



UAB Medicinos Projektai
I. Kanto al 15
LT-06214 Vilnius
Lithuania

Date: 2017-10-12

AUTHORIZATION LETTER

To whom it may concern,

We, Bösl Medizintechnik GmbH, with its registered office at Charlottenburger Allee 13, 52068 Aachen, Germany, being a manufacturer of a complete line of equipment for compression therapy, authorizes the company UAB Medicinos Projektai, I. Kanto al 15, 06214 Vilnius to promote, sell, do installations, support and maintenance for Bösl Medizintechnik GmbH products.

Aachen, 2017-10-12

Dr. Michael Klöppels
CTO, BÖSL Medizintechnik GmbH



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UAB „Medicinos Projektai“
I.Kanto al 15
LT-06214 Vilnius
Lietuva

2017.10.12

Įgaliojimas

Kam tai skirta:

Mes, Bosl Medizintechnik GmbH, turinti registruotą biurą adresu Charlottenburger Allee 13, 52068 Aachen'as, Vokietija, esame visos prietaisų linijos skirtos kompresinei terapijai gamintojas, įgaliojame kompaniją UAB Medicinos Projektai, I.Kanto al. 15, 06214 Vilnius reklamuoti, parduoti, instaliuoti, palaikyti ir prižiūrėti Bosl Medizintechnik GmbH produktus.

Aachen, 2017-10-12

Dr. Michael Kloppels
CTO, BOSL Medizintechnik GmbH

EG-Konformitätserklärung EC-Declaration of Conformance

Hersteller / Manufacturer:
Bösl Medizintechnik GmbH

Anschrift / Address:
Charlottenburger Allee 13, D-52068 Aachen, Germany

Produkt / Product:
Therapiesystem / Therapie system
vasoflow 200 Gradient / vasoflow 100 Gradient / vasoflow mini
lympa-mat Digital Gradient / lympa-mat 300 Gradient / comprimed 100 Gradient

Klassifizierung / Classification:
(Richtlinie 93/42/EWG, Anhang IX, Regel IX) / (MDD, Annex IX, rule IX)
IIa

Wir erklären in eigener Verantwortung, dass die obengenannten Produkte den einschlägigen Bestimmungen der nachfolgenden EG-Richtlinien und Normen entsprechen

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentation's are retained under the premises of the manufacturer and the notified body

Richtlinie / General applicable directives:
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 inklusive Änderungsrichtlinie 2007/47/EG über Medizinprodukte, Anhang I
Medical Device Directive: COUNCIL DIRECTIVE of 14 June 1993 concerning medical devices (MDD 93/42/EEC including 2007/47/EG), Annex I

Angewendete Normen / Standards applicable to the products are:
EN 60601-1; EN 60601-1-2; EN 60601-1-6; EN 1041; EN ISO 14971; EN 980

Benannte Stelle / Notified Body:
TÜV Rheinland LGA Products GmbH
Tillystrasse 2 - D-90431 Nürnberg - Germany - CE 0197

Konformitätsbewertungsverfahren / Conformity Assessment Route:
Anhang II (ohne Abschnitt 4) in Verbindung mit Anhang VII
Annex II (without Section 4) with Annex VII

EG-Zertifikatnummer / EC-Certificate Number:
HD 600401210001

This declaration is valid for all above mentioned products, witch are CE-marked after the signature date below.

Aachen den 01.01.2012
Ort und Datum der Ausstellung
Place and date of issue


Erik Küppers
Geschäftsführer
General Manager

EB – Atitikties Deklaracija

Gamintojas:

Bosl Medizintechnik GmbH

Adresas:

Charlottenburger Allee 13, D-52068 Aachen, Vokietija

Produktas:

Terapinė sistema

**Vasoflow 200 GRADIENT/ vasoflow 100 GRADIENT/ vasoflow mini/ lymphamat Digital GRADIENT/
lymphamat 300 GRADIENT/ Comprimed 100 GRADIENT**

Klasifikacija:

Medicinos Prietaisų Direktyva, IX priedas, IX taisyklė

Ila

Savo atsakomybe mes deklaruojame, kad aukščiau išvardinti produktai atitinka sekančias EB tarybos direktyvos ir standartus. Visa patvirtinta dokumentacija yra saugoma pagal gamintojo dokumentaciją ir notifikavimo įstaigą.

Bendrosios taikomos direktyvos:

**Medicinos Prietaisų Direktyva: 1993 metų birželio 14d Tarybos Direktyva dėl medicinos prietaisų
(MDD 93/42/EEB įskaitant 2007/47/EG), I Priedas**

Standartai taikomi produktams:

EN 60601-1; EN 60601-1-2; EN 60601-1-6; EN ISO 1041; EN ISO 14971; EN 980

Notifikavimo įstaiga:

TUV Rheinland LGA Products GmbH

Tillystrasse 2 – D – 90431 Niurnbergas – Vokietija – CE 0197

Atitikties įvertinimo Maršrutas:

II Priedas (be 4 skyriaus) su VII priedu

EB – Sertifikato Nr:

HD 600401210001

Ši deklaracija galioja visiems išvardintiems produktams, kurie yra pažymėti CE ženklu po pasirašymo datos nurodytos apačioje

**Aachenas 2012.01.01
Išrašymo vieta ir data**

**Erik Koppers
Generalinis ir kokybės
užtikrinimo direktorius**



lymphamat[®]

GRADIENT

12

1 Gradient intermittent compression
1 for specific treatment of lymphatic oedema

12-chamber-system 1.3.

- gradient treatment pressure
- overlapping air chambers
- pneumatic controlled system

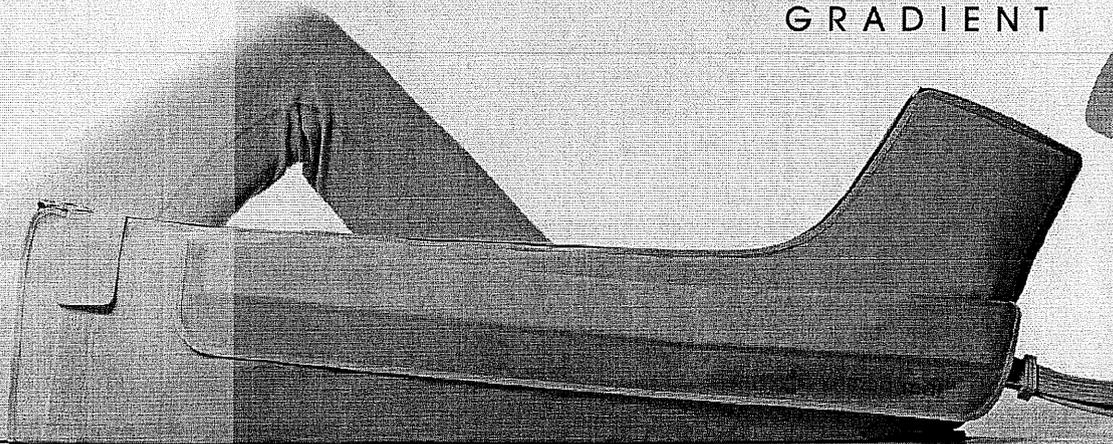
www.lymphamat.de



lymp^ha-mat[®]

GRADIENT

12



The Gradient System

Next to manual lymphatic drainage, intermittent pneumatic compression has been firmly integrated into up-to-date physical decongestion therapy. Its effectiveness is demonstrated and documented in numerous studies.

The 12-chamber system **lymp^ha-mat[®] GRADIENT** has been established and successful for many years. It is known worldwide for its pneumatic pressurization with the gradient principle, and for its overlapping air chamber system integrated in the treatment sleeves.

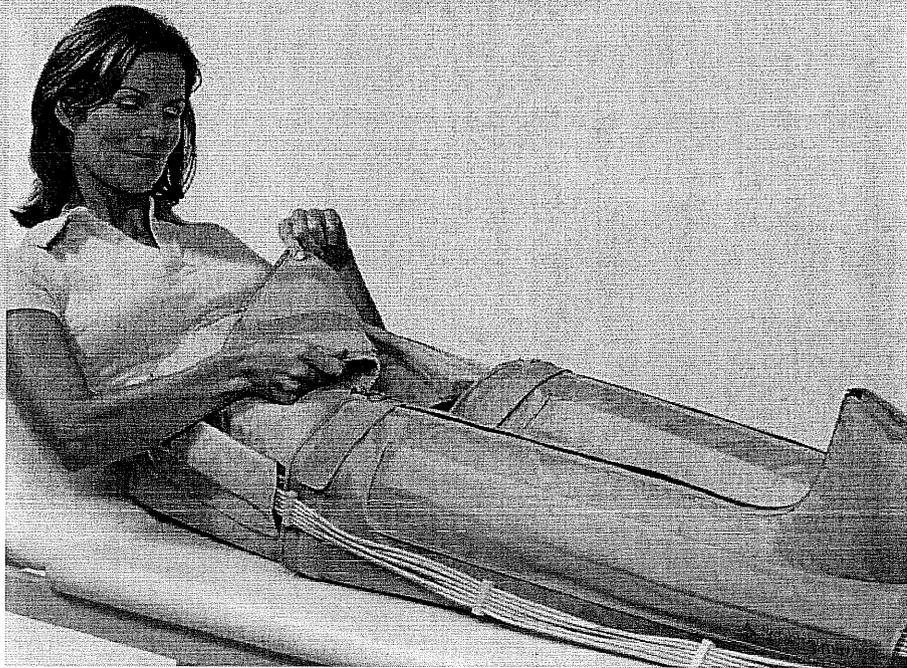
lymp^ha-mat[®] GRADIENT is suited for all kinds of limb oedema, having its focal point in the treatment of lip-oedema, lymphatic oedema and mixed forms – in clinical, ambulant and domestic fields.

Pressure gradient generates a physiologically efficient pressure decline. Thus the fluid mobilized in the high pressure range (100%) may pass unhamperedly through the low pressure levels (80% and 60%). A significantly minimized pressure at the sleeve's end relieves the adjacent drainage area and is highly positive on lymphatic oedema.

The concept of gradient intermittent compression is a result of extensive medical research. It was developed following the manufacturing of compression stockings and thrombosis stockings.

The air chambers have hand's breath and overlap at 50%. In combination with gradient pressure they prevent interchanging flowing which has an unphysiological strain on the valves, and effectively promote the venous and lymphatic reflux. The tissue is decongested, metabolism and gas exchange are significantly improved.

The convincing therapy results of **lymp^ha-mat[®] GRADIENT** set new standards in pneumatic decongestion therapy.



The Principle

In one compression cycle, a sleeve's twelve overlapping chambers are filled with air in succession, ascending in a distal direction.

Chambers 1 - 4 to 100%, chambers 5 - 8 to 80%, chambers 9 - 12 to 60% of the set pressure. All the chambers remain filled with air until the last chamber has attained the desired pressure. The air is then released simultaneously from all twelve chambers, and after an interval the inflation cycle begins once again.

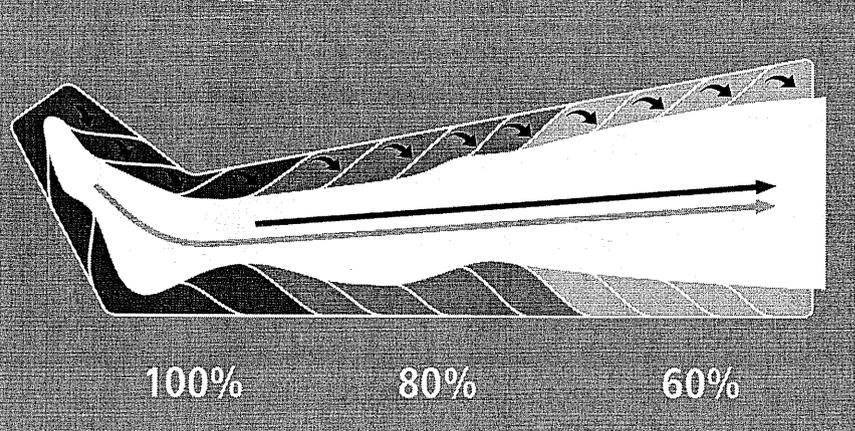
The Treatment Sleeves

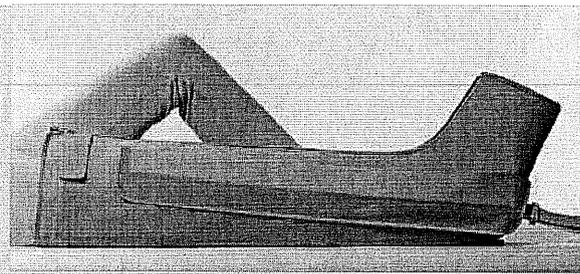
The up-to-date and easy-to-use treatment sleeves result from our 20 years of experience in the field of intermittent compression.

Our sleeves consist of only high-quality materials which are extremely robust, easy to clean, disinfected and fully tolerated by the body. They meet DIN EN ISO standards and thus pass strict biological tests.

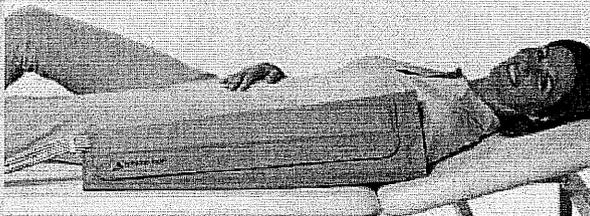
The internal air chamber system contains twelve overlapping air chambers produced in long-life polyurethane. It is covered with a special textile which is dirt-repellant and easy to clean in daily use. Multiple plugs, zippers and Velcro fastenings simplify the handling.

If additional decongestion of abdominal and pelvic area is required, the 24-chamber-compression trousers or a combination of hip and leg sleeves is recommended.

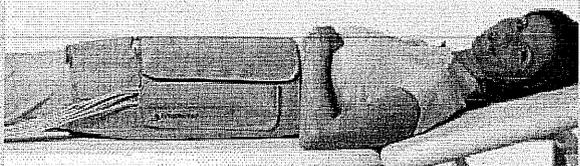




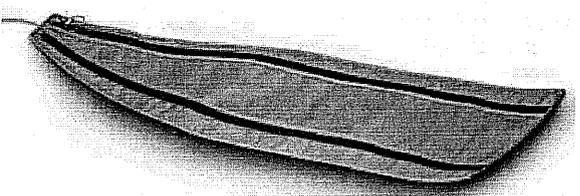
leg sleeve with 12 air chambers
full-length zip, Velcro fastening
Size M: thigh circumference 75 cm, length 85 cm
Size L: thigh circumference 88 cm, length 85 cm
special sizes available



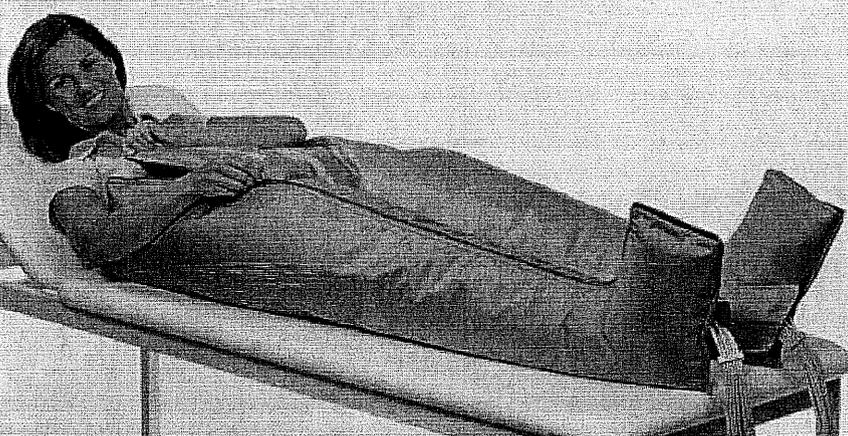
1.2. arm sleeve with 12 air chambers
Velcro fastening
upper arm circumference up to 58 cm, length 71 cm
special sizes available



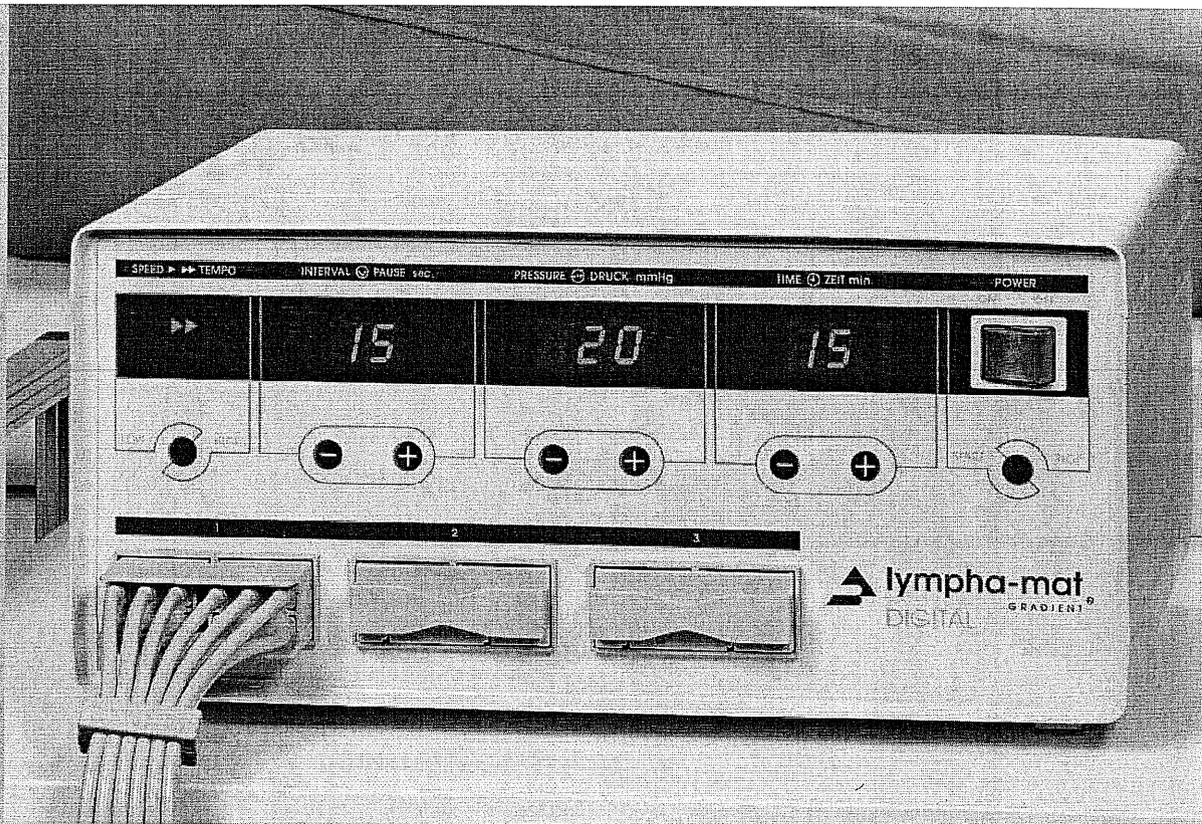
hip sleeve with 6 or 12 air chambers
variable Velcro fastening on front and rear
separate air chamber for the groin
hip circumference adjustable up to 150 cm, length 38 cm
expansion fitting available



Expansion fitting with one air chamber
for 12-chamber leg sleeve
for 24-chamber compression-trousers
circumference expansion 13 cm



compression-trousers with 24 air chambers
hip circumference up to 150 cm
thigh circumference 83 cm
3 full-length zips



The Therapy Device

lympho-mat® GRADIENT means up-to-date and efficient decongestion therapy. The gentle and quickly noticeable effects of the **lympho-mat® GRADIENT** system make it one of today's preferential therapy devices. Easy handling and up-to-date therapy sleeves characterize this product, which has been valued by doctors and patients alike.

lympho-mat® DIGITAL GRADIENT is a perfected and high-performance therapy device for users in clinics and medical practices. Compression cycles, pressure loads, intervals and length of therapy are choosable according to the individual clinical picture. A patient-operated switch allows the interruption of therapy at any time, keeping the set treatment parameters.

lympho-mat® 300 GRADIENT, developed especially for domestic use, is robust and high-performing. The gradient pressurization decongests gently, and the fixed interval of 15 seconds gives time enough to exploit the lymphangiomotoric cycles.

Supportive Home Therapy

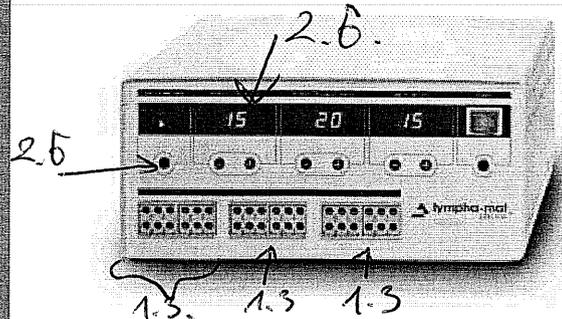
... is necessary in some cases and makes good economic sense. In case of chronic diseases, the therapy can be continued at home as directed by the doctor, providing considerable support. This reduces the number of physiotherapy sessions necessary and compensates in therapy-free periods. The patient is best equipped and can independently determine when to start the daily treatment. In case of acute complaints the patient can react instantly.

Home therapy is expedient in the case of increasing need of therapy, chronic syndromes, drug intolerance (e.g. diuretics), or intolerance of permanent compression.

lympa-mat®

GRADIENT **12**

lympa-mat® DIGITAL GRADIENT



- 2.1. - connection for 3 treatment sleeves
- simultaneous treatment of 2 legs and hip possible
- graduated pressurization
- membrane keyboard/digital display
- 2.4. - exact setting of the individual treatment parameters possible
- 2.5. - two-stage compression speed
- 2.2. - pressure setting 20 - 120 mmHg
- 2.3. - controller for setting the interval between compression cycles, 5 - 90 sec.
- 2.7. - integrated timer / automatic disconnection
- patient-operated switch (remote control)
- high-performance unit for continuous operation
- dimensions: w 37 cm, h 18 cm, d 25 cm
- weight: 6.1 kg

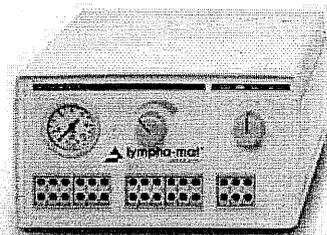
Indications

- thromboembolic prophylaxis
- post-thrombotic syndrome
- ulcus cruris
- venous oedema
- post-traumatic oedema
- minor lymphatic oedema
- lipoedema
- mixed forms of oedema
- peripheral arterial occlusive disease under strict observation
- sensory disturbance caused by hemiplegia

Contra-indications

- decompensated cardiac insufficiency
- extensive thrombophlebitis, thrombosis or suspected thrombosis
- erysipelas
- severe unbalanced hypertension
- acute soft-part-trauma of extremities
- neuropathy
- occlusive processes in the sector of lymphatic drainage

lympa-mat® 300 GRADIENT



recognized therapeutic aid

- connection for 3 treatment sleeves
- simultaneous treatment of 2 legs and hip possible
- graduated pressurization
- pressure setting 20 - 100 mmHg
- integrated timer / automatic disconnection
- 15 sec. interval
- dimensions: w 26 cm, h 16 cm, d 25 cm
- weight: 4.6 kg

Made in Germany



- Certified Management System
- ISO 13485:2003



2 years device guarantee.
The units and treatment sleeves are maintenance-free.

BÖSL Medizintechnik GmbH
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Anschließen der Behandlungsmanschetten
 Connection of treatment sleeves
 Raccordement des manchettes de traitement



Es können gleichzeitig drei Behandlungsmanschetten an das Gerät (A7) angeschlossen werden. Die Stecker 1 und 2 sind für die Beinmanschetten/Armmanschetten und Kompressionshose, der Anschluss 3 ist für die Hüftmanschette vorgesehen.

Three treatment sleeves can be connected to the unit (A7) simultaneously. Connectors 1 and 2 are for the leg sleeves/arm sleeves and compression trouser, connector 3 is intended for the hip sleeve.

Trois manchettes de traitement peuvent être branchées simultanément sur l'appareil (A7).

Les fiches 1 et 2 sont prévues pour les manchettes pour jambes/manchettes pour bras et le pantalon de compression; le branchement 3 est prévu pour la manchette pour hanches.

Schlauchstecker der Behandlungsmanschetten in die Anschlussbuchse (A7) einführen.

Insert tube connector of the treatment sleeves into (A7) socket. Please note the top/bottom markings on the tube connector!

Introduire la fiche des manchettes de traitement dans la douille de branchement (A7). Veiller à respecter les désignations top/en haut et bottom/en bas inscrites sur la fiche de la manchette.

Bitte beachten Sie die Kennzeichnungen top/oben bzw. bottom/unten auf dem Schlauchstecker!

Make sure not to bend the air tubes of the treatment sleeves sharply, because otherwise the respective air chambers could not be filled properly.

Éviter toute pliure au niveau des tubes afin que les différentes chambres à air puissent se remplir sans problème.

Die Luftschläuche der Behandlungsmanschetten sollten nicht geknickt sein, um eine Füllung der einzelnen Luftkammern zu gewährleisten.

When carrying out treatment, the connection points not to be used (A7) must be closed with the supplied blind plugs.

Lors du traitement les branchements (A7) non utilisés doivent être fermés à l'aide des fausses fiches qui font partie de la livraison.

Bei der Behandlung müssen die nicht benötigten Anschlüsse (A7) mit den mitgelieferten Blindsteckern verschlossen werden.

Technische Daten
 Technical data
 Caractéristiques techniques



Das Model **lympho-mat® DIGITAL** ist für den Gebrauch in allen Einrichtungen einschließlich Wohnbereichen und solchen bestimmt, die unmittelbar an ein öffentliches Versorgungsnetz angeschlossen sind, das auch Gebäude versorgt, die für Wohnzwecke genutzt werden.

Model **lympho-mat® DIGITAL** is suitable for all facilities including residential areas and those directly connected to a public supplying system which is also supplying residential buildings.

Le modèle **lympho-mat® DIGITAL** est prévu pour une utilisation tant dans des lieux résidentiels que dans des institutions publiques reliés au réseau d'alimentation général.

Stufenlose Druckeinstellung
 20 - 120 mmHg

Stepless pressure setting
 20 - 120 mmHg

Réglage continu de pression de
 20 - 120 mmHg

Intervall/Pause 5 - 90 Sek.
 variable

5 - 90 sec. interval variable

Temps de pause/intervalles de
 5 à 90 secondes variable

Nennspannung AC 230V
 Nennfrequenz 50/60 Hz
 Nennstrom 0,5 A

Rated voltage AC 230V
 Rated frequency 50/60 Hz
 Rated current 0,5 A

Tension nominale AC 230V
 Fréquence nominale 50/60 Hz
 Courant nominal 0,5 A

— 2 x T 1,6 A

— 2 x T 1,6 A

— 2 x T 1,6 A

Maße:
 B - 37 cm, H - 18 cm, T - 25 cm
 Gewicht: 6,1 kg

Dimensions:
 W - 37 cm, H - 18 cm, D - 25 cm
 Weight: 6,1 kg

Dimensions:
 l - 37 cm, H - 18 cm, P - 25 cm
 Poids 6,1 kg

Klassifikation:
 Typ BF

Schutzklasse I.

Classifications:
 Typ BF

protection class I.

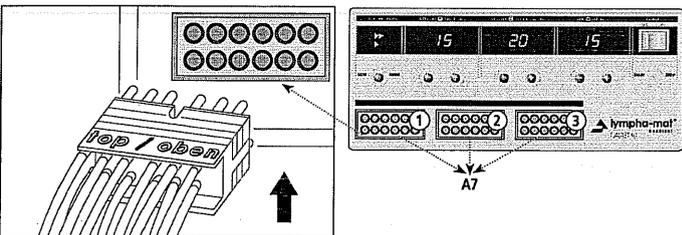
Classement:
 Typ BF Classe de protection I.

Behandlungsempfehlungen
 Treatment recommendations
 Recommandations pour le traitement

Während der Behandlung sollte der Patient bequem und entspannt liegen. Zur Unterstützung der Therapie kann die zu behandelnde Extremität (Bein oder Arm) leicht hochgelagert werden. Der Manschettendruck sollte bei Therapiebeginn niedrig gewählt und bei Bedarf gesteigert werden. Der Druck (Pressure) darf nie so eingestellt werden, dass Unbehagen oder Schmerzen auftreten. Die Behandlung soll entspannend und angenehm sein.

During treatment the patient should lie relaxed. For support of therapy, the extremity being treated (arm, leg) should be elevated slightly. At the beginning of the therapy the pressure should be set low and then if necessary be increased. The pressure should never be set to the uneasiness or inconvenience of the patient. The treatment should be relaxed and comfortable.

Pendant le traitement, le patient doit être allongé de manière confortable et détendue. Afin de faciliter la thérapie, l'extrémité à traiter peut être élevée légèrement. Au début du traitement, la pression de la manchette doit être peu élevée et, au besoin, peut être augmentée progressivement. La pression ne peut pas être réglée de telle manière qu'elle puisse engendrer des douleurs ou des gênes. Le traitement doit être agréable et relaxant.



Lympha-mat Digital GRADIENT

GRADIENT 12

- Pajungimas 3 rankovėms
- Vienu metu galima gydyti 2 kojas ir klubus
- Graduotas slėgis
- Membrininė klaviatūra/ skaitmeninis displėjus
- Tikslus individualių gydymo parametrų nustatymas
- Dviejų lygių kompresijos greitis
- Slėgio nustatymas 20-120mmHg
- Regulatorius intervalų nustatymui tarp kompresijų ciklų, 5-90 sekundžių
- Integruotas laikmatis/ automatinis atjungimas
- Paciento jungiklis (nuotolinio valdymo)
- Aukštos kokybės prietaisas ilgalaikiam naudojimui
- Išmatavimai: plotis 37cm, aukštis 18cm, gylis 25cm
- Svoris: 6.1 kg

Lympha-mat 300 GRADIENT

- Pajungimas 3 rankovėms
- Vienu metu galima gydyti 2 kojas ir klubus
- Graduotas slėgis
- Slėgio nustatymas 20-100mmHg
- Integruotas laikmatis/ automatinis atjungimas
- 15 sekundžių intervalas
- Išmatavimai: plotis 26cm, aukštis 16cm, gylis 25cm
- Svoris: 4.6 kg

12 Kamerų kojų rankovės su užtrauktuku per visą iklgį, tvirtinamos VELCRO lipdukais
M dydis: šlaunies apimtis 75cm, ilgis 85cm
L dydis: šlaunies apimtis 88cm, ilgis 85cm
Galimi specialūs dydžiai

12 kamerų rankų rankovė tvirtinama VELCRO juostelėmis žasto apimtis iki 58 cm, ilgis 71cm
Galimi specialūs dydžiai

6 arba 12 kamerų klubo rankovė VELCRO tvirtinimo juostelės priekyje ir gale, atskira kirkšnies oro kamera
klubų apimtis reguliuojama iki 150cm, ilgis 38cm
Yra galimybė užsakyti platesnę

Praplėtimo juosta su viena oro kamera 12 kamerų kojų rankovėms, 24 kamerų aplikatoriui-kelnėms, apimtį
praplečia 13cm

24 kamerų aplikatorius-kelnės klubų apimtis iki 150cm, šlaunies apimtis 83cm, 3 užtrauktukai per visą ilgį