

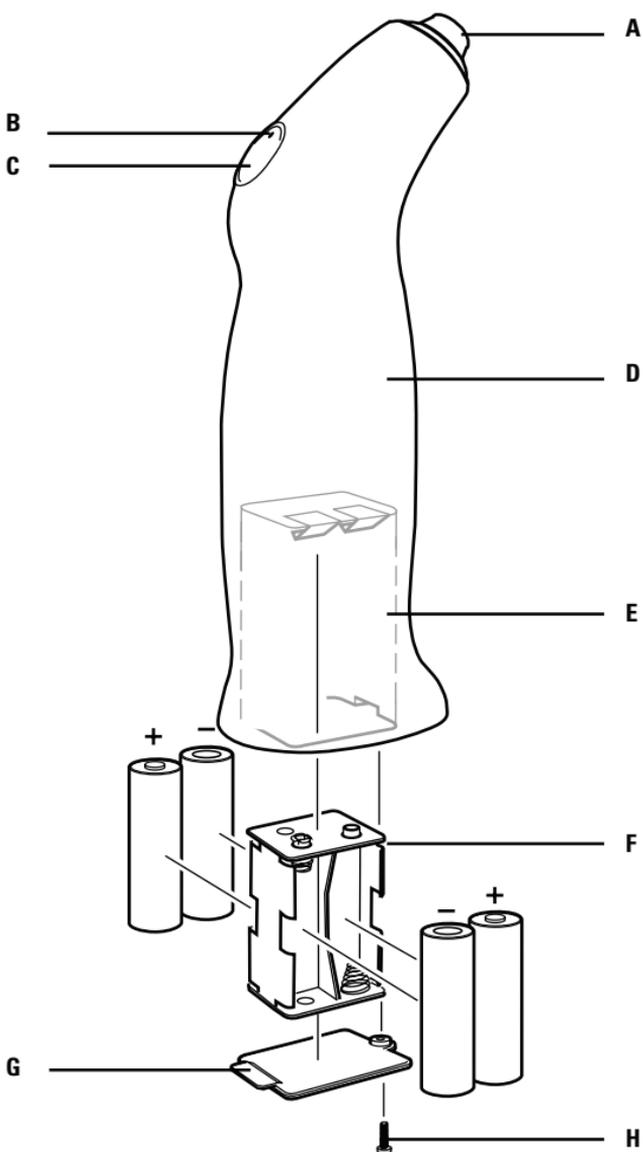
Treatlite yourself



SE: Bruksanvisning
GB: User Guide
ES: Instrucciones
DE: Gebrauchsanweisung
IT: Istruzioni per l'uso
FR: Consignes d'utilisation

TREATLITE
active

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 Electromagnetic environments REV:1 20120316

1. Introduction

Congratulations on your purchase of this quality Treatlite product. To ensure best possible use of the product, read through the entire User Guide before starting your treatment. This will help you achieve the most optimal treatment results.

2. Standards and directives

Treatlite Active fulfills the following standards and directives:

Standards: - IEC 60601-1
- IEC 60601-1-2
- IEC 60825-1
- EN ISO 14971

Directives: - 93/42/EEC
MEDDEV 2.4/rev.9

Treatlite Active fulfills the requirements of standard IEC 60601-1-2, which guarantees a certain degree of immunity against electromagnetic influence. However, certain portable and mobile communication equipment may affect the product. See the section about electromagnetic environment for more information.

3. Marking and classification

3.1 Classification

Classification in accordance with IEC 60825-1:

Treatlite Active is a class 1M laser and its laser radiation shall not be viewed directly with optical instruments, such as binoculars or a magnifying glass.



3.2 Marking on the product

There is information about Treatlite Active on the battery lid. The open book symbol is a request to read the user guide for instructions of use. The year after the company symbol is the year the product was manufactured. The serial number (s/n) is made up of the year of manufacture, the week of manufacture and a special ID. The product must not be disposed of as household waste. It must instead be disposed of specially as electronic waste in accordance with EU directive 2002/96/EC. The CE mark shows that the manufacturer affirms that this product fulfills all national requirements for medical equipment. Refer to 3.1 for more information on the laser warning.



4. Technical specifications

4.1 Electrical properties and environment

Property	Classification
Type of power supply	Internal power supply
Type of protection against electrical surge	Type B
Usage environment	Temperature 10-30°C Relative humidity 10-90%
Transport and storage environment	Temperature -40 - +70°C Relative humidity 10-100% Air pressure 500-1060 hPa
Degree of protection against water	No protection against water penetration
Degree of protection against ignition of gases	No protection against ignition of gases
Degree of use	Continual use

4.2 Batteries

Treatlite is powered by four batteries of type AA or R6, 1.5 volts. The lifetime for one set of batteries is about 2 - 4 hours or about 500 - 2000 treatments depending on the quality of the batteries. If Treatlite is not used for a longer period of time, the batteries should be removed.

Rechargeable NiMH batteries of type AA or R6, 1.2 volts can be used. When recharging the batteries, please read the user manual for the battery charger being used. All types of batteries should be disposed of at a recycling station after use.

4.3 Laser and LiteNozzle

The laser light in Treatlite Active has the wavelength of 808 nm and a maximal power of 120 mW.

The LiteNozzle (probe) spreads the light to reduce the effect of the laser light on the eye. The laser light exits through the centre of the flat, round surface of the LiteNozzle and appears as a weak red light.

5. Reporting defects

If you as a user discover a fault or are hurt when using Treatlite, e.g. when changing batteries or during treatment, or if you have any viewpoints you wish to share, please contact us using the details provided below.

6. Contact information

Address:

Treatlite Corporation AB
Tersmedens väg 6
371 42 Karlskrona
SWEDEN

Contact:

Telephone: +46 (0) 455 617 800
E-mail: contact@treatlite.com
Web: www.treatlite.se

7. Figure description

See figure on page 2:

- | | |
|-----------------------|------------------------|
| A. Probe/LiteNozzle | E. Battery compartment |
| B. LED/Dose indicator | F. Battery holder |
| C. Start button | G. Battery lid |
| D. Handle | H. Screw for lid |

8. Installation

8.1 Installing and changing batteries

1. Undo the screw on the battery lid with a screwdriver.
2. Open the lid and remove the battery module.
3. Install new batteries. Note + (plus) and – (minus) for the batteries in the battery module.
4. Refit the battery module and battery lid.
Finally, fasten the screw.

8.2 Protector (Face it) for LiteNozzle

Before treatment, a new Face it protector should be placed over the LiteNozzle. See chapter 10 Maintenance for more information.

9. Functions

9.1 Starting the laser

1. Press the Start button.
2. An acoustic signal and flashing of the LED in the Start button indicate that the laser light has been activated.
3. The laser light is activated for about 24 seconds and is then stopped automatically. This is indicated by two short acoustic signals and flashes.

9.2 Battery indicator

When the battery is starting to run low, this is indicated at the start of treatment by Treatlite Active repeating an acoustic and light signal for 8 seconds. No laser light is activated during this signal. This is repeated each time the product is started until the batteries are replaced. The same signal is used if incorrect batteries (e.g. voltage too high) are used.

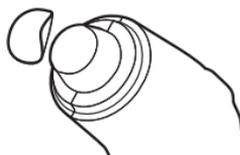
9.3 Dose indicator

Treatlite Active has a built-in dosage system that tells the user when a correct dose has been given (approx. 24 seconds). This is done with an acoustic and light signal. One press equals one dose. See the treatment suggestions under point 12 for a suitable number of doses.

10. Maintenance

10.1 Protector for LiteNozzle

Before each new treatment, a new Face it protector should be placed on the LiteNozzle. Treatlite Active shall not be used without the protector because the head has an uneven surface that easily accumulate bacteria and particles that can be transferred during treatment. No protection other than Face it may be used. The protector may only be used for one treatment and must then be discarded. Pull gently on the protector to ensure it is properly secured before starting treatment. 1 sheet of 20 protector dots is included.



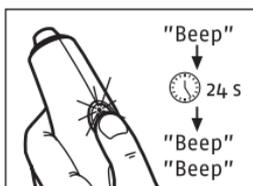
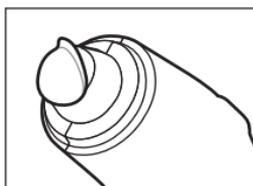
10.2 Cleaning

Use Treatlite moist towelettes or hand disinfectant for skin to clean the unit. Wipe the outside only.

11. Treatment and use

11.1 Treatment method

Start by diagnosing the area you wish to treat and read the treatment suggestions under point 12. Before starting treatment, place a new protector on LiteNozzle. During treatment, position LiteNozzle against the surface you wish to treat and press the Start button. Treatlite Active beeps once to indicate that treatment has started. Hold LiteNozzle against the treatment surface until dosage is complete. This is indicated by Treatlite Active beeping twice.



Make sure that LiteNozzle is in contact with the skin during the entire dosage period. The skin surface covered by LiteNozzle has now received one dose. Repeat the procedure on another area of skin, looking at the suggestions in point 12 Treatment suggestions. Do not treat the same area more than once during one treatment session.

For difficult-to-reach areas, like the neck and back, it is a good idea to ask someone for help. For areas of injured skins/sores, LiteNozzle should be held against the nearest skin surface that is intact.

11.2 Improper treatment

- If treatment is not performed as often as recommended, the optimal results may not be achieved. However, there is no danger associated with this.

- If treatment is performed more often than recommended, this may inhibit results, i.e. no or negative treatment results. However, there is no danger associated with this.
- Using too high a dose during one treatment, i.e. treating the same area several times, has the same results as treating too often.
- If healthy skin is treated, nothing happens. There is no danger associated with this.
- If the incorrect diagnosis is treated, treatment results will be poorer. However, there is no danger associated with this. If you are uncertain about your diagnosis, contact a physician.
- Diagnoses other than those specified must not be treated with Treatlite as the dosage system is only designed for these specified treatments.

11.3 Side effects

At present, there are no known side effects.

12. Treatment suggestions

If you are uncertain about your diagnosis, contact a physician.

TREATLITE ACTIVE:

12.1 Pain

Treatment of pain during movement is applied e.g. upon acute or prolonged overload, after exercise or sport, in case of mild trauma or a non-severe damage to muscles, inflammation in tendons or worn joints.

For chronic joint inflammation, such as rheumatoid arthritis, the laser has a pain relieving effect and reduces stiffness in the morning. Prior to all laser treatment, we recommend that the area of pain be examined and diagnosed by a licensed practitioner. We also recommend the use of exercise and, if relevant, relaxation programmes.

In the event of severe trauma to the hip, wrist or fingers, if there is no improvement after four to five days of treatment and sudden-onset fever, sudden swelling of the joints or general affliction, contact a healthcare provider immediately.

Laser treatment with Treatlite Active results in improvement or healing for 90% of those treated. Laser treatment can be combined with medications available on the market today and can also be given to individuals with pacemakers. In the event of uncertainty, consult your physician. An initial and fleeting heat at the treatment site is an effect of the treatment. Read about energy transfer. No serious side effects have been reported.

Because the laser head, LiteNozzle, is in contact with the skin, energy is applied to a desired treatment point the same size as the surface of the head. Different dosages are required depending on the diagnosis – see treatment scheme. Clear pain relief is usually obtained about 15 to 30 minutes after treatment. Sometimes, the start of the healing process can be experienced as increased pain for 6 to 24 hours after treatment. It is important to follow the treatment scheme as both insufficient dosage and overdose have a negative effect on treatment results.

Direct pain may be experienced when pressing against an overloaded or mildly injured area. Indirect pain or trigger points present themselves as no more than moderate pressure triggering relatively heavy pain locally or as simultaneous pain at another location, e.g. with Fibromyalgia. Always apply 1-2 doses (1-2 presses) to each treatment point. We suggest marking each treatment point with a skin-marking pen (available as an accessory).

Treatment scheme for various tendon afflictions

Location	Number of treatment points
Tennis elbow	2-3
Shoulder	2-3
Achilles heel	2-3
Under soles of feet (e.g. heel spur)	2-3

Treatment scheme for various joint affliction

Location	Number of treatment points
Finger	1-2
Ankle	2-4
Elbow	2-4
Shoulder	2-4
Shoulder blade	1-2
Neck	4-12
Lumbar area	4-8
Hip	2-4
Knee (inside)	3-6
Ankle (e.g. sprain)	2-4

Treatment interval

Treat daily for two weeks or once every other day for three to four weeks. When the treatment effect is achieved, reduce the number of Treatlite Active doses by about 30%.

Note: Increase the load on the treated/pain-free/healed body part gradually over several days. Additional treatment suggestions are found at www.treatlite.se.

12.5 Contraindications

For reasons of caution, pregnant women should avoid treatment. However, no negative effects have been reported.

13. Troubleshooting guide

All repairs and maintenance requiring that the device be opened may only be performed by the manufacturer.

No acoustic or light signal at start

- Check that the batteries and battery module are correctly positioned.
- Change the batteries.

If the handle feels warm

The handle sometimes becomes a bit warm after a period of prolonged use. In such cases, switch off Treatlite for 15-20 minutes before resuming treatment.

Suspect that no laser light is coming from LiteNozzle

The laser light in Treatlite is practically invisible to the eye, but can be seen as a dark red dot in LiteNozzle after start. The laser light is most easily seen in a dark room. Never stare into the laser light.

If your problem cannot be found in the troubleshooting tips or the recommendation does not correct your problem, contact Treatlite Corporation AB. Contact details are found at point 6 Contact information.

14. Service and accessories

The product is covered by a 2-year warranty for normal use and care. Store the product in a dry place. Information on service offerings is available at www.treatlite.se.

For available accessories, visit www.treatlite.se.

15. Frequently asked questions

Is the laser harmful to the eye?

Laser is a loaded word that often provokes respect or concern. However, nowadays lasers have become commonplace and are found in everything from laser pointers to laser levels and CD players. These lasers are perfectly safe. However, strong lasers, like those used for industrial purposes, are potentially harmful. In Treatlite, the laser light is created in the LiteNozzle and is equivalent to that in a laser level. A good rule of thumb is to never stare into laser light, no matter where it is coming from.

Can I treat myself with a laser pointer?

The laser light of a laser pointer is much too weak to be useful for treatments. It is easy to believe that the laser light in Treatlite is weak since it is hard to see. But, that is because the eye has difficulty perceiving this type of laser light. The laser light in a laser pointer is a different type that the eye has an easier time seeing. In fact, the laser light in Treatlite is about 100 times stronger than that of a laser pointer.

What is LiteNozzle and what does it do?

LiteNozzle converts the laser light so that it is not harmful to the eye without losing the helpful treatment properties.

Can I treat afflictions other than pain?

Laser is used to treat many other different afflictions and problems. However, this requires special knowledge and the treatment must be performed by a specially trained healthcare provider. Treatlite Active has a built-in treatment system specially designed to treat the afflictions described under point 12.1. It must not be used to treat afflictions or problems other than those specified.

Does the pain disappear for good?

After treatment with Treatlite Active, the pain will lessen or disappear. Treatlite Active stimulates the body's own healing processes while working as an inflammation inhibitor. Read more at www.treatlite.se.

Does it always work?

We are all unique individuals and therefore may react slightly differently to the treatment. Most will achieve good results while others will see only slight improvement. In general, more than 90% of the population achieve good results.

Electromagnetic environment

Treatlite uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. Treatlite is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. For more information about electromagnetic environment see below.

Electromagnetic emissions

Treatlite is intended for use in the electromagnetic environment specified below. The customer or the user of Treatlite should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Treatlite uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Treatlite is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

Treatlite is intended for use in the electromagnetic environment specified below. The customer or the user of Treatlite should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / Burst IEC 61000-4-4	N/A		
Surge IEC 61000-4-5	N/A		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	N/A		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration

– electromagnetic immunity

Treatlite is intended for use in the electromagnetic environment specified below. The customer or the user of Treatlite should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			<p>Portable and mobile RF communications equipment should be used no closer to any part of Treatlite, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d=1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m	3 V/m	<p>$d=1,2\sqrt{P}$ 80 MHz to 800 MHz $d=2,3\sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> 

NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electro-magnetic propagation is affected by absorption and reflected from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Treatlite is used exceeds the applicable RF compliance level above, Treatlite should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Treatlite.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and Treatlite

Treatlite is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Treatlite can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Treatlite as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (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	0.24
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 rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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