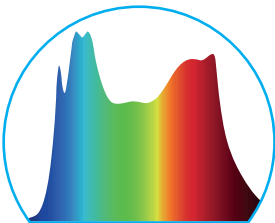




PHOTOTHERAPY PAVILION



Developed and validated in
collaboration with

NIMH NATIONAL INSTITUTE
OF MENTAL HEALTH



USER MANUAL

Medical Device

Risk class I

The phototherapy pavilion is an interior installation - a pavilion. There is space to seat 3 people on a comfortable upholstered bench, and if necessary 3 additional places to sit on soft stools.

The phototherapy pavilion is almost cubic in shape with each side measuring 2.5 meters. The design of the pavilion consists of opposing sides, two full and two open, with the latter including blackout curtains. The entire frame of the pavilion consists of 3 structural segments that can be divided up for transport. The ceiling and half of one side wall are fitted with LED light sources with a diffuser so that the entire surface acts as a light source with balanced brightness. The other inner and outer wall surfaces are upholstered with soft light fabric and the floor is carpeted. The space inside the pavilion is automatically ventilated.

The technology of the phototherapy pavilion is based on unique LED technology with a balanced color spectrum, comparable to natural daylight. This spectral composition with a full representation of the 460-520 nm spectral band in combination with a unique solution for spatial light distribution (large-area, multi-sided lighting) and the high intensity of illumination that is achieved in the space is a guarantee of higher efficiency for non-image light perception systems. The lighting is designed to support the synchronization of a person's circadian rhythms and to positively influence the user's psychological disposition.

Intended purpose:

The medical device is designed to influence circadian rhythms, supporting their synchronization and influencing physiological processes associated with the regulation of mood, sleep, cognitive functions and other functions.

User Instructions:

In order to correctly use the phototherapy pavilion, please read the User Instructions carefully before first use. The manufacturer bears no responsibility for damage or injury caused by neglecting the instructions given in this manual. This User Manual contains a description of the phototherapy pavilion and instructions for its use and maintenance.

We recommend visiting the phototherapy pavilion especially in the early morning and morning hours. Regular exposure to intense light early in the morning acts as a signal for the biological clock and helps maintain the regularity of sleep and wakefulness.

Warnings and safety instructions before use

Never use after sunset!

Use only after consultation with a specialist.

It is always important to monitor one's own individual reaction. We highly recommend consulting the use of the phototherapy pavilion as part of an individual sleep/chronobiological consultation.

If the light seems too intense, please wait at least 5 minutes. In most cases the eyes adapt by then. If the feeling persists that the brightness is too high, you can ask the attending staff to reduce the intensity.

Control instructions

- (Before the first use, it is necessary to check whether the phototherapy pavilion is connected to the power source.)
- The pavilion can be used in 2 operating modes:
 - "THERAPY" mode - light therapy as part of sleep consultation (managed according to expert recommendations)
 - "CIVIL" mode - day lighting of the box for individual sitting (without medical supervision)
- Before entering the pavilion, turn on the light using the switch on the right side on the outer wall of the box. The light will automatically switch to "CIVIL" mode. Switching to the "THERAPY" mode and its configuration according to the type of therapy is set by the operator via the remote interface. An application for a mobile phone / tablet was created to control the mode and is available to the attending staff. In the intuitive user interface, the bright light can be turned on, off, turned on for a certain period of time, or the lighting intensity can be decreased. When leaving the phototherapy pavilion, do not forget to turn off the light by pressing the same switch.
- For a greater sense of privacy and better therapeutic effects, the space of the pavilion can be visually closed with fabric curtains on both entrance sides of the box.

Access to control mode

- **Always follow the instructions of a professionally qualified person!** Always discuss all problems with a professionally qualified person.
- If you notice mild problems such as headache, burning eyes – avoid looking directly into the light surface, adjust (increase) the distance of the light surface of the device from the eyes, take a break of several days until the symptoms disappear.
- If moderate to severe problems such as nausea or sleep problems occur, stop therapy immediately, ensure that you are using the device according to the instructions of a professionally qualified person, and consult a professionally qualified person for further use of the device.

Comply with the basic requirements set out in the article "Information about EMC–Electromagnetic Compatibility"

Access to control mode

- To access the control mode, the pavilion must be connected to the mains. It then automatically generates a Wi-Fi access point called "LightTherapy"
- Connect to the "LightTherapy" Wi-Fi on the device from which you want to control the pavilion.
- Enter the password: spectrasol and wait for your device to connect to the Wi-Fi network.
- Ignore messages that the network is not connected to the Internet
- Enter the address 192.168.4.1 in your web browser.
- settings page will open

Light Therapy

Basic Settings

Therapy Light On/Off

Civil Light On/Off

Advanced Settings

Clouds On/Off

Therapy Level [%] 95

Civil Level [%] 80

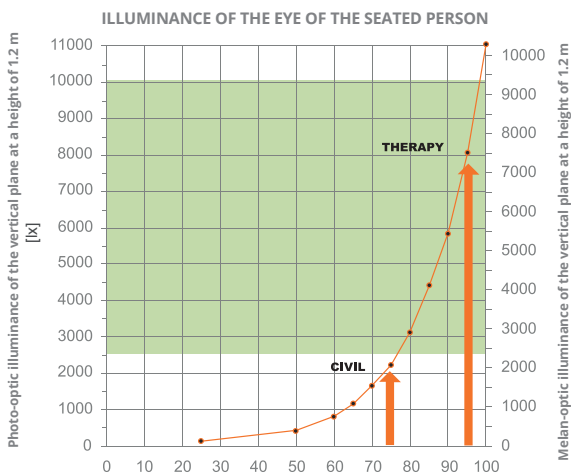
Therapy Timer [min], 0=off 30

Fan Speed [%], 25% is minimal 50

Runtime 138 sec sign.out

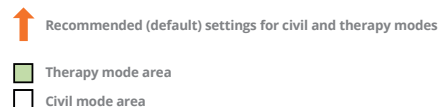
Callouts:

- BASIC SETTINGS**
Virtual sliders turn therapeutic or civil mode on or off. The one activated here will be turned on after pressing the button on the outer wall of the sauna.
- Setting up the intensity of the therapeutic mode 0-100%. Leave the recommended default values set or adjust them using the diagram below.
- Setting the therapy time
- Sauna lighting time counter
- CLOUDS MODE experimental beta function RECOMMENDED TO LEAVE OFF
- Setting the intensity of the therapeutic mode 0-100%. Leave the recommended default values set or adjust using the diagram below
- Climate control setting
It affects the volume of ventilation and the speed of air exchange to ensure an optimal



Light intensity setting

Light intensity settings in the control mode (web user interface) are entered in percentages in the fields described above. The percentages of intensity are not directly proportional to changes in illuminance. If you want to set other values than the recommended default ones, use the diagram of the dependence of the set intensity in % on real photopic and melanopic illuminance.



Instructions for proper maintenance on the phototherapy pavilion

Maintenance on the pavilion can be carried out with ordinary cleaning products. The diffusion material covering the surface of the LED lamps is maintenance-free; any dirt can be gently wiped off with a dry, soft cloth. Increased attention should be paid to disinfecting the space between individual therapies.

FAQ - Frequently Asked Questions

Is it possible to use the phototherapy pavilion at other times of the day/night than in the morning?

You can use the phototherapy pavilion at any time of the day to increase your energy and motivation/improve your mood. It is especially suitable if you do not have the opportunity to stay in bright daylight, which is always better. However, keep in mind that in the late afternoon and evening the light can affect the time you fall asleep - you may fall asleep later than usual.

What happens when the pavilion is disconnected from the power source?

The pavilion will turn off when disconnected from the power source. After reconnecting it to the electric current, the pavilion lights up in "CIVIL" mode. However, the previous settings will be stored in the control unit and prepared to start in the "THERAPY" mode.

Is it cold or hot in the cabin?

The space of the light pavilion is connected to the space of the corridor. If you feel cold, the air flow (draught) can be decreased by closing the curtain. On the other hand, when a higher ventilation is required than the cabin ventilation system provides, the curtains can be left open.

Technical specifications

The highest horizontal illuminance at floor level can reach up to 6,000 lx; the vertical illuminance at eye level of a sitting person can reach up to 10,000 lx. These values are achieved using a total of 6.75 m² of luminous surface, which allows creating a natural environment without the feeling of over-lighting.

The control of light sources, their switching and brightness regulation are managed via the DALI bus. User control of the light pavilion in THERAPY mode is done through the WiFi interface. An application for a mobile phone / tablet was created to control the mode and is available to the operating staff. In the intuitive user interface, the bright light can be turned on, off, turned on for a certain period of time, or the lighting intensity can be decreased.

The phototherapy pavilion must be connected to a 230V 16A socket, protected by a 25A circuit breaker (the pavilion contains its own 16A B fuse and a circuit breaker). The lighting power is 800 W when operating in CIVIL mode and a maximum of 3000 W when starting in THERAPY mode.

The pavilion space is continuously ventilated during operation; the flow of ventilation air in the space for users reaches 150 m³. The ventilation air from the pavilion area and from the area of the lamps is discharged above the roof of the pavilion. We recommend coordinating the location of the air discharge within the central climate control system, so that the heat loads can be discharged to outside the building, especially in the summer.

Indication

The medical device is designed to influence circadian rhythms, supporting their synchronization (e.g. for hospitalized patients or clients who do not have the opportunity to stay in sufficient daylight; for individuals with unstable circadian rhythms; for persons with circadian rhythm disorders, etc.) and affecting physiological processes associated with the regulation of mood, sleep, cognitive functions and other functions. The medical device is designed to treat or support the treatment of depression (unipolar and bipolar) of seasonal and non-seasonal nature. It can also be used as a supportive intervention in medical care and prevention, e.g. for people with increased sensitivity to seasonal changes, who suffer from seasonal mood changes or seasonal affective disorder.

Contraindication

- A side effect of some drugs can be, for example, a changed sensitivity to light. Therefore, inform a professionally qualified person whether and what kind of painkillers, antidepressants, and other prescription medications you are taking.
- A patient with any eye disease (glaucoma and cataracts, inflammation of the retina, etc.) must consult an ophthalmologist before using the device for the first time.
- A patient with any neurological disease (especially migraines, epilepsy, etc.) must consult a neurologist before using the device for the first time.

Possible side effects

Among the most frequently mentioned side effects of phototherapy are eye irritation or fatigue. Nausea, dizziness, headaches and insomnia may also occur after late evening light or early awakening after morning phototherapy. When phototherapy is applied at an inappropriate time of day (i.e. later in the afternoon, evening and night), there is a risk of an ill-advised shift in the circadian rhythm. At too high a dose of light (i.e., at too high a light intensity or too long exposure to light), the adverse effects described above may occur, including the increased sleep fragmentation we described. We would also like to mention the seasonal changes in the sensitivity of photoreceptors and the entire visual system, which can influence not only the clinical response, but also the possible occurrence of adverse effects of phototherapy.

In general, increased caution should be observed during phototherapy in patients with certain eye or skin diseases or patients using photosensitizing medication.

Adverse effects usually disappear within a few days after reducing the intensity of light or adjusting the length of phototherapy. If you notice mild problems such as headache or burning eyes, avoid looking directly into the light surface, adjust (=increase) the distance of the light surface of the device from the eyes and take a break for a few days until the symptoms disappear. Inform a professionally qualified person about the occurrence of adverse effects.

If moderate to severe problems such as nausea or sleep problems occur, stop therapy immediately, ensure that you are using the device according to the instructions of a professionally qualified person, and consult a professionally qualified person for further use of the device.

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Servisní středisko: Spectrasol, s.r.o. <https://www.spectrasol.eu/kontakt/>

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Report possible side effects to the contact:
info@spectrasol.cz



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