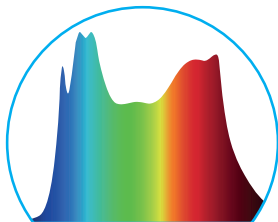




# PHOTOTHERAPY PANEL ON/OFF



Developed and validated in  
collaboration with

**NIMH** NATIONAL INSTITUTE  
OF MENTAL HEALTH



## USER MANUAL

## Medical Device

Risk class I

The SPECTRASOL phototherapy panel (hereafter referred to as the “device”) is a portable device the size of cabin baggage (65 x 35 x 16 cm) designed as a metal carrying case to ensure good portability and durability. The device consists of two panels – left and right. The dominant part of the surface of both panels is made up of a diffuser that scatters light from the LED modules integrated inside the device and thus forms the main illuminating part of the therapeutic aid. After opening, the total illuminating surface is 53.5 x 60 cm. The open device can be placed stably on a table so that the light surface is at the eye level of the person sitting. In the lower part of the left panel there is a connector for connecting the main switch power cable, control button and indicator lights. The device, which weighs 8 kg, can be safely carried using the fixed handle.

The device is equipped with technology that ensures safe and reliable operation, including adequate light output.

### 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:

For proper use and to ensure the specified service life of the device, please read this User Manual carefully before first use. The manufacturer bears no responsibility for damage or injury to health caused by non-observance of the instructions given in this manual. The manual includes a description of the device and instructions for its use and maintenance. However, the User Manual does not in any case replace the recommendation of a doctor with knowledge of the issue (hereinafter referred to as “professionally qualified person”).

**Caution:** As part of the therapy, the phototherapy panel cannot be used other than in accordance with the instructions of a professionally qualified person. The device is used exclusively in the early morning and morning hours. Exposure at the wrong time can have a strong negative effect on the circadian rhythm and thus emotional stability, so never use the device in the evening or at night!

### 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 the professionally qualified person whether you are taking painkillers, antidepressants, and other prescription medications and what kind. 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.

## STARTING UP

### Operating the device:

1. Place the phototherapy panel on a firm surface such as a table (see Figure 1). For correct orientation, check that the UP arrow on the sticker on the outside of the panel points towards the ceiling and the DOWN arrow towards the mat on which the panel opens. Open the device along the vertical axis. Remove the power cable from the space in the left panel of the device and plug it into the connector in the right panel. The center of the lighting surface should be at your eye level. Sit or stand approximately 50 cm from the center of the illuminating surface (approximately the distance of an outstretched arm). The device placed in this way has optimal efficiency. Follow the basic requirements set out in the article "Information on EMC – Electromagnetic Compatibility"
2. You can read, write, talk on the phone or work during therapy. Avoid looking directly into the light source. However, try to keep the recommended distance of the eye in front of the device at 50 cm (see Fig. 1 Model situation of recommended use). At the same time, however, you must ensure that objects (books, newspapers, etc.) do not block more than  $\frac{1}{4}$  of the illuminating surface. The recommended duration of therapy is determined by a professionally qualified person. Therapy should not exceed 60 minutes/day. Never leave the device unattended during therapy.
3. After finishing the therapy, turn off the device with the switch in the lower part of the left panel, then disconnect the plug from the socket and then disconnect the power cord from the connector in the left panel. Store the power cord in the space in the right panel and secure it properly with a zip tie. Then close the panel. When closing, it is necessary to take into account the risk of damaging (pinching) the cable. Clean the closed panel to keep them from obstructing the normal operation of the space and to minimize the risk of accidental damage.

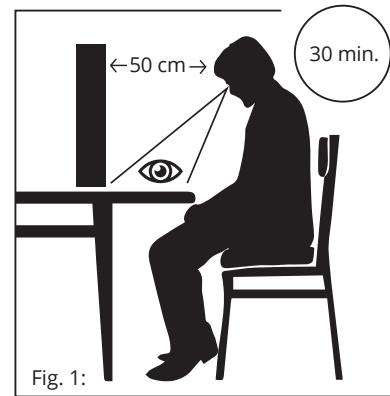


Fig. 1:

**Model situation of recommended use**

### Caution:

If the light seems too intense after starting the device, wait about 5 minutes; in most cases the eyes adapt during this time. If the feeling of too high brightness persists, it is possible to adjust (increase) the distance of the light surface of the panel from the eyes. If you decide to do so, make a note of this fact in your diary for later consultation with a professionally qualified person.

Due to the unusually high intensity, eye pain and headaches may occur during the first few uses, but these will stop in subsequent uses. If the problem persists, stop using the device and contact a professionally qualified person.

### Equipment maintenance

- Apart from keeping it clean, the device does not require any special maintenance (i.e. adjustment, calibration, etc.).
- Before cleaning and maintenance, make sure that the device is switched off and disconnected from the mains.
- Clean the device only with a damp cloth
- After cleaning, make sure that no water or other liquid has entered the device.
- If you do not use the device for a long time, store it in a dry place and out of the reach of children.
- Do not leave the device connected to the mains with the power cord if you are not going to use it for a long time.

## SAFETY INSTRUCTIONS

- Never use the device in damp places or immerse it in water or other liquids.
- Before use, remove all packaging and inspect the device for any damage.
- The device may only be used by a person who has been prescribed therapy by a professionally qualified person.
- Children should not be left unattended near the device when it is in use. It is not a toy!
- Keep the power cord away from heat and open flames.
- The minimum distance between the device and flammable objects must be at least 1 meter.
- Do not disassemble the control panel or other parts of the device.
- The operating voltage must correspond to the values specified in the technical sheet.
- Never touch the device with wet hands. Do not allow any liquid to get on the device. The device can only be used if it is completely dry.
- Protect the device from strong impact, as it could damage the internal components.
- If the power cord is damaged, stop using the device immediately and contact a professionally qualified person. The cord must be replaced immediately. Never attempt to repair the power cord yourself.
- Should the device suffer accidental mechanical damage, e.g. falling from a table, the device must not be used any further without having its basic functions checked by the manufacturer or a contracted service provider.
- In the event of malfunction of the device caused by extremely strong interference, turn off the device and wait for the effects of the interference to disappear, or move the device and operate it out of range. Follow the basic requirements set out in the article "Information about EMC – Electromagnetic Compatibility".

### Repairs

- Do not attempt to repair the device yourself. This could lead to serious personal injury and financial damage.
- If the device is damaged in any way or does not function properly before first use, stop using it and contact the device manufacturer.

## TROUBLESHOOTING

Malfunction	Possible cause	Solution
The phototherapy panel does not light up	The device is turned off	Turn on the device
	The device is not connected to the mains	Connect the device to the mains
	Power cord damage	Ask a professionally qualified person to replace the power cord
	Damage to the power connector	Contact a professionally qualified person, arrange to have the device fixed.
	Malfunction of the LED module or electronics	

## INFORMATION ABOUT DISPOSAL

The device is classified as electrical and electronic equipment and must not be disposed of with household waste at the end of its normal life. Disposal and recycling are governed by the directive on waste electrical and electronic equipment (WEEE) No. 2002/96/EC. You can find out information about the disposal of waste electrical and electronic equipment from your local authorities.

### Information about EMC – Electromagnetic Compatibility

The device meets the requirements for electromagnetic resistance according to IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8 and IEC 61000-4-11. It can therefore be used in an environment where the quality of the power supply is typical of a home healthcare environment and that of professional healthcare facilities.

An electrostatic discharge may disrupt ongoing therapy. After the electrostatic discharge has subsided, restart the device. After restarting, the program selected will automatically start again.

Wireless communication devices such as wireless home networks, mobile phones, cordless phones and their base stations and portable radio stations can affect this device and must be located at least 1 m away from this device. Similarly, it can cause radio interference to surrounding devices and the device itself. Here, too, the principle of correct location applies.

## TECHNICAL DATA

### Light parameters

Light distribution	direct
Optical system	opal PS cover
CCT real1	5000 K
CRI	80
Flicker	Flicker free
Brightness of the illuminating surface	<7000 cd/m <sup>2</sup>
Illuminating surface	53.5 x 60 cm
Illumination*	3100 lx
Melanopic illumination*	3175 lx
Rhodopic illumination*	3135 lx
L-cone-optic illumination*	3161 lx
M-cone-optic illumination*	3060 lx
S-cone-optic illumination*	2112 lx

\* at a recommended exposure distance of 50 cm

### Electrical parameters

Supply	100–260 V 50–60 Hz
Connection	IEC 14
Power	maximum 40W

### Mechanical parameters

Body	drawn Al profile,
Surface finish	Al anodized sheet, adhesive
Luminaire weight	8 kg
Luminaire cover	IP20
Maximum ambient temperature	25 °C
Calculated lifetime of the LED	L80B20 70.000 h

**Service Center:** Spectrasol, s.r.o. <https://www.spectrasol.eu/kontakt/>

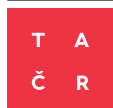
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Report possible side effects to the contact:  
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