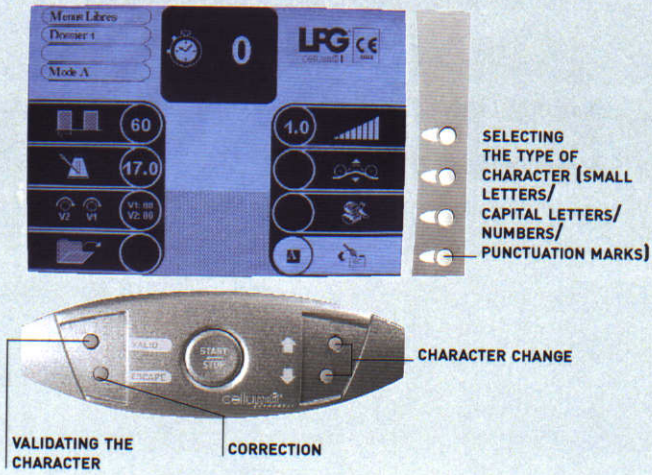
Personalization of file names from the free menu

Having selected a FILE from the FREE MENU, select the icon by pressing the corresponding key.
Press the selection key to choose the type of character (capital letters, small letters, number or punctuation marks) which will make up the new name of your FILE.
Use the navigation keys to scroll the characters available for each category and validate your choice by pressing the VALID key.
Warning: The name you give to your FILE must not exceed 16 characters.
After having entered the last character, hold the VALID in order to put the new name into service.



Personalization of program names from the free menu

After selecting a PROGRAM from the FREE MENU, select the icon by pressing the relevant key.
Press the select key to choose the type of character (capital letters, small letters, numbers or punctuation marks) which will make up the new name of your PROGRAM.
Use the navigation keys to scroll the characters available for each category and validate your choice by pressing the VALID key.
Warning: The name you give to your PROGRAM must not exceed 16 characters.
After having entered the last character, hold the VALID in order to put the new name into service.



This function is only possible in free menu

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MAINTENANCE FILE . . . . . .P. 40

! *ALL THE MAINTENANCE OPERATIONS DESCRIBED IN THIS SECTION MUST BE CARRIED OUT WITH THE UNIT SWITCHED OFF AND THE POWER CABLE DISCONNECTED.*

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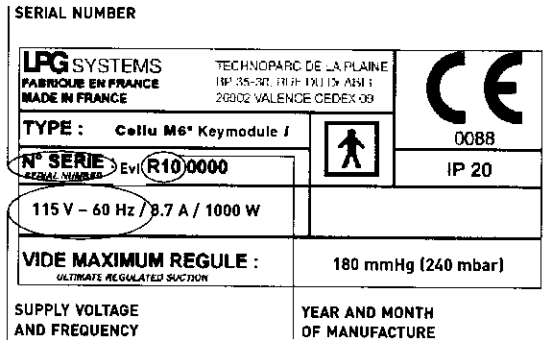
Identification rating plate

Your unit is identified by a serial number shown on the rating plate.
The rating plate also shows the permitted supply voltage for the unit.

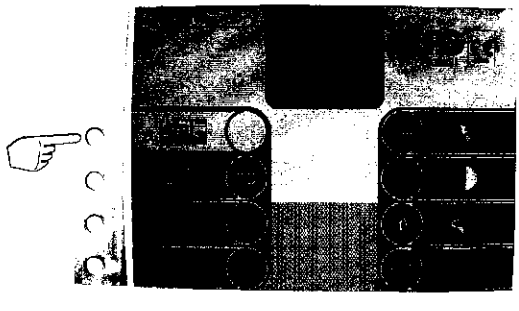
When you contact LPG One Customer Service because of a technical problem, please indicate the serial number of your Cellu M6® Keymodule *i*.
The letter indicates the year of manufacture:
R = 2001, S = 2002, T = 2003, U = 2004...
while the two figures indicate the month of production :
01 = January, 02 = February, 03 = March...



Time meters

Your unit comprises several TIME METERS that total the operating hours of the various units for periodic maintenance purposes.
These meters can be seen at control panel level, from the CONFIGURATION screen and MAIN HEAD screen.
Access the TIME METERS by pressing the key relating to the icon .

FROM THE CONTROL PANEL



The identification rating plate is located on the bottom, behind the unit.

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Time meters

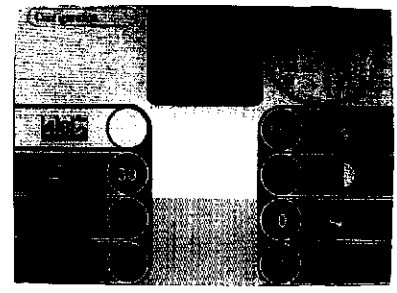
CHM: Machine Time Meter that totals the number of hours your machine has been operating.

CHTP: Main Head filter Time Meter totals the number of hours the main head has been operating.

CHTA: Auxiliary Head filter Time Meter totals the number of hours the auxiliary head has been operating.

CUT: Main Head Unit Meter totals the number of hours the main head has been operating.

CUS: Keymodule® Unit Meter totals the number of hours the Keymodule® connected to the main head has been operating.



To display the TIME METERS of the main head, go to the MAINTENANCE MENU of the main head by pressing the key twice in succession .

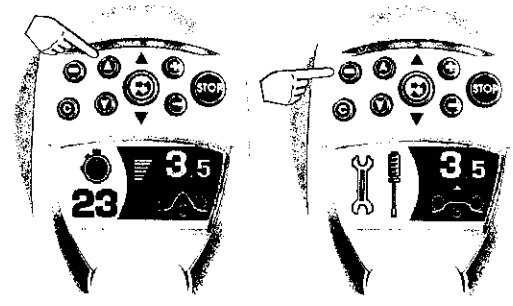
From the MAINTENANCE MENU, one press on the key will display the TIME METERS of the main head.

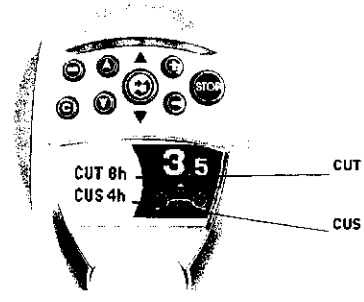
CUT: Main Head Unit Meter totals the number of hours the body of the main head has been operating.

CUS: Keymodule® Unit Meter totals the number of hours the Keymodule® of the main head has been operating.

Press the key twice in succession to return to the monitor screen.

FROM THE MAIN HEAD





For further information, please see pages 98 and 99 (Replacing filter cartridges).

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Cleaning the unit

We recommend that you clean your unit as often as possible, not only for reasons of hygiene and aesthetics but also because cleaning the unit will help keep it in a good state of repair and extend its life.

Using a vacuum cleaner with fine nozzle, clean the following sections:

- The inside of the access drawer to the auxiliary heads, (having already removed all the auxiliary heads)
- The inside of the access door to the filters

Using a moist sponge, clean the following sections:

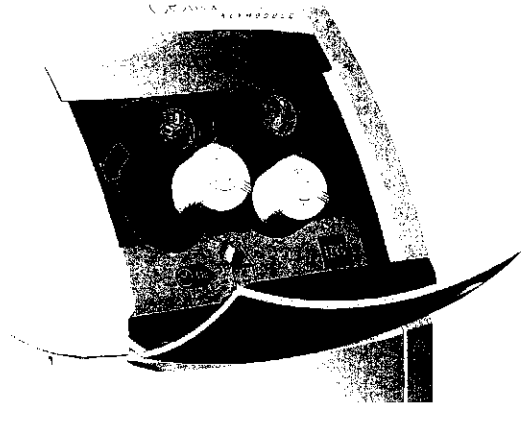
- All the external hoods
- Hoses
- The power cable

Using a cloth soaked with a little domestic cleaning product not containing alcohol, clean the following sections:

- Monitor screen and control panel
- The inside of the access drawer to the auxiliary heads
- The inside of the access door to the filters

Replacing filter cartridges

Your unit accommodates 2 filters. One is for filtering the circuit of the main head while the other filters the circuit of the auxiliary heads. The filter cartridge guarantees the efficiency of your unit and extends its useful life. Remember to change the cartridge every forty hours.



! *Do not use aggressive products, such as acetone, trichloroethylene or alcohol at 90°, or abrasive sponges.*

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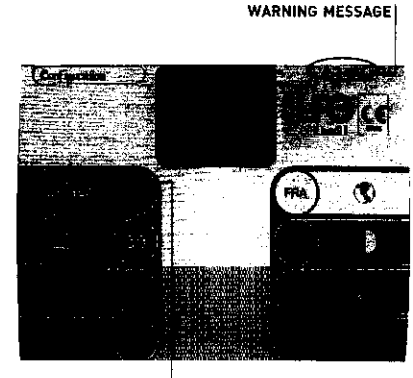
Replacing filter cartridges

Replacement of filter cartridges:
If a filter change request occurs, a warning message is displayed at the top right of the CONTROL screen of the control panel and an icon showing the filter that requires changing appears in the CONFIGURATION screen. This happens each time the pump shuts down until the filter change has been acknowledged.



1 = Main head filter (warning message number: 22000)

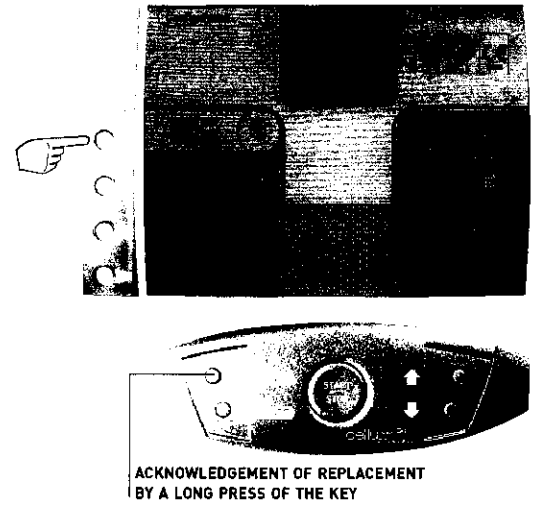
2 = Auxiliary head filter (warning message number: 22001)

Open the filter access hood. Unscrew the filter cartridge and replace with a new one.

Once the cartridge is in place, validate the operation by selecting the icon representing the filter you have just changed, by pressing the appropriate key and hold the VALID.

To confirm replacement, the icon depicting the filter disappears.

Remember to purchase new cartridge filters from LPG Systems® Customer Service, so that you always have a spare on hand.



Never use your unit without LPG® filter cartridges.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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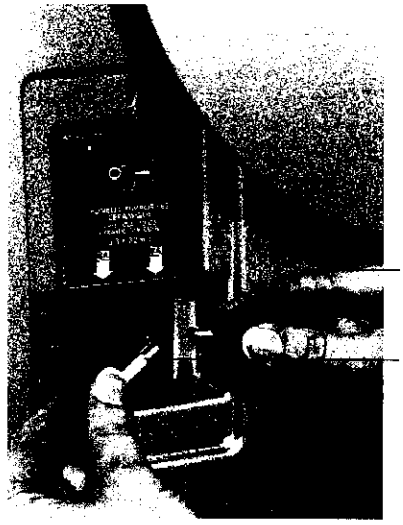
Replacing fuses

Your unit is protected against short-circuits by 2 ceramic 6.3 mm x 32 mm time-delay fuses.

Fuse replacement:

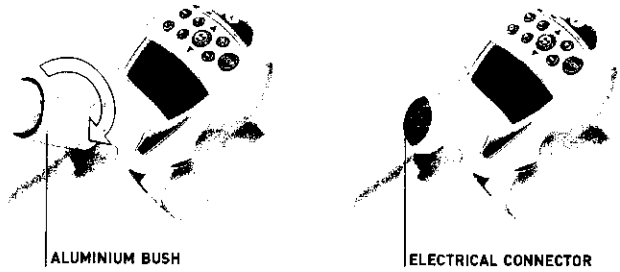
- Disconnect the supply cable from the mains
- Loosen one of the 2 fuse holders
- Remove the fuse
- Repeat the same operation for the second fuse holder
- Replace with the fuses supplied in the maintenance kit.

Remember to purchase new fuses from LPG Systems® Customer Service, so that you always have a spare on hand.



Instructions for disconnecting the treatment heads

Because of its rapid-fit twist connection, the main treatment head can easily be disconnected from its hose by loosening the aluminium connection bush.



To connect the head, take hold of the hose and proceed with its electrical connection and then screw tight by tightening the aluminium bush.

If fuses with the incorrect rating are used, this could result in damage to the entire electrical system. See page 107 concerning the identification of fuse ratings to be used

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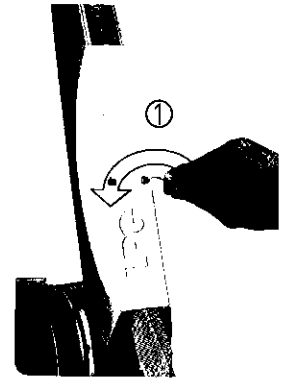
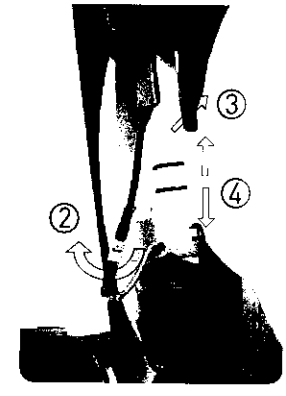
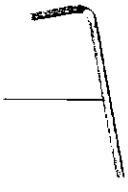
Instructions for disconnecting the treatment heads

Disconnecting the treatment heads and hoses is quick and easy.

1 : Loosen the two screws and remove the rear screen located on the mobile arm, using the small, hex key.
2 : Loosen and disconnect the electric connection.
3 : Remove the plastic connection from its housing.
4 : Disconnect the plastic connection.

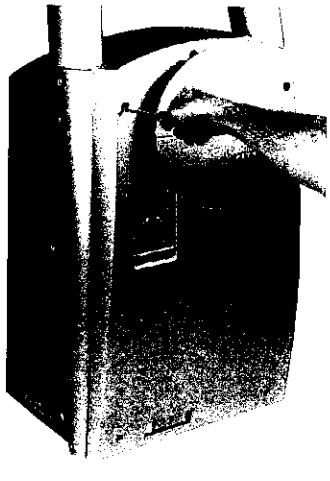


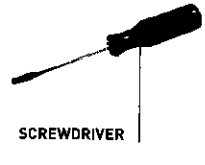




Access to the technical items

Disconnect the supply cable. Open the rear door to gain access to the technical elements using a screwdriver. Only loosen the 4 fixing screws a quarter turn.





! *Connection system identical for the two circuits.*

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Replacing the filters of the vacuum generator

The vacuum generator has two filter cartridges:

- One paper cartridge at the inlet, on the left side
- One metal cartridge on the discharge side, on the right side

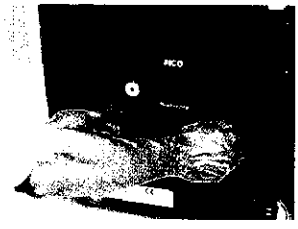
These two cartridges must be replaced after every 1000 hours of operation.
If a filter change request occurs, a warning message is displayed at the top right of the CONTROL screen of the control panel and an icon showing the pump filters that require changing appears in the CONFIGURATION screen. This happens each time the pump shuts down until the filter change has been acknowledged.

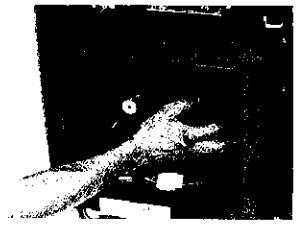
= Vacuum pump filter (warning message number: 22002)

No special tool is required for this operation.

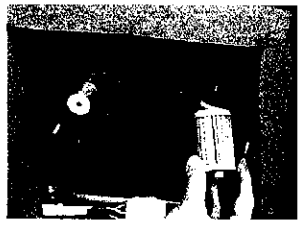
1 : Open the rear door to gain access to the technical elements
2 : Loosen the two knurled nuts of the vacuum generator hood
3 : Unscrew the cover
4 : Unscrew the central knurled nut
5 : Remove the cartridge from the spring
6 : Replace with a new cartridge
7 : Repeat the same operation for the second cartridge
8 : Once the new filters are in place, validate the operation by selecting the icon representing the filters you have just changed, by pressing the appropriate key and hold the VALID.

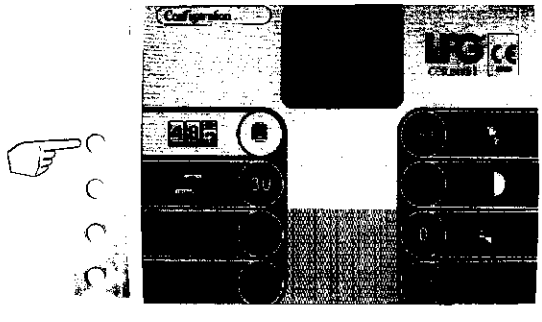
To confirm replacement, the icon depicting the filters disappears.

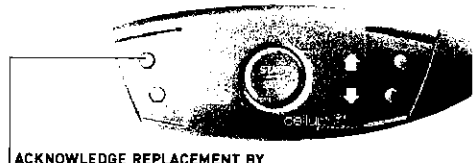

②


③

④


⑤


⑧



It is important to replace the filter cartridges one after the other, so that the correct cartridge is replaced in its housing. The Cellu M6® must be switched off before proceeding with a filter cartridge change. The unit must also be cold, so as to avoid any risk of burning.

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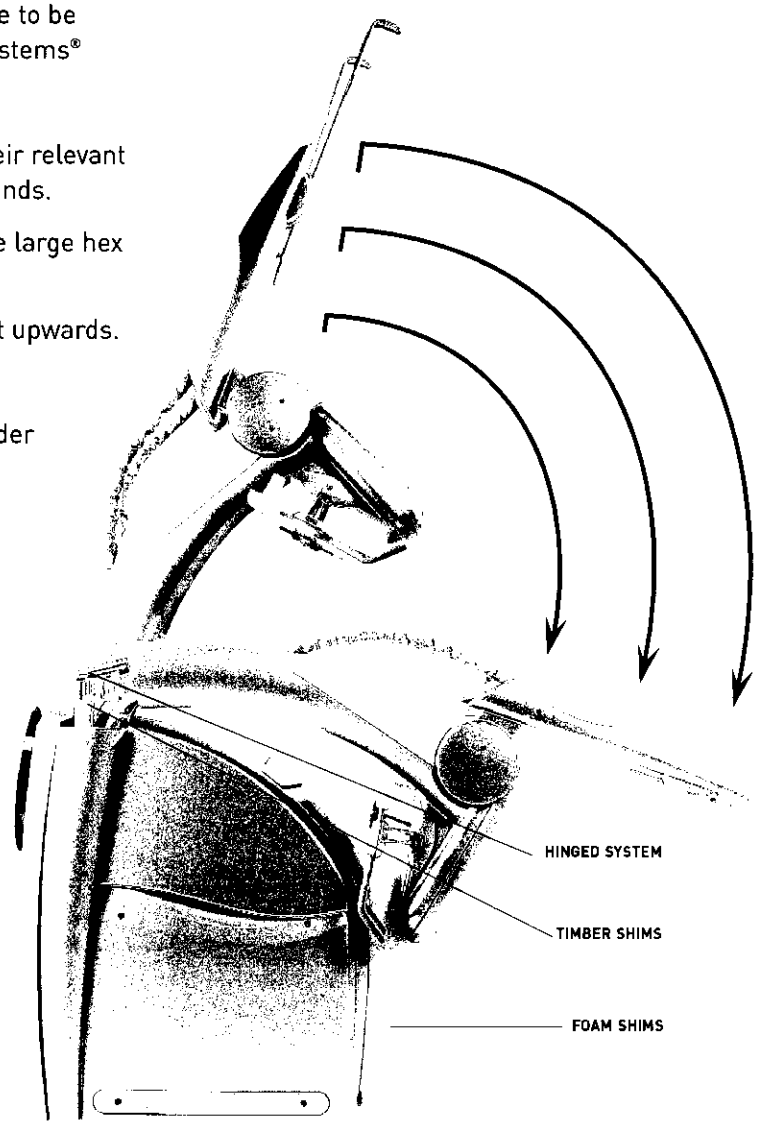
Transport/Storage

In the event of having to relocate the unit by professionals, it is essential to pack the unit in its original packaging.
Where the unit is only being moved a short distance or when stored for a short while in the folded position, it is essential to insert the two shims provided for this purpose

If you require any information on the packaging, shims and procedure to be adopted, please contact LPG Systems® Customer Service.

- Fix the treatment heads to their relevant support using large rubber bands.
- Loosen the 4 screws using the large hex key.
- Pull the top section of the unit upwards.
- Bend while holding the unit.
- Insert the various shims in order to protect the hoods.



LPG Systems® will not be liable for damage caused by transport or storage in the folded position, if the shims provided for this purpose, are not in place.

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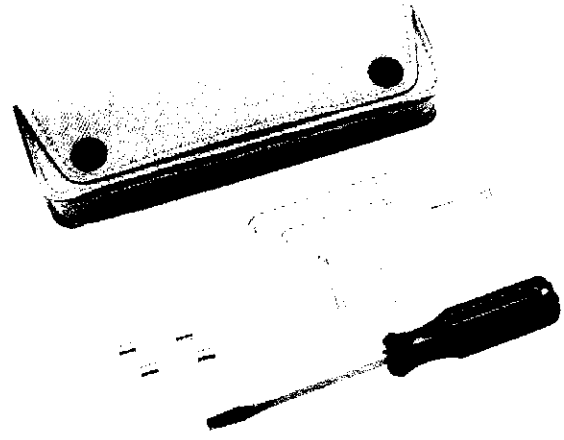
Maintenance kit

The tools supplied with the equipment in the tool box are sufficient to carry out the maintenance operations defined in this guide.

Contents of the maintenance kit:

- 4 hole covers
- 2 spare fuses
- 2 hex key (model No. 2.5 and 5)
- 1 torx T10 key
- 1 torx T30 key
- 1 screwdriver



Maintenance file

Replacement of the filter cartridge for the main head circuit ..... 40 hours
Replacement of the filter cartridge for the auxiliary head circuit ..... 40 hours
Overhaul of the main head ..... approx. every 1000 hours
Replacement of the vacuum generator filters ..... 1000 hours

DATE	NUMBER OF HOURS	OPERATIONS CARRIED OUT

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A little problem! What should I do ?

If your unit is not working properly, proceed with the following checks before calling Customer Service of LPG Systems®:

- Is the unit properly connected to a main plug?
- Is the main plug live?
- Is the ON switch lit up?
- Are the fuses of the unit in good order?
- Are the filter cartridges clean and properly in place?
- Are the hoses free?
- Are the hoses properly connected to the mobile arms of the balancer?
- Are the sealing valves of the main head in their proper place, clean and moving?
- Is the Keymodule® of the main head correctly fitted?
- When switching on, the main head screen is blocked in the MAINTENANCE MENU. This means that there is a compatibility problem with the electronic boards of the T70 and Cellu M6® Keymodule *i*. Please contact Customer Service of LPG Systems®.

Once these checks have been carried out and if the malfunction persists, please contact Customer Service of LPG Systems®, or the nearest authorized dealer,indicating the model of your unit, its serial number and operating time in hours (see pages 96 and 97 re access to the time meters).

LPG One Customer Service :
Tel.: 888.730.0144
Fax : 888.571.0040

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General characteristics

Dimensions: Length x width x height .....60 x 46 x 210 cm
Net weight .....90 kg
Maximum set pressure .....180 mmHg (240 mbar)
Fuses .....Time-delay
.....Dimensions 6.3 x 32 mm
Cooling .....By way of mechanical ventilation incorporated in the pump
Protection index .....IP 20
Electrical protection class 1

Unit fitted with patented treatment heads.

The Cellu M6® Keymodule *i* is marked CE 0088 as a medical device by virtue of Annex V of regulation 93/42/EEC (standards 60601-1-1 and 60601-1-2)

Electrical properties

115V - 60Hz

Supply voltage .....115 V AC
Frequency .....60 Hz
Intensity consumed .....8.7 A
Power consumed .....1000 Watts
Ceramic fuses T16A

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TREATMENT HEAD

cellum6 KEYMODULE

Registered trademark

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Contents

9 DESCRIPTION OF MAIN HEAD T70 . . . . . .P. 46

9 DESCRIPTION OF KEYMODULE® . . . . . .P. 47

9 FUNCTIONS INCORPORATED IN THE MAIN HEAD . . . . . .P. 49

9 DESCRIPTION OF AUXILIARY HEADS . . . . . .P. 51

9 FUNCTIONS INCORPORATED IN THE AUXILIARY ADAPTER . . . .P. 53

9 MAINTENANCE . . . . . .P. 54

The manufacturer reserves the right to amend the product technical specifications without prior notice. Any reproduction, even in part, is prohibited. All the illustrations of this treatment head supplement are non-binding.

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Main head T70

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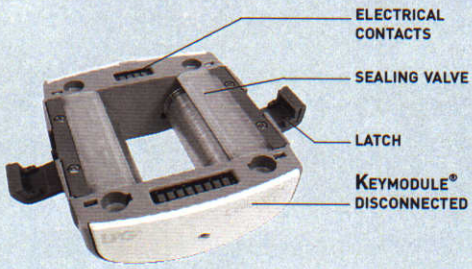
Keymodule®

The Keymodule® is the bottom interchangeable section of the T70 main head. It comprises the motorised rollers and sealing valves.

You have three Keymodule® the characteristics of which differ from the motorized rollers in several points:

- Diameter and texture of the rollers
- Rigidity of return springs



Keymodule® i50 :
This is recommended for the programs in the treatment of lymphedema.
It is characterized by the following points:

- Roller diameter: 26 mm
- Extra-soft springs

Movement and direction of rotation are visually displayed by LEDs for the Keymodule ™ treatment head.

Before running your unit for the first time, ensure that a Keymodule® was properly connected to the T70, because otherwise the screen will display an error message.

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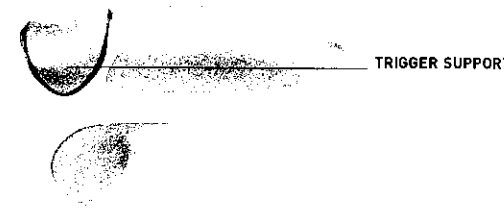
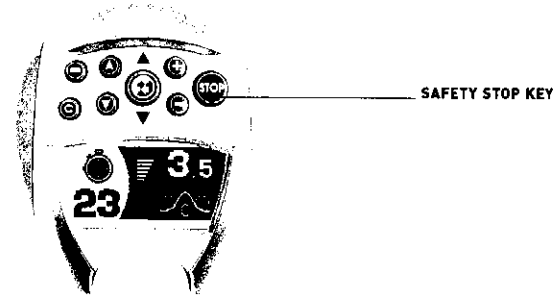
Functions incorporated in the main head

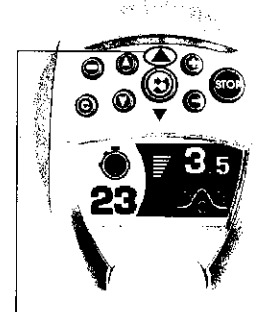
Apart from setting the treatment intensity, duty cycle, frequency or method of treatment, the main head also incorporates the start/stop and reverse functions and displays the direction of movement, as well as adjusting the volume and selecting the keyboard beep pitch.



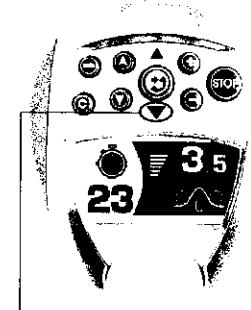
START/STOP function:
Once the pump has been switched on by the START button on the control panel keyboard, treatment start and stop are controlled by the main head.
To start treatment, press the trigger.
To stop treatment, press the STOP key.



Indication of the direction of head movement (where the rollers move in the same direction):
Each time the trigger is pressed, this reverses the direction of head movement. The direction of movement of the main head is indicated throughout treatment by flashing lights.



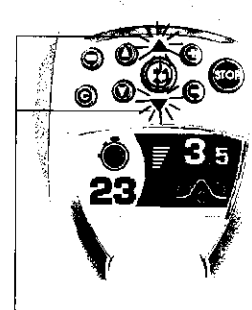
FORWARD MOVEMENT



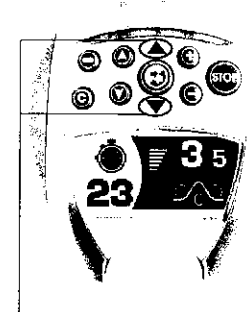
BACKWARD MOVEMENT

Reverse mode and LEDs:
When you are in reverse mode (the rollers are turning in the opposite direction), the flashing LEDs become specific:

- In wound/wound mode (where the 2 rollers wind the fold), the 2 diodes are lit and flashing
- In unwound/unwound mode (where the 2 rollers unwind the fold), the 2 diodes are lit and continuous.



WOUND/WOUND MODE



UNWOUND/UNWOUND MODE

These functions are only possible provided the main treatment head has been selected.

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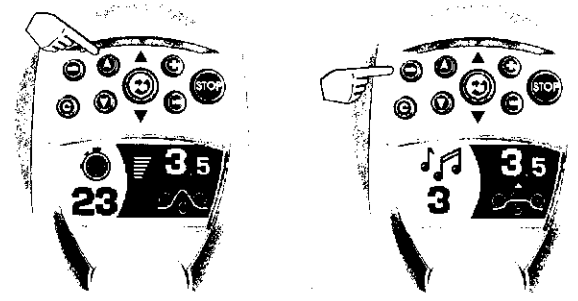
Functions incorporated in the main head

Adjusting the volume and selecting the keyboard beep pitch:
An audible beep is heard every time a key on the keyboard is pressed. The volume and pitch of the beep can be changed.
To regulate the volume of the keyboard beep (quiet, soft, average or loud), go to the RING MENU of the main head by pressing the key followed by pressing the key to gain access to the VOLUME parameter.

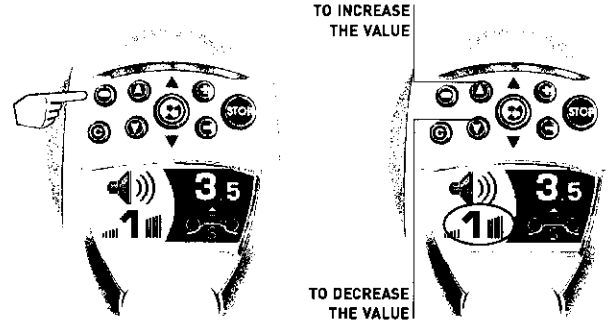


Validate the selection via the key the VOLUME value will start to flash.
Use the and keys to adjust this parameter to your requirements.

- 0: silent
- 1: soft
- 2: average
- 3: loud

Validate by pressing the key.

Use the key to return to the monitor screen.



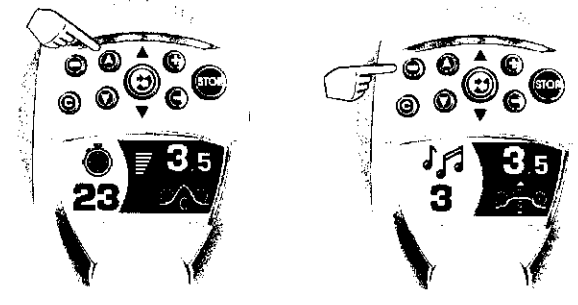
To regulate the pitch of the keyboard beep (low, medium or high) from the VOLUME parameter, press the key to gain access to the TONE parameter. Validate by pressing the key and the TONE value will start to flash.

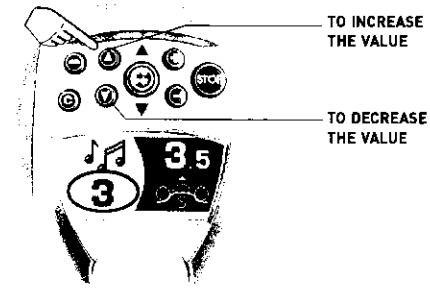
Use the and keys to adjust this parameter to your requirements.

- 1: high pitch
- 2: medium pitch
- 3: low pitch

Validate by pressing the key.

Use the key to return to the RING MENU and then to the monitor screen.





These functions are only possible provided the main head has been selected.

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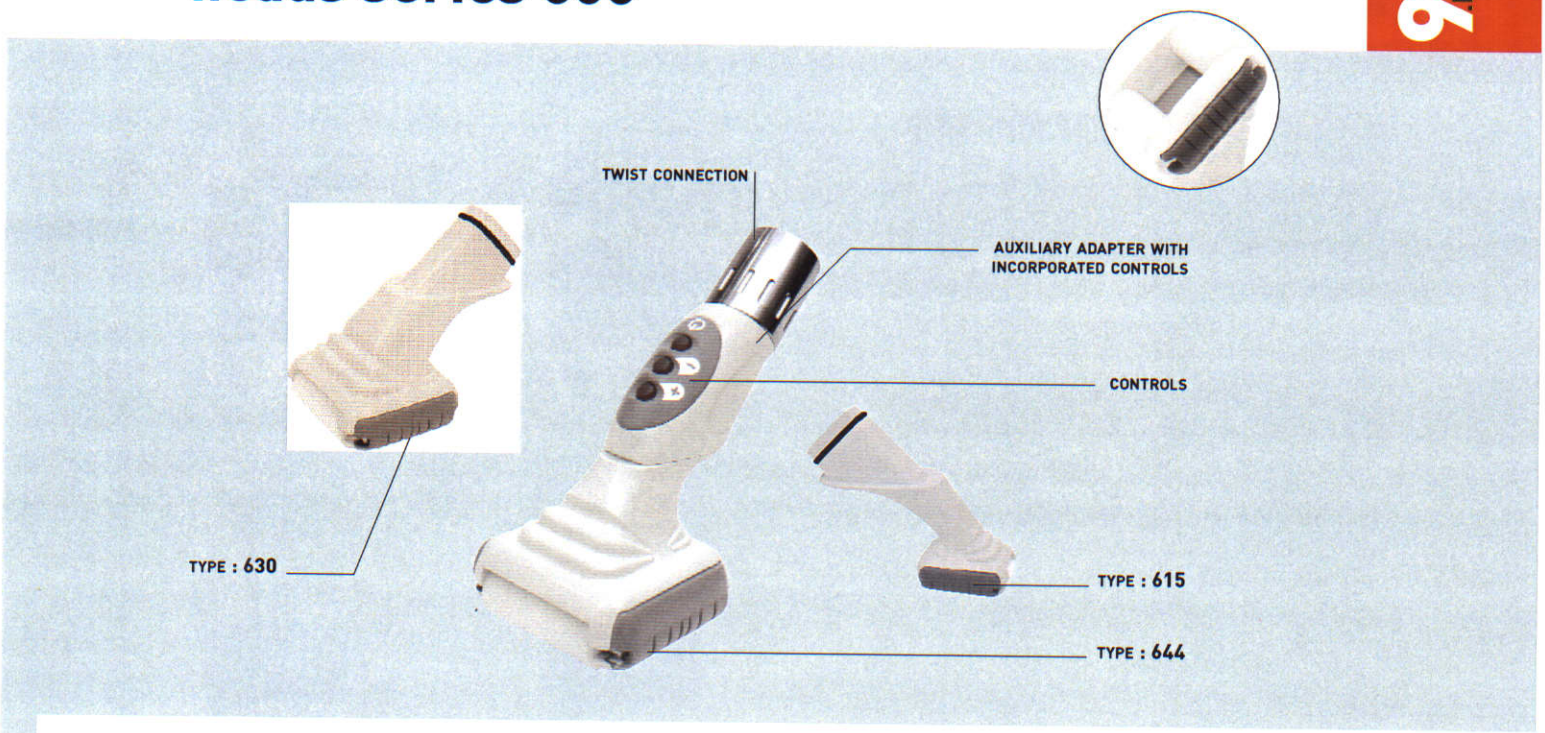
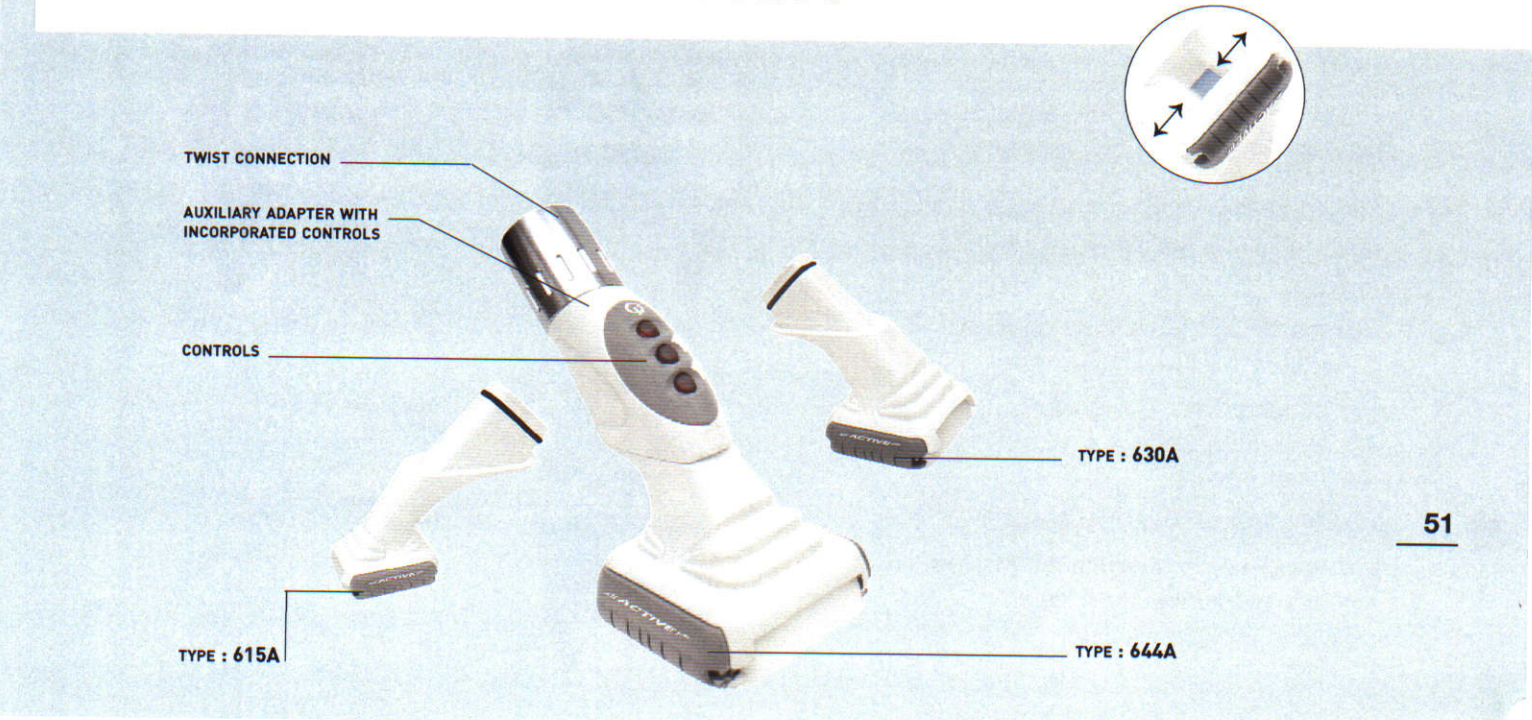
Auxiliary heads series 600



Auxiliary heads series 600 – active



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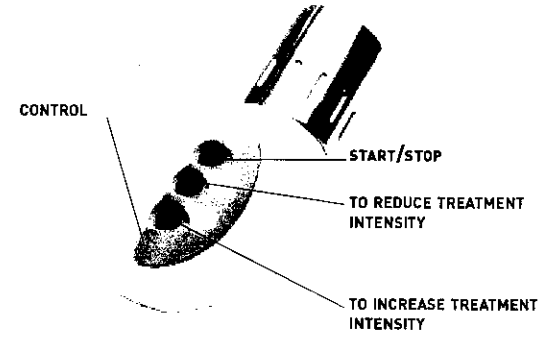
Functions incorporated in the auxiliary adapter

Because the control is incorporated in the auxiliary head connection, you can start or stop your treatment by operating the START/STOP switch and adjust the treatment intensity using the +/- keys without having to go to the control panel of your unit.



These functions are only possible provided the auxiliary treatment head has been selected.

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Index

CLEANING THE MAIN HEAD . . . . . .P. 55

CLEANING THE AUXILIARY HEADS . . . . . .P. 57

OVERHAUL OF THE KEYMODULE® . . . . . .P. 58

All the maintenance operations described in this section must be carried out with the unit switched off and the supply cable disconnected.

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Cleaning the main head

For hygiene reasons, the treatment heads must be cleaned after each use, using antiseptic wipes with a bactericidal and fungicidal solution.

Special attention must be paid to those parts coming into contact with the patient.

Cleaning the tightness valves:

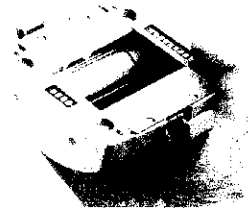
1) Release the Keymodule® as shown on the photos

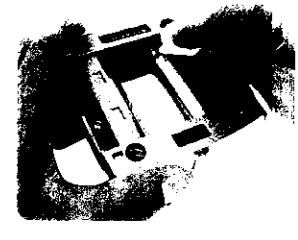
2) Make sure that the cursor is in the top position (see page 112)

3) Bring the roller to the center

4) Remove the corresponding sealing valve by handling it as shown on the photo. Repeat this operation for the other valve.

5) Then clean the valves and their location





Replace the valves after:
100 hours' operation.

! *Do not use aggressive products, such as acetone, trichloroethylene or alcohol at 90°, or abrasive sponges.*

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Cleaning the main head

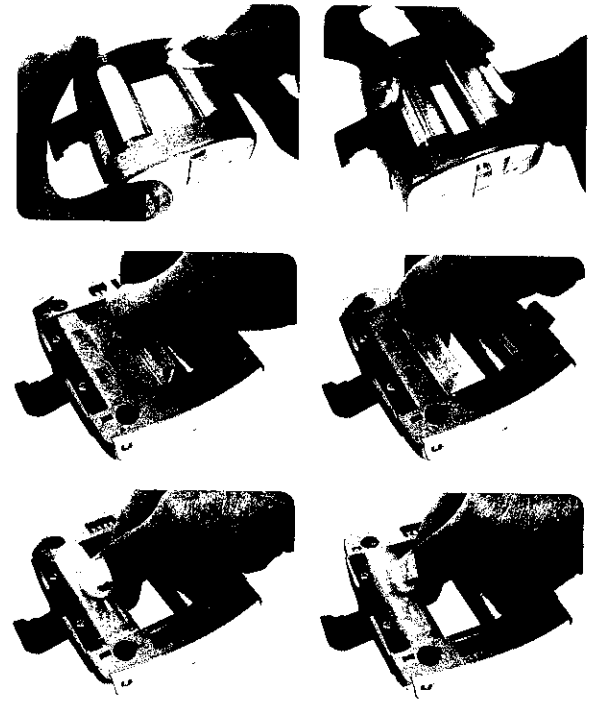
Cleaning the Keymodule® :

1) Turn the Keymodule® and clean the rollers on either side. Manually turn the rollers so as to gain access to the entire surface area.

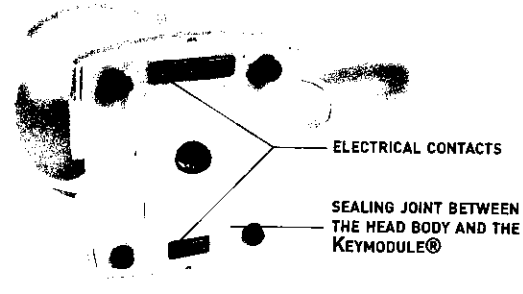
2) Turn the Keymodule® again and refit the sealing valves as shown on the photos.

3) Do not forget to clean the sealing joint between the Keymodule® and head body.

4) Check that the electrical contacts are clean and dry and proceed in the reverse sequence to refit the Keymodule® onto the main head.

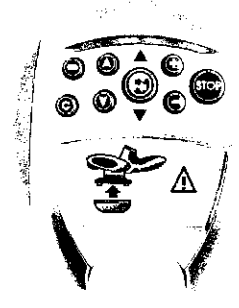


Now check that the head is operating correctly.
To do this, operate the head in the palm of your hands to ensure the correct sealing of the treatment chamber and visually inspect the movement of the valves and that of the rollers.



WARNING: if the Keymodule® is not fitted to the main head, if it is incorrectly positioned or even faulty, the main head screen will display the icon alongside:

Check the assembly of the Keymodule®.



Do not use aggressive products, such as acetone, trichloroethylene or alcohol at 90°, or abrasive sponges.

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Cleaning the auxiliary heads

For hygiene reasons, the treatment heads must be cleaned after each use, using wipes containing an antiseptic, bactericidal and fungicidal solution.

Cleaning the auxiliary heads:

- Disconnect the auxiliary head of the adapter for cleaning purposes.
- Remove the two head rollers to proceed with quick and efficient cleaning.
- Clean the rollers and the treatment chamber.
- Refit the rollers and check that they rotate freely.
- For cleaning, use cotton swabs containing the same solution.

Do not use aggressive products, such as acetone, trichloroethylene or alcohol at 90°, or abrasive sponges.

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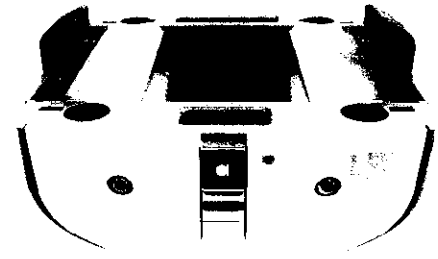
Overhaul of the Keymodule®

The Keymodule® is a high-technology unit comprising numerous mobile micro-mechanical parts. The unit must be returned to our Technical Support Center if certain wear items require replacing.



The head may start to lose some of its characteristics at around 1000 hours of operation.

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General warranty conditions

You have just purchased an LPG® unit. Purchasing this unit implies full legal acceptance of the present general conditions by the purchaser / professional operator. If the unit has been sold by an approved agent of LPG Systems®, the operator must refer to the general guarantee conditions of his supplier, which will not, under any circumstances, have the effect of increasing the manufacturer's commitment under the present warranty. This warranty can only be implemented and is only valid provided the guarantee slip has been duly filled in and returned to LPG Systems® within 15 days following delivery, irrespective of the country in question. All warranty slips that are only partially filled in will be rejected.

LPG Systems® guarantees this unit againt all manufacturing flaws or defects in the raw materials. The present warranty is valid for a period of one year with the first operator, without this exceeding 2000 hours of operation from the date of invoice. During this period, we undertake to exchange or repair, free of charge, any part acknowledged by ourselves as being faulty, without this necessarily entailing a complete replacement of the unit. Shipping costs and return forwarding costs of the unit or spares to/from our After Sales department, are not covered by this warranty.

Any replacements or repairs under the warranty, whether these cause an immobilization of the unit or not, will not have the effect of extending the period of cover, under any circumstances. The replaced parts become the property of LPG Systems®. No compensation will be awarded for inconvenience enjoyment. The purchaser is duty-bound to give us the necessary time and means to proceed with any repairs and replacement deliveries of spares. Failure to comply will absolve us from our obligation under the warranty.
It is expressly agreed that the company accepts no liability in the event of use exceeding the level of professional qualification of the operator or where the unit is used incorrectly.
The courts located within the jurisdiction of the registered office of LPG Systems® are alone competent in the event of disputes, despite any other clause, which may specify a different jurisdiction featuring on the commercial invoices of the contracting parties.

The warranty is also excluded in cases of:

- Damage that occurred during transport. This unit is forwarded at the risk and peril of the recipient. It is up to the latter to check that it is in a perfect state prior to delivery;
- Non-observation of the installation rules and the LPG Systems® operator's manual, failure to carry out maintenance of the unit and to clean the filter cartridges, connecting the unit to a faulty electric line or one which does not have an earth connection, or to a power supply whose voltage is different to the one indicated on the unit;
- Resale of the unit (except in the case of exemption and only with the express agreement of LPG Systems®;
- Modification, fitting accessories or dismantling the unit;

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General warranty conditions

- Any intervention work not scheduled in the LPG Systems® operator's manual and which was carried out on the unit by the operator or third party not approved by LPG Systems®;
- Using inappropriate consumables or parts not supplied by LPG Systems®;
- Blocage of the unit as a result of the aspiration of a foreign object or through the use of consumables other than those recommended and/or supplied by LPG Systems®;
- Wear to all parts of the unit as a result of normal use;
- The unit being dropped, in the event of impact, lightning, fire, force majeure, water damage and natural disasters.

Under no circumstances will this warranty give rise to any form of damages or compensation.

Limitation and exoneration of liability

Non-compliance with the general guarantee conditions during the term of the warranty and following expiry of the latter, may lead to LPG Systems® being exonerated of any liability in the event of damage attributed to the products supplied.

LPG Systems® will not be held liable with respect to equipment/material losses or physical accidents (i), following installation that does not comply with the statutory or regulatory provisions of the country where the unit is to be used or (ii) which could jeopardize a Cellu M6® Keymodule *i* unit, which was the subject of intervention work not scheduled in the LPG Systems® operator's manual and/or carried out by the operator or a third party not authorized by LPG Systems®.

LPG Systems® will be absolved of its liability in the event of use exceeding the level of professional competence/qualification of the operator or resulting from the incorrect use of the unit.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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WARRANTY

To be filled in by the manufacturer

LPG One
Customer Service Office
7060 State Road 84, Davie, 33317

Tel: 888.730.0144 - Fax: 888.571.0040

Type of unit: Cellu M6® Keymodule *i*

To be completed and returned to LPG Systems®

Name: .....

Adress: .....

Country: .....

Tel.: .....

Type of establishment: .....

Profession: .....

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Type of unit: **Cellu M6® Keymodule *i***
Serial number: .....
Date: .....

To validate the warranty, detach this slip and return to the address below within 15 days following use of the unit:
LPG One - Customer Service Office
7060 State Road 84, Davie, 33317

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118