CognitoLite™

Electronic Cranial Phototherapy Device

Our brain is fundamental to our very existence. It is the most important part of our body second only to our heart and lungs. Many things can go wrong in this area, some age related and some degenerative. Transcranial phototherapy is an invisible light treatment which is applied to the outside of your head.

Warning: As a safety feature, the CognitoLite will not turn on if the ambient temperature is over 35 degrees centigrade.

How to use

- 1. Remove any make up prior to using the CognitoLite, as this may impair light transmission across the skin.
- 2. Clean the rim of the device (the area that is in contact with your skin) with an antiseptic wipe or a tissue dampened with a little diluted antiseptic before use. **DO NOT immerse the CognitoLite in water**.
- 3. Connect the lead from the transformer into the CognitoLite and then plug the transformer into a convenient mains electricity socket. Do not use the CognitoLite in a wet or humid environment e.g. the bathroom.
- 4. When plugged in the fans will not be turning or may turn slowly and will speed up as the device warms up to ensure the panels do not become uncomfortably hot.
- 5. Press the "On" button. You will hear an audible beep and the green lights will light up indicating the CognitoLite is in active treatment mode.
- 6. Place the Cognitiolite over your head with the rim resting on level with the eyebrows.
- 7. Close your eyes and gently, rotate the eye modules so that they come within a few millimetres of your **closed eye lids**. If you inadvertently open your eyes, the low level invisible light emissions will not harm your eyesight. It is, however, recommended that you keep your eyes shut during the active phase of the treatment (green LEDs illuminated)
- 8. After approximately six Minutes the CognitoLite automatically switches off and beeps, however the fans will keep on turning. Each module has a green LED, which is illuminated when the module is activated.
- 9. Only one six-minute treatment twice a day is necessary.
- 10. You cannot over treat with the CognitoLite[™].
- 11. Establish a daily routine of morning and evening treatments, to achieve the best result.
- 12. Never use the CognitoLite in an area where isolation from the mains supply is obstructed.
- 13. Always unplug your CognitoLite from the mains supply when not in use.
- 14. If you wish to discontinue treatment before the end of the treatment cycle unplug the power connector from the CognitoLite and unplug the power supply from the mains supply socket.
- 15. The mains plug of the power supply acts as the disconnect device for the equipment.

Fault finding

- 1. A panel become uncomfortably warm, and the fan is not turning, this is a fault, please contact the manufacturer.
- 2. A Red light comes on the device buzzes before the end of the treatment session the ambient temperature may be too high, switch on the device in a cooler room without using the helmet, if this recurs, this is a fault, do not use the CognitoLite again. Please contact the manufacturer.
- 3. The CognitoLite buzzes and a red light flashes on the back control module the ambient temperature is too high. Move to an air-conditioned room, unplug the CognitoLite, wait a few minutes and then plug the CognitoLite in again, if this recurs in a cool room (ambient temperature less than 30 degrees centigrade), this may be a fault, contact the manufacturer.

Power Supply

Contents of the case is:

- a. Instructions for use.
- b. CognitoLite[™] Device
- c. Mains 12-volt power
- supply

CognitoLite[™] Device



CognitoLite[™] treatment aperture



Front view, with eye modules

Control Module



Top view

1. "On" switch

- 2. Indicator light, normal operation, flashes green, overtemperature – flashes Red
- 3. 12-volt power connector, remove power to switch device off
- 4. Eye panels
- 5. Front treatment modules
- 6. Upper front treatment panels
- 7. Modular interface
- 8. Upper side panels
- 9. Lower side panels
- 10. Control Module, there are no light sources in this module.

Module indicator lights, normal operation – continuous green, overtemperature - Red

Cleaning Instructions

- 1. The CognitoLite **<u>should not</u>** be cleaned with water.
- 2. Use clean gauze or cotton wool, place a small amount of surgical spirit on the gauze or cotton wool. Allow the CognitoLite time to dry before turning it on again.
- 3. Wipe the surfaces that have been in contact with the patient firmly and dry the surfaces with a fresh piece of gauze or cotton wool.

Do not use solvents or household cleaning chemicals to clean the CognitoLite

How to apply the CognitoLite



Gently rotate the eye pieces down so that they are a few millimetres from the skin of the closed eyelids.

Do Not push them against the eye, this may cause injury to the eyelids. **Always keep your eyes closed** during treatment, failure to do so will run the risk of accidental injury to the eyes.

At the end of a treatment cycle, rotate the eye pieces away from the eyes before removing the helmet. After inserting the DC power supply into the back of the CognitoLite place the power supply on a surface close to where you are sitting.

Place the CognitoLite gently over your head using both hands.

Ensure the bottom of the CognitoLite rim rests on the brow as shown.

Warning: Whilst the CognitoLite can expand a small amount, applying excessive force to expand the CognitoLite, will cause permanent damage to the device.



Warning

- 1. The CognitoLite should not be used if the area of skin to be treated is broken or weeping as this may result in cross infection.
- 2. The CognitoLite should only be used by adults or under adult supervision.
- 3. Whilst the CognitoLite is safe and will not harm your eyes, nonetheless it is recommended that you should shut your eyes during the entire treatment cycle.
- 4. In the event the CognitoLite becomes uncomfortably warm please, remove the CognitoLite, unplug your CognitoLite, and allow it to cool down. Generally, this will only occur in the event the ambient temperature is over 34C, however if this occurs in ambient temperature of less than 30C, there may be a fault and the manufacturer should be contacted.
- 5. Each module has a cooling fan, never cover the CognitoLite when operational, it will overheat and cause injury if used when too warm.
- 6. Only the SUPPLIED 12 volt power supply should be used with the CognitoLite.
- 7. No modification of the CognitoLite is permitted, and will invalidate the warranty
- 8. Never obstruct the power supply, always leave enough room to remove the power supply from the mains socket quickly if the need arises.

- 9. If either the power supply or the CognitoLite appears to have been damaged **DO NOT** use the product. Please contact the manufacturer for evaluation.
- 10. **Do NOT** modify either the CognitoLite or the power supply in any way risk of serious injury.
- 11. Please read **the Important Safety instructions** regarding the use of the power supply below

Product Specification

Name of product; CognitoLite[™]

Manufacturer; Maculume Ltd, 9 Castle Close, Spennymoor, County Durham, DL16 6TR.

Telephone: +44 1388 817 605; Fax: +44 1388 812571

E-mail CognitoLite@gmail.com

Dimensions; 280mm x 270mm x 170mm

Power; Mean Well: GSM90B12-P1M, 12 volt

LED; Class 1 LED product, 1068nm+/-12nm wavelength.

IP30 – no protection against ingression of water, protection of ingress of particles >5mm in diameter.

Non-sterile product.

Type B applied part

Not suitable for use in an oxygen rich environment.

Power Supply Specifications:

Mean Well: GSM90B12-P1M,

Input: 100 - 240V ~ 47 - 63Hz 1.25 - 0.5A

Output: 12V, 7A max

IMPORTANT SAFETY INSTRUCTION

When using an electrical appliance, basic safety precautions should always be followed, including the following:

Read All instructions before using power supplies

DANGER: To reduce the risk of electric shock: a power supply should never be left unattended when plugged in. Always unplug this power supply from the electrical outlet immediately after using.

WARNING: To reduce the risk of burns, fire, electric shock or injury to persons:

- 1. Do not allow this power supply to be used as a toy. Pay close attention when this power supply is being used by or near children.
- 2. Use this power supply only for its intended use.
- 3. Never operate this power supply if damaged in any way including any damage to the 12 volt outlet.

- 4. Never operate this power supply if it has been dropped in water or has become wet. Please return the power supply back to the manufacturer.
- 5. Never drop or insert any objects into any openings.
- 6. Do not use outdoors.
- 7. Do not operate where aerosol sprays are being used or where oxygen is being administered.

Transport and Storage Conditions

Should be transported in a dry environment

Temperature -10C to +60C Relative humidity <70% Atmospheric pressure changes will not affect the functionality of the product.

Operating Environment

Temperature -10C to +35C Relative humidity <70% Barometric pressure has no influence on the operation of the CognitoLite

Symbol Definitions:

Do not dispose of in household waste – Recycle.



Indicates the treatment surface on the CognitoLite and the part applied to the body.



Indicated that operating instructions should be read before using the product.



Connector has the centre at +12 volts, 2.5mm connector



Class II electric shock protection, indicating the 12 Volt output has a double layer of insulation between it and the mains supply.

Warranty

- The CognitoLite has been manufactured with the greatest care. The warranty period is two years from the date of purchase. Please retain the sales receipt as proof of purchase. During the warranty period, faulty products can be sent to the service address shown below. The device must be returned together with the sales receipt and completed warranty card with a description of the fault. A new or repaired CognitoLite will be returned.
- 2. The guarantee is in addition to your statutory rights. Your statutory rights are not affected.
- 3. This warranty does not apply to cases of damage caused by accident, improper use, and force majeure. This warranty will be invalidated if the device is tampered with in any way whatsoever.
- 4. If the device is returned to us for repair, it must be packed correctly, preferably in the case supplied, as we cannot accept any responsibility for damage caused in transit.
- 5. The CognitoLite is for personal use only.

For Warranty claims please contact the address below:

Maculume Ltd, 9 Castle Close, Spennymoor, County Durham, DL16 6TR Email: <u>service@maculume.com</u>; **Telephone:** +44 1388 817 605; Fax: +44 1388 812571

Warranty Return Sheet

Do not return the CognitoLite before you have contacted the manufacturer. Customer name:	
Country:	Post code:
Date purchased:	Serial number:
	(this can be found above the "on" button)
Description of the fault:	

Ship the CognitoLite to:

Returns Maculume Ltd 9 Castle Close Spennymoor, DL16 6TR County Durham United Kingdom