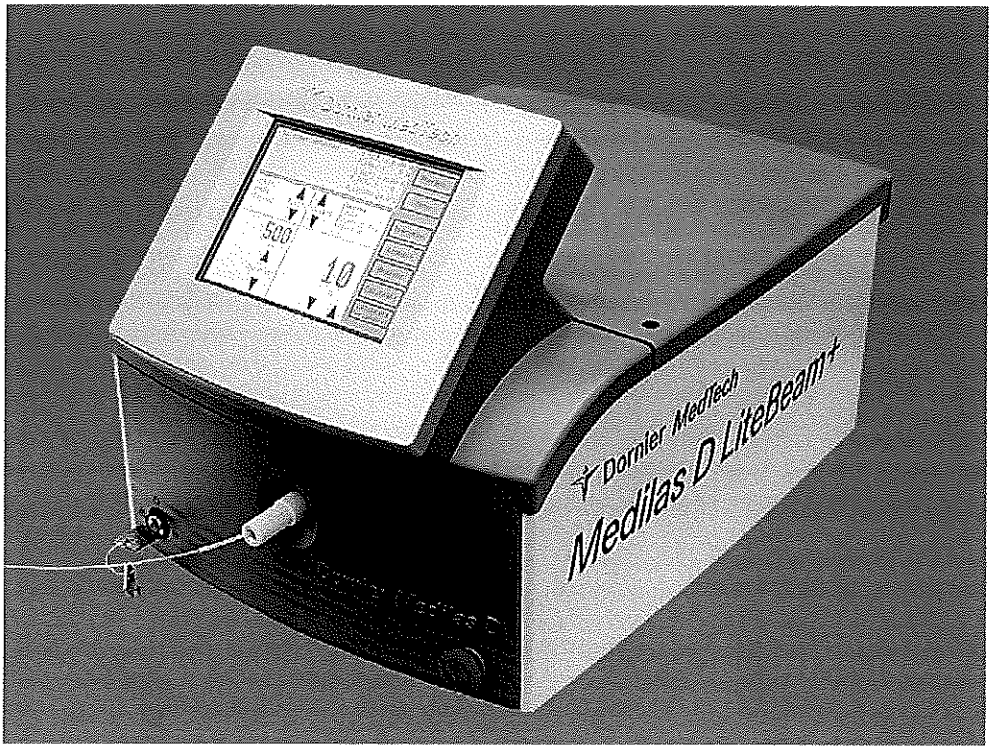
Dornier Medilas D 30
Dornier Medilas D 60

Dornier *Medilas D 30*: LiteBeam+

Dornier *Medilas D 60*: MultiBeam; FlexiPulse

Operating Manual



WARNING	**This device must be operated by trained personnel.**
CAUTION	Federal law restricts the sale of this device by a physician.

20186

Dornier *MedTech*

OPERATING MANUAL FOR DORNIER *MEDILAS D 30/60 LASER*

Manufacturer

Dornier MedTech Laser GmbH
Argelsrieder Feld 7
D-82234 Wessling GERMANY

U.S. Distributor

Dornier MedTech America, Inc.
1155 Roberts Blvd.
Kennesaw, GA 30144 U.S.A.

Documents for the Installation's Operator

Operating Manual, *Medilas D 30/60*

Operating Manual Identification Number

Dornier MedTech America, Inc. Part No.: 20186

Peripheral units for the Dornier *Medilas D 30/60* are delivered with their own operating manuals.

The Dornier *Medilas D 30/60* Medical Equipment Book is supplied with the Dornier *Medilas D 30/60.*

Manufacturer's Responsibility

Dornier is responsible for the safe operation, reliability, and performance of the Dornier *Medilas D 30/60* under the following conditions:

- Installation, adjustment, maintenance, and modification of the device have been carried out by the employees of Dornier or persons authorized by Dornier.
- The electrical installation in the relevant room complies with national standards of the respective countries where the Dornier *Medilas D 30/60* is marketed.
- The device is operated in accordance with the operating manual.

Regulatory Statement for the United States

CAUTION

Federal law restricts this device to sale on or by the order of a physician.

Dornier *Medilas D 30/60 Laser*

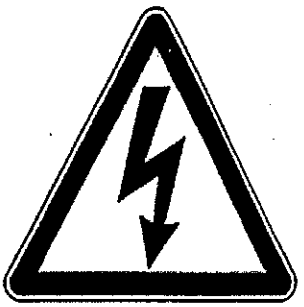
U.S. Distributor

Dornier MedTech America, Inc.
1155 Roberts Blvd.
Kennesaw, GA 30144

Warning and Caution Definitions

WARNING

High Voltage



The device is charged with dangerously high voltages once it is connected to the power supply.

The device may only be serviced by trained service technicians.

The device must be completely disconnected from the power supply before cleaning and disinfecting, installing, or during servicing, maintenance, and repairs.

The device can be secured against unauthorized operation by removing the key from the main switch.

WARNINGs and CAUTIONs are listed at the beginning of each subsection and include items that may endanger a person or may damage equipment. Combined with complete training in using the Dornier *Medilas D 30/60*, WARNINGs and CAUTIONs alert the user to potential hazards of ignoring or following instructions improperly.

See definitions for WARNINGs, CAUTIONs and NOTEs, below.

WARNING	**A warning indicates that a person may be endangered if instructions or procedures are followed incorrectly or ignored.**

CAUTION	**A caution indicates that equipment may be damaged if instructions or procedures are followed incorrectly or ignored.**

NOTE	A note provides further information for the reader.

OPERATING MANUAL REVISION DATA

Operating Manual Revision History Log

This section contains the revision history for this operating manual. The Document Change Order (DCO) contains the approval documentation for the appropriate document revisions. This section is updated with each revision. Should you have any questions about the revisions, please contact the Dornier MedTech Regulatory Department at 1-800-831-0859.

Revision	DCO No.	Date	Software	Description of Revision
A	06-201	7/21/2006	1.1X	Original release of manual. Based on the German "Rest of World", part no. K2011506.
B	07-020	06/18/2007	1.1X	Based on "Rest of World", part no. K2011744
C	07-239	09/24/2007	1.1X	Changes based on "Rest of World", part no. K2011982
D	08-092	03/31/2008	1.1X	Add "For treatment of incompetence and reflux of superficial veins in the lower extremity, and for endovascular coagulation of perforator veins." To section 1.8 and delete "See Tables Below" from section 1.10.2.
E	11-022	08/31/2011	1.1X	Changes based on "Rest of World", part no. K2012763

Operating Manual Section Revision Table

This section contains the current revision level of each section of the operating manual as listed in the table below. Should a revised section be sent to the owner of the operating manual, they will be responsible for replacing the revised sections as needed and maintaining the Manual accordingly. Should you have any questions about the revisions, please contact the Dornier MedTech Regulatory Department at 1-800-831-0859.

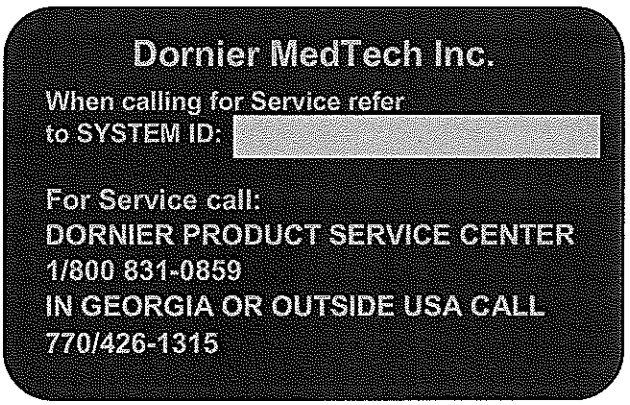
Section	Section Name	Revision Date
1	Introduction	08/31/2011
2	Safety	08/31/2011
3	Description	08/31/2011
4	Operation	08/31/2011
5	Specifications	08/31/2011
6	Maintenance & Troubleshooting	08/31/2011
7	References	09/24/2007
8	Advisories	09/24/2007
9	Service Reports	09/24/2007
10	Options	09/24/2007
11	Other	09/24/2007

HOW TO CALL FOR DORNIER SERVICE

A request for Dornier service is received, dispatched by satellite pager and closed by the Dornier Customer Service Center ("CSC"), open 5 days per week, from 8:00 am to 6:00 pm, Eastern Time. After 6:00 pm Eastern Time, and during weekends, all calls are routed to an after hours voicemail system.

Customer - places all USA and Canadian service calls through one number (1-800-831-0859), identifies the system ID number, and states the nature of the problem.

The system ID number is printed on a red tag displayed on the back of the equipment. See the sample below.



Customer Service Representative - confirms the location and alerts the appropriate Field Engineer by pager.

Field Engineer - accepts the assignment, contacts you and arranges a service call, if required.

Service Call Completed - The Field Engineer reports the details to CSC. CSC uses the report to close the call and update the service file on your Dornier *Medilas D 30/60.*

Address your inquiries as follows:

Dornier MedTech America, Inc.
Customer Service Center
1155 Roberts Boulevard
Kennesaw, GA 30144
1-800-831-0859

DECLARATION OF CONFORMITY

Dornier *MedTech*

Konformitätserklärung / Declaration de Conformité
Dichiarazione di Conformità / Declaration of Conformity

Dornier MedTech GmbH Argelsrieder Feld 7 D-82234 Wessling	mit der Fertigungsstätte avec le site de production con il stabilimento di manifatturiero with the manufacturing site	**Dornier MedTech Laser GmbH** Argelsrieder Feld 7 D-82234 Wessling

Wir erklären in alleiniger Verantwortung, dass das Medizinprodukt / Nous déclarons sous notre propre responsabilité que le dispositif médical / Dichiariamo sotto nostra responsabilità che il dispositivo medico / We declare under our sole responsibility that the medical device

	Typ / type / tipo / type	*Modelle / modèle / modello / variants*
Laserchirurgiegerät	**Dornier Medilas D30**	***Dornier Medilas D LiteBeam***
Appareils laser pour la chirurgie		***Dornier Medilas D LiteBeam+***
Apparecchio laser per la chirurgia		***Dornier Medilas D 1064***
Surgical laser equipment	**Dornier Medilas D60**	***Dornier Medilas D MultiBeam***
		Dornier Medilas D FlexiPulse

der Serialnummern / avec des numéros de série / con i numeri di serie / with serial numbers *D30-001* bis/à/a/to *D30-999*
D60-001 bis/à/a/to *D60-999*

der Klasse / de la classe / della classe / of class **II b**
nach Anhang II der Richtlinie 93/42/EWG / selon l'annexe II de la directive 93/42/CEE / secondo l'allegato II della direttiva 93/42/CEE / according to annex II of directive 93/42/EEC

allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EEC incl. aller Nachträge entspricht, die anwendbar sind / remplit toutes les exigences de la directive sur les dispositifs medicaux 93/42/CEE y compris les amendement qui le concernent / soddisfa tutte le disposizione della direttiva 93/42/CEE compresi i addenda che lo riguardano / meets all provisions of the directive 93/42/EEC incl. all amendments which apply to it.

Angewandte harmonisierte Normen, nationale Normen Normes harmonisées, normes nationales appliqués Norme armonizzate o nazionali applicate Applied harmonized standards, national standards	**DIN EN IEC 60601-1:1996** *Electrical safety of medical products* **DIN EN IEC 60601-2-22:1996** *Electrical safety of medical lasers* **DIN EN IEC 60825-1:2007** *Safety of laser devices* **DIN EN IEC 60601-1-2:2007** *Electromagnetic compatibility* **EN ISO 13485:2003+AC2007** *Quality management system* und andere / et d'autres / ed altri / and others
Konformitätsbewertungsverfahren Procédure d'évaluation de la conformité Procedimento di valutazione della conformità Conformity assessment procedure	nach Anhang II der Richtlinie 93/42/EWG / selon l'annexe II de la directive 93/42/CEE Secondo l'allegato II della direttiva 93/42/CEE / according to annex II of directive 93/42/EEC (EG – Konformitätserklärung) (Declaration de Conformité de la CE) (Dichiarazione di Conformità di CE) (Declaration of CE Conformity)
Konformitätsbewertungsstelle Organe resp. de l'évaluat. de la conformità Organo incaric. della valutaz. della conform Notified Body	CE 1275 LGA InterCert GmbH Tillystr. 2, D-90431 Nürnberg

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Wessling, 22. Aug. 2010

Dornier MedTech GmbH
Leiter Qualitätsmanagement
Director Quality Management

Dornier MedTech Laser GmbH
Leiter Qualitätsmanagement
Director Quality Management

TABLE OF CONTENTS

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1 INTRODUCTION

1.1 Intended Medical Use – Application Area

The Dornier Medilas D is a diode laser system for multi-disciplinary use in the OR and doctor's office.

The power emitted to the tissue is up to:

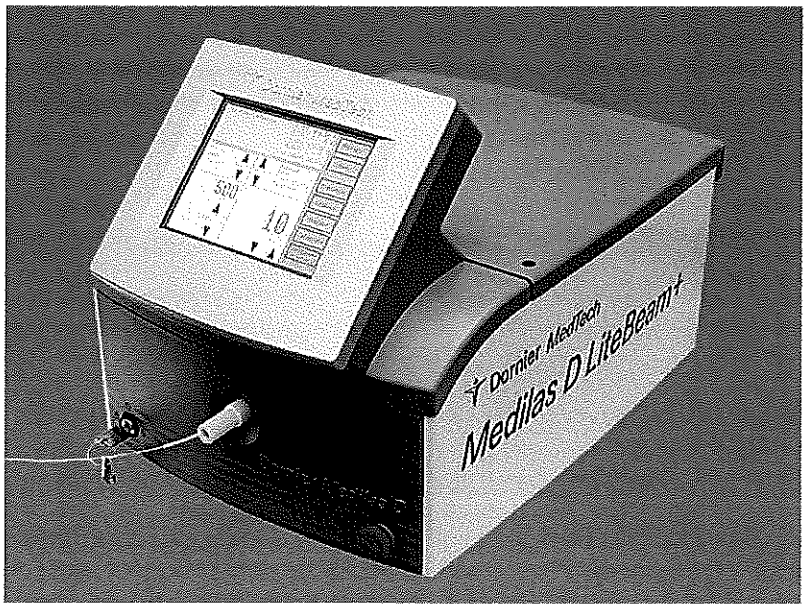
30 W: Dornier Medilas D; LiteBeam+ (940 nm)

60W: Dornier Medilas D MultiBeam (940 nm); FlexiPulse (940 nm).

WARNING: **The Dornier Medilas D must be used only in accordance with its intended purpose.**

Section 1 presents basics about Dornier *Medilas D 30/60.* A brief explanation outlines how the laser develops and delivers energy to the patient, in Section 1.2.1.

Figure 1-1 **Front View, Medilas D30/D60 (as example LiteBeam+)**



Because it has various treatment modes and light guide systems adapted to the particular application, the Dornier Medilas D is suitable for optimized laser application, both with and without contact:

- Non-contact coagulation and vaporization with the light guide protections system (LPS);
- Optimized contact cutting or contact vaporization with fibertom® regulation:
- Interstitial coagulation with tissue contact with the light guide protection system (LPS).

1.2 Biological and Physical Characteristics

This section presents general principles of laser production and clinical effects.

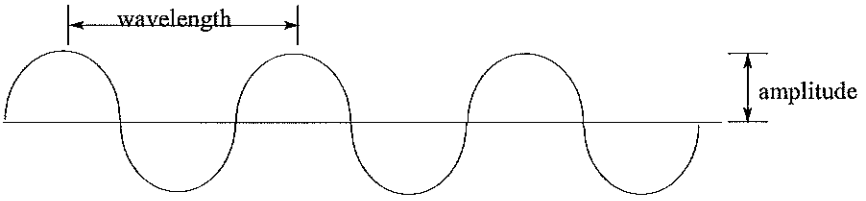
1.2.1 General Principles of Laser Production

LASER is an acronym for Light Amplification by Stimulated Emission of Radiation. Laser surgery is surgery with a laser.

1.2.1.1 Light

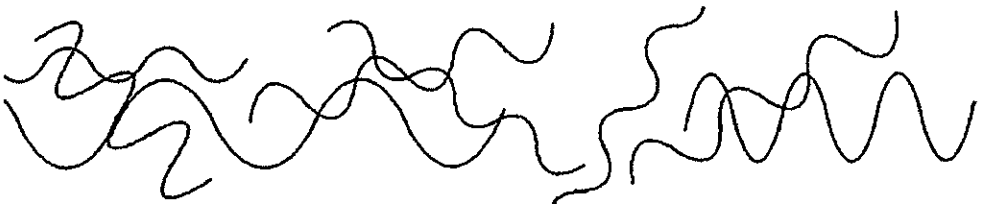
Described as a wave, light has frequency and travels at constant velocity, depending on the medium. Measurements of waves also include wavelength and amplitude, shown in Figure 1-2.

Figure 1-2 Graph, Wave Measurements



Ordinary, or incoherent, light is diffused, unfocused and random in direction, orientation and delivery of energy. Sunlight, reflected and refracted by many surfaces, is an example of incoherent light, such as depicted in Figure 1-3.

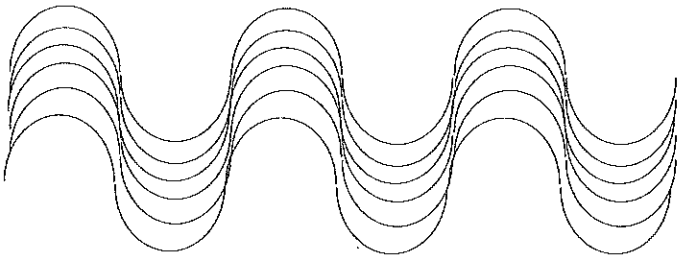
Figure 1-3 Graph, Incoherent Light Waves



1.2.1.2 Amplification

Within a laser, amplification might be called coordination of energy waves into an efficient delivery pattern. A laser beam includes light that is not only coherent, but also monochromatic and collimated. Light within the resonator increases energy until released as a laser beam. Figure 1-4 depicts coherent monochromatic laser waves.

Figure 1-4 Graph, Laser Waves



Laser waves do not destroy or cancel each other during travel away from the source. At the end of any length journey, lasers have almost as much energy to deliver as when they left the source.

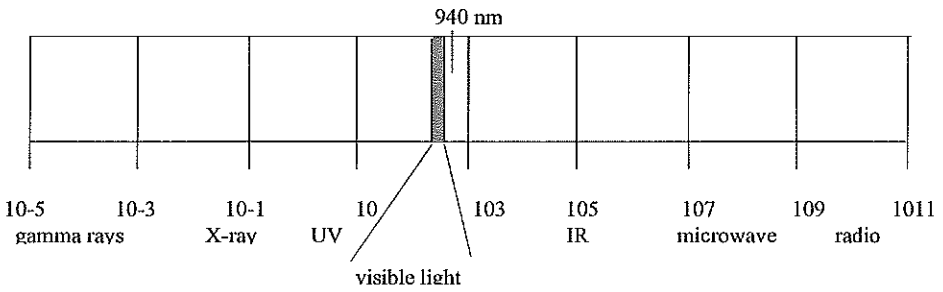
1.2.1.3 Stimulated Emission

In Dornier *Diode Family Lasers*, the laser medium is a semiconductor that transforms electrical current within a diode directly into laser light. Light emerging spontaneously from the diode is amplified through stimulated emission. The amplification is very high so that the diode laser achieves a higher efficiency than a solid-state laser.

1.2.1.4 Radiation

The electromagnetic spectrum includes electromagnetic wavelengths from very short gamma rays to very long radio waves. The diode laser has a wavelength of 940 nm. CFR lists 940 nm as invisible light on the electromagnetic spectrum, shown in Figure 1-5.

Figure 1-5 Graph, Electromagnetic Spectrum by Wavelength (nm)



1.2.2 Clinical Effects

1.2.2.1 Absorption of Radiation by Body Chemicals

A small–diameter optical fiber applies laser light through a small–bore operating channel of an endoscope. The physician looking through the endoscope can see the fiber tip in relationship to tissue.

Wavelengths of greater than 319 nm are photoradiant, not ionizing radiation. Unlike X–rays, the 940–nm laser delivers no potentially mutagenic or carcinogenic hazards to persons in the treatment room.

Observing changes due to absorptive heating may indicate temperature ranges, as listed in Table 1-1.

Table 1-1 Changes Due to Absorptive Heating

Temperature Range (°C)	Visual Change	Biological Change
100	Smoke plume	Vaporization, carbonization
90 to 100	Puckering	Drying
65 to 90	White/gray	Protein denaturalization
60 to 65	Blanching	Coagulation
37 to 60	None	Warming, welding

1.2.2.2 Laser Surgery

Dornier *Medilas D 30/60 Laser* may be used for non–contact and contact surgery.

In laser surgery, tissue change is effected by three variables:
1. Power, usually measured in Watts
2. Spot size, usually measured in cm^2
3. Time, usually measured in seconds

Understanding the relationships among the three variables is most important when using the laser in non–contact applications.

Laser surgery may be performed when the user seeks a combination of thermal destruction with minimal mechanical injury and coagulation of the tissue surface. For purposes of this manual, all desired effects are termed "tissue change." Tissue changes depend upon temperature level achieved during laser radiation. As optical characteristics of tissue vary, so also do thermal effects vary with different power and pulse durations of laser radiation. Temperature achieved is principally, but not exclusively, a function of the power density (irradiance) of the laser beam.

1.2.2.3 Patient Selection

Selecting and monitoring the patient, as well as providing all treatment and therapy, are fully the responsibilities of the physician.

1.2.2.4 Informing the Patient

As in all medical procedures, the physician is responsible for fully explaining the medical aspects of laser surgery and associated risks to the patient. Risks of combustion, perforation and laser–induced hemorrhage should be fully explained to the patient and should be included in the written informed consent.

The patient completes all applicable consent forms.

1.3 Indications and Intended Use

1.3.1 Dornier Medilas D 30/60 Laser

The Dornier Medilas D Family Lasers, specifically the Medilas D LiteBeam +, Medilas D MultiBeam, and Medilas D FlexiPulse, are indicated for use in medicine and surgery, in the following medical specialties:

- Urology
- Plastic Surgery
- General Surgery
- Dermatology
- Gynecology
- Pulmonary Surgery
- Gastroenterology
- ENT
- Radiology

The Dornier Medilas D Family Lasers, specifically the *Medilas D LiteBeam +, Medilas D MultiBeam,* and *Medilas D FlexiPulse,* are intended for use in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopies), in incision/excision, vaporization, ablation and coagulation of soft tissue in contact and non-contact open surgery (with or without a handpiece), in the treatment and/or removal of vascular lesions (tumors) and removal of unwanted hair, and for endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

1.3.2 Fibers

Dornier supplies fibers with proprietary connectors.

For specifications of fibers supplied by Dornier, see Section 5, or contact Dornier Laser Customer Services at 1-800-DORNIER (1-800-367-6437).

1.4 Contraindications

Dornier strongly recommends that the physician weigh advantages and disadvantages of using diode laser. Other surgical modalities or other wavelengths may be more appropriate due to any or all the following factors:

- Depth of penetration
- Volume of necrosis
- Propensity of scarring

Contraindications include the following conditions:

- Unacceptable risk to tissue in proximity of target, such as nerves or vessels that may be damaged by thermal effects.
- Patient cannot tolerate endoscopes necessary for procedure.

No laser fiber should be used endoscopically in any procedure where the endoscope is contraindicated. The laser should be used only in specialties listed Section 1.3.

1.5 Precautions

Physicians exercise increased caution when considering laser therapy for patients with the following conditions:

- Difficulty with previous endoscopic procedures
- Tissue not fully visible endoscopically
- Any obstruction near known arteries or veins, as revealed by pre–treatment evaluation to locate arteries or veins
- Previous esophageal–tracheal fistulae or episodes of aspiration
- Discomfort during previous laser treatments, possibly requiring analgesia
- Current or recent radiotherapy; clinical studies have shown that radiotherapy patients are at greater risk of perforation or tissue erosion
- Methane gas in bowel, which can be ignited by laser
- Large incompetent perforators along the saphenous vein.
- Incompetent branches at saphenofemoral junction, including anterior lateral branch.

1.6 Adverse Effects

The possibility of adverse events, such as chills, fever, edema or hemorrhage may occur, due to complications from the procedure, concurrent illness or treatment application.

Results from conventional or laser endoscopic therapy includes the following non–thermal complications:

Endoscopic

- Perforation
- Aspiration
- Induced hemorrhage
- Allergic reaction to medication
- Hypertension
- Arrhythmia
- Pain

Results from conventional or laser endoscopic therapy includes the following thermal complications:

Acute

- Induced hemorrhage
- Ulceration
- Perforation
- Edema
- Pain
- Fever
- Leukocytosis

Chronic

- Delay in healing
- Perforation
- Delayed hemorrhage
- Tissue erosion

1.7 Directions for Use

Find specific directions for use in Section 4 of this operating manual. Preview the entire manual in preparation for patient treatments.

1.7.1 Laser Surgery

Success in laser use also depends on two choices:

- Analysis of vascularity and water content of target tissue
- Appropriate power density of the particular task

Power density may be modified by changing either of two variables:

- Power output of the laser
- Surface area of energy application

As a general rule, tissue reactivity to lower power should be established before increasing power to prevent over–penetration, which may result in unwanted damage. Defocusing, by moving the fiber away from the tissue, increases the area of impact and markedly attenuates power. Actual tissue interaction, however, depends heavily on time. At a given power density, the longer the exposure, the greater the lateral spread of destruction in a given area. Passing the beam more rapidly over tissue minimizes lateral spread of thermal damage.

Manipulating power output, spot size and time determines effects of cutting, coagulation and vaporization for each tissue type. Skill in choosing and handling the laser is developed through experience and practice. Therefore, Dornier recommends that low power and short lasing duration be set until user has become fully familiar with interactions of laser energy and tissue effects. Only then should the user attempt to use higher power levels.

1.7.2 Laser Surgery – Contact

1.7.2.1 Bare Fibers

Contact–laser surgery, with bare fibers, delivers high–power densities at low–power settings for constant, yet very small, contact areas.

A bare fiber used in contact surgery, tissue debris may cause tip damage, even at low power, such as less than 25 W.

1.7.3 Laser Surgery – Non–contact

Power, time and distance values cited in literature include applications for coagulation and induction of hemostasis associated with removal of vascular tumors (i.e., glomus tumors, hemangioblastomas, and angioplastic meningiomas). At a power of 20 W, with a pulse duration of 0.2 to 0.3 seconds, the distance from the target is cited as 3 to 5 mm.

When using diode in non–contact, unfocused manner, the user should be aware of increased risk of each of the following:

- Back scatter, or reflection
- Forward scatter, or penetration
- Complications of bleeding and cavitation

Primarily, non–contact diode energy is used for photocoagulation and photoablation of tissue. Dornier recommends full familiarization with the diode laser's capabilities. Laser energy can interact with tissue to cause delayed cell necrosis. Tissue perforation may occur due to excess energy application.

Under certain lasing conditions, excess gas volume could insufflate the treated organ, distending the organ and reducing overall thickness of wall tissue. Danger of perforation of thin-walled organs is increased when using high power and/or long pulse durations.

1.8 Endovascular Treatment

For treatment of incompetence and reflux of superficial veins in the lower extremity, and for endovascular coagulation of perforator veins

NOTE: This section applies to the *FlexiPulse*.

1 The access site(s) should be marked and sterilized with betadine and entrance into vein should be obtained with a 16-gauge needle and catheter placed under ultrasound guidance, or the catheter will be introduced through a small stab wound for vein access.
The following accessories are recommended to be used for this procedure:

- Phlebectomy Pack, order number 9507000; Endovenous Basic Pack, order number 9507001;
- Micro-Introducer Kit, 5 French, order number 9507002; Long Introducer Kit, order number 9507003
- 600 Micron Single Use Lightguides: order number K2011824, 600 Micron fiber, single use, 2.5m and order number K1008084, 600 Micron fiber, single use, 3.5m
- 400 Micron Single Use Lightguides: order number K2011822, 400 Micron fiber single use, 2.5m and order number K2010710, 400 Micron fiber, single use, 3.5m
- Reusable Lightguides: order number K2012875, 600 Micron fiber, reusable, 3 times use, 2.9m; order number K2012879, 400 Micron fiber, reusable, 3 times use, 2.9m; order number K2011826, 600 Micron fiber, reusable, 5 times use, 3.5m and order number K2011828, 400 Micron fiber, reusable, 5 times use, 3.5m
- Thin Wall Lightguides: order number K2012393, 600 Micron thin wall fiber, single use, 3.5m

2 A sterile bare fiber should be introduced into the vein through the catheter and positioned using both the aiming beam and ultrasound guidance.

3 The use of duplex ultrasound is recommended to protect the saphenofemoral junction (SFJ) from laser energy during localization of the laser delivery system and laser deployment for the procedure.

4 Apply energy using the following initial parameters: 10-12 watts continuous mode with LPS, with 1 second bursts, followed by incremental withdrawal of the laser fiber in 1-2 mm increments, along the length of the vein to be treated. The power can be modified according to clinical observations and obtained initial results at the discretion of the physician.

5 Concurrent ambulatory phlebectomy for large varicosities and side branches and perforators should be performed at the time of intraluminal procedure to shorten the follow-up course of treatment.

6 The completed procedure should consist of 140-160 firings of the laser, depending on length of the vein closed.

1.9 Removal of unwanted hair

NOTE: This section applies to the *LiteBeam +*, *MultiBeam* and *FlexiPulse*.

Determine skin type (according to Fitzpatrick Skin Type Chart)

Table 1-2 Fitzpatrick Classification of Skin Types

Skin Type	Characteristic
I	Always burns, never tans
II	Always burns, sometimes tans
III	Sometimes burns, always tans
IV	Rarely burns, always tans
V	Moderately pigmented
VI	Black skin

1.9.1 Parameter Settings

1 Treatment without cooling is limited to maximum 30 J/cm^2.

2 Treatment at greater than 30 J/cm^2 requires cooling.

3 Cool skin between 0-5 degrees C with ice or by using commercially available cooling devices.

4 Ensure skin stays between 0-5 degrees C during treatment.

5 Adjust laser settings to match Fitzpatrick Classification of Skin Types as shown in Table 1-1.

6 Ensure that spot size on screen matches spot size on hand piece.

7 First treatment: Test area

7a Select test areas

7b Start with lowest setting (area 1)

7c Increase energy density and use in area 2

7d If changes in skin occur, stop treatment

7e Note setting

7f Allow patient to present for treatment follow-up and inspect test area (after 6 weeks) – growth cycle dependent on body location

7g Use same settings for treatment as in the area where the highest effectiveness of removal of unwanted hair was observed without injury of the skin

7h Be sure to observe changes in skin pigmentation

7i Take pictures before and after treatment

CAUTION **Darker skin types are more sensitive than lighter skin types. Settings too high can cause blistering, burn, hyper- or hypo- pigmentation. Select test area prior to any laser application in an area not obviously visible or readily seen.**

1.9.2 Treatment

Always do a test patch during the first treatment session.

1 Shave or clip the hair to get a "five o'clock shadow" (approx. 1 mm long hair)

2 The tissue is cooled by placing ice locally at the target site with good contact, or by use of commercially available cooling devices.

3 The cooling bag remains on tissue for 2-3 minutes prior to treatment.

4 Treat area with settings evaluated in test treatment.

1.10 Removal of Vascular Lesions

NOTE: **This section applies to the *MultiBeam* and *FlexiPulse*.**

Treatment settings for removal of vascular lesions vary. The settings depend on the skin classification (based on Fitzpatrick scale), the treatment area (face, legs, etc), vessel size, and whether treatment is performed with cold gel packs or a commercial cooling device.

1.10.1 Pretreatment

1 Evaluate the patient's skin type based on Table 1-1. Take any necessary pre-treatment photos.

2 At physician's discretion, prescribe or provide topical anesthetic.

3 Perform a test spot treatment to observe for hyperpigmentation or other side effects. Test spot areas are as follows:

- **3a** Face – behind the ear
- **3b** Arms and upper torso – axilla
- **3c** Legs – behind the knee

4 Verify that the spot size on the hand-piece and the digital display on the device match.

1.10.2 Treatment

1 Cool the treatment area with a cool pack or commercial cooling device.

2 Apply a light layer of clear gel over the treatment area (ultrasound or clear aloe vera gel is recommended).

3 Set the treatment parameters on the laser. Verify that the spot size on the hand-piece and the digital display on the device match.

4 Begin with the lowest treatment setting and adjust according to patient tolerance.

5 Hold handpiece at 90 degree angle to skin with tip gently resting on skin. Do not press down to indent skin. If using a commercial air cooler, cool the area to be treated with the laser hand piece directly behind it.

6 Work from proximal leg to distal leg. Treat spider veins from outer perimeter towards center of complex of feeding reticular vein.

7 Fire the laser 3-6 times. Apply a cold gel pack or commercial air cooler to cool the skin post treatment. In areas of very dense spider vein concentration, it may be necessary to decrease power slightly or provide extra cooling. Continue treatment as required.

8 Re-treat as necessary (usually 2-4 treatments 4-6 weeks apart).

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2 SAFETY

This Section describes the following safety aspects that must be observed when operating the Dornier *Medilas D 30/60*:

- Responsibilities of the User
- User Training
- Explanation to Patients
- Warning and Safety Precautions for Electromagnetic Compatibility in Compliance with EMC Standard EN 60601-1-2:2007
- EMC Compatibility
- Laser Safety
- Laser Safety Officer
- Eye Protection
- Safety for the Patient
- Safety for the Dornier *Medilas D 30/60* Laser
- Responsibilities of Dornier MedTech
- Dornier *Medilas D 30/60* Safety Equipment
- Safety During Transport
- Accessory Sterilization
- Warning and Information Labels

Each operator must have read and understood the Operating Manual in its entirety prior to using the Dornier *Medilas D 30/60*. The Laser Safety Officer (LSO) is responsible for compliance with safety regulations regarding laser handling.

The safety of patient and user(s) requires a continuing commitment by the manufacturer, owner and user(s). Like all technical apparatus, lasers require correct installation and handling, together with routine maintenance and service to support safe operating conditions.

The laser is enclosed in a protective housing. The external panels must remain securely closed to protect users from internal modules and to protect internal modules from damage. Removal of screws or external panels from laser does not prevent operation of laser. There is no internal fail-safe interlock in the laser.

Dornier installs labels on internal modules in which high voltages are located. Some voltages are lethal. Only properly trained service personnel should open panels on lasers that are marked with the following symbol:

2.1 Responsibilities of the User

Each user must have read and understood the operating manual completely prior to using the Dornier *Medilas D 30/60*. Prior to each treatment, the user must check the functional performance of the Dornier *Medilas D 30/60* in order to rule out any risk to patients or other parties. If the Dornier *Medilas D 30/60* is used in conjunction with peripheral units, the operating manuals for the peripheral units must also have been thoroughly read and understood.

The owner of the laser has the responsibility of operating the laser only in accordance with ANSI Z136.3. Owner's responsibilities, include, but are not limited to, the following activities:

- Comply with applicable government regulations
- Meet NEC or CSA standards for electrical installation of the facility
- Meet CSA Z386, Laser Safety in Health Care Facilities requirements in Canadian facilities using the Dornier *Medilas D 30/60* Laser.
- Order installation adjustments, service and modification by properly trained service personnel only
- Ensure continuing compliance by appointing a Laser Safety Officer (LSO) to perform duties outlined in ANSI Z136.3
- Install lasers in rooms designed for medical-laser use
- Ensure that all necessary safety precautions have been taken
- Enforce laser protections
- Ensure operation of laser in accordance with the operating manual
- Perform proper maintenance and call for annual service
- Call for repair when necessary
- Comply with requirements of applicable professional associations
- Provide operational training for additional users, including doctors, nurses and technicians, who are certified in laser surgery
- Ensure that each staff member can take proper steps in case of malfunction
- Ensure that all users are properly trained in Diode laser surgery

2.2 User Training

Laser may be operated only by qualified and trained staff members under the direction of a physician and in accordance with the operating manual. Under no circumstances are unskilled or unqualified persons to operate the laser. In addition to training, the user must read and understand fully the operating manual before operating the laser.

Under no circumstances shall untrained or unqualified operating personnel operate the Dornier *Medilas D 30/60.*

Physicians who use the laser must be familiar with the medical aspects of Diode laser surgery, including the current scope of indications and contraindications.

Physician training should include review of published literature, medical meetings and presentations, didactic courses, hands-on laboratory experience, and observation/participation in cases performed by physicians experienced in laser therapy.

Before using any fiber, the physician should fully understand use of Diode laser, safety considerations, tissue interaction, and proper technique specific to treatment for which physician intends to use the fiber. Practice with fibers should include the following activities:

- Using low power levels and short pulses to gain familiarity with fiber operation.
- Setting lowest power required to achieve desired tissue effect

Success of the laser treatments depends largely on the user's experience and knowledge of the biophysical connections.

2.3 Explanation to Patients

The treatment process must be explained to the patient. The patient must give written consent to any treatments.

2.4 Warning and Safety Precautions for Electromagnetic Compatibility in Compliance with EMC Standard EN 60601-1-2:2007

Electric medical products are subject to special precautionary measures with regard to EMC, and are permitted to be installed and put into operation only in compliance with the EMC information contained in the Operating Manual.

Portable and mobile radiofrequency communication devices can influence electric medical products.

The EMC requirements according to EN 60601-1-2:2007 apply in combination with the power line type H05VV (length: 3 m, or approximately 10 ft) that is connected to the Dornier Medilas D 30/60.

CAUTION: **Use of accessories or lines other than those listed - with the exception of internal original spare part components - can lead to increased emission or reduced interference immunity with regard to the Dornier Medilas D 30/60.**

2.4.1 Manufacturer's Declaration on EMC Emission

Guidelines and Manufacturer's Declaration – Electromagnetic Emission		
The Dornier *Medilas D 30/60* unit is intended for operation in the electromagnetic environment specified below. The user of the *Medilas D 30/60* must ensure that it is used in such an environment.		
Emission measurements	**Conformance**	**Electromagnetic environment – guidelines**
Radio frequency emissions according to CISPR 11	Group 1	The *Medilas D 30/60* uses radio frequency energy exclusively for its internal function. Its radio frequency emission is very slight and it is unlikely that there will be interference with neighboring electronic devices.
Radio frequency emissions according to CISPR 11	Class A	The *Medilas D 30/60* is intended for use in all facilities, other than residential areas and any areas that are directly connected to a public supply network that also supplies buildings.
Harmonics according to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker according to IEC 61000-3-3	Not applicable	

WARNING: **The Dornier *Medilas D 30/60* may not be used in the immediate vicinity of other devices or in a stacked arrangement with other devices. If operation near or stacked with other devices is necessary, the Dornier *Medilas D 30/60* should be observed in order to verify that its operation in this arrangement complies with the regulations.**

2.4.2 Manufacturer's Declaration on EMC Interference Immunity

Guidelines and Manufacturer's Declaration – Electromagnetic Interference Immunity			
The Dornier *Medilas D 30/60* unit is intended for operation in the electromagnetic environment specified below. The customer or user of the Dornier *Medilas D 30/60* must ensure that it is used in such an environment.			
Interference immunity tests	**IEC 60601 test level**	**Conformance level**	**Electromagnetic environment guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or should be covered with ceramic tiles. If the floor is covered with synthetic material, the relative air humidity must be at least 30%.
Bursts according to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The line voltage quality should correspond to that for a typical business or hospital environment.
Impulse voltages (surges) according to IEC 61000-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage	± 1 kV normal mode voltage ± 2 kV common mode voltage	The line voltage quality should correspond to that for a typical business or hospital environment.
Voltage dips, short breaks and fluctuations in the line voltage according to IEC 61000-4-11	< 5 % VT for ½ period (> 95 % dip) 40 % VT for 5 periods (60 % dip) 70 % VT for 25 periods (30 % dip) > 5 % VT for 5 s (> 95 % dip)	< 5 % VT for ½ period (> 95 % dip) 40 % VT for 5 periods (60 % dip) 70 % VT for 25 periods (30 % dip) > 5 % VT for 5 s (> 95 % dip)	The line voltage quality should correspond to that for a typical business or hospital environment. If the *Medilas D 30/60* user requires continued function even when breaks occur in the energy supply, we recommend that the Dornier *Medilas D 30/60* be supplied from an uninterruptible power supply or battery.
Magnetic field at supply frequency (50/60Hz) according to IEC 61000-4-8	3A/m	3A/m	Magnetic fields at line frequency should correspond to the typical levels found in business and hospital environments.
NOTE: V_T is the a.c. supply voltage before application of the test level			

Guidelines and Manufacturer's Declaration – Electromagnetic Interference Immunity			
The Dornier *Medilas D 30/60* unit is intended for operation in the electromagnetic environment specified below. The customer or user of the Dornier *Medilas D 30/60* must ensure that it is used in such an environment.			
Interference immunity tests	**IEC 60601 test level**	**Conformance level**	**Electromagnetic environment guidelines**
			Portable and mobile radio devices are not used at a distance to the Dornier *Medilas D 30/60* (including the lines) that is less than the recommended working clearance that is calculated according to the equation that is appropriate for the transmit frequency.
Recommended working clearances:			
Conducted radio frequency disturbances according to IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	3 Veff	$d = 1.2 \sqrt{P}$
Radiated radio frequency disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
Where P is the transmitter's nominal output in watts (W) according to information provided by the transmitter manufacturer and d is the recommended working clearance in meters (m). The field strength of stationary radio transmitters should be less than the conformance level[B] for all frequencies, according to an examination at the location[A]. Disturbances are possible in the vicinity of devices that carry the following symbol: 			
NOTE 1 *At 80 MHz and 800 MHz, the higher frequency applies* *NOTE 2* *These guidelines may not hold true in all situations. The propagation of electromagnetic waves is influenced by absorptions by and reflections from buildings, objects and people.*			
A *Theoretically, the field strength of stationary radio transmitters, such as base stations for radio communication telephones and mobile land radio services, amateur stations, am and fm radio and television broadcasts, cannot be accurately determined in advance. In order to determine the electromagnetic environment with regard to stationary transmitters, a study of the location should be conducted. If the measured field strength at the location where the Dornier Medilas D 30/60 is used exceeds the above conformance levels, the Dornier Medilas D 30/60 should be observed in order to verify that it functions properly. If unusual characteristics are observed, you may need to take additional measures, such as changing the alignment or placing the Dornier Medilas D 30/60 in a different location.* B *The field strength is less than 3 v/m above the frequency range of 150 KHz to 80 MHz.*			

Recommended Working Clearances between portable and mobile radio frequency communication devices and the Dornier Medilas D 30/60

The Dornier *Medilas D 30/60* unit is intended for operation in an electromagnetic environment in which the radio frequency disturbances are controlled. The customer or user of the Dornier *Medilas D 30/60* can help to avoid electromagnetic disturbances by maintaining the minimum distance between portable and mobile radio frequency devices (transmitters) and the Dornier *Medilas D 30/60* – depending on the output power of the communication device, as specified below.

Transmitter's nominal output W	Working clearance according to transmit frequency m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose nominal output is not specified in the above table, the distance can be determined by using the equation that belongs to the particular column, where P is the transmitter's nominal output in watts (W) according to the transmitter manufacturer's information.

NOTE 1
To calculate the recommended working clearance for transmitters in the frequency range from 80 MHz to 2.5 GHz, an additional factor of 10/3 was used in order to reduce the probability that a mobile or portable communication device inadvertently brought into the patient area could lead to a disturbance.

NOTE 2
These guidelines may not hold true in all situations. The propagation of electromagnetic waves is influenced by absorptions and reflections from buildings, objects and people. In order to determine the electromagnetic environment with regard to mobile transmitters, a study of the location should be conducted. The Dornier Medilas D30/D60 should be observed in order to verify that it functions properly. If unusual characteristics are observed, you may have to take additional measures, such as changing the alignment or placing the Dornier Medilas D30/D60 in a different location.

2.5 Laser Safety

- The Dornier *Medilas D 30/60* is a device in the permissible limits class B according to EN 55011 (Electromagnetic Compatibility). The user must conform to the EMC guidelines.
- During operation, the area in which the maximum allowable irradiation can be exceeded (the "laser area") must be marked off and identified. Furthermore, it must be ensured that, in closed areas, operation of Class IV laser equipment is indicated on the accesses to the laser area by warning lights.
- Protective goggles must be worn in the laser area during laser emission.

WARNING Reflecting materials can cause uncontrolled deflection of the laser beam. Glass surfaces or highly polished metal surfaces within a few meters of the laser can cause dangerous scattered laser radiation. Surfaces of this type that are good reflectors should be avoided in the laser area. Optic curtains of fire-retardant, poorly reflecting material can be used against scattered radiation.

- If it is necessary to bring instruments into the radiation passage during medical use, the user must use instruments whose design and material ensure that they largely eliminate dangerous reflections. This requirement is met if the instruments for medical use in the laser area have dark or dull surfaces and have radii that are as small as possible. Flat surfaces should be avoided.
- If the laser beam is used for medical purposes and it is possible for the maximum authorized irradiation of the coma to be exceeded, the operator must ensure that optical equipment to be used for observation or adjustment is equipped with suitable protective filters.
- If laser radiation is used with freely moving fibers or applicators, the user must ensure that auxiliary devices and covering materials that may inadvertently be exposed to the laser beam are at minimum flame retardant. This requirement is met if the inadvertently irradiated materials do not continue to burn or drip smoldering pieces after the beam is switched off.
- Lasers require special expertise and care in handling and use. Only physicians who have received training on the device, taking into consideration operating instructions, and who are familiar with the laser's therapeutic effect and possible risks, are permitted to use the laser.
- The user is responsible for sufficient medical subject knowledge and correct performance of the operation.
- Protective measures must be taken against fire and explosion risks when using laser radiation in body areas or cavities with oxygen-enriched air or where flammable gases or vapors exist or can occur and may be ignited by high temperatures.
- At least once a year, all personnel who work in the laser area must be instructed in laser safety and unit operation. Training must be documented in writing and instructions must be given after unit changes or the introduction of new units.

- In case of an incident (in cases of injury or near injury) instruction must be given promptly before the device is used again. Incidents must be reported to the manufacturer.

2.6 Laser Safety Officer

The Laser Safety Officer is responsible for:

- Implementing safety measures
- Examining protective equipment
- Training users with regard to safety measures and operation of the Dornier *Medilas D 30/60*
- Marking out the laser area
- Checking the red warning lights at the entrance to the laser area
- Secure safekeeping of the unit's key
- Secure safekeeping of the Dornier *Medilas D 30/60*
- Correct connection of the Dornier *Medilas D 30/60* after it has been moved

2.7 Eye Protection

Because of the high energy density, the eye is particularly at risk. The eye can be damaged by even weak laser radiation.

Laser area according IEC 608251 (issue 03-2007):

The eye safe distance to the laser output is defined as Nominal Ocular Hazard Distance NOHD. Outside of this area safety goggles are not required if using laser light transmission fibers without focusing optics (fiber beam divergence full angle a=20°):

The NOHD distance referred to the distal end of a bare fiber is:

4,0 m for Models Medilas D, LiteBeam+ (940 nm), MultiBeam (940 nm), FlexiPulse (940 nm)

WARNING: **Irreversible eye injuries can occur.**
Each person inside the laser area must wear protective goggles.

The protective goggles for the Dornier Medilas D 30/60 laser system must comply with at least the following conditions:

Dornier Medilas D	Laser type	Wavelength of the filtered radiation	Protection class EN 207:2002	Manufacturer symbol
LiteBeam+	D	940 nm	L4	Acc. EN 207:2002
MultiBeam				
FlexiPulse				

Protective goggles do not offer complete protection; for this reason, keep the exposure time short. The protective goggles are not permitted to be used if they show any signs of damage whatsoever.

CAUTION: **The recommended protection class applies only if accessories without imaging optics are used, such as light guides with a bare fiber tip. For accessories with reflecting optical components, such as focus applicators, effective protection is only guaranteed if the system is used as prescribed. In addition, compliance with appropriate national standards, each in the valid version, is necessary. Examples of such standards are: IEC 60825 (Safety of Laser Products)**

2.8 Safety for the Patient

2.8.1 Operating the Dornier *Medilas D 30/60*

A number of safety devices for ensuring direct patient safety have been built into the Dornier *Medilas D 30/60.*

All functions are continuously and automatically monitored.
The therapy laser can only be released if all functions are working properly. In addition, you must comply with the safety aspects given in the Chapter "Safety" of this Operating Manual.

WARNING: **The Dornier *Medilas D 30/60* generates a high-energy laser beam.**
You are not permitted to operate the Dornier *Medilas D 30/60* in an explosive and/or combustible atmosphere.

An explosive or combustible atmosphere arises, for example, from vapors generated by anesthetics, cleaning agents, or disinfectants, or from oxygen enrichment resulting from the administration of oxygen for respiration.

2.8.2 Use of Laser Radiation

The Dornier *Medilas D 30/60* is a Class 4 laser product in accordance with IEC EN 60825-1:2001.

WARNING: **The Dornier *Medilas D 30/60* generates a high-energy laser beam. Improper use can result in injuries to persons and/or damage to equipment. All stipulated safety precautions must be taken; the corresponding safety aids must be used and kept in proper working order.**

2.8.3 Replacement of Parts

In order to ensure the reliable function of the Dornier Medilas D 30/60 and thus the patient's safety, use only original spare parts from Dornier MedTech. Spare parts are manufactured by Dornier MedTech in compliance with especially high quality requirements regarding materials and production, and are checked for proper functionality.

2.9 Safety for the Operating Staff

2.9.1 Training the Operating Staff for the Dornier *Medilas D 30/60*

Untrained or unqualified operating personnel are not permitted to operate the Dornier *Medilas D 30/60* under any circumstances whatsoever.

Dornier MedTech offers comprehensive Dornier *Medilas D 30/60* training sessions for the operating personnel and physicians. Experienced Dornier MedTech staff or authorized representatives conduct the necessary training.

The success of a laser treatment depends largely on the user's experience and knowledge of the biophysical coherences.

2.9.2 Duty of the Operating Staff

Operating and cleaning personnel are advised to exercise extreme care when handling the Dornier *Medilas D 30/60.* For more information in this regard, refer to the Chapter "Cleaning".

2.10 Laser Safety

All applicable regulations for radiation protection must be complied with for the operation of the Dornier *Medilas D 30/60.* If the regulations are not clear, you must ask the clinic's appointed laser safety officer.

WARNING: **Irreversible injuries can occur. Under no circumstances may the retina of the eye or the skin be subjected to direct or reflected (for example, by shiny materials) laser radiation. The laser safety goggles provide only short-term protection from direct laser light.**

Considered as the laser area is the area in which the levels for the maximum permissible radiation (MPR) can be reached or exceeded.

If hand applicators are used for open work, the entire OR must be considered as the laser area.

You must allow for an unintentional deflection of the laser beam.

Protective goggles that offer sufficient protection must be worn inside the laser area.

The laser area must be marked with signs on the doors and warning lights; it must be kept as small as possible and it must be secured so that unauthorized persons cannot enter.

The number of people in the laser area must be kept as small as possible.

Reflecting, shiny materials must be removed from the laser area or covered with cloths of low flammability. Flammable materials must be removed.

Steps must be taken to prevent the formation of gases, dust and mist in the laser area as a result of the exposure to laser radiation. Materials that are at risk must be removed or protected by suitable measures.

Only instruments that are suitable for laser treatment may be used during laser treatment. The shape and surface finish of instruments suitable for laser treatment prevent reflections of the laser beam.

A sufficient quantity of suitable, functioning protective equipment must be available.

If endoscopes are used without a video camera, suitable laser protection filters must be used for the endoscope. The user does not need to wear safety goggles during laser endoscopy with laser protection filters. All other people in the area must wear safety goggles.

When using laser radiation in body areas with oxygen-enriched air or where flammable gases or vapors exist or can occur, you must take protective measures against the fire and explosion risk.

All people who work in the laser area must be instructed on laser safety and device operation at yearly intervals. Participation in the instruction must be confirmed in writing.

CAUTION: **The recommended protection class applies only if accessories without imaging optics are used, such as light guides with a bare fiber tip. For accessories with reflecting optical components, such as focus applicators, effective protection is only guaranteed if the system is used as prescribed. In addition, compliance with appropriate national standards, each in the valid version, is necessary. Examples of such standards are: IEC 60825 (Safety of Laser Products)**

2.11 Safety Measures for the Dornier *Medilas D 30/60*

2.11.1 Electrical Installation of the Dornier *Medilas D 30/60*

Operate the Dornier *Medilas D 30/60* only in areas used for medical purposes; the wiring systems in the area must comply with the respective national standards for wiring systems. The Dornier *Medilas D 30/60* is only permitted to be plugged into a power outlet with a separate fuse. The Dornier *Medilas D 30/60*

is a Protection Class 1 device in accordance with IEC EN 60601-1-2:2007. The Dornier *Medilas D 30/60* must therefore be grounded according to regulations.

For information on correct operation with regard to electromagnetic compatibility, see the chapter "Warnings and Safety Precautions for Electromagnetic Compatibility in Compliance with EMC - Standard EN 60601-1-2:2007"

The casing edges of the Dornier Medilas D 30/60 must be placed at least 20 cm from the wall in order to ensure that there is no interference with the supply air and exhaust. Installation in closed cabinets is not permitted.

2.11.2 Operating Position of the Dornier *Medilas D 30/60*

The Dornier *Medilas D 30/60* may be operated only in the positions shown in the chapter "Preparing for the Startup".

2.11.3 Combining the Dornier *Medilas D 30/60* with Accessories

The Dornier *Medilas D 30/60* must be combined only with approved light guides, instruments and accessories.

2.12 Responsibility of Dornier MedTech

Dornier MedTech assumes responsibility with respect to safety, reliability and performance of the Dornier *Medilas D 30/60* under the following conditions only:

- Installation, adjustment, maintenance, and modifications are performed only by Dornier MedTech personnel or persons authorized by Dornier MedTech.
- The electrical installation in the relevant room complies with applicable national standards.
- The Dornier Medilas D 30/60 is operated according to the applicable Operating Manual.

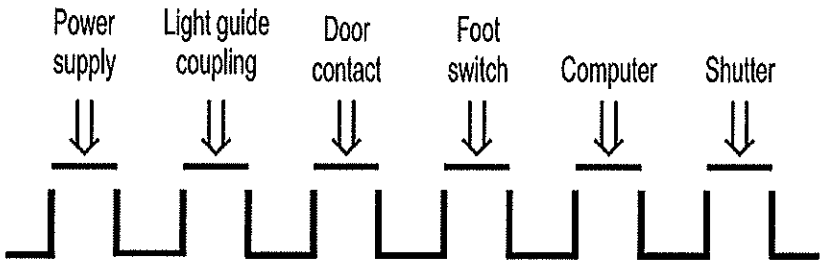
2.13 Dornier *Medilas D 30/60* Safety Equipment

2.13.1 Laser Safety Chain

To avoid unintentional laser release, a chain of safety equipment has been built into the Dornier *Medilas D 30/60*; this chain reliably prevents incorrect laser release. The laser safety chain consists of hardware switches that are connected in series.

Laser radiation cannot be released even if only one switch is open, which means that one safety requirement is not met. The last link in the laser safety chain is the shutter, an electronic switch that short-circuits the power pack at the output so that in case of safety failure the laser diode will be switched to the power-off state.

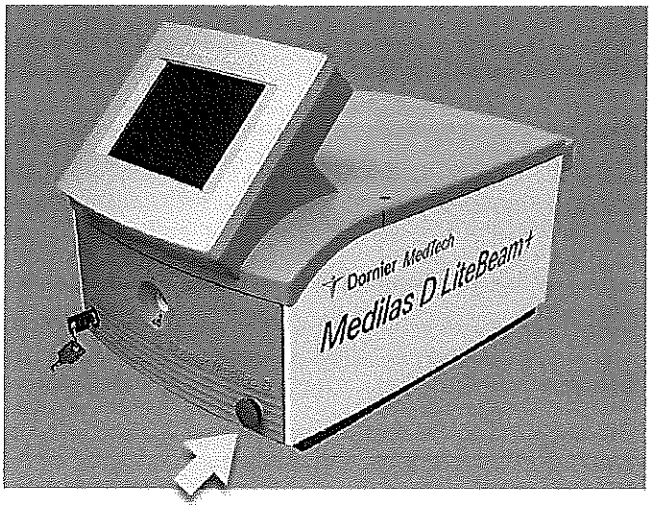
Figure 2-1 Laser Safety Chain



2.13.2 Laser Off

An Emergency OFF switch is provided for quick cutoff during operation; when activated, this switch cuts off the power to the Dornier *Medilas D 30/60*.

Figure 2-2 Emergency OFF Switch



2.13.3 Laser Alarm

During laser release, an acoustic signal sounds to warn of the laser radiation.

2.14 Safety During Transport

You are only permitted to transport the Dornier *Medilas D 30/60* as described in the chapter "Transporting the Dornier *Medilas D 30/60*".

2.15 Accessory Sterilization

You must comply with legal regulations when sterilizing accessories. In particular, you must comply with the degassing time after sterilization.

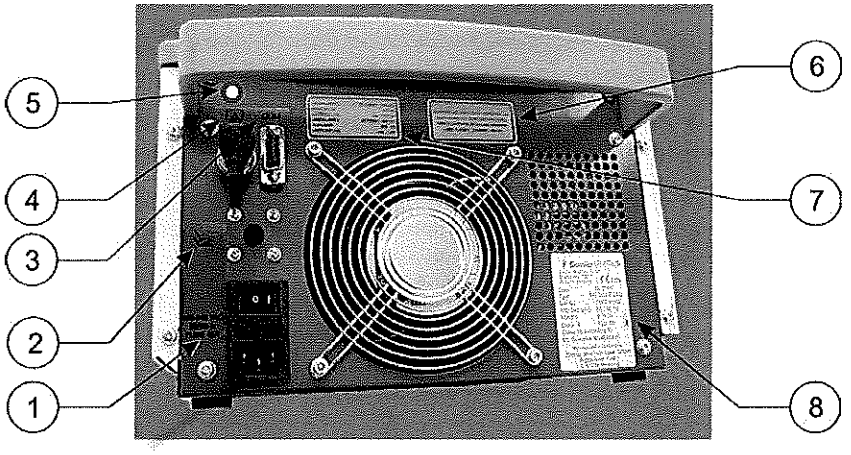
You must comply with the information and warnings in the operating manuals for the accessories that you are using.

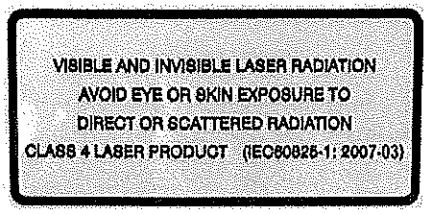
2.16 Warning and Information Labels

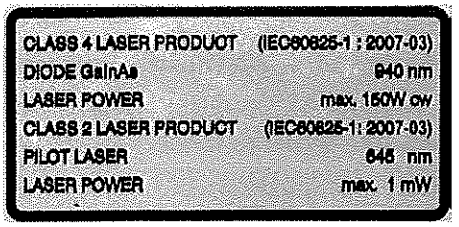
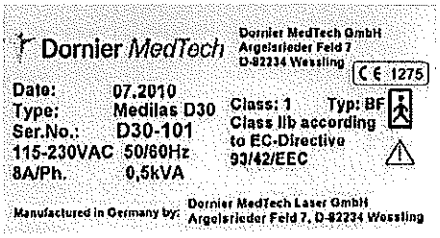
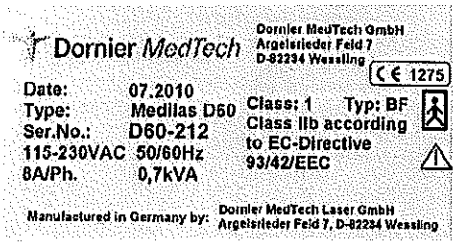
Numerous warning and information labels have been placed on the Dornier Medilas D 30/60.

Figure 2-3 shows the warning and information labels and their positions on the back of the Dornier Medilas D 30/60; Figure 2-4 shows the labels on the front of the unit.

Figure 2-3 Warning and Information Labels, Back of the Unit

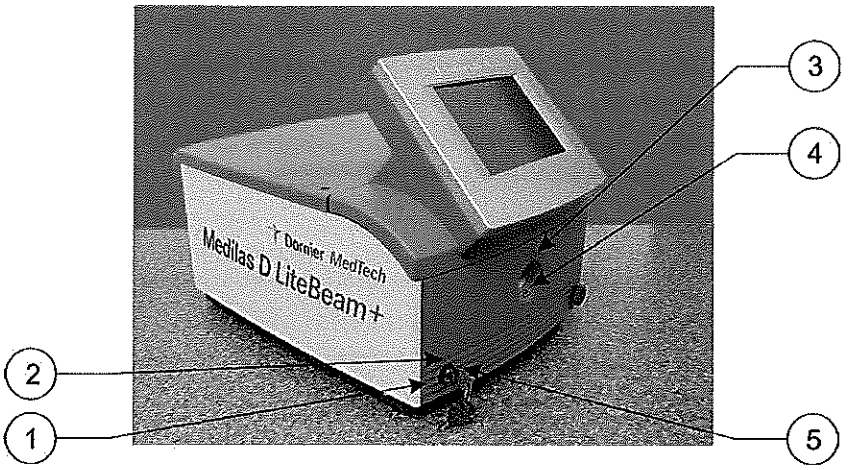


Positions in Figure 2-3	Sign	
1	115-230VAC 50/60Hz FUSE 8A	Power cable connection
2		Footswitch connection
3	COM	Service interface port
4		Door contact connection
5		China RoHS Declaration of Conformity label.
6		Warning for laser radiation class 4.

Positions in Figure 2-3	Sign	
(7)		Specification for laser radiation[1]
(8)	 	For the valid type name, series number and date please refer to the label on your individual laser unit.

[1] Label for the specification of the laser radiation is just one example. For the valid data please refer to the label on your individual laser unit.

Figure 2-4 Warning and Information Labels, Front of the Unit



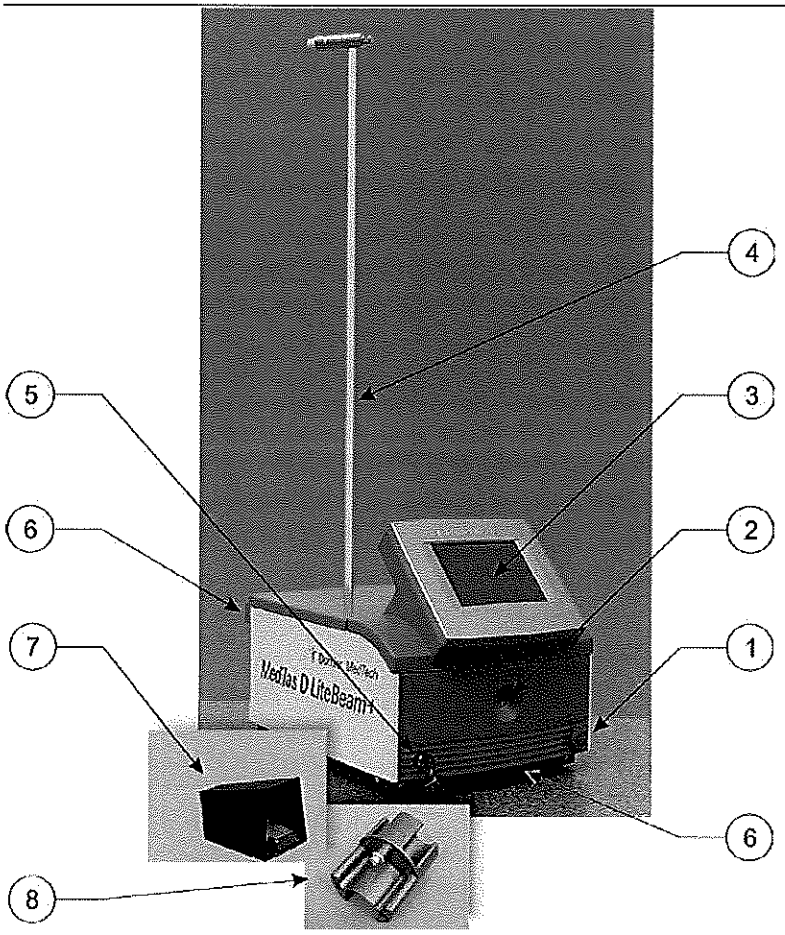
Positions in Figure 2-4	Sign / emblem	
1		Observe instructions in Operating Manual
2		Key switch OFF position
3		Light guide connection
4		Caution: laser radiation!
5		Key switch ON position

3 DESCRIPTION

3.1 Dornier *Medilas D 30/60* Design

The Dornier *Medilas D 30/60* is built into a mobile casing.

Figure 3-1 Dornier Medilas D 30/60 Design



1	Emergency stop	5	Key switch
2	Light guide connection	6	Carrying handle
3	Control panel (Touch screen)	7	Footswitch
4	Light guide holder	8	Hand piece Holder (contained in the scope of delivery depend on Model variant)

3.1.1 Accessories

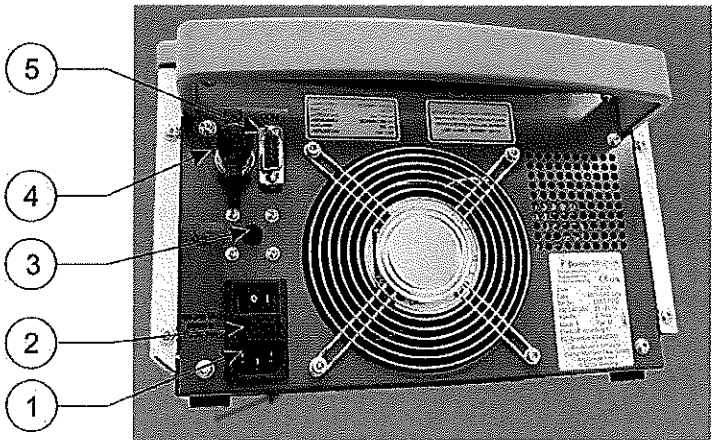
Please refer to the applicable Dornier MedTech accessory list for the accessories for the Dornier *Medilas D 30/60.*

3.2 Connections

3.2.1 Electrical and Pneumatic Connections

Electrical and pneumatic connections are located on the back of the Dornier *Medilas D 30/60.*

Figure 3-2 Connections (Back of Unit)



(1) Power supply connection

(2) Fuse holder

(3) Footswitch connection

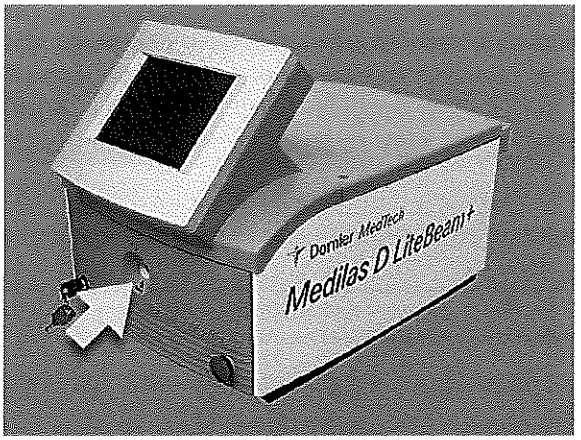
(4) Door contact connection

(5) Service interface (COM) and peristaltic pump connection

3.2.2 Light guide connection

The light guide connection is located on the front of the Dornier *Medilas D 30/60;* it serves to connect the therapy fiber and the application hand piece.

Figure 3-3 Light guide connection

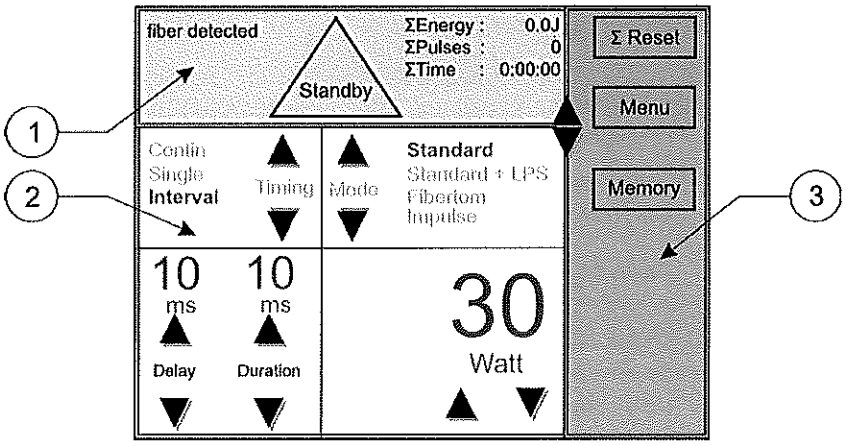


3.3 Control Panel

The control panel is shown on a display. The display is equipped with a touch screen.

The control panel is divided into three areas (fields) that are separated from one another by double lines and highlighted in different background colors.

Figure 3-4 Division of the Control Panel



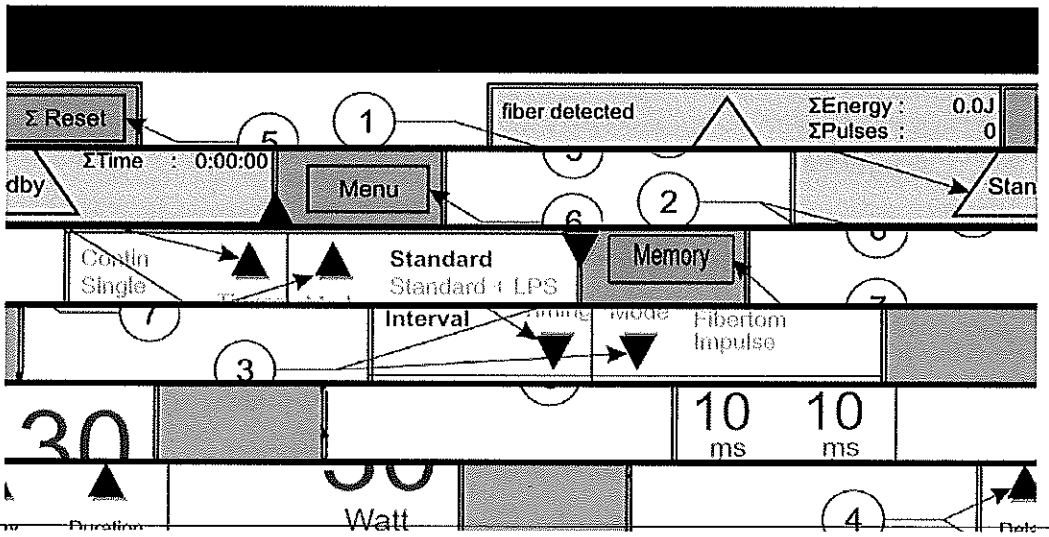
No.	Name	Function
(1)	Gray information field	General information on the operating status is shown in this field.
(2)	White laser parameter field	Laser parameters are shown; they can be changed with the UP/DOWN buttons (black arrows).
(3)	Orange button field	These buttons can be used to change the display mode or to change the laser parameters as a whole.

The control panel displays functions, operating modes, parameters and the keypads that are active at a particular time. The control panel is used for input and for displaying unit functions by touching the function symbol or simulated buttons. The function symbol turns blue or the simulated button appears with a gray background as confirmation of the input.

NOTE: When you press a button, you must make sure that only one action point on the touch screen is active. If more than one action point is active, there will be an unwanted activation of control functions.

CAUTION: The keys and buttons can be activated by a slight touch; too much pressure can destroy the display.

Figure 3-5 Control Panel with Buttons



No.	Designation, button	Function
1	Laser button	The laser button frees the footswitch for laser release 2 seconds after it is pushed
2	Timing buttons	Selects the pulse form of the therapy beam
3	Mode buttons	Selects the operating mode
4	Up/down buttons	Modifies the particular parameter
5	Reset button	Sets all log data to 0
6	Menu button	Enables the menu functions
7	Memory	Calls up pre-stored laser settings

3.4 Operating Modes

The Dornier *Medilas D 30/60* has 4 operating modes.

3.4.1 Operating Modes, Comparison of the Models

Product name	Wavelength	Operating modes			
		Standard	Standard+LPS	Fibertom®	Pulse
Dornier *Medilas D 30/60* LiteBeam+	940 nm	X	X	X	X
Dornier *Medilas D 30/60* MultiBeam	940 nm	X	X	X	X
Dornier *Medilas D 30/60* FlexiPulse	940 nm	X	X	-	X

X = adjustable
- = not available

3.4.2 Standard Mode (+ LPS)

Standard mode is for non-contact coagulation and vaporization. The laser power is regulated to the power level that you have selected.

In Standard+LPS mode, the LPS = Lightguide Protection System is additionally activated.

The LPS function protects the light guide tip. If there is carbonization on the fiber tip and white light results, the LPS switches the therapy laser off. There are five possible settings for the LPS level.

WARNING: LPS does not guarantee that carbonization at the fiber tip will be detected in all cases.

3.4.3 Fibertom® Mode

NOTE: This mode is only available on the LiteBeam+ & MultiBeam Models

Fibertom® mode is used for temperature-regulated cutting and vaporization in a contact procedure. Power regulation with temperature monitoring of the fiber or application tip reduces contamination* and prevents the destruction of the fiber tip resulting from a temperature that is too high. As a result of automatic fibertom® power regulation, the actual distal power may be considerably less than the selected power.

Non-contact coagulation is only conditionally possible with a fiber tip that has been contaminated and burned in during contact cutting, because fibertom® power regulation reduces the laser power, consequently preventing incandescence of the fiber tip.

*Contamination: Pollution with blood or tissue

3.4.4 Impulse Mode

Impulse mode is for non-contact coagulation. Using the selected energy density (fluency) E and depending on the maximum available power P_{max} and the spot size used, the minimum pulse duration $t_{min} = E/P_{min}$ is calculated. Then the pulse duration t_{min} is displayed and P_{max} is selected.

The peak power in the laser spot has a Gaussian distribution profile.

The pulse duration can subsequently be changed, with the setting range limited by the minimum and maximum power.

If the peak power or spot size changes, the minimum pulse duration is automatically adjusted.

The setting of the minimum pulse duration with the change of the peak power is not always desired. Starting from software version 1.20, the unit recognizes the pulse delay change. With the increase of the peak power the pulse duration remains constant, as it must be increased to reach the desired peak power. During the reduction of the peak power the pulse duration remains constant, as the change is <50 J/cm2 in relation to the starting value. If the change is >50 J/cm2, the minimum possible pulse duration will be adjusted automatically.

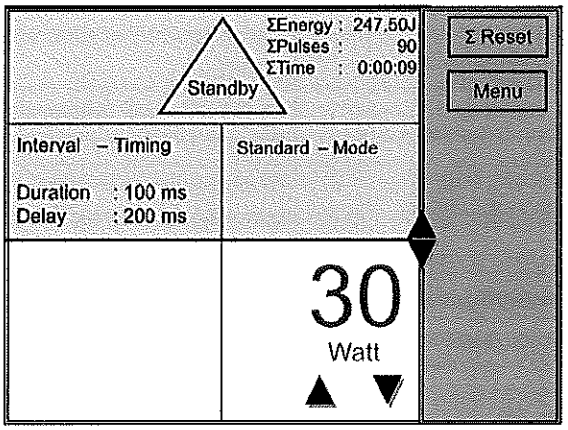
WARNING: **Impulse mode may only be used in combination with focusing applicators*. If fibers are used without applicators, energies can be applied that are higher than what is shown on the display.**

* for transcutaneous applications (AngioSpot; EpiSpot; VarioSpot D)

3.4.5 Restricted Operating Mode

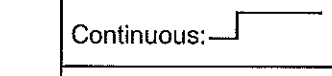
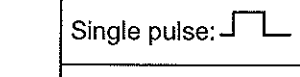
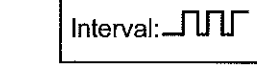
If you will only be altering certain parameters during a treatment and if you want to prevent unintentional alteration of a laser parameter, the Dornier Medilas D30/D60 can be switched to a restricted operating mode.

Restricted Operating Mode



3.4.6 Adjustable Parameters and Value Ranges

The Dornier *Medilas D 30/60* is equipped with a battery. All settings are stored when the Dornier *Medilas D 30/60* is switched off and can be used again immediately when the unit is switched on again.

Available pulse forms	
Pulse form	**Description**
Continuous: 	Laser power is delivered as long as the footswitch is operated.
Single pulse: 	Laser power is delivered for a preselected duration, as long as the footswitch is operated.
Interval: 	Laser power is delivered in a preselected delay/duration interval, as long as the footswitch is operated.

Adjustable parameters	
Parameter	**Description**
Power	To adjust the therapy laser beam's power. The selected power corresponds to the set value; in fibertom® mode this is an upper limiting value.
Pulse duration	Adjustment of the active phase of one pulse of the therapy laser beam
Pulse delay	Adjustment of the inactive phase between two pulses of the therapy laser beam

NOTE: In pulse operation, the selected application time (dosage) counts only the actual laser time, without pulse breaks. For example, if the pulse duration is 1 s, the pulse break is 1 s and the time selected is 20 s, then the treatment will take 39 s to complete.

A special form of the adjustable parameter is the DOSAGE. In this case, the total amount (dosage) of the radiation is specified. You can specify the dosage by adjusting the time, energy or number of pulses.

The dosage can be interrupted any number of times with the footswitch, and then the treatment can subsequently be continued with the remaining radiation quantity. By pressing the dosage button or by changing the time, energy, time of pulses or treatment mode, the radiation can be interrupted and then restarted with the original total radiation quantity.

DOSAGE Settings	
DOSAGE	**Description**
Time	For setting the application time, in seconds/minutes.
Energy	For setting the energy to be applied, in joules/kilojoules.
Pulses	For setting the number of pulses to be applied.

Value Ranges

Operating modes		Pulse form	Power (W)	Energy density (J/cm²)	Spot Ø mm	Pulse interval (s)	Pulse duration (s)	Dosage Time (s/min) / Energy (J/kJ) / Number of pulses (Pulses)
Standard (+LPS)		Continuous	2 – 15/30/60-	-	-	-	-	- / - / -
		Single pulse	2 – 15/30/60-	-	-	-	0,01 - 10	10 s - 10 min / 100 – 10 k / 5 – 150
		Interval	2 – 15/30/60	-	-	0,01 - 10	0,01 - 10	10 s - 10 min / 100 – 10 k / 5 – 150
Fibertom®		Continuous	2 – 15/30/60	-	-	-	-	- / - / -
		Single pulse	2 – 15/30/60	-	-	-	0,01 - 10	10 s - 10 min / 100 – 10k / 5 – 150
		Interval	2 – 15/30/60	-	-	0,01 - 10	0,01 - 10	10 s - 10 min / 100 – 10k / 5 – 150
Impulse	LiteBeam+ *	Single pulse	-	10-998[1]	0.5; 1.0; 1.5	-	0,01 – 0,2[3]	-
	MultiBeam *			10-1998[1][2]	0.5; 1.0; 1.5			-
	FlexiPulse			10-9998[1][2]	0.5; 1.0; 1.5; 3.0[2]; 4.0[2]			-
	LiteBeam+ *	Interval	-	10-998[1]	0.5; 1.0; 1.5	0,20 – 2	0,01 – 2[3]	-
	MultiBeam *			10-1998[1][2]	0.5; 1.0; 1.5			-
	FlexiPulse			10-9998[1][2]	0.5; 1.0; 1.5; 3.0[2]; 4.0[2]			-

*for models with wavelength 940 nm only

- Cannot be selected

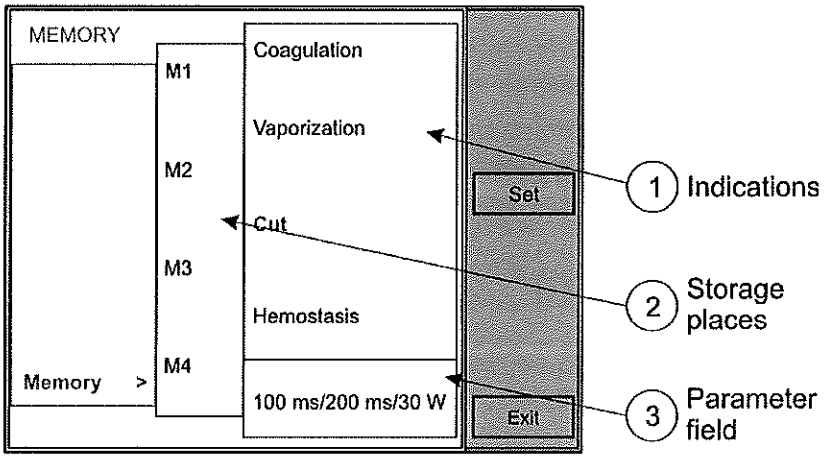
1) Dependant on adjusted spot diameter
2) Available from SW version 1.30
3) Dependant on adjusted energy density and spot diameter

The Dornier Medilas D 30/60 is equipped with a battery. All settings are stored when the Dornier Medilas D 30/60 is switched off and can be used again immediately when the unit is switched on again.

3.5 Memory Function

You can use the laser parameter memory for the storage of individual therapy settings. The "Memory" function simplifies the storage and calling up of the individual settings of the therapy parameters.

Figure 3-6 Dornier Medilas D 30/60 Design



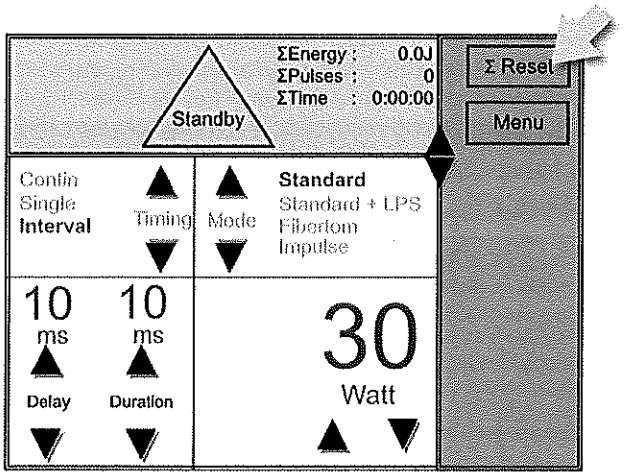
CAUTION **Dornier MedTech accepts no liability for personal injuries or property damages that result from use of the "Memory" function.**

3.6 Log

The Dornier *Medilas D 30/60* automatically keeps a log of:

- the total of all pulses output
- the total applied energy
- the total application time

You can reset all log data to 0 by pressing the "Σ Reset" button. If you press the "Σ Reset" button again, the deleted data will be again indicated for 5 seconds.



After the Dornier *Medilas D 30/60* is switched on, the log data is always reset back to 0.

3.7 Peristaltic Pump

Starting from software version 1.20 it is possible to operate the peristaltic pump Dornier PP-1800 over the COM interface (see "Electrical and Pneumatic Connections", page 3.2 and "Treatment with Irrigation", page 4.1)

Follow the directions given in the operating manual of the peristaltic pump.

Consider the section "Accessories for Irrigation", page 3.2.

Peristaltic pump setting see page 4.21.

3.8 Menu

The menu allows you to define and save default settings separately.

Adjustable Parameters and Key Functions in the Menu

Function/Setting	Description
Pilot	Select the pilot light operating mode
*Continuous**	Pilot light lights continuously
*Impulse**	Pilot light switches off briefly at the beginning of the pulse delay
Blinking	Pilot light blinks (on 200 ms, off 200 ms)
Off	Pilot light is switched off when the pedal is pushed
LPS level	To adjust the unit's shutdown level
1	Lowest temperature (sensitive)
2	Low temperature
3	Default setting
4	High temperature
5	Highest temperature (not sensitive)
Dosage	Select the dosage setting
Energy	Dosage is selectable as energy
Time	Dosage is selectable as time
Pulses	Dosage is selectable as number of pulses
LITT	Change to LITT program window
LITT mode	Program LITT treatment parameters
Options	Further settings
Key alarm	Adjust the volume of the feedback sound generated by the system when a button is pressed.
Laser alarm	Adjust the volume of the laser alarm
Language	Select the language for display texts
German	All texts are displayed in German.
English	All texts are displayed in English.
French	All texts are displayed in French.
Spanish	All texts are displayed in Spanish.
Italian	All texts are displayed in Italian.
Portuguese	All texts are displayed in Portuguese.
Time	Set real-time clock
Date	Set the date (day/month/year)
Time	Set the time of day (hour/minute)
Operation	Select the operating setting.
Therapy	Treatment is possible in this setting.
Demo	Demonstration of the functions and operation. No treatment is possible.
Service	Only for authorized service personnel.

* If in addition to the setting Continuous, the menu option Impulse is switched on, the pilot laser is briefly switched off automatically at the beginning of the pulse delay.

3.8.1 Pilot

The pilot laser simulates the invisible therapy laser beam with visible light. You can adjust the pilot laser brightness in steps from 0 - 10, in increments of 1. In addition, you can have the pilot blink.

The pilot laser is a Laser Class 2 laser in accordance with IEC 60825:2001-01.

NOTE: If the brightness level is 0, the pilot laser will be invisible.
In this case, the unit is only permitted to be used for contact applications.

3.8.2 Dosage

If you select the dosage adjustment from the menu, *Dosage* appears in the laser parameter field (Timing field) on the display and you can select the parameters respective.

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4 OPERATION

This section presupposes that you are familiar with the control elements of the Dornier *Medilas D 30/60.* Read and consider the "Description" section.

4.1 Consider Safety

Read and consider the "Safety" section.

Perform a visual check each time before starting the unit.

NOTE: If the visual checks show any problems, the Dornier Medilas D 30/60 should not be put into operation.

In this case, inform your responsible service office.

1. Check the console and casing of the Dornier *Medilas D 30/60* for mechanical damage.
2. Check cables and hoses for mechanical damage.
3. Check connections for mechanical damage.
4. Check the footswitch for smooth running.

4.2 Preparing for the Treatment

4.2.1 Treatment without Irrigation

If you would like to perform a treatment without irrigation, please skip to the chapter "Treatment With Instruments".

4.2.2 Treatment with Irrigation

Starting from software version 1.20 it is possible to operate the peristaltic pump over the COM interface (see "Electrical and Pneumatic Connections, page 3.2)

4.2.3 Treatment with Gas Irrigation

You can perform a treatment with gas irrigation with a peristaltic pump approved by Dornier MedTech.

Follow the directions given in the peristaltic pump operating manual.

WARNING: **There is a risk of embolism. If you use gas-irrigated light guides, do not allow the gas to reach the open bloodstream.**

When gas-irrigated light guides are used in endoscopy, gas continuously flows into the operation area, so that you must very carefully check the gas pressure inside the body in order to avoid injuring the patient.
You must ensure that pressure is released on time. Use of an insufflator with automatic measuring increases safety.

In the case of CO_2 hysteroscopy, gas irrigation must be done only with an insufflator suitable for hysteroscopy. The pump that is available as an accessory is not suitable for hysteroscopy.

4.2.4 Treatment with Liquid Irrigation

You can perform a treatment with liquid irrigation with a peristaltic pump approved by Dornier MedTech.

Follow the directions given in the peristaltic pump operating manual.

CAUTION: **If the light guide is inserted into an instrument that has already been introduced, a base flow must be adjusted in order to prevent body fluids from penetrating into the light guide system.**

4.2.5 Treatment with Instruments

A number of instruments are available as accessories for the Dornier *Medilas D 30/60.*

Follow the directions given in the accessory operating manual.

WARNING: **If the laser beam hits inner parts of the instrument, the user's eyes may be damaged, and the instrument itself may be damaged.**
The light guide must stick out of the distal end of the instrument channel during laser release.

4.3 Preparing for the Startup

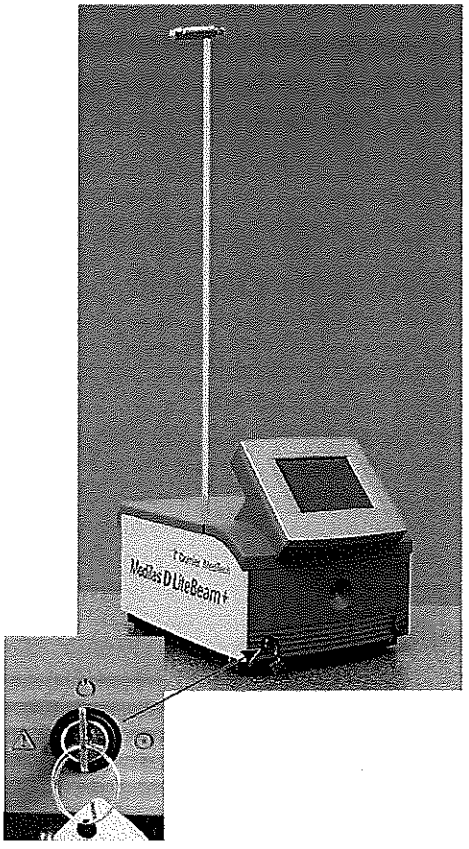
CAUTION **The Dornier *Medilas D 30/60* is a protection class IPX0 unit according to IEC60601-1-2:2007, which means that it is equipped with normal protective measures to prevent dust and liquids from penetrating, and is not water-tight. Incorrect function can result if the air humidity level is high or if water and dust penetrate into the casing. Corrosion of the internal mechanisms and electronics can lead to irreparable damage.**

Sudden changes in temperature (such as when the unit is moved from a warm area with a high level of air humidity to an air-conditioned, cooler room) can result in the formation of condensation on optic components.

For this reason, before starting up the unit, you should make sure that the Dornier *Medilas D 30/60* has been set up in the intended working area for a few hours for acclimatization, in order to avoid destruction of optic components as the result of condensation.

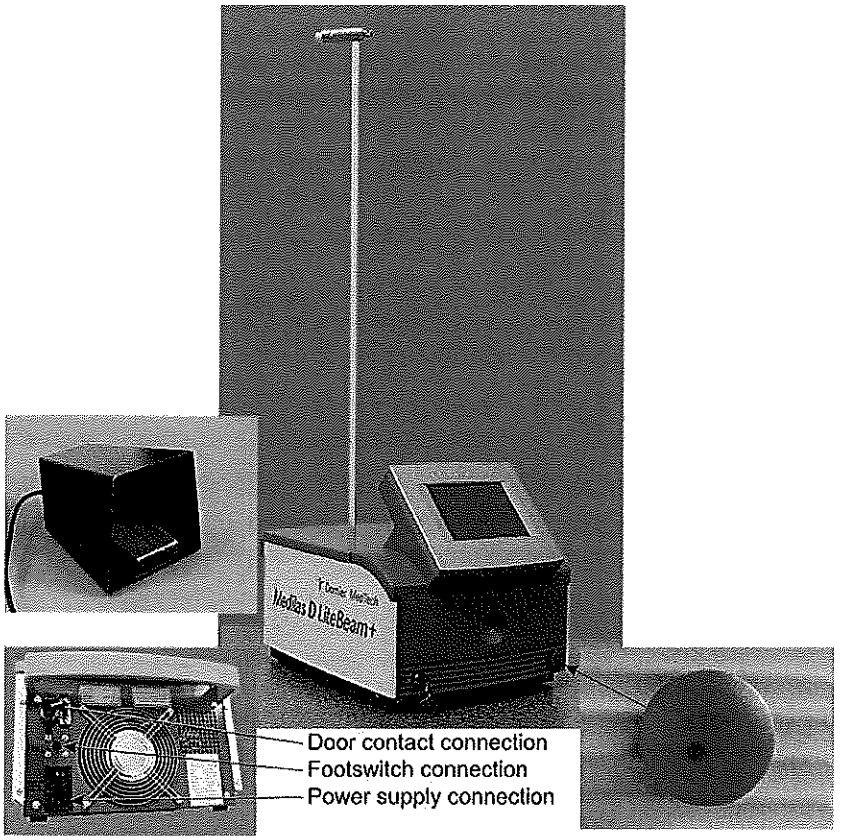
1. Put the Dornier *Medilas D 30/60* into its operating position as shown in Figure 4-1.

Figure 4-1 Operating Position



2. Put the key switch into the "OFF" ◯ position.

3. Clearly mark the laser area (see the chapter "Laser Safety Officer").



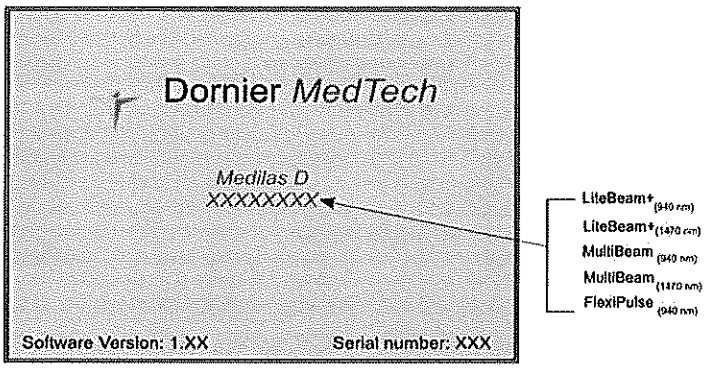
4. If you do not need it, unplug the door contact switch on the Dornier Medilas D 30/60 and replace it with the bridge connector included in the delivery.
5. Connect the footswitch cable to the Dornier Medilas D 30/60.
6. Unlock the red Emergency OFF button by gently pulling, if it is pressed in (locked).
7. Connect the power supply cable to the electric power supply.

4.4 Starting the Dornier *Medilas D 30/60*

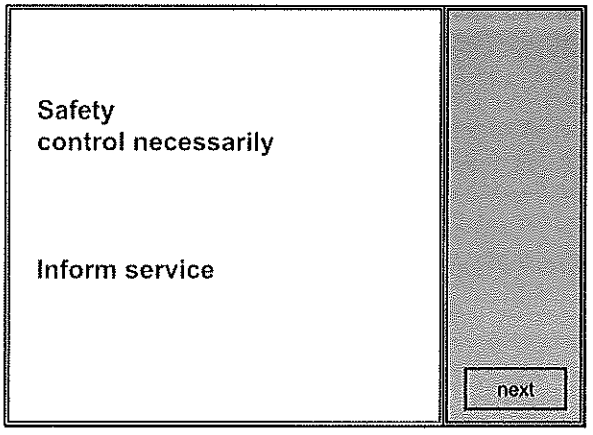
WARNING: **Use of the operating devices or adjustment capabilities in a way other than that described here can result in dangerous radiation.**

1. Carry out the steps for preparing for the startup.
2. Turn the key switch clockwise to the ⊙ position and switch on the Dornier Medilas D 30/60.

The Dornier Medilas D 30/60 accomplishes a display test, afterwards appears for approx. 3 seconds switching on picture shown below.

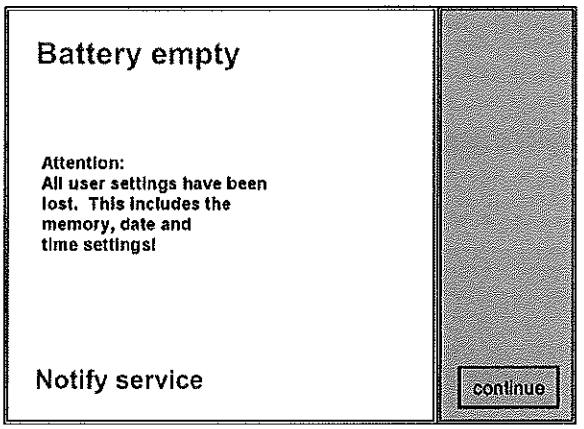


If a safety check is required, the following switching on picture appears.



Confirm this message by pressing the "next" button.

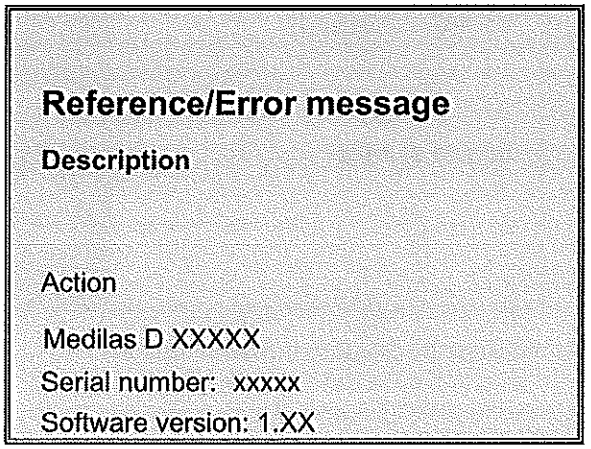
If the supplying batter for the control and system-monitoring device is empty, the following switching on picture appears.



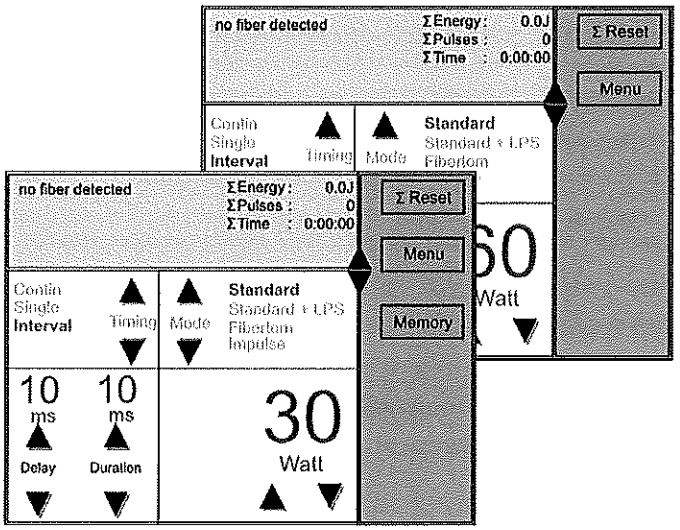
WARNING: **If the supplying battery is empty, all user settings have been lost. This includes the memory, date and time setting! Notify service.**

Confirm this message by pressing the "continue" button.

NOTE: If an error occurs during the startup, the Dornier Medilas D 30/60 displays the following screen with a number and an explanatory text. In this case, please perform the actions requested by the device. If the error still remains, please inform Dornier Service and tell the Service staff member the error message, the software version and the unit's serial number.



If the self-test completes successfully, the Dornier *Medilas D 30/60* displays the following screen, for example:

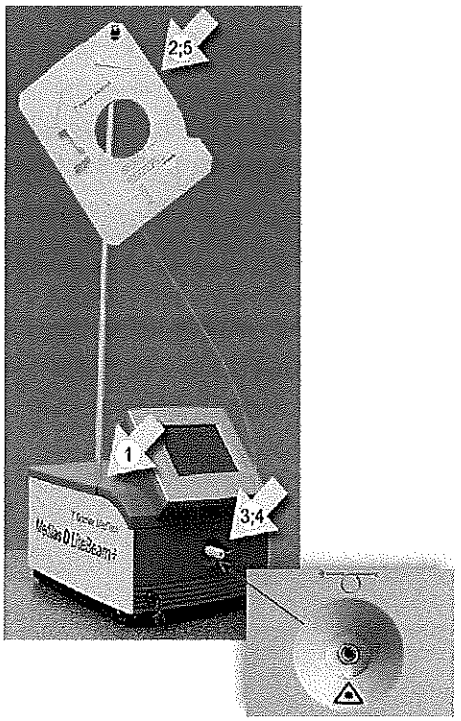


4.5 Connecting the Light Guide

WARNING: Please observe the corresponding information on sterilization and connection in the light guide operating manual.

WARNING: Put on protective goggles.

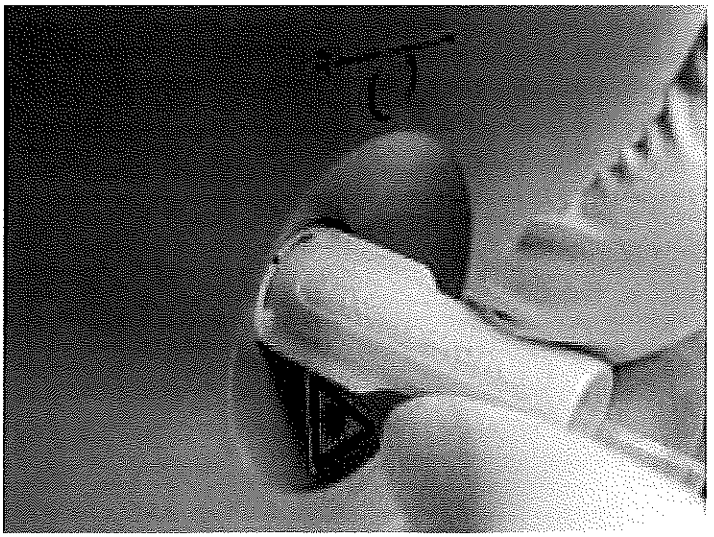
Figure 4-2 Unit with Light Guide Connected



1. Attach the light guide holder to the Dornier *Medilas D 30/60.*
2. *Check the sterile packing of the light guide for damage.*
3. Remove the light guide from the sterile package and carefully weave the fiber out of its fixation on the connector or open and remove the clip.
4. Insert the light guide connector into the unit's light guide connection and turn it carefully clockwise and screw on.

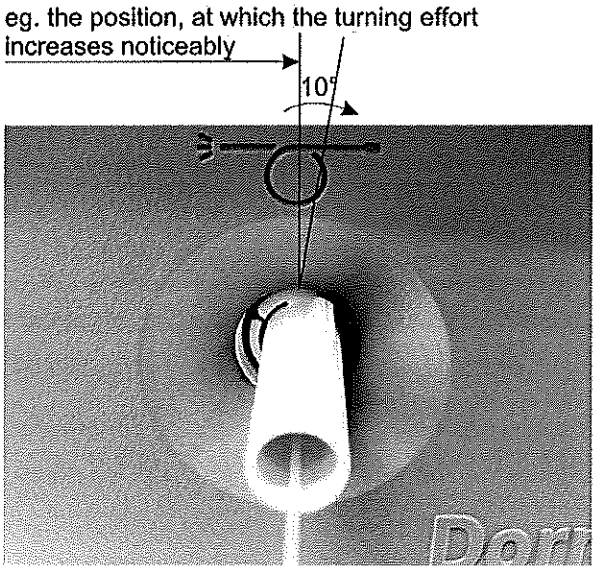
CAUTION: Avoid the excessive application of force when screwing on, in order not to damage the thread of the light guide connector. For screwing on touch the light guide connector only at the narrow end of the handle (Figure 15).

Figure 4-3 Screwing on the light guide connector



Note: **The D-light guide connector must be screwed on to a complete stop until it is fully tightened (approx. a half to whole rotation).**
The D-light guide connector is optimally tightened, if it is turned for another 10° after the turning resistance increases noticeably (Figure 4-4).

Figure 4-4 D-light guide connector optimally tightened

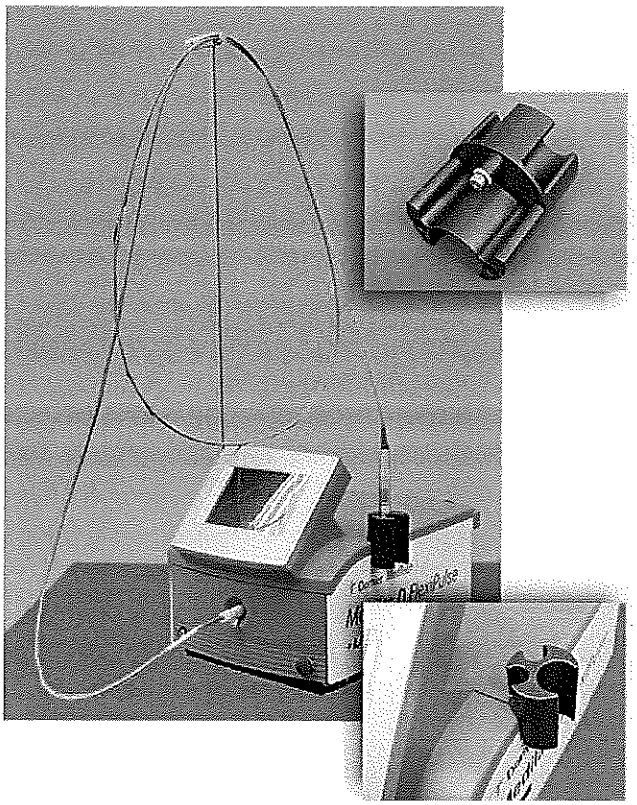


NOTE: SMA-light guide connector must be screwed on to a complete stop until it is fully tightened (about 5 rotations are necessary).
Message "No fiber detected" disappears from the display and the laser button appears.

5. Check the firm fit of the light guide connector.
6. Hang the light guide with cardboard on the light guide holder.

The hand piece holder is contained in the delivery depending on Model variant.

Figure 4-5 Unit with attached hand piece

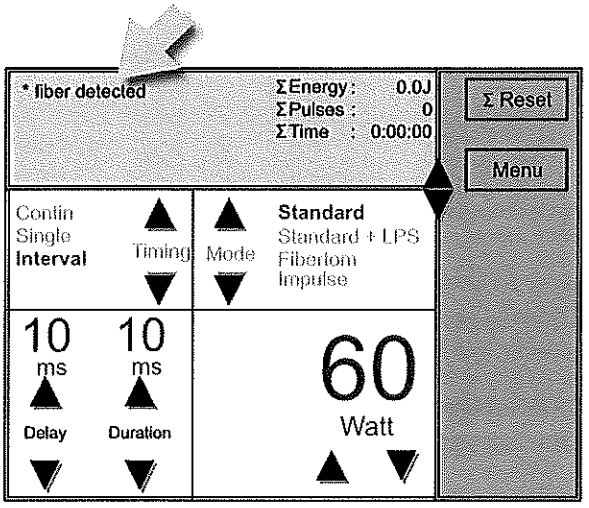


WARNING: Please observe the corresponding information for the hand piece connection in the hand piece operating manual.

The unit recognizes the connection of the light guide and the message on the touch screen"*no fiber connected" will be replaced by the message"*fiber connected".

If the laser device and the light guide are equipped with a fiber identification system, the device recognizes automatically the type of Dornier light guide used and indicates the appropriate message.

For information for the type of light guide consider the accessory catalog and the operating manual of the light guide (for further information, see chapter "Messages", page 6.3.



4.6 Checking the Light Guide

Refer to the light guide operating manual for information on your light guide's radiation characteristic.

CAUTION: **If the radiation characteristic does not correspond to the description in the light guide operating manual, the full functionality of the light guide cannot be achieved. Thus expected treatment success cannot be guaranteed.**

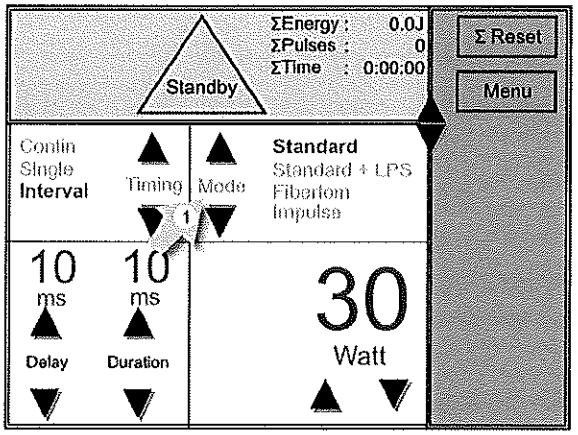
1. Point the pilot light beam at a light surface and check the radiation characteristic (see the light guide operating manual).
2. If necessary, replace the light guide and check the new one.

4.7 Operating Mode Settings

CAUTION: **When switching to a different operating mode, use only light guides that are suitable for the operating mode that you require. Unsuitable light guides could be damaged.**
Observe the information in the light guide operating manual.

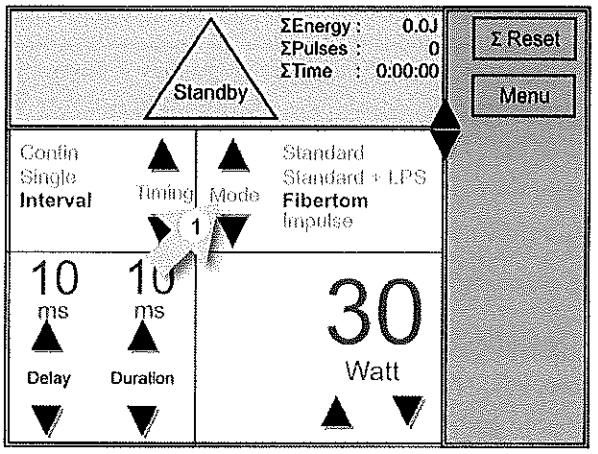
NOTE: The most recently used parameters are stored separately for each operating mode (Standard + LPS, Fibertom® and Impulse), (for information about operating mode, see page 3.5) so that the time and/or power settings may also change when you switch operating modes.

4.7.1 Selecting Standard (+LPS) Mode



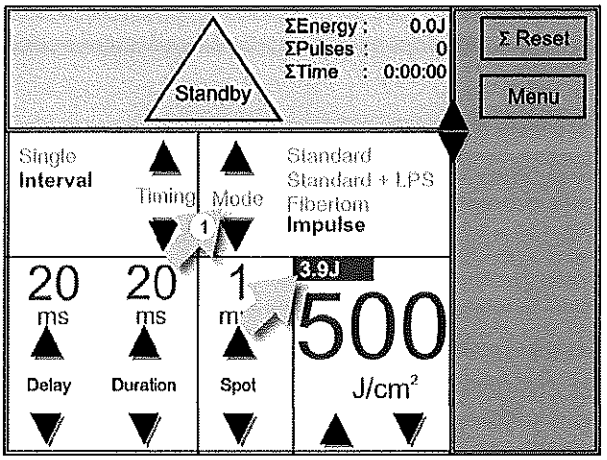
Press the buttons ▲▼ in the Mode field until the **Standard (+LPS)** display is shown in blue.

4.7.2 Selecting Fibertom® Mode



1. Press the buttons ▲▼ in the Mode field until the **Fibertom** display is shown in blue.

4.7.3 Selecting Impulse Mode



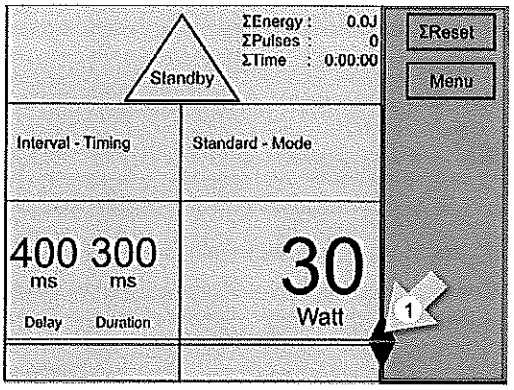
1. Press the buttons ▲▼ in the Mode field until the **Impulse** display is shown in blue.

Additionally, the resulting energy for each pulse is indicated.

During therapy in the impulse mode, the device offers additional optical support. For more information see the chapter Setting the Pilot Laser Mode to "Continuous", page 4.30.

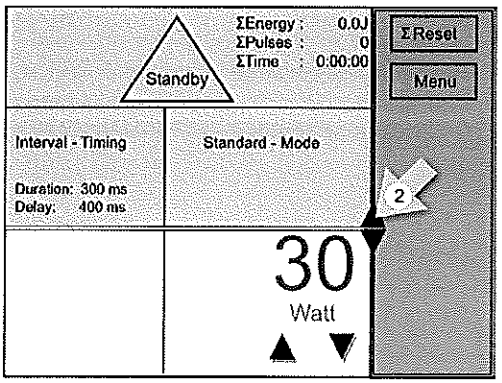
4.7.4 Selecting Restricted Operating Mode

If you will only be altering certain parameters during a treatment and if you want to prevent unintentional alteration of a laser parameter, the Dornier *Medilas D 30/60* can be switched to a restricted operating mode.



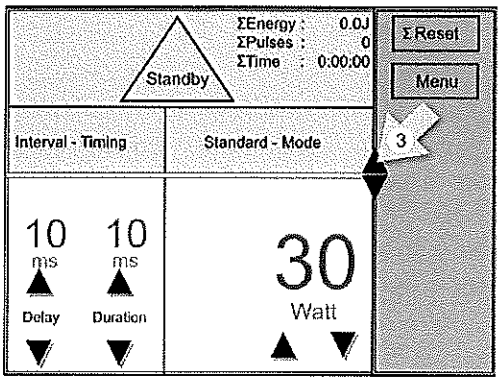
By pressing the selector switch, you can switch to restricted operating mode.

In this case, you are unable to change any laser parameters. They are shown on the display.



By pressing the selector switch again, you have the possibility to reduce the restrictions in the operating mode.

In this case, you can only change the laser power. The rest of the parameters are shown in the grey information field on the display.



By pressing the selector switch one more time, you can further reduce the restrictions in the operating mode.

In this case, you can no longer change the pulse form (Timing) and operating mode. They are now shown in the grey information field on the display.

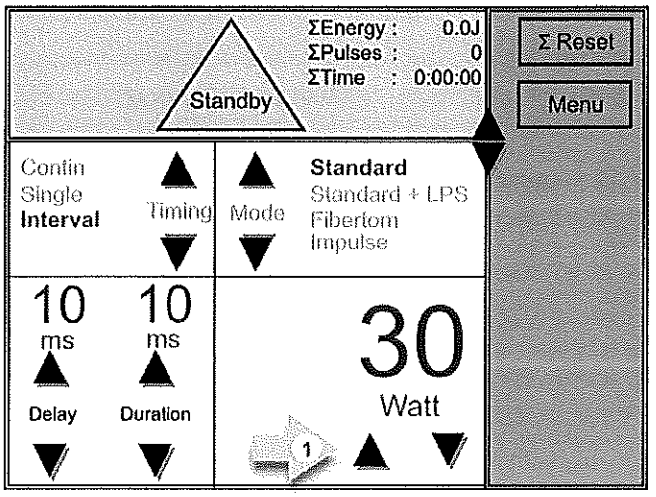
You can use the selector switch to switch back to normal operating mode.

4.7.5 Setting Laser Parameters

You can set various parameters, depending on the operating mode and pulse form that you have selected.

NOTE: When you leave an operating mode, the parameters that you have selected are saved. When you call the operating mode again, the most recently selected parameters are shown again.

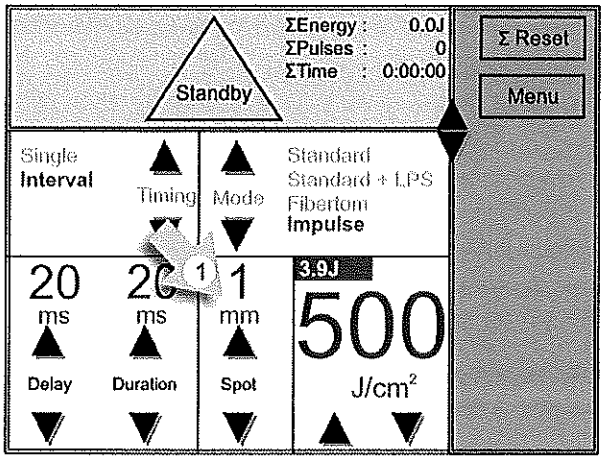
4.7.5.1 Setting the Power



1. Press the ▲ ▼ buttons until the required power is displayed.

4.7.6 Setting the Spot Diameter (in Impulse Mode only)

NOTE: The spot diameter must be adapted to the hand piece used. The spot diameter value is marked on the hand piece (see Table 6 Value Ranges, page 3.9.



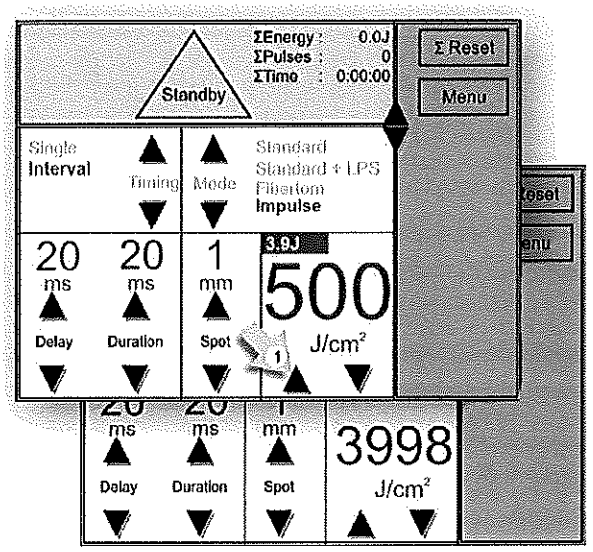
1. Press the ▲ ▼ buttons until the required spot diameter is displayed.

NOTE: If you change the spot diameter or energy density, the minimum possible pulse duration is also calculated and set immediately.

Additionally, the resulting energy for each pulse is indicated. (refer to the information regarding the impulse mode on page 3.6

4.7.7 Setting the Energy Density (in Impulse Mode only)

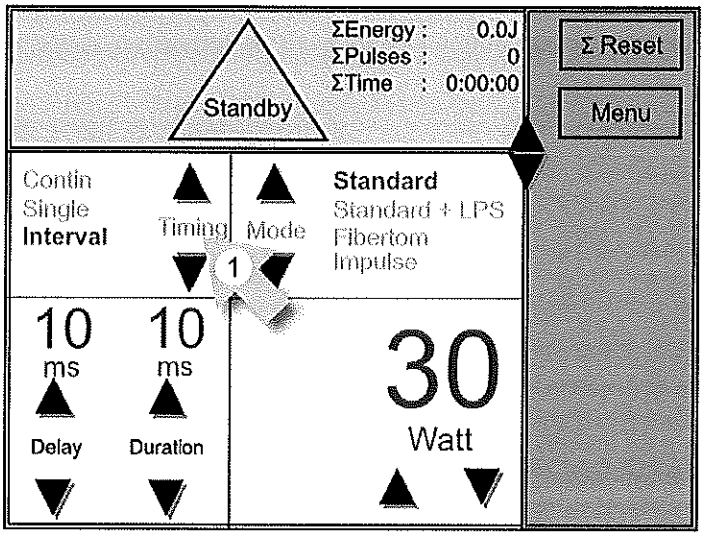
It is recommended, to adapt the spot diameter first to the hand piece used (see Chapter "Setting the Spot Diameter (in Pulse Mode only)") and only then to continue with the setting of the power density.



1. Press the ▲ ▼ buttons until the required energy density is displayed.

   Within the range 10 to 998 J/cm² (three-figure) the number is displayed in maximum size, within the range 1000 to 9998 J/cm² (four-figure) the number changes to the next smaller size.

4.7.8 Setting the Pulse Form

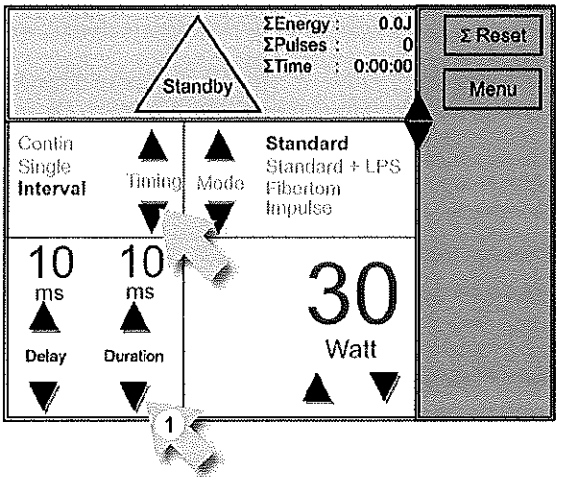


1. Press the ▲ ▼ buttons in the Timing field until the required pulse form is shown in blue text.

NOTE: In Impulse mode, only the single pulse and interval pulse form can be selected.

4.7.9 Setting the Pulse Duration

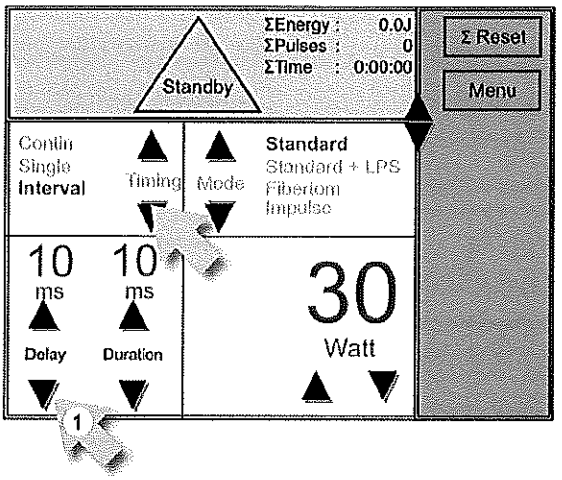
You can only set the pulse duration if you have selected the single pulse or interval pulse form.



1. Press the ▲ ▼ buttons until the required pulse duration is displayed.

4.7.10 Setting the Pulse Delay

You can only set the pulse delay if you have selected the interval pulse form.



1. Press the ▲ ▼ buttons until the required pulse delay is displayed.

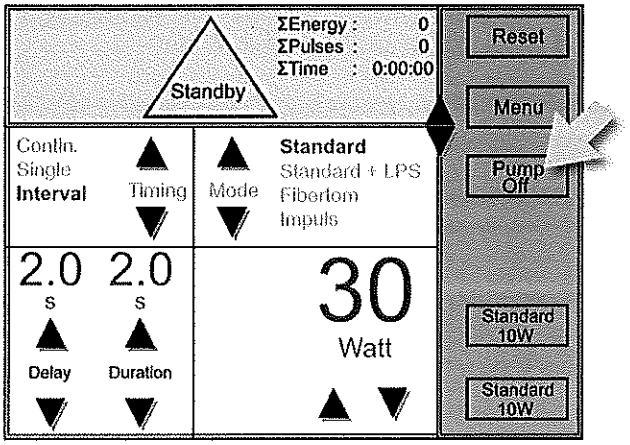
4.8 Peristaltic Pump Settings

Starting from software version 1.20 it is possible to operate the peristaltic pump Dornier PP1800 over the COM interface (see "Electrical and Pneumatic Connections", page 3.2 and "Treatment with Irrigation". page 4.1.

NOTE: Refer to the operating instruction of the peristaltic pump.

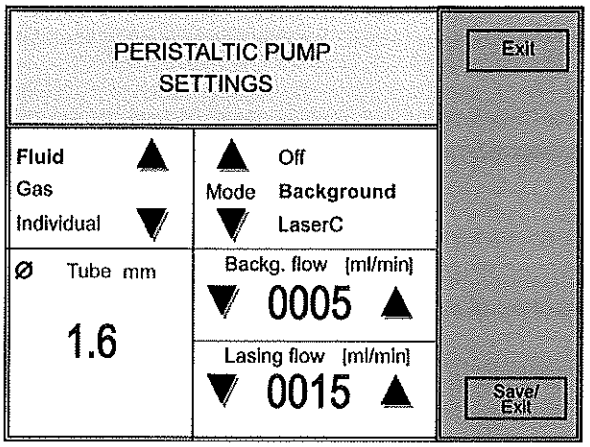
Refer to the section "Accessories for Irrigation", page 3.2.

The unit recognizes automatically, if the peristaltic pump is attached. The button "Pump Off" appears on the screen. The settings for the peristaltic pump are steerable over this button.



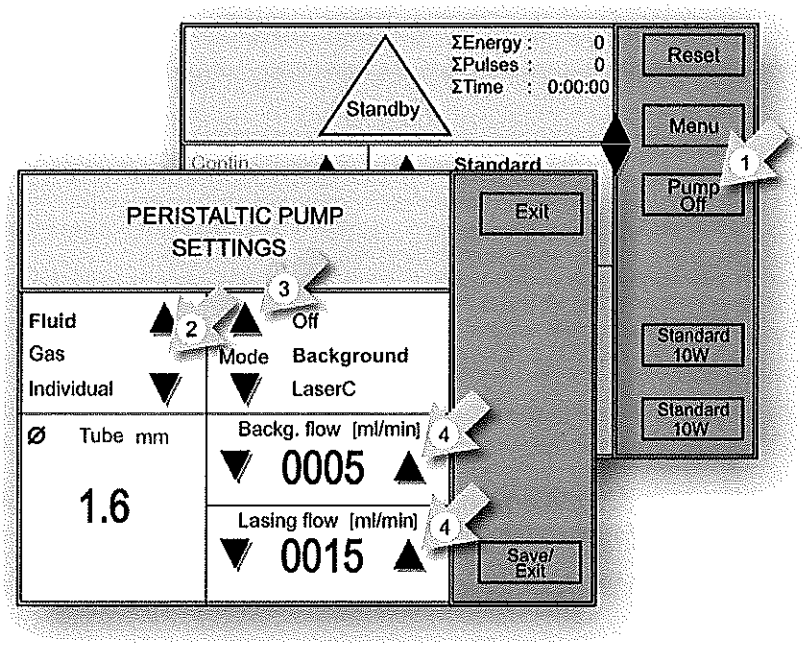
- ***Possible settings for the mode of operation***

off	The peristaltic pump is switched off.
background	The peristaltic pump runs constantly with the flow adjusted before.
laserC	The peristaltic pump runs with two different flows: – background flow - the foot switch is not pressed – lasing flow - the foot switch is pressed



For possible settings for the flow and for the hoses specifications, see the operating instruction of the peristaltic pump Dornier PP-1800.

4.8.1 Switching on and setting the Peristaltic Pump



1. Press the button ☞*Pump Off*.

   The unit changes into the menu "Peristaltic pump settings".

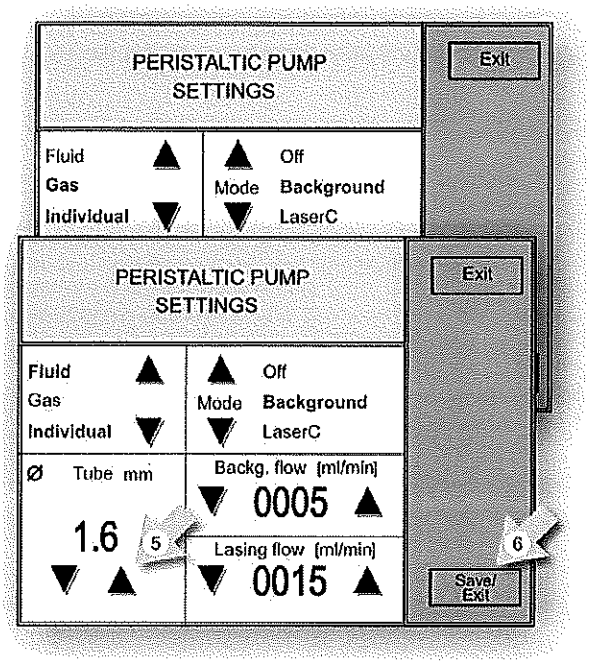
2. Press the buttons ▲ ▼, until the desired cooling agent is indicated in blue.

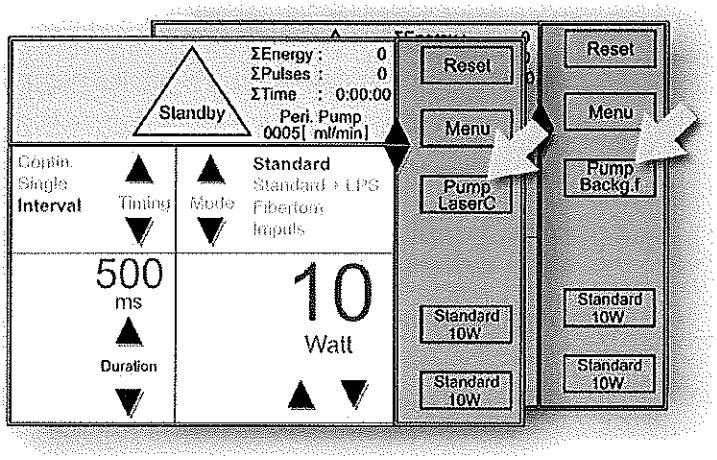
3. Press the buttons ▲ ▼ in the mode field, until the desired operation mode is indicated in blue.

4. Press the buttons ▲ ▼, until the desired flows are adjusted.

NOTE: It is possible to set the background flow to "0" in the "LaserC" operation mode. The pump runs exclusively, if footswitch is pressed down.

For the setting of cooling agent Gas / Individual or Fluid / Individual, additionally the inside diameter of the used hoses must be adjusted.

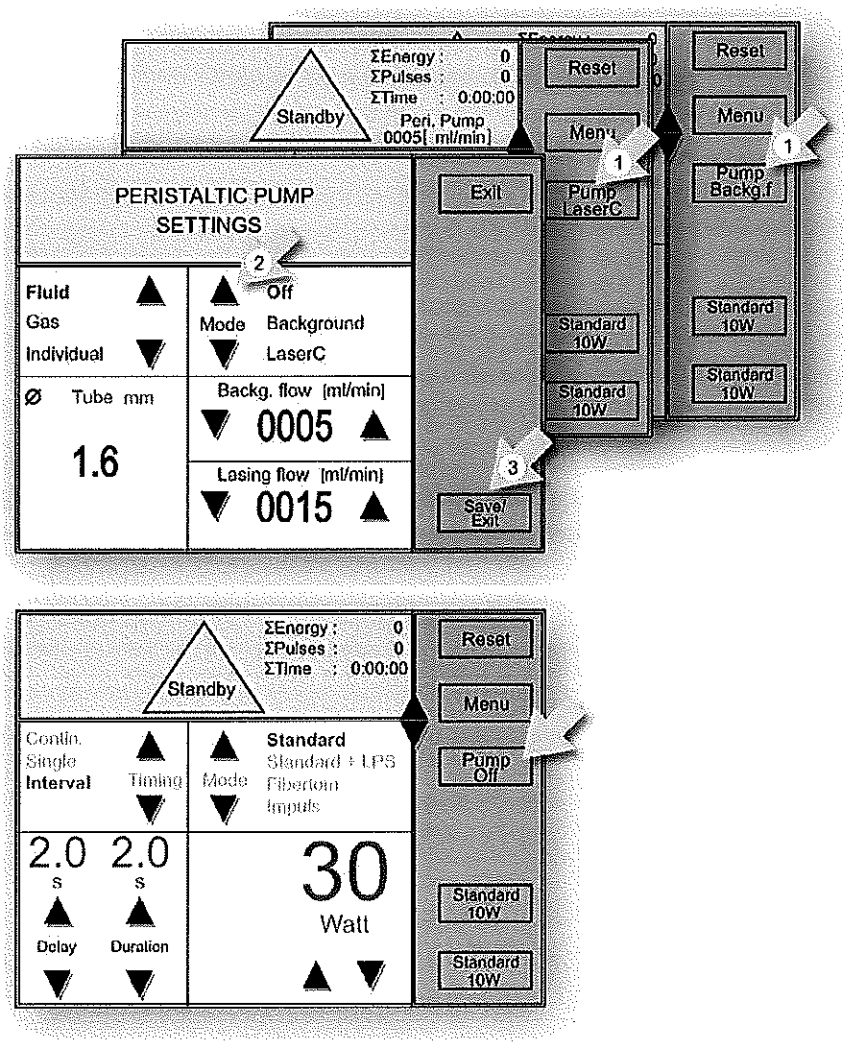




5. Press the buttons ▲ ▼, until the actual hose diameter is adjusted.
6. Press the "Save/Exit" button to save the changes and leave the menu or press the "Exit" button if you do not want to store the changes.

The inscription of the button "Pump Off" changes and indicates the mode of operation of the peristaltic pump. In grey information field the flow rate is faded in.

4.8.2 Switching off the Peristaltic Pump



7. Press the button ☞ *Pump xxx.*

The unit changes into the menu "Peristaltic pump settings".

8. Press the buttons ▲ ▼, until **Off** is indicated in blue.
9. Press the "Save/Exit" button to save the changes and leave the menu.

The inscription of the button "Pump xxx" changes to "Pump Off".

4.9 Releasing Therapy Laser Radiation

WARNING **Warn all people in the laser area before you release the laser beam. All people present in the laser area must wear safety goggles.**

WARNING **You are not permitted to press the laser button until you have targeted the light guide on the operation field.**

WARNING **If you set the Dornier *Medilas D* pilot laser to light intensity level 0, you are permitted to use the Dornier *Medilas D* only for contact treatment.**

WARNING **If you cut with contact and press the fiber against the tissue at a high pressure, the fiber tip may break.**
Avoid using too much pressure when pressing the fiber against the tissue.

WARNING **Under no circumstances are you permitted to remove the light guide from its connection during the therapy.**

WARNING **Visually check the tissue effect continuously during the therapy.**

WARNING **If the light guide is lifted off of the tissue in fibertom® mode, full power can be applied to the tissue if the light guide is not contaminated*. The result is a coagulation effect at high power. If the light guide is contaminated, the power is automatically regulated down to a lower level.**

WARNING **Follow the respective operating manuals for the accessories used.**

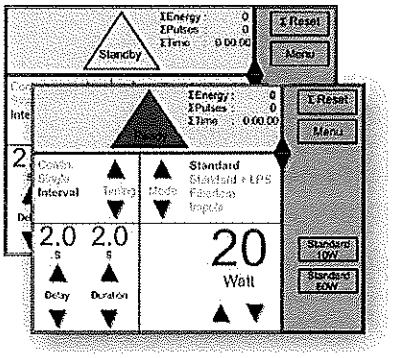
NOTE The light guide must be blackened for contact cutting in fibertom® mode. Blackening is not required for coagulation application.
Instead of tissue, a blood-soaked sterile swab can be used for blackening the light guide.

*Contamination: Pollution with blood or tissue

NOTE If you do not want to burn in the light guide, skip to operating step 4.

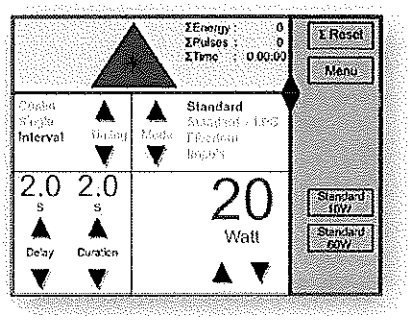
1. Select fibertom® mode.
2. Select pulse form "continuous".
3. Set the power to 20 watts.
4. Press the laser button.

The laser button "Standby " would be replaced by laser button "Ready" and shines after 2 seconds constantly. Thus the foot switch is approved for laser release.



5. If the laser button "Ready" shines constantly, press the footswitch.

During laser radiation the laser button with the laser symbol is flashing and a laser alarm can be heard.



For therapy in the impulse mode, if optical support is switched on, the laser key with the laser symbol flashes during laser radiation in time with the pulse duration. At the same time the warning tone is audible.

If you press the laser button during laser operation, irradiation is interrupted. Laser release is not possible until after you press the laser button again and then press the footswitch.

If you have selected a dosage and then interrupt and resume the treatment, laser radiation will continue to be released until the corresponding dosage has been reached.

4.10 Switching Off the *Dornier* Medilas D

WARNING: Before removing the light guide from the operation field, you must switch the therapy laser to "Standby".

WARNING: Each laser device that is not in use should be protected against unauthorized use, for example, by pulling the key out of the key switch.

1. Put the key switch into the OFF position.
2. Turn off the irrigation, if it is connected.
3. Remove the light guide from the instrument if necessary.
4. Disconnect the irrigation hose from the light guide connector if necessary.
5. Remove the light guide connector from the light guide connection.
6. Clean the Dornier Medilas D as described in the Chapter "Cleaning".

4.11 Transporting the *Dornier* Medilas D

CAUTION: **Strong vibrations can cause misalignments or defects in the Dornier *Medilas D* and necessitate a safety inspection.**
Do not subject the Dornier *Medilas D* to strong vibrations during transport.

Preparing for Transport

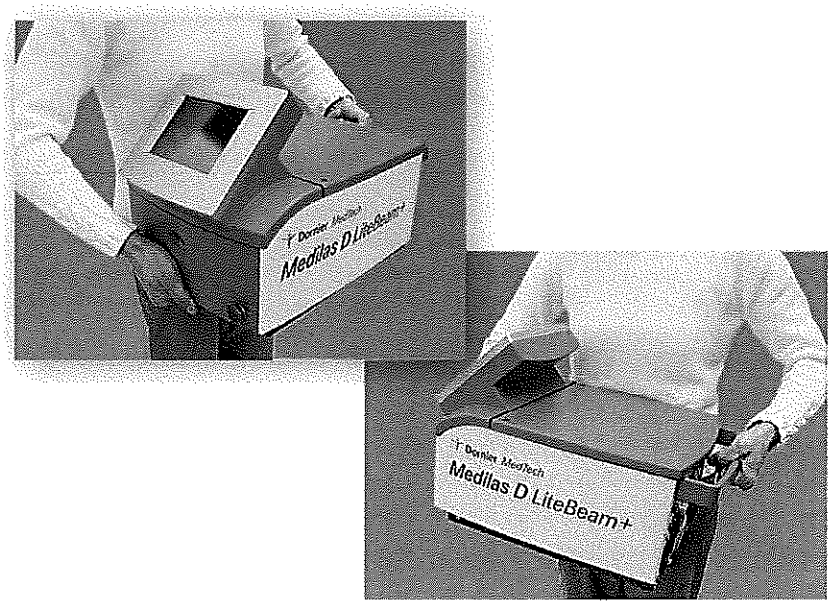
1. Switch off the Dornier Medilas D with the key switch.
2. Pull the power plug out of the power supply.
3. Pull the footswitch cable out of the unit.
4. Pull out the door contact plug, if there is one.

Carrying the Dornier *Medilas D*

CAUTION: **It is possible to damage the unit during transport.**
If the Dornier *Medilas D* is held only on one handle during transport, the unit may be damaged.
You must always transport the Dornier *Medilas D* with both hands.

1. Place the Dornier Medilas D in the carrying position, as shown in the figure, and transport it.

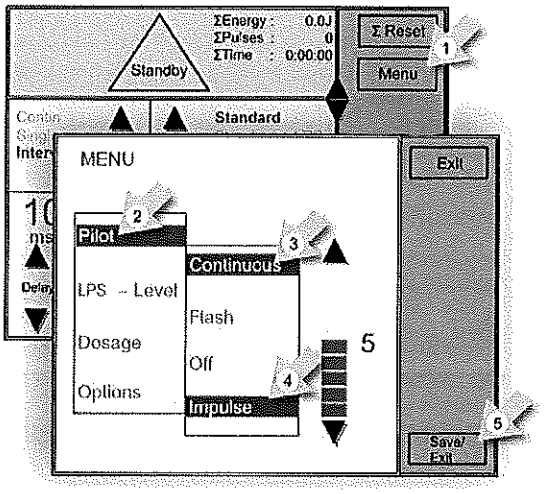
Carrying Position for the Dornier Medilas D



4.12 Menu Settings

Pilot Laser Adjustments

4.12.1 Setting the Pilot Laser to "Continuous"

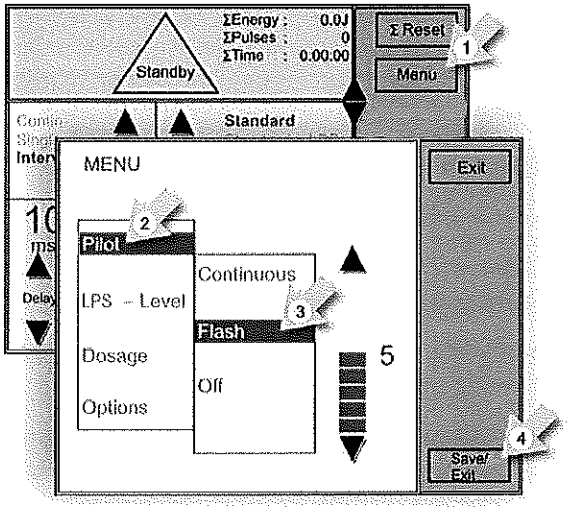


1. Press the "Menu" button.
2. Select the ☞ *Pilot* menu dialog.
3. Select the ☞ *Continuous* setting.

During therapy in the impulse mode, the unit offers additional optical support (starting from the software version 1.20).

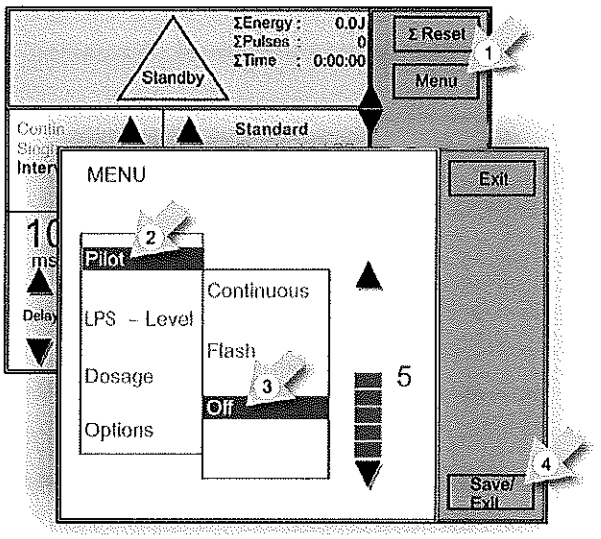
4. As required the option ☞ *Impulse* switch on or off.
5. Press the "Save/Exit" button to save the changes and leave the menu.

4.12.2 Setting the Pilot Laser Mode to "Flash"



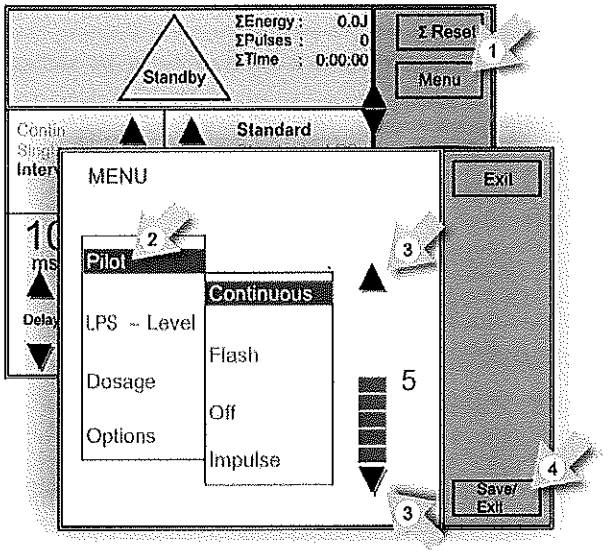
1. Press the "Menu" button.
2. Select the ☞ *Pilot* menu dialog.
3. Select the ☞ *Flash* setting.
4. Press the "Save/Exit" button to save the changes and leave the menu.

4.12.3 Switching off the Pilot Laser



1. Press the "Menu" button.
2. Select the ☞ Pilot menu dialog.
3. Select the ☞ *Off* setting.
4. Press the "Save/Exit" button to save the changes and leave the menu.

4.12.4 Setting the Pilot Laser Light Intensity



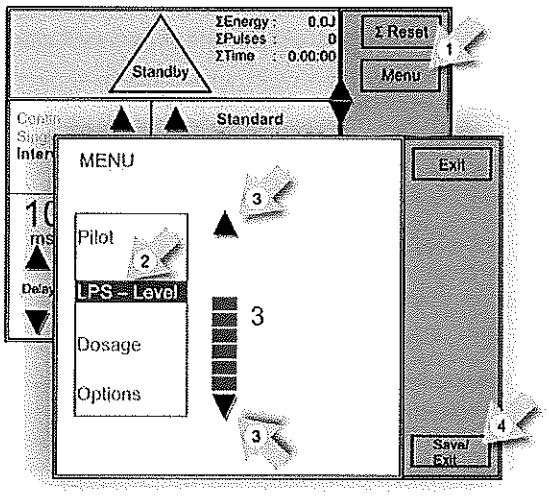
1. Press the "Menu" button.
2. Select the ☞ Pilot menu dialog.

You can control the light intensity setting visually.

3. Press the ▲▼ buttons so often, until the pilot light has achieved the desired light intensity.
4. Press the "Save/Exit" button to save the changes and leave the menu.

NOTE: If you set the Dornier Medilas D 30/60 pilot laser to light intensity level 0, you are permitted to use the Dornier Medilas D 30/60 only for contact procedures.

4.13 Setting the LPS Level

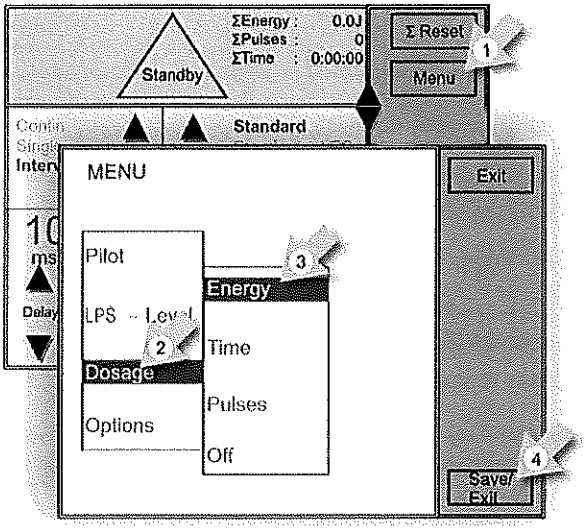


1. Press the "Menu" button.
2. Select the ☞ LPS-Level menu dialog.
3. Press the ▲▼buttons so often, until the LPS level has reached the value that you would like.
4. Press the "Save/Exit" button to save the changes and leave the menu.

4.14 Dosage Settings

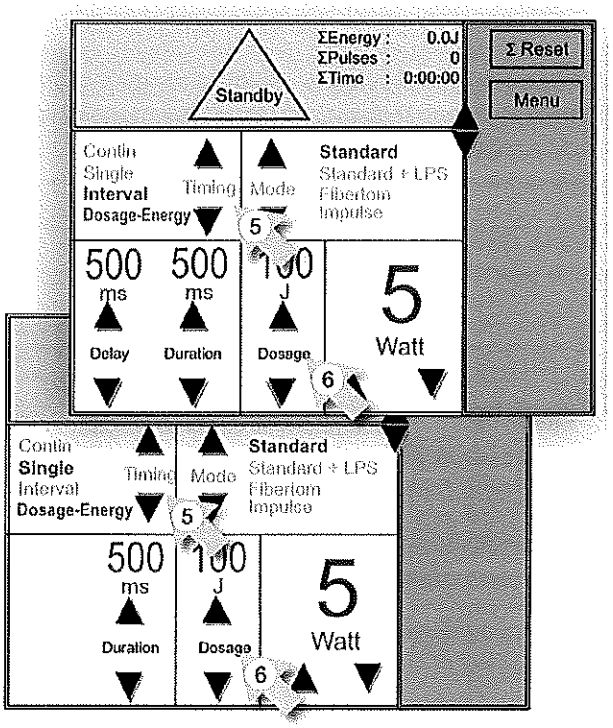
You can only set the dosage if the corresponding function is activated in the menu.

4.14.1 Setting the Dosage in Terms of Energy



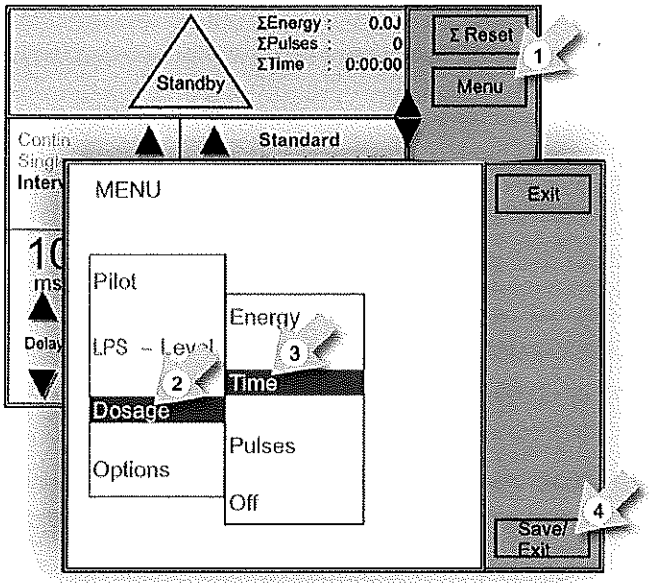
1. Press the "Menu" button.
2. Select the ☞ *Dosage* menu dialog.
3. Select the ☞ *Energy* setting.
4. Press the "Save/Exit" button to save the changes and leave the menu.

NOTE: The Timing field then shows Dosage-Energy; and you can select pulse forms connected with this setting.



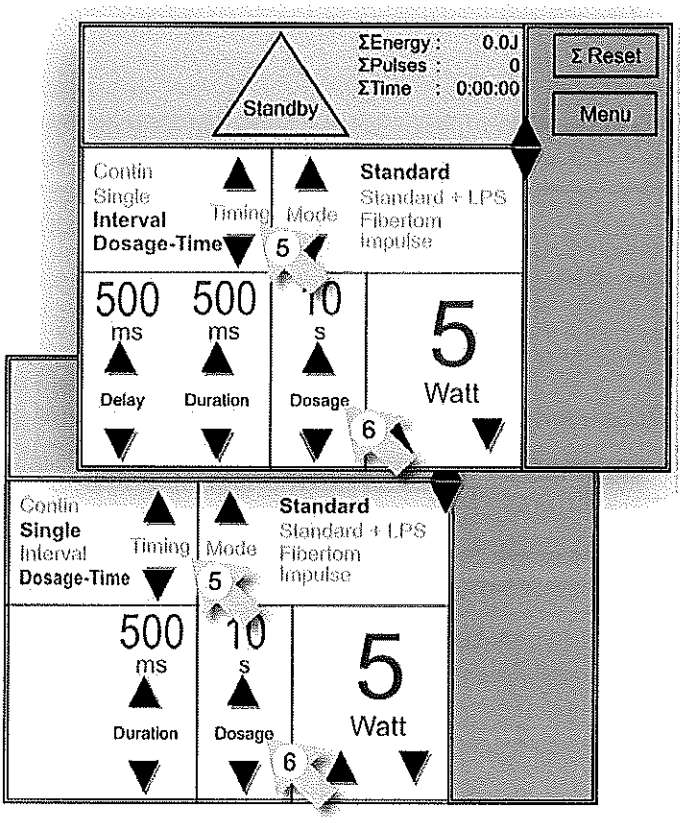
5. Use the ▲▼ buttons in the Timing field to select Interval/Dosage-Energy or Single/Dosage-Energy.
6. Use the ▲▼ buttons in the Dosage field to select the appropriate value.

4.14.2 Setting the Dosage in Terms of Time



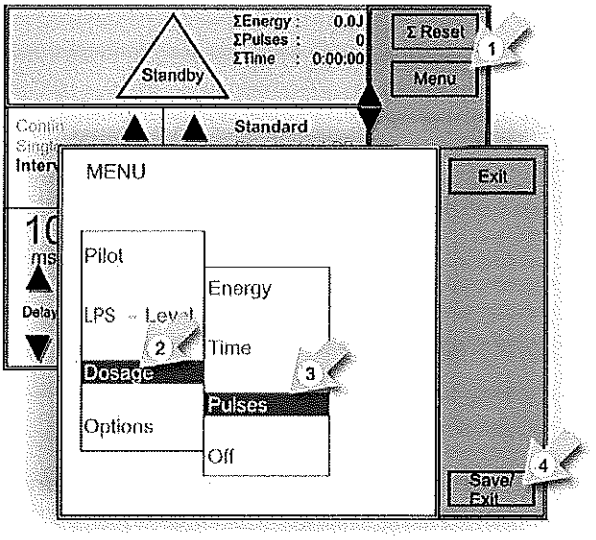
1. Press the "Menu" button.
2. Select the ☞ *Dosage* menu dialog.
3. Select the ☞ *Time* setting.
4. Press the "Save/Exit" button to save the changes and leave the menu.

NOTE: The Timing field then shows *Dosage-Time*; you can select pulse forms connected with this setting.



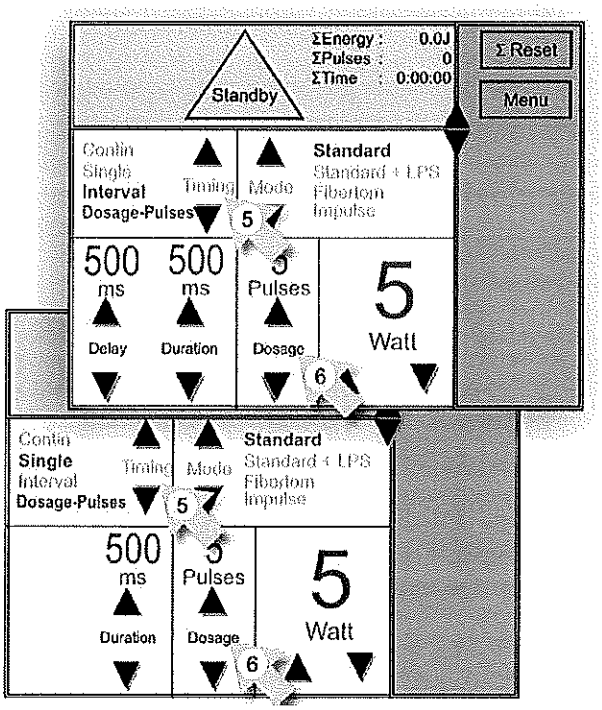
5. Use the ▲ ▼ buttons in the Timing field to select Interval/Dosage-Time or Single/Dosage-Time.
6. Use the ▲ ▼ buttons in the Dosage field to select the appropriate value.

4.14.3 Setting the Dosage in Terms of the Number of Pulses



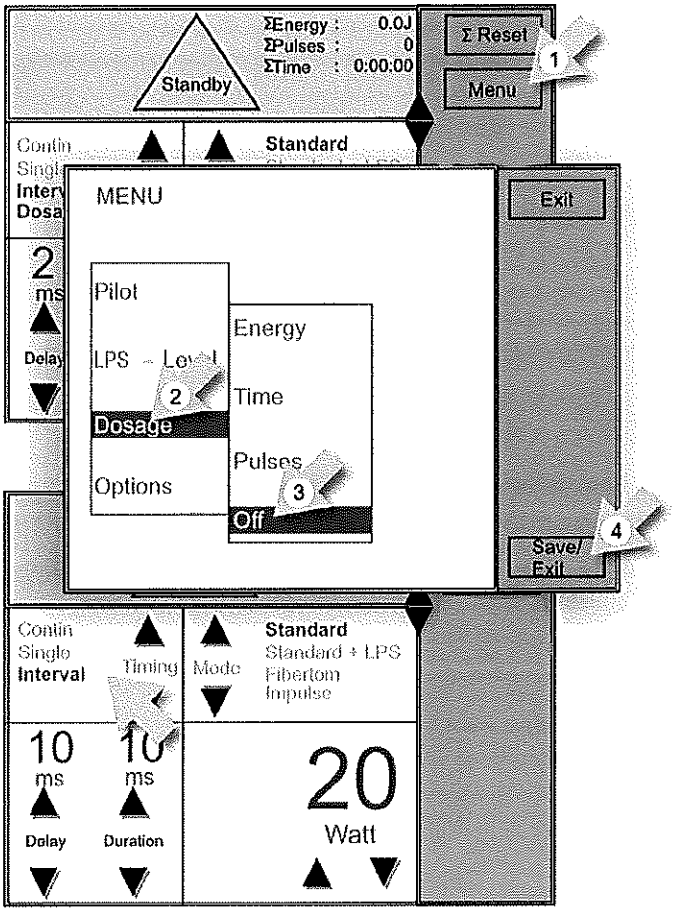
1. Press the "Menu" button.
2. Select the ☞ Dosage menu dialog.
3. Select the ☞ Pulses setting.
4. Press the "Save/Exit" button to save the changes and leave the menu.

NOTE: The Timing field then shows *Dosage-Pulses*; you can select pulse forms connected with this setting.



5. Use the ▲ ▼ buttons in the Timing field to select Interval/Dosage-Pulses or Single/Dosage-Pulses.
6. Use the ▲ ▼ buttons in the Dosage field to select the appropriate value.

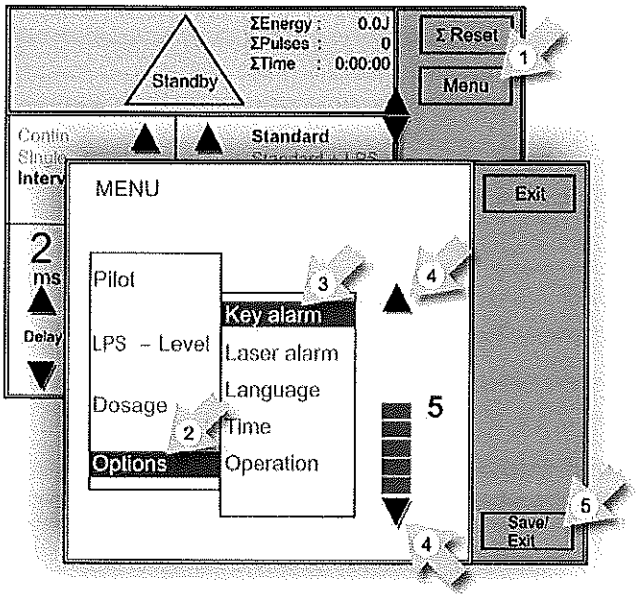
4.14.4 Switching off the Dosage



1. Press the "Menu" button.
2. Select the ☞ Dosage menu dialog.
3. Select the ☞ Off setting.
4. Press the "Save/Exit" button to save the changes and leave the menu.

NOTE: Dosage is no longer shown in the Timing field.

4.15 Adjusting the Key Alarm Volume

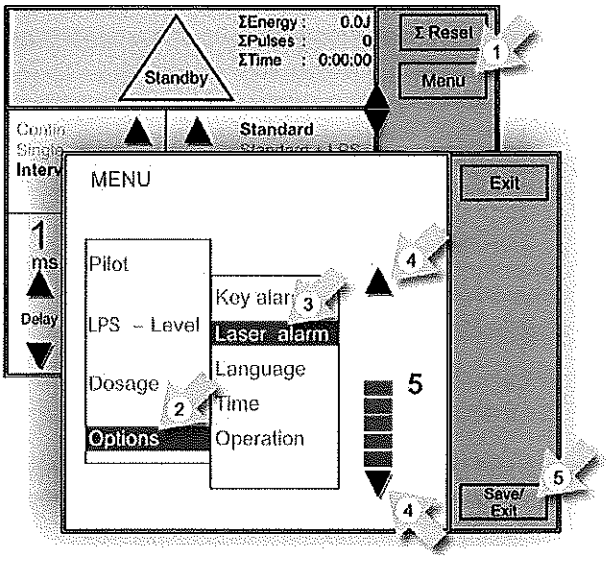


1. Press the "Menu" button.
2. Select the ☞ *Options* menu dialog.
3. Select the ☞ *Key alarm* setting.
4. Use the ▲ ▼ buttons to select the required volume.

The volume can be examined acoustically.

5. Press the "Save/Exit" button to save the changes and leave the menu.

4.16 Adjusting the Laser Alarm Volume

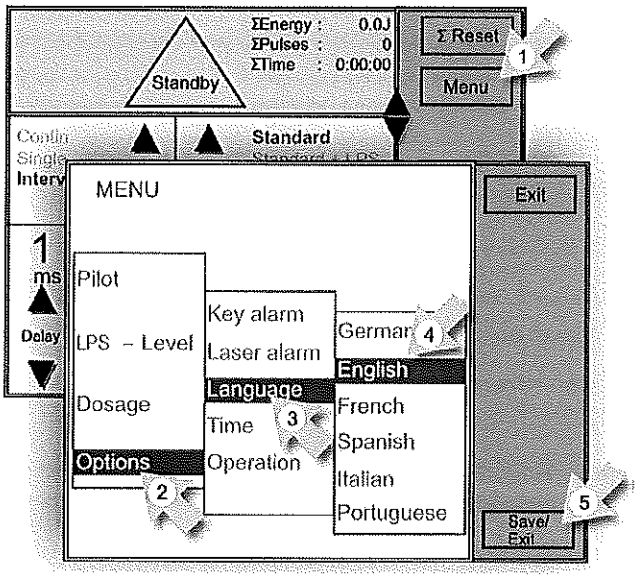


1. Press the "Menu" button.
2. Select the ☞ *Options* menu dialog.
3. Select the ☞ *Laser alarm* setting.
4. Use the ▲ ▼ buttons to select the required volume.

The volume can be examined acoustically.

5. Press the "Save/Exit" button to save the changes and leave the menu.

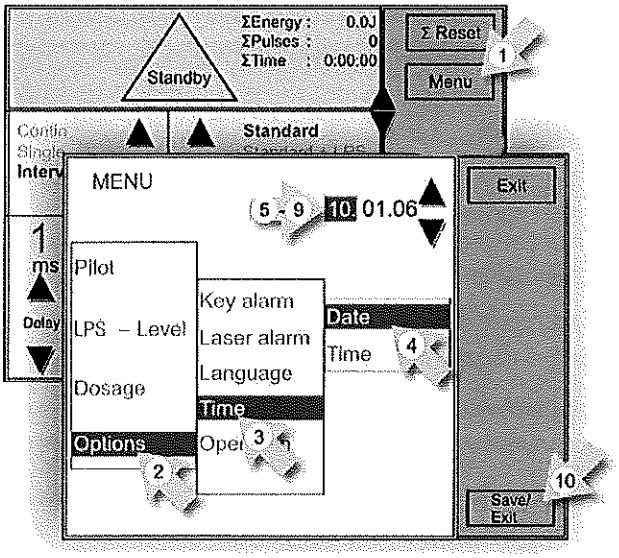
4.17 Language Selection



1. Press the "Menu" button.
2. Select the ☞ *Options* menu dialog.
3. Select the ☞ *Language* setting.
4. Select the language that you want (☞ for example, English).
5. Press the "Save/Exit" button to save the changes and leave the menu.

4.18 Clock/Time Settings

4.18.1 Setting the Date



1. Press the "Menu" button.
2. Select the ☞ *Options* menu dialog.
3. Select the ☞ *Time* setting.
4. Select ☞ *Date*.

The day representation is selected and is shown inversely.

5. Use the ▲▼ buttons to set up the day (e.g.**10**.01.06).
6. Press the month representation.

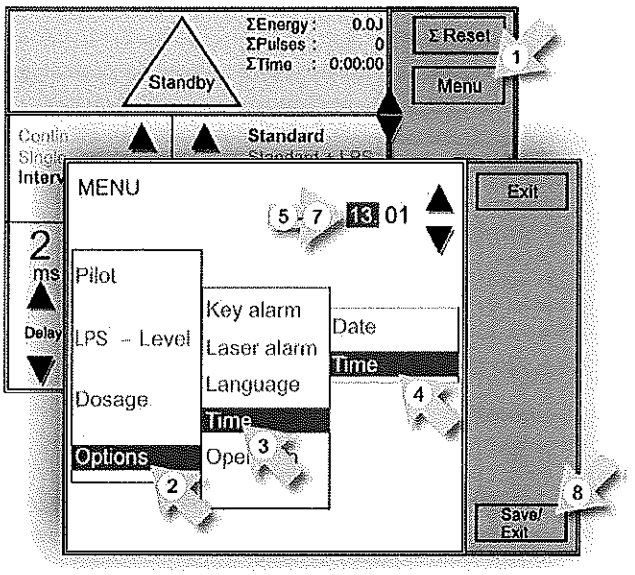
The month representation is selected and is shown inversely.

7. Use the ▲▼ buttons to set up the month (e.g.10.**01**.06).
8. Press the year representation.

The year representation is selected and is shown inversely.

9. Use the ▲▼ buttons to set up the year (e.g.10.01.**06**).
10. Press the "Save/Exit" button to save the changes and leave the menu.

4.18.2 Setting the Time of Day



1. Press the "Menu" button.
2. Select the ☞ Options menu dialog.
3. Select the ☞ Time setting.
4. Select ☞ Time.

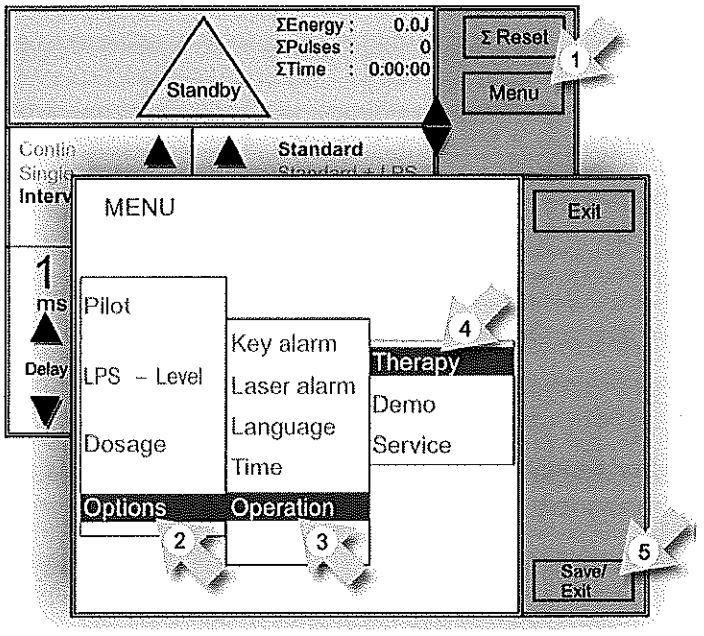
The hour representation is selected and is shown inversely.

5. Use the ▲▼ buttons to set up the hours (e.g. ■.01).
6. Press the minute representation.

The minute representation is selected and is shown inversely.

7. Use the ▲▼ buttons to set up the minutes (e.g.13.■).
8. Press the "Save/Exit" button to save the changes and leave the menu.

4.19 Selecting Operation

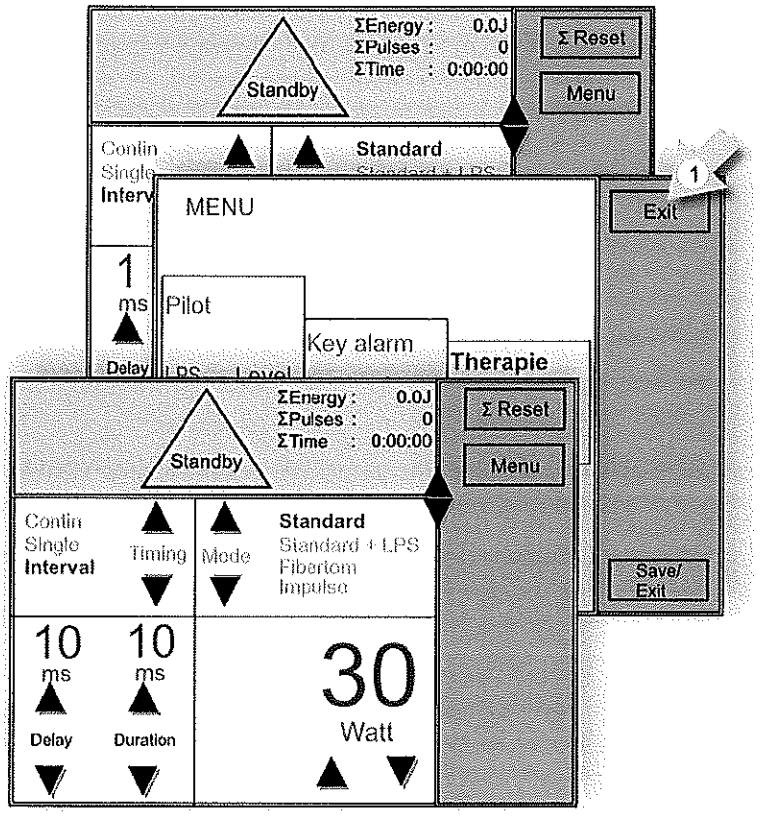


1. Press the "Menu" button.
2. Select the ☞ *Options* menu dialog.
3. Select the ☞ *Operation* setting.
4. Select the required operating mode in the Operation menu. (☞ for example, Therapy).
5. Press the "Save/Exit" button to save the changes and leave the menu.

Demo operation can only be used for demonstration purposes.
No treatment is possible.

Service mode is only accessible for service staff.
No treatment is possible.

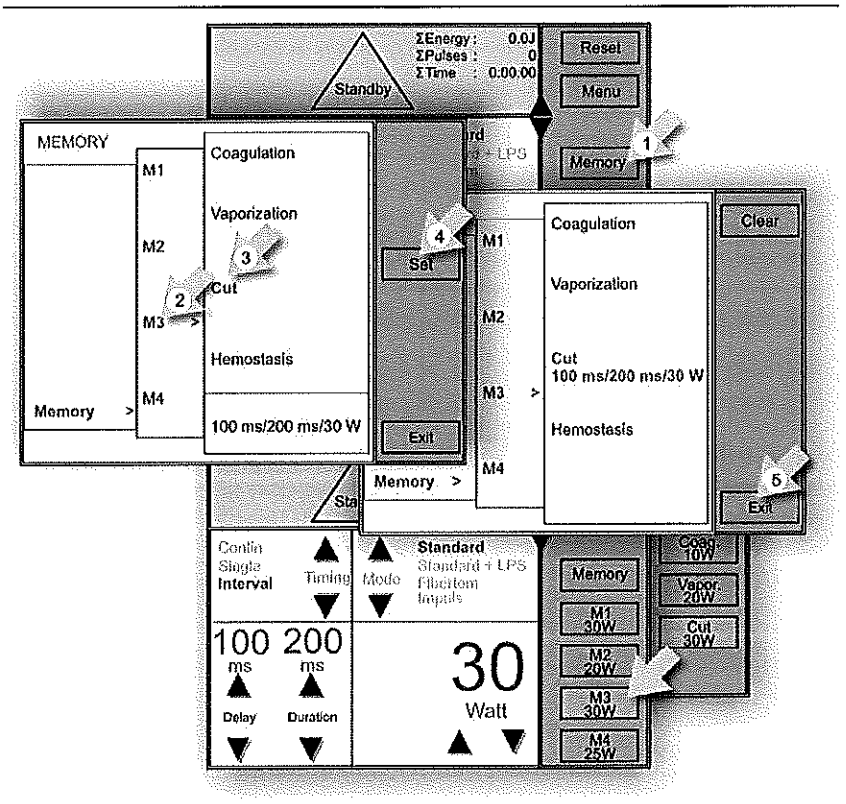
4.20 Ending a Menu without Saving Changes



1. Press the "Exit" button to go to therapy mode without saving the changes.

4.21 Using the Memory Function (Button "Memory")

4.21.1 Storing the Parameter Settings



Select the parameters that you require in therapy mode.

1. Press the "Memory" button.
2. Select a storage place (e.g., M3).
3. Optional select a storage name (e.g., cut).

If you do not select a storage name, the parameters will be saved in the storage place (e.g., M3).

4. Press the "Set" button.

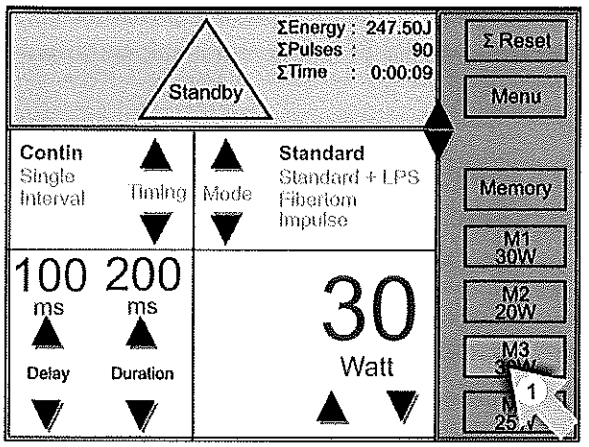
The parameters that you set in therapy mode are stored in the selected storage place.

NOTE: The pilot lasers intensity will be stored; however, not the pilot lasers mode.

5. Press the "Exit" button to go to therapy mode.

Now, in the therapy mode the Hot keys with stored parameters are available.

4.21.2 Calling up the Therapy Parameters

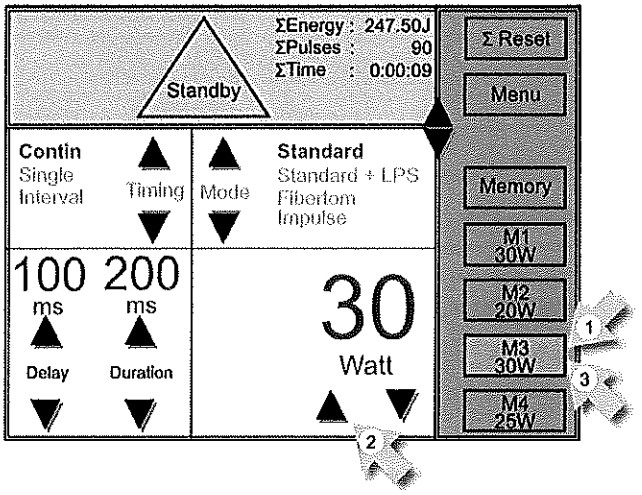


You can call up stored therapy parameters from the Memory with the hot keys.

1. Press the required therapy button (hot key) (e.g., M3 30W).

The M3 30W indication is now active in therapy mode and the corresponding button is highlighted in gray.

4.21.3 Changing Therapy Parameters



You can adjust the stored therapy parameters to meet your actual therapy requirements.

1. Press the required therapy button (hot key) (e.g., M3 30W).

The M3 30W indication is now active in therapy mode and the corresponding button is highlighted in gray.

2. Change parameters with the respective ▲▼ buttons.

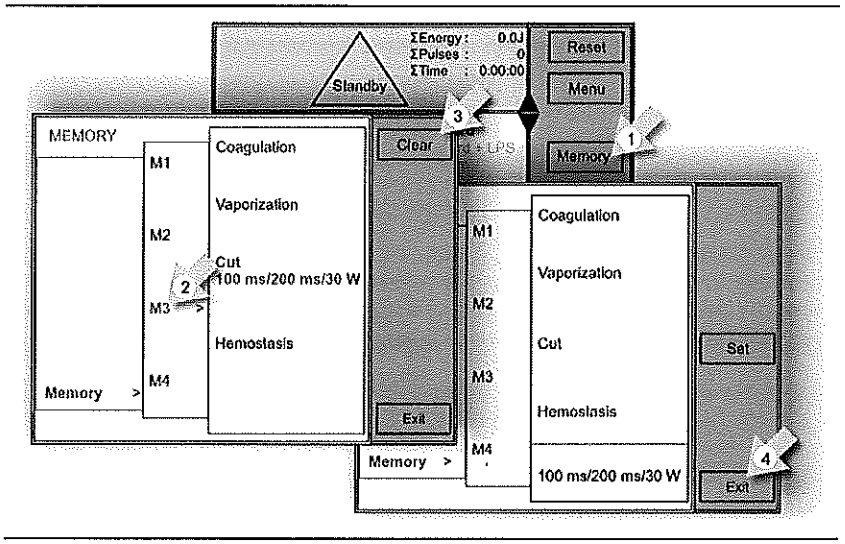
If you change a parameter, the selected therapy is deactivated.

3. Press the hot key that you want to change for at least 2 s to store the data.

The Memory incorporates the changed values.

NOTE: The pilot lasers intensity will be stored; however, not the pilot lasers mode.

4.21.4 Clearing Parameter Settings



1. Press the "Memory" button.

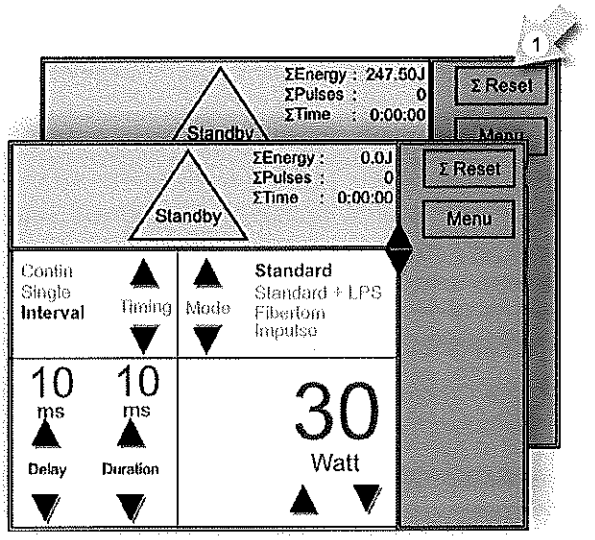
2. Select a storage place (e.g., M3).

3. Press the "Clear" button.

The parameters are removed from the selected storage place.

4. Press the "Exit" button to go to therapy mode.

4.22 Clearing the Log



The Dornier *Medilas D 30/60* automatically logs the total of all emitted pulses, the total applied energy and the total application time.

You can clear the log in the gray information field by pressing the "ΣReset" button.

2. Press the "ΣReset" button to clear the data saved in the log.

If the "ΣReset" button is pressed again, the data deleted last are again indicated for the duration by 5s.

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5 SPECIFICATIONS

This Section lists technical data and system classification for the Dornier *Medilas D 30/60.*

5.1 Technical Data Dornier Medilas D LiteBeam+ (940 nm)

Parameter	*Data*
Electrical connection	
Voltage	115-230 VAC
Frequency	50/60 Hz
Power consumption *940 nm*	0,5 kVA
Line fusing	8 A, medium time lag
Climate (during operation)	
Ambient temperature	+15° C to +30° C
Relative humidity	30% to 85%
Atmospheric pressure	700 hPa to 1060 hPa
Dimensions and weight	
Height	Body: 192 mm; incl. monitor: 303 mm
Width	297 mm
Length	Body: 375 mm; incl. monitor and handle: 464 mm
Weight	approx. 11,5 kg
Noise emission	
Maximum	L ≤ 65 dB
Noise during standby operation	L < 50 dB
Therapy laser	
Wavelength	940 nm
Laser power cw *940 nm*	2 – 30 Watt
Peak power (nom.)	40 Watt
Laser power distribution	Gauss profile
Pulse duration	0,010 s to 10 s and key down (cont.)
Pulse interval	0,010 – 10 s
Dosage	
Time	10s to 50s (in 10s steps); 1min to 10min(in 1min steps)
Pulses	5 – 150 pulses
Energy	100J – 10 kJ
Pilot laser	
Wavelength (red pilot laser)	640 nm
Wavelength (green pilot laser)	532 nm (optional)
Laser power	0 to 1 mW
Fiber	
Core diameter	min. 400 µm
NA	min. 0,22

5.2 Technical Data Dornier Medilas D MultiBeam (940 nm)

Parameter		*Data*
Electrical connection		
Voltage		115-230 VAC
Frequency		50/60 Hz
Power consumption		0,7 kVA
Line fusing		8 A, medium time lag
Climate (during operation)		
Ambient temperature		+15° C to +30° C
Relative humidity		30% to 85%
Atmospheric pressure		700 hPa to 1060 hPa
Dimensions and weight		
Height		Body: 192 mm; incl. monitor: 303 mm
Width		297 mm
Length		Body: 375 mm; incl. monitor und handle: 464 mm
Weight	*940 nm*	approx. 14,5 kg
Noise emission n		
Maximum		L ≤ 65 dB
Noise during standby operation		L < 50 dB
Therapy laser		
Wave length		940 nm
Laser power cw	*940 nm*	2 – 60 Watt
Peak power (nom.)	*940 nm*	80 Watt
Laser power distribution		Gauss profile
Pulse duration		0,010 s to 10 s and key down (cont.)
Pulse delay		0,010 – 10 s
Dosage		
Time		10s to 50s (in 10s steps); 1min to 10min(in 1min steps)
Pulses		5 – 150 Pulse
Energy		100J – 10 kJ
Pilot laser		
Wavelength (red pilot)		640 nm
Wavelength (green pilot)		532 nm (optional)
Laser power		0 to 1 mW
Fiber		
Core diameter		min. 400 µm
NA		min. 0,22

5.3 Technical Data Dornier Medilas D FlexiPulse (940 nm)

Parameter	*Data*
Electrical connection	
Voltage	115-230 VAC
Frequency	50/60 Hz
Power consumption	0,7 kVA
Line fusing	8 A, medium time lag
Climate (during operation)	
Ambient temperature	+15° C to +30° C
Relative humidity	30% to 85%
Atmospheric pressure	700 hPa to 1060 hPa
Dimensions and weight	
Height	Body: 192 mm; incl. monitor: 303 mm
Width	297 mm
Length	Body: 375 mm; incl. monitor und handle: 464 mm
Weight	approx. 15,5 kg
Noise emission n	
Maximum	L ≤ 65 dB
Noise during standby operation	L < 50 dB
Therapy laser	
Wave length	940 nm
Laser power cw	2 – 60 Watt
Peak power (nom.)	120 Watt
Laser power distribution	Gauss profile
Pulse duration	0,010 s to 10 s and key down (cont.)
Pulse delay	0,010 – 10 s
Dosage	
Time	10s to 50s (in 10s steps); 1min to 10min(in 1min steps)
Pulses	5 – 150 Pulse
Energy	100J – 10 kJ
Pilot laser	
Wavelength (red pilot)	640 nm
Laser power	0 to 1 mW
Fiber	
Core diameter	min. 400 µm
NA	min. 0,22

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6 MAINTENANCE AND TROUBLESHOOTING

This section contains information on:

- Cleaning
- Disinfection and sterilization
- Maintenance by the operator
- Safety inspections
- Messages
- Disposal

WARNING: **Only authorized personnel are permitted to carry out maintenance work on the Dornier Medilas D 30/60. Authorized persons are exclusively persons who have been trained by Dornier MedTech or by a company authorized by Dornier MedTech. One example of personnel authorized for maintenance work on the Dornier Medilas D 30/60 would be Dornier Service employees.**
Servicing by unauthorized persons can result in critical injuries to persons and/or serious damage to the Dornier Medilas D 30/60.

NOTE: The operating manual for each of the accessories describes the maintenance procedure for the particular accessory. Comply with the information in the operating manuals for the accessories.

6.1 Cleaning

WARNING: **Before cleaning the Dornier *Medilas D 30/60*, you must switch off the power supply of the unit. You are not permitted to expose parts of the Dornier *Medilas D 30/60*, in particular electrical parts, to splashed water.**

CAUTION: **You are only permitted to wipe the outside of the Dornier Medilas D 30/60 with a cloth dampened with detergents normally found in hospitals. You must be especially careful and gentle when cleaning the display.**

NOTE: The operating manual for each of the accessories describes the cleaning and disinfection procedure (if necessary sterilization) for the particular accessory. Comply with the information in the operating manuals for the accessories.

1. Switch off the Dornier *Medilas D 30/60* with the key switch.
2. Pull out the power plug.
3. Clean the Dornier *Medilas D 30/60.*

6.2 Disinfection and Sterilization

WARNING: **Before disinfecting the Dornier *Medilas D 30/60*, you must switch off the power supply of the unit. You are not permitted to disinfect the Dornier *Medilas D 30/60* with gas and/or spray disinfecting agents. You must comply with the manufacturer's information and legal regulations regarding disinfection and explosion protection.**

NOTE: The operating manual for each of the accessories describes the disinfection procedure for the particular accessory. Comply with the information in the operating manuals for the accessories.

1. Switch off the Dornier Medilas D 30/60 with the keyswitch.
2. Pull out the power plug.
3. Disinfect the Dornier Medilas D 30/60.

6.3 Maintenance by the Operator

CAUTION: **Trained and authorized hospital personnel can carry out routine maintenance work.**

NOTE: Authorized persons are exclusively persons who have been trained by Dornier MedTech or by a company authorized by Dornier MedTech.

The following routine maintenance work must be carried out:

Table 6-1 Routine Maintenance Work

Maintenance work	Interval
Check and clean outside surfaces	Before/after use
Check the disinfection and sterilization of accessories	Before/after use
Check the footswitch with hose	Before/after use
Check the laser warning light on the OR door	Before/after use
Check electric cables (flex and accessories cables)	Before/after use

6.4 Safety Inspections

WARNING: **Only authorized personnel are permitted to carry out safety inspections of the Dornier *Medilas D 30/60*. Authorized persons are exclusively persons who have been trained by Dornier MedTech or by a company authorized by Dornier MedTech.**

Safety inspections by unauthorized persons can result in critical injuries to persons and/or serious damage to the Dornier *Medilas D 30/60*.

WARNING: **Verifying that the laser power at the fiber end matches the value selected at the control panel is an obligatory component of the safety inspection. You can verify the laser power at the fiber end with a commercial laser power meter that is calibrated and suitable for the wavelength.**

Safety inspections include maintenance, adjustment and calibration work done at routine intervals.

NOTE: The interval for the Dornier Medilas D 30/60 is set at every 300 operating hours or at least every 12 months. If the interval is exceeded, a message appears on the Dornier Medilas D 30/60 display.

A function and safety inspection should be performed after each repair and after a change of location outside the hospital or doctor's office

6.5 Messages

Messages are shown in the display. An acoustic alarm can accompany a message.

Table 6-2 Messages

Message	Meaning	Action, reference
* No fiber detected	No light guide is connected	Check that the light guide is correctly connected
* Remote - interlock	Interruption in door contact	Check that the door contact switch is connected
* Footswitch	Footswitch contact does not open	Complete therapy and then notify Dornier Service
* LPS - Alarm	Triggered by the "Light guide Protection System" (LPS)	Check the light guide
* Overtemp. Please wait	Device has switched to "Standby" because the device temperature was too high.	Wait until the device is ready for operation again (do not switch off power). If the message is still displayed after 2-5 minutes, please inform Dornier Service.
* Undertemp. Please wait	Device has switched to "Standby" because the device temperature was too low.	Wait until the device is ready for operation.
* Fiber socket > 50°C	Light guide connection is too hot.	Interrupt laser operation until the message disappears. If the message appears again, change the light guide.

* Slight shutter damage	Function of the safety equipment for the laser diode is restricted	After completing the treatment, notify Service.
* Peri. Pump – Error	The connection between the unit and the peristaltic pump is interrupted.	Check connection to the unit. Restart the unit or switch off the peristaltic pump over the touch screen.

Table 6-3 ***Additional messages, if the laser device and the light guide are equipped with a fiber identification system***

Message	Meaning	Action, reference
* Fiber connected	Fiber is not Dornier light guide	Light guide is ready for operation.
„600µm single Bare fiber"; „600µm reuse(5x) Bare fiber" (Note: message is an example only)	The laser unit can communicate with a transponder. Transponder data are read and stored in the laser unit.	Light guide is ready for operation.
* Usage cycles detected: X	The number of registered cycles.	Light guide is ready for operation.
* Power setting for fiber not possible	The middle power setting for the unit is higher than the middle permissible power for the light guide.	Adjust power setting.
* Fiber sterility out of date	The durability date of the light guide ran off.	Replace by new light guide.
* Fiber not compatibly	Light duide is not released for the laser device	Replace by new light guide.
*Use Handpiece	A mode is selected, which is released only for a therapy with the hand piece.	Set another mode or use a handpiece.
*Use new fiber	The functionality of the light guide used is not guaranteed.	Replace by new light guide.

6.6 Disposal

The Dornier *Medilas D 30/60* is appropriate for a use in a period of 8 years.

At the end of the use and/or life span of the laser system, contact the manufacturer or its representative for disposal or recycling of the unit (WEEE 2002/96/EC: European guideline for the disposal of used electrical devices).

When you are finished using the optic fibers (light guides), dispose them according to local regulations for contaminated products. This minimizes the risks that could arise for the environment and personnel as a result of contamination and residues on used optic fibers.

Dispose of accessories according to the operating manual for that particular accessory.

7 REFERENCES

The References section contains a glossary for the Dornier *Medilas D 30/60*.

7.1 Glossary

Display	Display field and control panel
Laser	Acronym for **L**ight **A**mplification by **S**timulated **E**mission of **R**adiation. Generation and amplification of light at a particular wavelength by stimulated light emission.
Laser surgery	Performance of surgical work using a therapy laser. A laser beam's cutting effect is used for surgical purposes.
Laser beam, therapy laser	High-energy light beam of directional, coherent light at a specific wavelength.
Pilot laser	Weak laser beam in the visible light range. Serves as an aiming tool for the invisible therapy laser.
Logbook	Records treatment data.
Pulse Form	Laser beam as a time-power diagram
Shutter	Electronic short-circuit of the laser diode to prevent unwanted laser radiation
Repeat pulse	Several laser pulses emitted in succession with a specific pulse duration and pulse interval.

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