

Operating Instructions

CE 0197

451600-0154

Version 1



Timelas Vital

The area laser in the infrared spectrum



Item no. 205 256

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The **Timelas Vital** area laser is a medical product designed for the irradiation of skin layers. The laser may only be applied by qualified physicians who determine the dosage owing to their training knowledge.

The infrared laser beam works on the upper skin layers, visibly displaying its healing power.

The well known contra-indications regarding laser therapy should be observed in any case.

Relative contra-indications:

- Pregnancy
(uterus as well as hormonally active acupuncture points)
- Tumour patients, thyroid, ovaries and testicles
- Open fontanels respectively defective cranial vault

Absolute contra-indications:

- direct and indirect irradiation of the eyes

The appliance is not approved for use in potentially explosive or damp rooms. Do not store in humid rooms. Only use the laser in inside confined space with an ambient temperature between 10° C and 40° C.

Please read the operating instructions carefully before using the device!

- Prior to operation, the user has to report the operation of the laser to the authorities responsible for the maintenance of industrial health and safety standards.
- The laser may only be used by qualified persons ensuring an appropriate use of the laser owing to their training or knowledge and practical experience.
- Prior to operation, the user must make sure of the fail-safety and normal working conditions of the laser.
- The consulting room must be marked by a warning sign according to 417-IEC-5152 which is supplied with the device.
- Patient and therapist and all persons within the range of the laser must wear appropriate laser safety glasses.
- The **Timelas Vital** is secured against unauthorised use with a key switch. After use, the key should be taken out and locked up in a safe place.

Intended use

Indication

Contra-indications

Installment instructions

Important safety instructions

Laser class

The **Timelas Vital** belongs in laser class 3 B.

CAUTION: Looking into the laser beam is harmful to the eyes. Safety glasses must be worn. The precautionary measures according to VBG 93 for the application of laser beams must be observed.

Explanation of general symbols



This product is in accordance with the directive 93/42/EEC for medical products.



Read the operating instructions carefully before use!

REF

Symbol for the item respectively order number. This symbol is followed by the item respectively order number of the manufacturer.

SN

Symbol for the serial number. This symbol is followed by the serial number of the manufacturer.



Symbol for the year of construction. This symbol is followed by the year of construction.

Technical description

Technical data

Type of laser	CW-laser diode
Wave length	830 nm
Beam spread	7.5° respectively 18°
CW output power	16 x 40 mW (640 mW) +/- 20%
Power supply	100-230 VAC 50Hz
Power consumption	65-120 mA
Mains fuse	2 x T315 mA / 250 V
Laser class	3 B, according to the directive DIN EN 60825-1/03.97
Classification	IIa, according to the directive 93/42/EEC for medical products, annex IX

Description of the basic device

1. Key switch

Turning the key switch supplies the area laser with power, and the timer display comes up.

2. Operation LED "O/I"

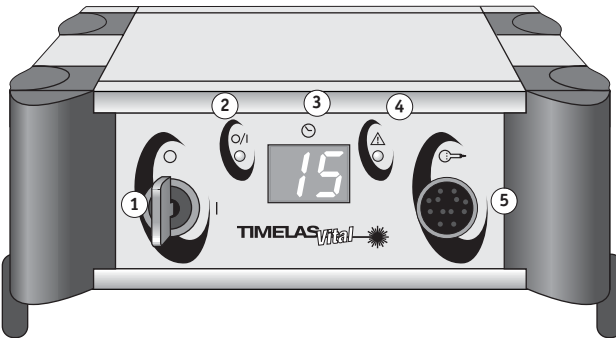
Actuating the main switch (located at the back side of the basic device) supplies the basic device with mains voltage, and the operation LED "O/I" comes up.

3. Timer

The display shows the remaining therapy time in minutes.

4. Fault indication

The fault indication comes up if the door contact plug (located at the back side of the basic device) is not connected or if the laser shows any error.



6. ✓ key

Pressing the ✓ key confirms the selected setting respectively starts the laser.

7. ⇨ key

Pressing the ⇨ key selects the desired setting.

8. Stop key

Pressing the stop key resets the setting to the basic setting respectively stops the therapy.

9. Laser ready LED

The illuminating laser ready LED means: **CAUTION**, the laser is ready for operation. After a break of 2 seconds the invisible laser beam can be started by pressing the ✓ key.

The flashing laser ready LED means: **CAUTION**, the laser emits dangerous laser beams which are harmful to the eyes.

Description of the area laser

Explanation of special symbols



Warning signs

10. Laser warning LED

The illuminating laser warning LED means: **CAUTION**, the laser emits dangerous laser beams which are harmful to the eyes.

11. Laser power meter

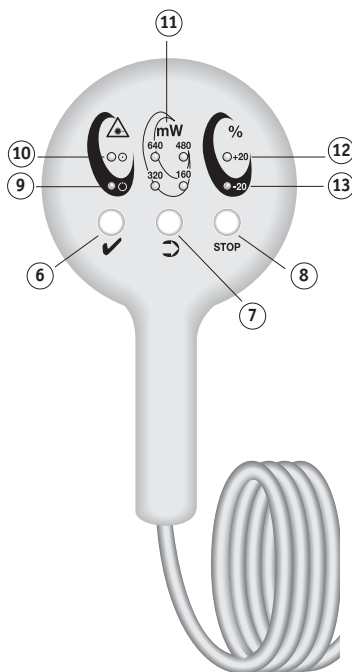
The selected laser power of 640, 480, 320 or 160 mW is shown.

12. Power deviation indication +20%

The steadily controlled laser output power deviates +20% from the set value.

13. Power deviation indication -20%

The steadily controlled laser output power deviates -20% from the set value.



Type BF application

A type BF application which assures protection against electric shock according to the requirements for regulation IEC 601-1, especially in respect to the authorised current leakage.

The illuminating laser ready LED means: **CAUTION**, the laser is ready for operation. After a break of 2 seconds, the laser will emit invisible laser beams by pressing the key.

The flashing laser ready LED means: **CAUTION**, dangerous laser beams are emitted which are harmful to the eyes.

The illuminating laser warning LED means: **CAUTION**, dangerous laser beams are emitted which are harmful to the eyes.



There are the following warning signs on the basic device:



Invisible laser radiation
Avoid eye or skin exposure
Laser class 3B, according to
DIN EN 60825-1/07.94





Operation

- Connect the door contact plug to the gate contact socket.
 - Connect the supplied mains cable to the mains connection socket (located at the back side of the device).
 - Set the main switch to "I", the operation LED "O/I" at the front side of the device will come up.
-
- Connect the area laser to the respective socket at the front side of the device.
 - Turn the key switch in clockwise direction, and the timer display at the front side of the device will come up. The LEDs at the area laser will all come up shortly, and a short tone will sound. Afterwards, the timer display will flash.

Select the therapy time by means of the  key (first the decimal minutes, then the digit minutes) and confirm by means of the  key. The therapy time can be set to 15 minutes maximally.

Select the laser output power of 640, 480, 320 or 160 mW by means of the  key and confirm by means of the  key.

When pressing the  key the laser ready LED illuminates and the pilot light flashes. The  key may only be pressed once again after a break of 2 seconds. Then, the invisible laser beam will be emitted. While the invisible laser beam is emitted, the laser warning LED illuminates and the laser ready LED and the pilot light flash.

During therapy, the laser output power is controlled steadily. In case of a deviation of the laser output power of -20% or +20% the respective yellow warning LED comes up and a warning tone sounds. In this case, switch off the laser and contact schwa-medico.

Therapy can be stopped at any time by pressing the STOP key. Otherwise, it will stop automatically on the end of the therapy time.

Connecting the basic device

Connecting the area laser

Selecting the therapy time

Selecting the laser output power

Starting therapy

Controlling the laser output power

Stopping therapy

Deleting the fault indication

The yellow fault indication comes up in case of the following errors:

- The door contact plug has not been connected to the respective socket at the back side of the basic device.
- The laser shows an error. For deleting the fault indication, switch off the laser by using the key switch. Then, switch off the main switch at the back side of the basic device. All displays will go out. Afterwards, switch on the main switch and put the key switch to the position "I". In case the fault indication will come up again, please contact schwa-medico.

General information

Warranty

During the warranty period of two years from the date of purchase, all repairs which may become necessary and are not due to incorrect use of the appliance will be carried out free of charge by the manufacturer.

Cleaning and disinfecting

Metal parts can be cleaned with alcohol of 80%. Remaining parts and parts which belong to the scope of supply can be cleaned with a moist, dust-free cloth.

Resetting, modifications and repairs

The manufacturer will accept responsibility for the safety and performance of the appliance provided resetting, modifications and repairs are carried out by authorized persons, and as long as the appliance is conducted in accordance with the operating instructions.

Circuit diagrams, spare parts list and setting instructions

Qualified technicians who are familiar with the technical features of the device can be provided with circuit diagrams, spare parts list and setting instructions.

Technical safety test

The **Timelas Vital** must undergo a technical safety test every 12 months. Please contact schwa-medico.

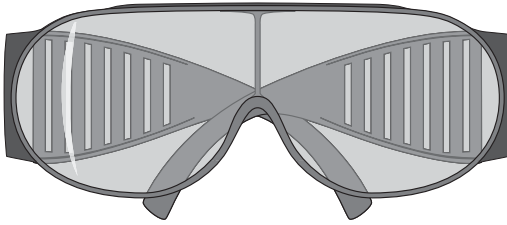
Laser safety glasses

There are the following laser safety glasses for patients:

- Laser safety glasses for patients PSB2, item no. 206 909

There are the following laser safety glasses for the user:

- Laser safety glasses LD2, item no. 206 907



The manufacturer agrees to take back old **Timelas Vital** devices and to dispose of them properly.

The **Timelas Vital** is supplied with the following accessories:

Basic device	Item no. 205 259
2 keys, 1 gate contact plug	
Area laser	Item no. 205 257
Mains cable	Item no. 450810-0043
Laser warning sign	Item no. 451400-0004
Operating instructions	Item no. 451600-0154
Laser safety glasses LD2	Item no. 206 907
Laser safety glasses for patients PSB 2	Item no. 206 909
Support BGN Pro	Item no. 205 262
Swan-neck SH 48	Item no. 205 263
Patient switch	Item no. 205 261

Disposal

Scope of supply

Einzelbeschreibung der sicherheitstechnischen Kontrolle

An dem Gerät sind die sicherheitstechnischen Kontrollen einschließlich der angeschlossenen Zubehörgeräte alle 12 Monate von Personen durchzuführen, die aufgrund ihrer Ausbildung, ihrer Kenntnisse und ihrer durch Praktische Tätigkeit gewonnenen Erfahrungen solche Kontrollen ordnungsgemäß durchführen können und die hinsichtlich dieser Kontrolltätigkeit keinen Weisungen unterliegen (siehe auch Bekanntmachung des BMA vom 02.04.1987).

1 Visuelle Überprüfung

Sichtprüfung:

- Gebrauchsanweisung / Gerätebuch vorhanden
- Überprüfung der Ausstattung auf Vollständigkeit
- Aufschriften, Hinweisschilder, Laserwarnschilder und Beschriftung der Stellteile richtig und vollständig
- Mechanische Beschädigung des Gerätes

Prüfung der Funktionsfähigkeit:

- Bedienfeld: Tasten und Anzeigen
- Laserbetätigungseinrichtung (Start- und Stop-Taste)
- Pilotlicht, Arbeitslaser
- Funktionskontrolle nach Gebrauchsanweisung durchführen

Das Gerät ist visuell auf mechanische Schäden und ordnungsgemäßen Zustand zu überprüfen. Die Netzleitung ist auf mechanische Fehler oder Schäden an der Kabelisolierung zu inspizieren.

2 Prüfung der Sicherheitseinrichtungen und sonstiger funktionaler Schutzmaßnahmen

Die Funktion der Folgenden Sicherheitseinrichtungen ist zu überprüfen:

- Schlüsselschalter
- Türschalter / Interlock
- Emissionswarneinrichtung (optisch und akustisch)
- Laserleistungsüberwachung
- Vorhandensein von geeigneten Laserschutzbrillen

3 Prüfung der elektrischen Sicherheit in Anlehnung an VDE 0751-1 (STK)

3.1 Ableitströme

- Erdableitstrom

- Gehäuseableitstrom

Der bei der wiederkehrenden sicherheitstechnischen Kontrolle gemessene Wert darf maximal das 1,5 fache des erstgemessenen Wertes oder des Grenzwertes nach VDE 0751-1 betragen

- Schutzleiterwiderstand

3.2 Messung der Ausgangswerte

- Messung der Laserleistung bei maximaler Leistung

16 x 40 mW +/- 8 mW

3.3 Geräteinterne Prüfung und Wartung

Überprüfung der installierten Sicherungen auf korrekte Werte

3.4 Eintragung in das Medizinproduktenbuch

Im Anschluß an den Umfang der STK:

„ Das Ergebnis ist mit Datum und Namen der Person bzw. der Firma, die die Prüfung vorgenommen hat, im Medizinproduktebuch zu dokumentieren bzw. zu ergänzen.“

Ist das Gerät nicht funktions- und/oder betriebssicher, so ist es instandzusetzen oder dem Betreiber die vom Gerät ausgehende Gefährdung mitzuteilen.

Achtung: Sind bei der Prüfung Mängel aufgetreten, durch die Patienten, Beschäftigte oder Dritte gefährdet werden, darf das Gerät nicht mehr betrieben werden.

Marketing

Tel. 06443/8333200

Produktberatung

Tel. 06443/8333222

Bestell-Service

Tel. 06443/8333110

Hersteller: PIERENKEMPER GMBH
Gehrnsstraße 5 · D-35630 Ehringshausen

Vertrieb:

schwa·medico

MEDIZINISCHE APPARATE
VERTRIEBSGESELLSCHAFT MBH



 <http://www.schwa-medico.de> 

Am Geiersberg 6 · 35630 Ehringshausen

Anzeige zur Inbetriebnahme einer Lasereinrichtung der Klasse 3 B (VBG 93, §5)

An die Gewerbeaufsicht

Name	<input type="text"/>
Straße	<input type="text"/>
PLZ/Ort	<input type="text"/>

Betreiber

Name	<input type="text"/>
Straße	<input type="text"/>
PLZ/Ort	<input type="text"/>

Hiermit gebe/n ich/wir die Inbetriebnahme einer Lasereinrichtung bekannt:

Gerät	Flächenlaser zur Stimulation der Hautoberfläche
Typ	Timelas Vital
Ref	205256
Hersteller	Pierenkemper GmbH Gehrstraße 5 35630 Ehringshausen
Laserkategorie	3 B
Strahlungsleistung	16 x 40 mW CW
Wellenlänge	830 nm

Herr/Frau ist mit den Sicherheits- und Schutzmaßnahmen für Laser Timelas Vital vertraut und zum Laserschutzbeauftragten bestellt.

Aufgrund meiner Ausbildung als Mediziner bin ich in der Lage, die Auswirkungen der Laserstrahlung am Menschen abzuschätzen, und bezüglich Technik und rechtlicher Situation (Laservorschriften) habe ich ausreichende Kenntnisse erworben.

Ort, Datum, Unterschrift (des Betreibers)

Anzeige zur Inbetriebnahme einer Lasereinrichtung der Klasse 3 B (VBG 93, §5)

An die Berufsgenossenschaft

Name	<input type="text"/>
Straße	<input type="text"/>
PLZ/Ort	<input type="text"/>

Betreiber

Name	<input type="text"/>
Straße	<input type="text"/>
PLZ/Ort	<input type="text"/>

Hiermit gebe/n ich/wir die Inbetriebnahme einer Lasereinrichtung bekannt:

Gerät	Flächenlaser zur Stimulation der Hautoberfläche
Typ	Timelas Vital
Ref	205256
Hersteller	Pierenkemper GmbH Gehrstraße 5 35630 Ehringshausen
Laserklasse	3 B
Strahlungsleistung	16 x 40 mW CW
Wellenlänge	830 nm

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