Anexa 13

Specificație tehnică completată

Model: LUMINA, Producător: ASTAR, Țara:Polonia

Specificarea tehnică deplină solicitată	Specificația tehnică propusă de ofertant
Lampa fototerapie pe stativ Descriere: Dispozitivul incalzeste tesuturile avand efecte benefice numeroase cum ar fi: relaxarea muschilor si vasodilatarea. Specificații tehnice: Intensitatea reglabila: 10% - 100%, pasul 10%; Mod de lucru: manual/prestabilit; Minim 4 programe disponibile; Dozaj precis si control electronic: obligatoriu; Filtre: rosu si albastru; Accesorii: Ochelari de protecție; Putere ≥300W; Temporizator 1 -30minute; Alimentare 230V, 50Hz.	Lampa fototerapie pe stativ **LUMINA** Descriere: Dispozitivul incalzeste tesuturile avand efecte benefice numeroase cum ar fi: relaxarea muschilor si vasodilatarea. **DA** Specificații tehnice: Intensitatea reglabila: 10% - 99%, pasul 10%; **DA pag1/1 din Lumina v5.0_Datasheet, conform răspunsului la clarifcare se acceptă 10%-99%**; Mod de lucru: manual/prestabilit; **DA, pag1/1 din Lumina v5.0_Datasheet** Dispozitivul nu dispune de careva programe prestabilite de catre producator, insa ofera posibilitatea utilizilatorului sa selecteze intensiutatea si durata terapiei pentru fiecare pacient in parte. Dozaj precis si control electronic: obligatoriu; **DA, pag.32 din Luminav5.0_instructions_for_use** Filtre: rosu si albastru; **DA, pag1/1 din Lumina v5.0_Datasheet** Accesorii: Ochelari de protecție; **DA** Putere: 375W; **DA, pag1/1 din Lumina v5.0_Datasheet** Temporizator 1 -30minute; **DA, pag1/1 din Lumina v5.0_Datasheet** Alimentare 230V, 50Hz.**DA, pag1/1 din Lumina v5.0_Datasheet**

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Lumina

Phototherapy

Features

product code	A-UO-A-AST-LUMINAV5PS
manual mode	✓
independent treatment channels	1

Phototerapy

brightness adjustment	✓
brightness or time display	✓
easy filter application (red or blue)	✓
filter protection mesh	✓
mobile stand (4 wheels)	✓
table stand	✓
stand height adjustment	✓
lamp angle adjustment regulation	✓
forced tube cooling	✓

Phototherapy technical parameters

bulb light intensity	10 - 99%
maximum power of the bulb	375 W
power consumption	max 450 W
treatment time	1 - 30 minutes

General technical parameters

device height	min. 1,2 m, max 1,9 m
dimension of the lamp base (WxD)	max 0,5 x 0,6 m
dimensions of table stand without lamp (WxDxH)	30,0 x 31,5 x 6,0 cm
table stand dimensions (without lamp) (WxDxH)	30,0 x 39,0 x 41,0 cm
weight of stand with lamp	13,7 kg
weight of table stand with lamp	5,5 kg
power supply, power consumption	230 V, 50/60 Hz, 450 W

ASTAR.

Lumina –
Instructions for use

CE
0197

Contents

Table of figures

1. Introduction

Read this Guide carefully before starting the unit operation!
Follow the recommendations presented in this Guide! This manual applies to 5.0 version and higher. Device version is located on the nameplate.

Therapeutic lamp Lumina should be installed by the seller.
The recipient has the right to insist on the product operation training.
The unit may only be operated by qualified personnel or under supervision of such personnel!
WARNING: The device is intended for adult patients only. It is not intended for use in a home healthcare environment.

Description of symbols used in this manual:

Read appropriate passage of this user guide, warnings or important information. Failure to observe warnings can lead to injuries.

Important notices and information.

Following texts marked with this symbol facilitates device operation.

NOTE:

This manual contains instructions for use and technical description. This instructions for use is provided in the paper form.

WARNING:

No modification of this equipment is allowed!

1.1 Manufacturer

ASTAR Sp. z o.o.
Ul. Świt 33
43-382 Bielsko-Biała, Poland
www.astar.eu

1.2 Risk management process

The manufacturer conducts continuous risk management process referring to the device construction, its intended use, method of operation and maintenance. Residual risks are presented in this manual in form of information about precautions, contraindications and warnings.

2. Intended use

The therapeutic lamp Lumina is an active, non-invasive medical device used to perform heating treatments with the use of thermal energy emitted by an infrared emitter, aimed at warming up the skin and subcutaneous tissue in the treatment area.

Due to the intended use the device can be used in hospitals, clinics, health centers, GP practices, rehabilitation offices and other health care facilities, under the supervision of qualified personnel.

Its specific medical purposes are:
- treatment or alleviation of disease,
- treatment or alleviation of an injury or disability.

The required radiation characteristics are achieved by application of a suitable type of filter (available blue and red filter). The intensity of heat exchange through radiation depends on temperature of radiation source related to the rating of the applied bulb, length of light wave, distance and angle of incidence as well as on circumstances accompanying the influence (e.g. influence of ventilation and/or air conditioning in the treatment room). Treatments are performed in non-contact method.

Special structure of the device makes it easy to operate and the controller, which is built-in the lamp tube, increase the comfort of operation.

Radiation emitted by the device is of non-ionizing nature (corresponding marking is placed on the lamp tube).

The device can be used to treatment conditions in the following areas:
- sports medicine,
- orthopedics,
- rheumatology,
- neurology,
- dermatology,
- aesthetic medicine.

Lamp application areas include:
- arthritis, spondylosis,
- chronic periarthritic inflammation, tendonitis,
- myalgia, contractions, post-traumatic complications,
- chronic neuritis, neuralgias,
- skin disorders, furuncles, sebaceous gland infection,
- chronic artery inflammations,
- acne,
- pathological muscle tension,
- acceleration of regeneration processes.

In addition, infrared radiation is used before stretching exercises, mobilizations, tractions, massages and kinesitherapies. It can also be used as a preparation prior to treatments of electrostimulation or biofeedback, as increased skin temperature boosts its conductivity.

A list of indications and contraindications is provided in section 9.

2.1 Intended users

The patient should not be the operator.

Users (operators) of the Lumina can be:

- specialists in the field of the infrared radiation therapy,
- physiotherapists specializing in the therapy of the musculoskeletal system,
- sports medicine specialists,
- aesthetic medicine specialists,
- trained personnel performing treatments under the supervision of the above-mentioned specialists.

The user should have:

- knowledge about the indications and contraindications for the use of the infrared radiation therapy,
- knowledge of the terminology and technical terms used in the manual (e.g. knowledge of units of physical quantities),
- practical skills in performing therapeutic treatments using devices for therapy, resulting from education, experience and training.

Physical and cognitive requirements of the operator:

- eyesight enabling to recognize elements of keyboard and display,
- hearing enabling to hear the patient's voice,
- reading comprehension that allows to read the instructions of use and information on the casing of the device,
- two functional upper limbs that allow to perform treatments and other activities related to the operation of the device (e.g. the bulb replacement),
- age in the range of admissible value of professional activity (depending on the regulations of the country where the device is used).

2.2 User training

The Lumina lamp user has to be properly trained in the device safe and effective use, before starting the operation. Training in the rules of operation can be carried out by representatives of the manufacturer or seller, based on this user manual.
Recommended training positions:

- information about the intended use of the device,
- occupational safety information,
- information on the construction and method of the heat generation,
- information on available settings and operation modes,
- instructions for use,
- indications and contraindications for the therapy,
- information on recommended maintenance, cleaning and disinfection,
- handling in the event of a technical malfunction.

Due to requirements of local law and regulations in different countries, additional training activities may be required. The user should inform the seller about such requirements in order to receive complete information.

3. Warranty and manufacturer's responsibility

The manufacturer warrants the device to be free of faults for the period of time and conditions stated in Warranty Certificate. The manufacturer also provides post-warranty service for a period of 10 years from launching the unit onto the market. The warranty includes all material and workmanship faults.

The manufacturer undertakes to observe the warranty agreement, if the following conditions are met:

- all repairs, changes, extensions and calibrations of equipment are performed by manufacturer or authorized service personnel,
- firmware updates are performed by the manufacturer, an authorized service personnel or distributor,
- the mains supply system in the treatment room meets requirements of standards in force,
- the unit is operated by qualified personnel, in compliance with instructions presented in this manual,
- the unit is operated in compliance with its intended use.

The warranty does not include consumables, such as mains cables, holders, fuses, filter glass as well as defects or damages caused by:

- incorrect placement, installation or configuration of the device,
- misuse or non-compliance with the instructions given in the manual,
- improper or inadequate maintenance by the operator,
- improper use in accordance with the environmental conditions specified for the product,
- unauthorized opening of the lamp tube casing,
- manipulation and / or unauthorized regulation,
- use of non-original accessories.

The warranty for the infrared lamp emitter is granted on the terms given by the manufacturers of these elements. You can find information on this on the infrared lamp emitter package.

The warranty does not cover any damage due to a failure to adhere to the recommendations stated in chapter 4.3 and 10 hereof.

The manufacturer is not liable in case of transmission of infection by equipment components.

The expected "life time" of the device is 10 years.

After elapse of 10 years from the date of introduction of device and accessories in the market the manufacturer is not liable for device and accessories' faults or its consequences. After elapse of the expected “life time” of the device the user bears the complete responsibility for the occurrence of medical incidents.

The manufacturer bears no responsibility for results of faulty installation, wrong diagnosis, wrong use of the device and equipment, failure to observe instructions in user manual and performance of repairs by unauthorized persons.

There are no parts in the device, except for fuses, an infrared radiator (bulb) and filters that the user is allowed to change by themselves. No parts can be serviced or maintained when the device is in use with a patient.

The firmware that is part of the device is not intended to be installed, configured or updated by the user.

On demand, the manufacturer makes available technical diagrams, parts lists, descriptions, instructions for calibration or other helpful information to appropriately qualified user's technical staff to repair these parts of unit, which are described by the manufacturer as a reparable.

4. Operational safety

4.1 Mains supply and operation mode

The Lumina lamp is designed for supply from AC mains with rating 230 V ± 10%, 50/60 Hz. It is a medical device under safety class I, type B. The unit may be used only in rooms, where the electric system is executed in compliance with standards in force. The unit is intended for continuous operation. It is not necessary to switch it off from the mains between particular treatment procedures.

The lamp is connected to the mains using the detachable power cord. The power supply cord is equipped with a mains plug that isolates the device from the supply mains on all poles simultaneously.

Recommendations related to isolation the device from the supply mains:

- **Do not position the device so that it is difficult to operate the disconnection of the device from the supply mains.**
- **To isolate the device from the supply mains, hold the mains socket-outlet with one hand, grasp the mains plug with second hand and disconnect it from the mains socket-outlet.**

Disconnection from the mains takes place after:

- **removing the mains cable plug from the mains power socket,**
- **removing the mains cable plug from the socket on the unit,**
- **switching the mains switch to the "0" position.**

4.2 Storage, operation and transport conditions

The unit must be stored in closed rooms, where the atmosphere is free from vapors and caustic substances and:

- the temperature is maintained between +5°C and +45°C,
- relative humidity does not exceed 75%,
- atmospheric pressure value is between 700 and 1060 hPa (70 – 106 kPa).

The unit is intended for operation under the following conditions:

- ambient temperature between +15°C to +30°C,
- relative humidity between 30% to 75%,
- atmospheric pressure between 700 to 1060 hPa (70 – 106 kPa).

If further transport of the device is required, use the delivery packaging. Transport shall be performed with covered transport means.
Recommended transport conditions:

- ambient temperature between -10°C to +45°C,
- humidity between 20% and 95%,
- atmospheric pressure between 700 to 1060 hPa (70 – 106 kPa).

4.3 WARNINGS and safety notes

The Lumina lamp is designed and manufactured so that its use does not endanger the health and safety of patients, users and third parties, as well as it ensures therapeutic benefits to patients, provided that it is operated under appropriate conditions and according to its purpose.

General information:

- **The unit may be only operated by qualified personnel (see chapter 2.1) in compliance with instructions presented further in this manual.**
- **To avoid the risk of electric shock, the equipment must only be connected to mains supply with protective earth pin.**

- **No modification of this equipment is allowed!**
- **The treatment station (bed, couch) shall be located away from other electric devices and water supply/ sewerage installation/ central heating system, so that it is impossible for the patient to touch any of them during treatment procedure.**
- **Do not position the lamp so that it is difficult to operate the disconnection of the device from the supply mains.**
- **The lamp shall only be used with filter installed! Filters are equipped with a protective mesh that protects the patient from any possible injury as a result of broken filter glass or bulb.**
- **Do not remove warning signs and labels put by the manufacturer on the unit casing.**
- **Avoid exposing the lamp to atmospheric factors (e.g. direct sunlight).**
- **Damaged cables, filters and/or bulb shall be replaced immediately. Pay special attention to the casing cracks, threadbare insulation and partially torn interconnecting cables.**
- **Prevent any fluid from penetrating inside the unit. In case of any fluid getting inside the lamp, switch the unit immediately off, disconnect from the mains and contact authorized service to inspect the unit.**
- **It is recommended to pay attention to the work of the cooling fan, the unit should not be used, if incorrect operation or its lack is stated.**
- **By any means do not cover the ventilation gaps. Do not insert any objects into vents. If the staff notice that the ventilation holes are clogged with dust, clean them with a vacuum cleaner. This operation can also be done by an authorized service center.**
- **It is forbidden to adjust the position of the lamp tube using the holder of the filter. For adjustment use handles located on the sides of the lamp tube.**
- **It is forbidden to place other devices on the stand.**
- **According to the device labeling: pushing, sitting on the stand and stepping is prohibited.**
- **The stability of the stand should be provided. The stand wheels are equipped with brakes, which should be locked during the treatment session. The table base should be placed on a flat, stable surface.**
- **The lamp can be moved with the table base without having to unscrew it. During transfer, it should be held by the tube or U-shaped holder (possibly additionally by the base itself), not by the handles on the front part.**
- **The unit may be only used with accessories, spare parts, which have been determined to be safe and appropriate inspection bodies have not issued contraindications against their use.**
- **After switching the unit off, wait for 10 seconds before you switch it on again.**
- **It is recommended to use bulbs:**
    - **manufactured by Signify (formerly known as Philips) – infrared lamp emitter R-125 IR375 CH 230V 375W or IR250CH 230V 250W, thread E27**
    - **manufactured by Fabryka Żarówek „HELIOS" – infrared lamp emitter R-125 E27, 230V 375W, thread E27**

  It is permissible to use other infrared radiators with the E27 threaded bulb provided that their rated power does not exceed 450W due to the permissible parameters of the casing.
- **Each serious incident concerned with the device should be reported to the manufacturer and competent authority of the country, where the user or patient resides. Serious incident means any incident that directly or indirectly led, might have led or might lead to any of the following:**
    - **the death of a patient, user or other person,**
    - **the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,**
    - **a serious public health threat.**

Occupational Health and Safety:

- **The operator must wear protective goggles during treatment.**
- **Patients should wear protective goggles when the light therapy is performed in the area around the face and chest.**
- **Do not look directly at the source of radiation without wearing protective goggles.**
- **The device is safe to use for treatment under reasonably foreseeable conditions.**
- **Do not use the lamp for lighting purposes.**
- **Do not use the lamp to heat the treatment room.**
- **It is unacceptable to operate the device without installed filter with a protective mesh.**
- **The patient is not allowed to touch any part of the lamp during and after treatment.**
- **The patient should remove jewelry and other metal parts from the exposure area.**

Increased temperatures:

- **Some parts of the lamp during work are very warm (filters, metal parts of the front cover), so special care should be taken to avoid burns. It is advisable to turn off the lamp and wait until it has cooled down before carrying out maintenance or repair work on the heating elements. Also placing other devices and accessories in the area of the lamp should be avoided.**
- **Lamp tube warms up during operation. Avoid touching the heated body of the lamp tube. Adjust position only with the holders located on the lamp tube sides. The permissible temperatures for control elements – holders and control panels, specified by the safety standard for medical devices, are not exceeded.**
- **Remove the filter by holding it only by its holder. Avoid touching the mesh and glass that heat up to high temperatures.**

Therapeutic:

- **The device is intended for adult patients (patient has to be conscious). Minor patients – only on the doctor's explicit recommendation, after considering contraindications.**
- **It is impermissible for the patient to carry out the treatment on their own.**
- **It is prohibited to leave the patients unattended during treatments.**
- **It is necessary to continuously update knowledge and follow literary activities in the scope of therapy.**
- **Patients with implanted electronic devices (e.g. cardiac pacemakers, cardioverter defibrillator, spinal cord stimulator) or other metal implants should be consulted by the physician prior to treatment.**
- **Prior to the treatment it is necessary to interview the patient, by taking into consideration relative and absolute contraindications to use infrared radiation therapy.**
- **Treatment parameters and area should be consistent with the medical indications.**
- **It is recommended to keep records of treatments including the parameters of therapy, the area of treatment, treatment technique, dose and symptoms after therapy.**
- **Do not perform treatments on patients under the influence of alcohol.**
- **Do not perform treatments on patients under the influence of intoxicants.**
- **It is necessary to ensure the adequate interval between treatments for the patient, in order to avoid an increase of the risk of complications.**
- **Seated or reclined position should be applied to the patients with respiratory disorders and breathing difficulties.**
- **During the operation, attention should be paid to the level of pain experienced by the patient – the settings and the intensity of the treatment should be adjusted to the current sensations.**
- **Treatments may result in disturbances in the form of an increase or decrease in the sensitivity threshold at the site of treatment.**
- **Take special care with patients with disturbed surface sensation.**
- **It is essential to avoid performing procedures in pregnant women.**

Use in veterinary medicine:

- **Take special care during veterinary procedures.**
- **Treatment procedure should be constantly monitored and the device should not be left unattended or under the supervision of an animal caretaker.**
- **If you are unsure about the practice of veterinary treatments, you should consult your veterinary specialist.**

4.4 Explosion proof environment

The Lumina lamp is not adopted to operation in rooms, where combustible gases or their vapors occur. It is recommended to avoid anesthetic or oxygen derivate gases, such as nitrous oxide (N2O) and oxygen. Some materials (e.g. cotton, wool) may after saturation with oxygen become combustible at high temperatures generated with normal operation of equipment. It is recommended that solutions of adhesive and combustible solvents be vaporized before equipment is operated. It is also recommended to pay attention to the danger of ignition of endogenous gases. The unit must be separated from the mains before approaching the disinfection room, where it is installed.

4.5 Electromagnetic environment

- Due to the intended use, the device can be used in hospitals, clinics, rehabilitation centers and other health care facilities under the supervision of qualified personnel.
- Simultaneous operation of the Lumina lamp with devices generating strong electromagnetic field, such as short wave, microwave diathermies, high frequency surgical equipment, MRI systems, may disturb unit operation. For this reason, it is recommended to maintain appropriate distance between these devices or to switch off the generator of strong fields during therapy with the unit. Manufacturer doesn't claim compatibility of the Lumina lamp with high frequency surgical equipment.
- As a result of electromagnetic disturbances of considerable intensity, the device may be subjected to interference with the flickering light bulb, interruptions in radiation emission or discontinuation of emission and return to initial settings. Due to the purpose and use of the lamp, none of the above-mentioned disturbances in the operation of the lamp cause any danger for the patient or the operator.
- WARNING: Use of the Lumina lamp adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Lumina lamp and the other equipment should be observed to verify that they are operating normally.
- It is recommended to use original accessories, spare parts and equipment of Astar.
- WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Lumina lamp, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE: Between the U-shaped holder and stand arm (on the upper side of the U-shaped holder), a washer should be located (Figure 6.2.) to provide adequate insulation between the lamp tube and the stand arm. This washer should also be placed between the table base and U-shaped holder (Figure 6.5). Fixing it from the bottom of the U-shaped holder is incorrect and may cause deterioration of immunity of the lamp to disturbances.

The unit meets requirements of electromagnetic interference emission and immunity standards and shall not pose a threat to correct operation of other devices. Compliance levels for emissions and immunity are given in section 11.2.

4.6 Labels

The lamp is marked with a symbol of non-ionizing radiation. Emitted radiation does not have the characteristics of ionizing radiation.

Figure 4.1. Classification label sample

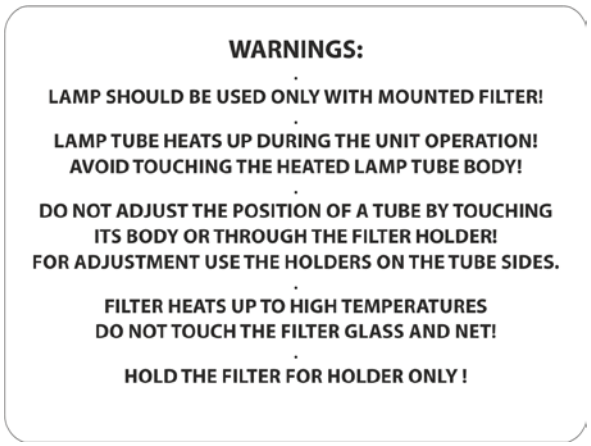


Figure 4.2. Warning label sample

4.7 Essential performance

Essential performance, in relation to the area of physical therapy available with the Lumina lamp, is presented in Table 4-1.

Table 4-1 Essential performance of the device

Physical therapy	Essential performance characteristics
Infrared radiation therapy	Generation of thermal energy using an infrared radiator (in the form of a glass bulb with an electrically heated filament) in the IRA and partially IRB wavelength range, which is aimed at heating the skin and subcutaneous tissue, with: • adjustable treatment time (1-30 minutes), • adjustable bulb intensity (10-99%). The device meets the requirements, which specifies: • appropriate type of infrared radiator (indicated by manufacturer), • the intended accuracy of the brightness level value displayed on the display, • the intended accuracy of the value of time remaining to the end of the treatment displayed on the display.

4.7.1 Tests of essential performance and basic safety

Calibrating or servicing the device shall be carried out by the manufacturer or an authorized service personnel in accordance with separate guidelines. If the warnings given in this manual are followed, there is no risk for persons performing the above-mentioned activities.

The user of unit must perform technical inspection of the unit at year's intervals. The inspection must be performed by a unit authorized by the manufacturer. The inspection is performed at the user's expense.

Test item	Method of checking	Acceptance criteria	Required measuring equipment
Safety test: • touch current measurement, • insulation resistance if necessary	The manufacturer allows the methods compliant with the requirements of the standards: • IEC 60601-1 • IEC 62353	The measurement results are within the limits specified by the applied standard	Safety tester meeting the: • IEC 60601-1 • IEC 62353 requirements
Control of correctness of the performed self-test	Visual inspection	No errors	No requirements
Evaluation of device function and operation	Manual and visual inspection	The keys respond properly to pressure	No requirements
		The bulb light intensity responds properly to changes	No requirements

Test item	Method of checking	Acceptance criteria	Required measuring equipment
Inspection of the mains cable condition	Visual inspection	No tear and bending of cable insulation	No requirements
Inspection of the wheels brake condition	Visual inspection	Unbroken and uncracked wheel brake	No requirements
Inspection of the condition of screws fixing the stand to the base	Visual inspection	Unloosened screws	No requirements
Inspection of the condition of knob fixing the lamp to the table base	Visual inspection	Unloosened knob	No requirements
Inspection of condition of the screw fixing the lamp tube to the stand	Visual inspection	Unloosened and not corroded screws, tightened to the maximum level	No requirements
Inspection of the condition of screws mounting the U-shaper holder to the lamp tube	Visual inspection	Unloosened and not corroded screws, tightened to the maximum level	No requirements
Inspection of the condition of screw on the stand or table base	Visual inspection	Unloosened and not corroded screw, tightened to the maximum level	No requirements

If the screws are loose, tighten them in accordance with the instructions given in section 6.
The inspection must also include checking the quality of applied accessories and treatment materials.

Positive result of the technical inspection confirms that basic safety and essential performance is maintained.

4.8 Thermal protection

A thermal protection component is installed in the unit, which works in a reversible way. The protection is activated when the temperature inside the unit exceeds 100°C (e.g. as a result of prolonged operation with deteriorated cooling or failure). Operation will be possible again when the temperature inside the unit falls below 85°C.
Details of how to proceed with the activation of the protection can be found in chapter 10.6.

4.9 Disposal

In case, when the disposal of the unit will become necessary (e.g. after elapse of its service life), please contact the manufacturer or manufacturer representative, which must react in an appropriate way i.e. collecting the unit from the user. The user may also contact companies specialized in removal and/or disposal of electrical devices or computer equipment. Under no circumstances should you place the unit along with other wastes. The name plate includes an appropriate symbol (see **Appendix A**).

The device is marked with an appropriate symbol compatible with the requirements of the directive on waste electrical and electronic equipment (WEEE) – see the table with symbol description used for marking the product in **Appendix A**.

Used infrared light bulb should be disposed of according to the rules for the used light sources. Bulbs used in Lumina lamp do not contain electronic components.

5. Device construction

5.1 General characteristics

Main elements of the Lumina lamp construction:
- base with wheels for easy position change,
- table base for lamp operation without a stand,
- stand with height adjustment (change range – 70 cm ± 2 cm),
- lamp tube with U-shaped holder, which is allowed to be mounted to the stand or table base.

The base of the device has been specially designed to provide stability and to easily move the lamp. Stand wheels equipped with brakes are made from high quality materials to provide their durability and reliability. Mounting the lamp tube on the table base ensures the stability of the lamp without using a stand. General view of the lamp is presented in Figure 5.1. and Figure 5.2.

Figure 5.1. General view of the Lumina lamp – stand construction (configuration)

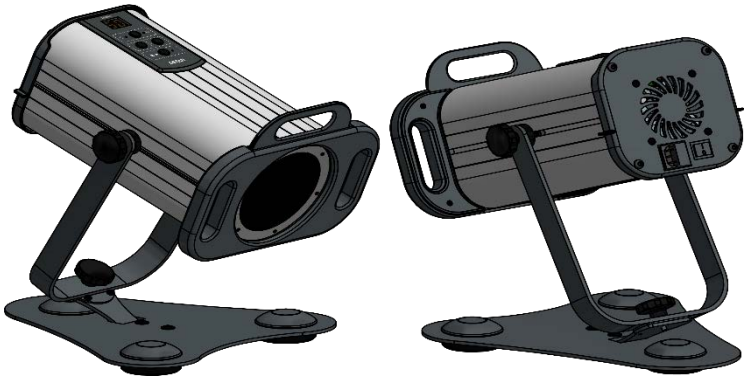


Figure 5.2. General view of the Lumina lamp – table construction (configuration)

The lamp stand mounted to the base has the possibility of height adjustment. At the top, an arm is attached to which the holder with lamp tube is mounted.
When using the table stand, it is possible to adjust the rake angle of the lamp tube.

The lamp tube is inseparable, but after removing the filter it is possible to replace the bulb (details – Figure 10.1.). On the front of the casing, holders are mounted to adjust the angle of inclination of the lamp tube (Figure 5.3.).

NOTE: Do not use the filter holder to adjust the angle of inclination of the lamp tube!

The filter surface is the output aperture of the lamp.

Figure 5.3. Lamp tube

At the rear side of the casing there are ventilation holes for cooling. The air flow is forced by the fan.
The mains switch, fuse socket and mains socket are located on the rear side of casing. Details are shown in the Figure 5.4.

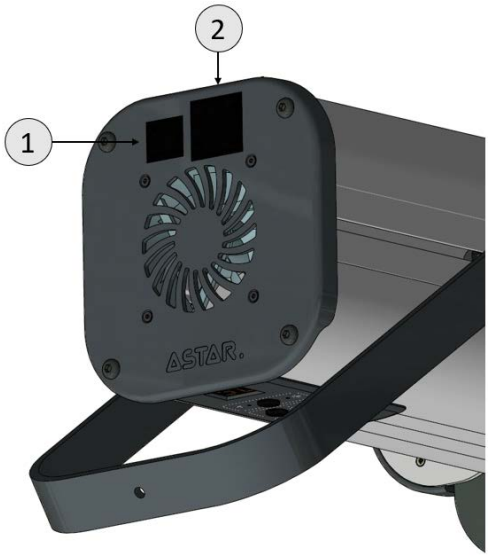


Figure 5.4. View of the rear side of the lamp tube

Symbol	Description
1	Mains rocker
2	Mains and fuse socket

5.2 Lamp controller

The controller works as a module built into the lamp tube.

The electronic controller system consists of:
- microcontroller module,
- user interface consisting of a two-digit seven-segment display, keys and LED diodes,
- power circuits providing adequate supply voltages,
- auxiliary circuits to control the fan and bulb.

Advanced microprocessor electronic system:
- manages all operating parameters and controls them in real time,
- controls the fan and bulb,
- cooperates with LED display, keys and signaling diodes.

Control panel view is shown in the Figure 5.5. Detail interface description, see section 8.3.

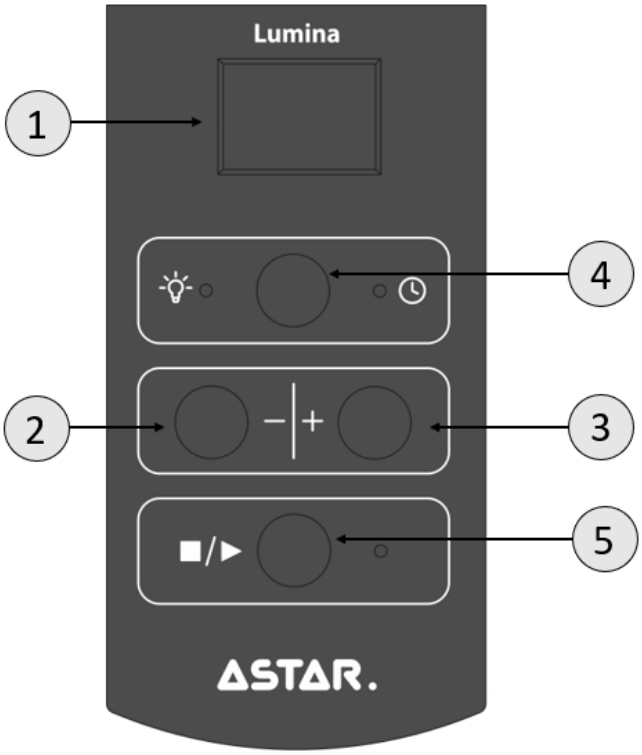


Figure 5.5. Interface panel description

Symbol	Description
1	Display
2	Decrease key
3	Increase key
4	Parameter change key
5	START/STOP key

5.2.1 Display

The display consists of two fields, where information about the operation of the device is displayed:
- time remaining to complete the treatment, or
- bulb brightness (as percentage of supply voltage duration).

5.2.2 Parameter change key

You can change the type of information shown on the display with this key. The display may indicate the remaining time of the treatment or the brightness level of the light bulb. The green LED diode next to the selected time symbol or brightness level will be lightened (Figure 5.6.).

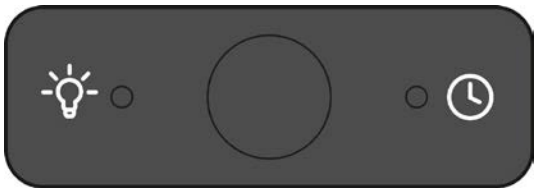


Figure 5.6. Parameter change key

5.2.3 INCREASE and DECREASE keys

With these keys you can change the selected parameter – time or brightness level (Figure 5.7.).

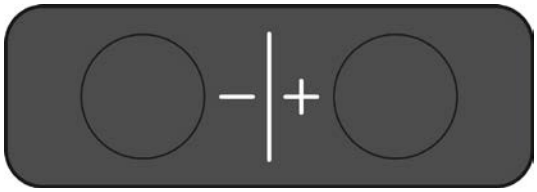


Figure 5.7. Increase and decrease keys

5.2.4 START / STOP key

The START / STOP key is used to start and stop the treatment procedure (Figure 5.8.). During the treatment, orange indicator situated on the right side of the key is lit on.

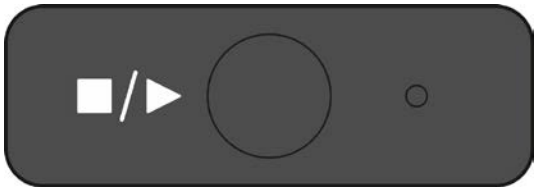


Figure 5.8. START / STOP key

5.3 Name plate

The name plate is located on the lamp tube. Among others there are following data on the name plate (see **Appendix A**):

- device name and version,
- UDI-DI code,
- serial number and date of production – UDI-PI code,
- nominal voltage and maximum power consumption,
- type of applied fuses,
- manufacturer's data.

6. Device installation and start-up

6.1 Device installation

The first installation should be performed by a qualified manufacturer's or distributor's representative!

After taking the device out of its packaging check whether the complete equipment has been delivered (details – section 11.3). In case of any discrepancies contact the seller.

After removing the unit from transportation packaging wait approximately one hour before proceeding to next installation steps. This is aimed at adaptation of the lamp to conditions in operation room.

The Lumina lamp shall be placed near mains socket with power input 230 V ± 10% and 50/60 Hz. Due to manufacturing under safety class I the unit can be connected only to a socket with protective earth pin. The light shall enable easy readout of display indicators, however the unit shall not be exposed to direct sunlight.

The device shall be set up in a position enabling free air flow access to the back of the lamp, where the ventilation holes are situated. It is unacceptable to cover aforementioned vents in any way.

6.2 Assembling – lamp on a stand

- Set the base with mounted wheels on the floor.
- Take out of the packaging the stand and the arm, and then fix it to the base (Figure 6.1.) with the supplied screws. Tighten the screws with an Allen key.
- Take out of the packaging the lamp tube along with the U-shaped holder.
- Slip the U-shaped holder into the protective holder (Figure 6.2.).
- Set the U-shaped holder so that you can screw the screw into the threaded hole in the stand arm. Tighten firmly (Figure 6.3.).
- Attach the mains cable to the stand with the clips. Adjust the clip position, make sure the cable is not bent, strained, or twisted (Figure 6.4). This will make it easier to set up the lamp tube. Before attaching the clip to the stand, tilt the rubber washer, insert the clip, and push the washer again.

Ask another person for help if you have any difficulties with assembling the lamp tube.

Figure 6.1. Assembly of a stand to the base

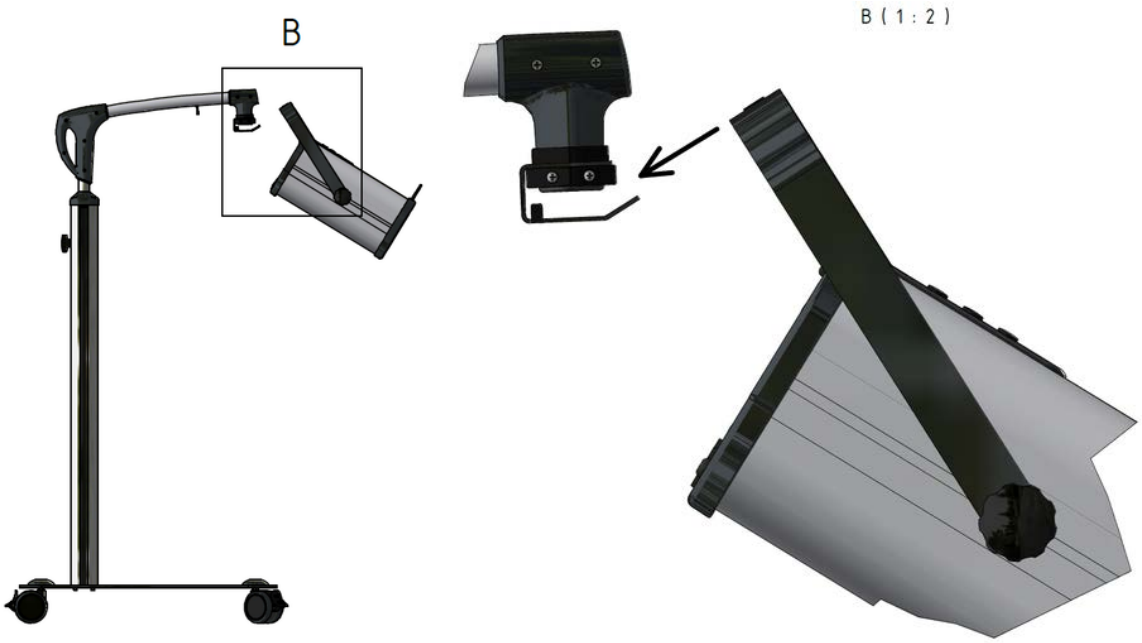


Figure 6.2. Hanging the lamp tube on a security holder

Figure 6.3. Assembly of a lamp tube to the stan

Figure 6.4. Attachment of mains cable clips

6.3 Assembling – lamp on a table stand

- Set the stand table base on the flat surface.
- Take out of the packaging the lamp tube along with the U-shaped holder. Loosen the knobs that attach the U-shaped holder to the lamp tube. Move the U-shaped holder into the mount position on the table base as shown in the Figure 6.5.
- Place the U-shaped holder on the base support. Lean against the plastic screw heads placed on the base support. Screw the U-shaped holder to the base using the knob (Figure 6.6).
- Connect the mains cable.

Ask another person for help if you have any difficulties with assembling the lamp tube.

Figure 6.5. Correct position of the U-shaped holder mounted to the base

Figure 6.6. Positioning of the bushing, U-shaped holder and knob.

6.4 Filter and bulb assembly

The device is equipped with two types of filters – blue and red. The mechanical structure of filter prevents the filter from slipping out of the lamp tube. Filters are equipped with a protective mesh that protects the patient from any possible injury as a result of broken filter glass or bulb.

Prior to the operation, the filter should be inserted (holding the handle) into the slot located in the upper front of the lamp tube. The protective mesh should be on the outside of the tube – visible when after installing the filter in the tube.

The bulb and filter installation is shown in the Figure 6.6., part c and d. The method of disassembly of the bulb and filter is shown in the Figure 6.6., parts a and b.

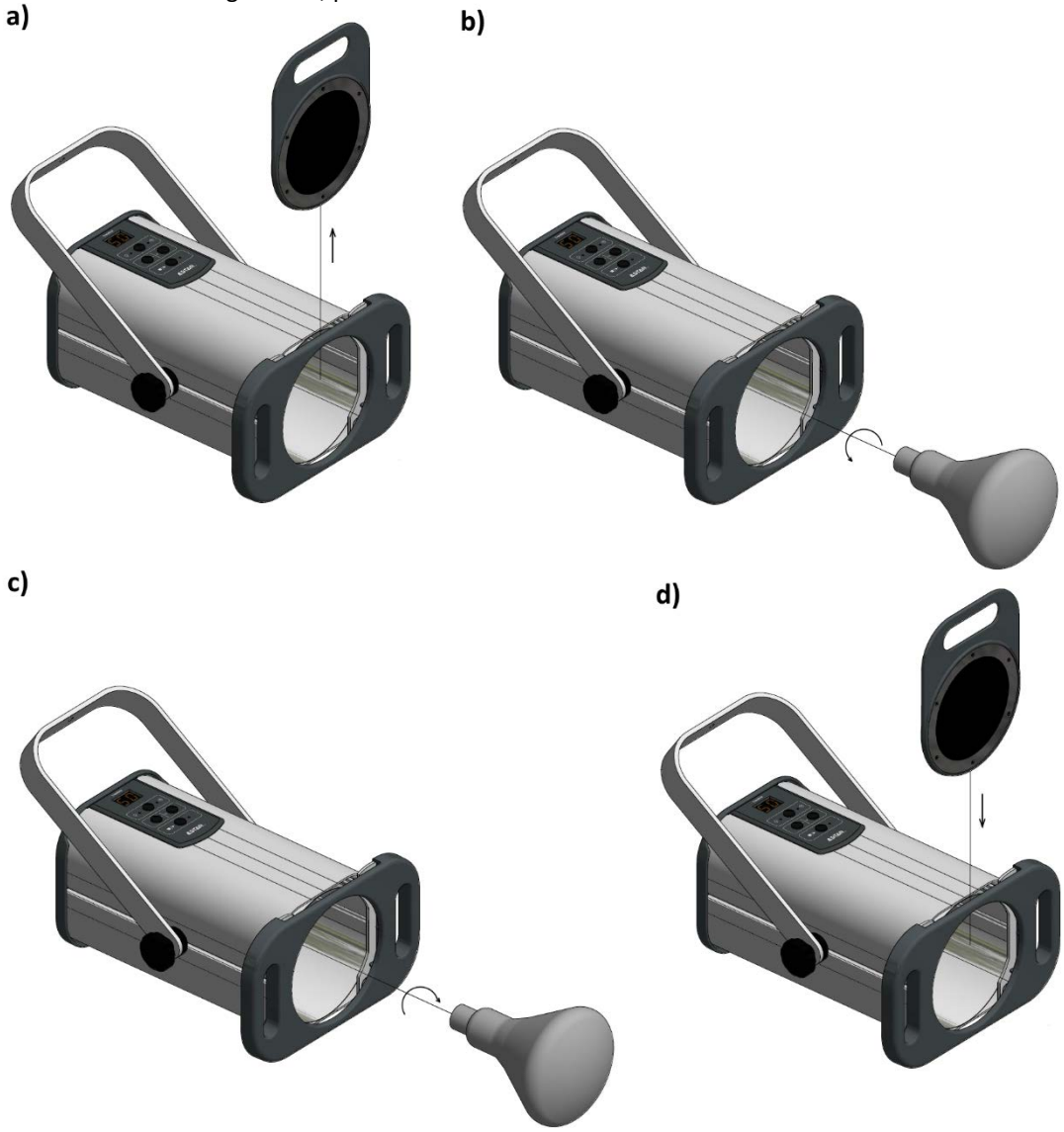


Figure 6.7. Assembly / disassembly of the bulb and filter

6.5 First operation

Connect the mains cable to the socket located on the lamp tube, then to the mains power supply. Then turn on the lamp with the use of mains switch. After switching the mains supply on, the unit starts its operation from self-test on the internal functional blocks.

The device is properly installed and is ready to perform safely and as intended by the manufacturer if:

- **it is connected to a mains socket (with grounding pin) with a voltage in the range 230 V ± 10% V and a frequency of 50/60 Hz,**
- **accessories appropriate for the user's intended therapy are connected,**
- **self-test result is positive.**

If the display does not work after switching the mains supply on, check the fuses and the mains cable. Care shall be given to apply fuses with rating given on the name plate. If fuses and cables are working properly, contact the authorized service.

6.6 Transport position – lamp on the stand

If you need to transport the lamp at a distance greater than that found in the treatment room, such as a move into another room, it is advisable to prepare the lamp accordingly. For this purpose:

- lower the stand and lock its position, in this position by tightening the screw (see section 7.2), disconnect the mains cable from the tube,
- unlock all the brakes and transport the stand,
- after transport and positioning in the new place lock the brakes and connect the mains cable.

7. Device operation

7.1 Patient preparation and treatment performance

7.1.1 General

To perform safe and effective treatment procedure you are obliged to:

- make sure if there are no contraindications to perform the treatment,
- the patient should be placed in a comfortable position providing relaxation of tissues in the treatment area, the patient should be in lying position in case of treatment performed near the head,
- seated or reclined position should be applied to patients with respiratory disorders or breathing difficulties,
- inform the patient about the sensations during the treatment procedure, if the communication with the patient is difficult, increase the distance between the lamp and the patient to avoid burns, also control the degree of tissue overheating during the treatment procedure.

The treatment effectiveness depends on the choice of parameters to the current patient's condition. The patient's condition changes over time. Its observation and assessment should take place before, during and after therapy. Such an action is necessary for changing the parameters in order to adapt them to the actual condition of the patient.
It is recommended to keep records of treatments including the parameters of therapy, the area of treatment, treatment technique, dose and symptoms after therapy. If the treatment does not generate the intended effects, change of treatment parameters should be taken into consideration. It is necessary to continuously update knowledge and follow literary activities in the scope of therapy.

When performing therapy, it is recommended to follow the guidelines given in the following sections.

NOTE:
Using the methods of control, adjustment or performance of procedures other than those specified herein may result in exposure to hazardous radiation.

7.1.2 Infrared radiation therapy

- **Make sure that the lamp is equipped with filter with a protective mesh! Mesh must be directed outside the tube.**
- **It is necessary to explain to the patient the specificity of the treatment and sensations occurring in the course of infrared radiation.**
- **In the place of radiation, it is necessary to assess the continuity of the skin and superficial sensation. Take special care with patients with disturbed superficial sensation.**
- **It is necessary to keep special caution if communication with the patient is hindered. Then increase the distance from the lamp to avoid burns, also control the degree of tissue overheating during the procedure.**
- **It is necessary to consult and check during the treatment the degree of heat sensation by the patient (by means of touch or by placing a palm between the radiated surface and the reflector of an infrared lamp).**
- **When the level of feeling of heat is uncomfortable for the patient, they should immediately report this to the therapist.**
- **Intensity of the emitted radiation may be adjusted by changing the distance of the lamp from the heated surface.**
- **The distance of the reflector of the lamp from the radiated surface should be within a range of 60-75 cm for lamps of large power (750-1000W), in case of lamps of lower power at the distance within a range of 45-50 cm.**
- **It is necessary to ensure that the infrared radiation is at right angle on the tissue.**
- **After the treatment it is necessary to check carefully the skin of the patient. In palpation assessment the skin should be slightly or moderately warm with noticeable heat erythema with speckled pattern in the**

area of radiation. Intensity of radiation may differ due to intensity of the treatment and content of pigment in the skin.

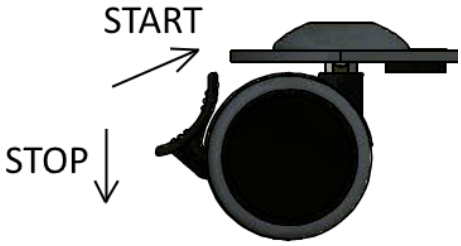
- **The risk of occurrence of burns is decreased by: cautious and careful application of treatments (including the assessment of an ability to differentiate by the patient the intensity of temperature), the adequate communication to the patient of the information concerning the character of heat stimulus, checking the degree of the skin's overheating during the treatment.**

The example of application is presented below.

Applicator	Example
The lamp tube on the stand	

7.2 Setting the lamp on a stand

Operation scheme:

Step	Description	
1.	Set the lamp position: • unlock the brakes – START position, • move the lamp, • lock the brakes – STOP position.	
2.	Set the height of lamp tube: • unscrew the knob screw on the stand, • use the handle to set the stand height, • tighten the screw.	

Step	Description		
3.	Set the direction of the lamp tube:	• unscrew (approx. 1 turn) the knob screw that attaches the tube to the stand,	
		• turn the tube in the right direction by holding the handles located on the front of the lamp tube,	
		• tighten the knob screw.	

Step	Description		
4.	Set the operating angle of the lamp tube:	• unscrew (approx. 1 turn) the knob screws placed on the U-shaped holder, left and right,	
		• set the appropriate lamp angle of operation by holding the handles located on the front of the lamp tube,	
		• tighten the knob screws placed on the U-shaped holder, left and right.	

7.3 Setting the lamp on a table stand

While working with a table stand, you are able to adjust the operating angle of the lamp tube.

Figure 7.1. Setting the operation angle of the lamp tube.

Operation scheme:

Step	Description	
1.	Unscrew (approx. 1 turn) the knob screws placed on the U-shaped holder, left and right.	
2.	Set, by controlling the handles located on the front of the lamp tube, the appropriate lamp angle of operation.	
3.	Tighten the knob screws placed on the U-shaped holder, left and right.	

7.4 Lamp configuration change

Note: Ask another person for help if you have any difficulties with assembling the lamp tube.

If the lamp is assembled on a stand and you want to work on the table base:

Step	Description	
1.	Unplug the mains cable from the lamp and remove it from the clips.	
2.	Holding the lamp tube, unscrew the fixing screw. Slide the lamp tube from the holder.	
3.	Set the base on a flat surface.	
4.	Unscrew the knob screws that attach the U-shaped holder to the lamp tube. Move the U-shaped holder into the assembling position on the table base.	
5.	Place the U-shaped holder on the base support. Lean against the plastic screw heads placed on the base support. Screw the U-shaped holder to the base using the knob screw.	
6.	Connect the mains cable. Set the lamp according to the section 7.3.	

If the lamp is assembled on a table base and you want to work on the stand:

Step	Description
1.	Set the base with mounted wheels on the floor. If the base is not assembled, see section 6.2.
2.	Disconnect the mains cable from the controller.
3.	Holding the lamp tube, unscrew the fixing screw. 
4.	Set the tube with the controller and U-shaped holder positioned upwardly. Slip the U-shaped holder into the protective holder. Set the U-shaped holder so that you can screw the screw into the threaded hole in the stand arm. Tighten firmly. 
5.	Attach the mains cable to the stand with the clips. Adjust the clip position, make sure the cable is not bent, strained, or twisted. This will make it easier to set up the lamp tube. Before attaching the clip to the stand, tilt the rubber washer, insert the clip, and push the washer again. 
6.	Set the lamp according to the section 7.2.

7.5 Treatment time setting

Operation scheme:

Step	Description
1.	Switch on the unit.
2.	By pressing the **Parameter Change Key** set the display to the treatment time indication mode – so that the green LED diode next to the symbol ⏲ is lit on.
3.	Use the **Increase / Decrease Keys** to set the desired time value (in minutes).

7.6 Bulb brightness level setting

Operation scheme:

Step	Description
1.	Switch on the unit.
2.	By pressing the **Parameter Change Key** set the display to the brightness level indication mode – so that the green LED diode next to the symbol is lit on.
3.	Use the **Increase / Decrease Keys** to set the desired brightness level.

NOTE: Adjustment of the brightness level is also possible during the treatment.

7.7 Start and end of the treatment

Operation scheme:

Step	Description
1.	Switch on the unit. Set the treatment parameters – see sections 7.5 and 7.6.
2.	Press the **START / STOP key** ■/▶ to start the treatment – start of the treatment is signaled by the sound and indicated by the orange LED diode lit on.
3.	To finish the procedure – press the **START / STOP key** ■/▶ again .
4.	The end of the treatment is signaled by the sound and the indicator on the START / STOP key is off.
5.	Press START / STOP key to turn off the buzzer.

The fan is switched on synchronously with the bulb. At the end of the treatment procedure, the fan is still working for some time while cooling the lamp tube.

8. Definitions and parameters

8.1 Terminology

Luminous sources of infrared radiation – lamps simultaneously emitting infrared and visible radiation. There are low-power (250 - 500 watts) or high-power (600 - 1500 watts) lamps that consist of an electrically heated filament placed in a glass bulb. These lamps emit radiation in the short infrared range (IRA, partly IRB).

Subranges of infrared used in medicine:

- IRA - wavelength 760 - 1400 nm,
- IRB - wavelength 1400 - 3000 nm.

8.2 Treatment parameters

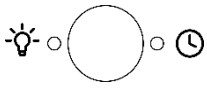
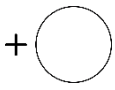
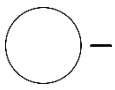
The Lumina lamp is intended for continuous operation in manual mode.

Characteristic of treatment parameters:

Symbol	Description	Available parameters
	Treatment time	Range: **1** – **30 minutes** Regulation: 1 minute Default value: **15 minutes**
	Bulb light intensity	Range: **10** – **99 %** Regulation: 10 % Default value: **99 %** **Maximum radiation power at settings 99: 375W** **Average radiation intensity at a distance from the lamp tube:** • **20 cm (treatment field diameter 28 cm): 0,61 W/cm²** • **30 cm (treatment field diameter 33 cm): 0,44 W/cm²** • **40 cm (treatment field diameter 39 cm): 0,32 W/cm²** • **50 cm (treatment field diameter 46 cm): 0,23 W/cm²**

8.3 Interface elements

Interface elements characteristic:

Symbol	Description	Action
	Digital display	Brightness level or indication of treatment time
	Parameter change key	 The display shows the remaining time of the treatment
		 The display shows the brightness level of the bulb
	Increase key	Increase the time / brightness value
	Decrease key	Decrease the time / brightness value

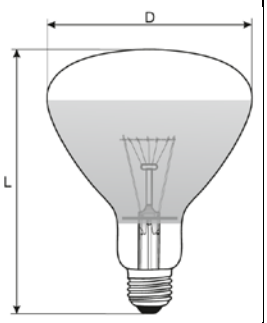
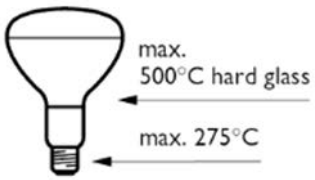
Symbol	Description	Action
■/▶ ◯	START / STOP Key	Start the treatment
		End of treatment

Start of treatment is signaled acoustically.

8.4 Characteristics of the radiation sources used in the Lumina lamp

Infrared heat emitters are manufactured by Fabryka Żarówek "Helios" and Signify (formerly known as Phillips). Detailed characteristics of radiation sources mentioned above are shown in the Table 8-1 and Figures 8-1 - 8-5 (based on manufacturer's data).

Table 8-1 Detailed characteristics of radiation sources

Type of infrared radiator	R-125 IR250CH 230V 250W (Signify/Philips)	R-125 IR375CH 230V 375W (Signify/Philips)	R-125 E27, 230V 375W (Helios)
Wattage [W]	250	375	375
Voltage [V]	230 – 250		230
Cap/base	E27		E27
Finish	CLEAR		CL
Lamp life 100% [h]	5000		5000
Net weight [g]	137.1		-
Dimensions [mm]	A max = 179.0	A max = 183.0	L=170, D=125
			
Permissible bulb base/pinch temperatures			-

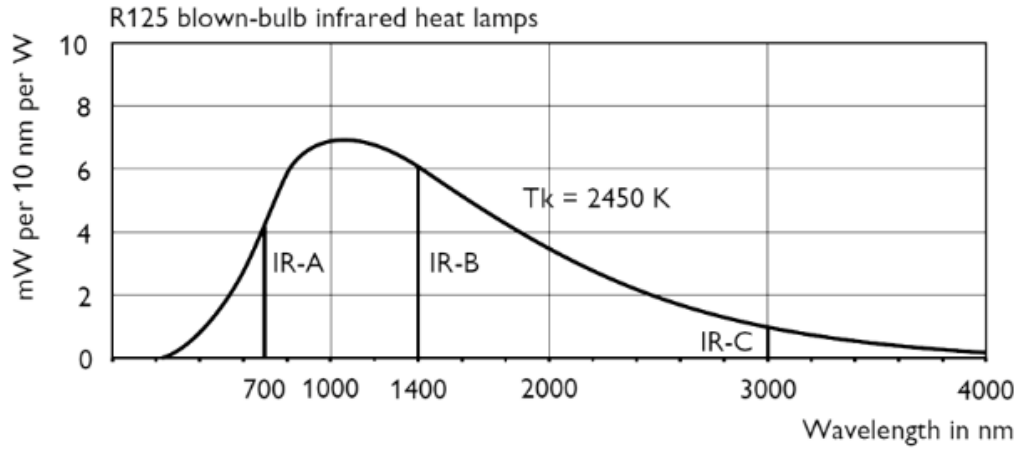


Figure 8-1 Spectral power distribution – R125 blown-bulb infrared heat lamps (Signify/Philips)

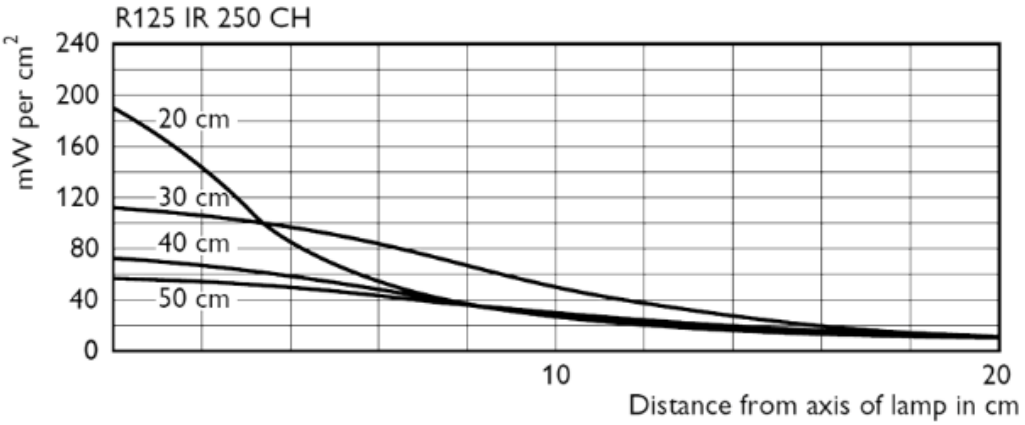


Figure 8-2 Radiation intensity at 20-30-40-50 cm from the front of the bulb – R125 IR250CH (Signify/Philips)

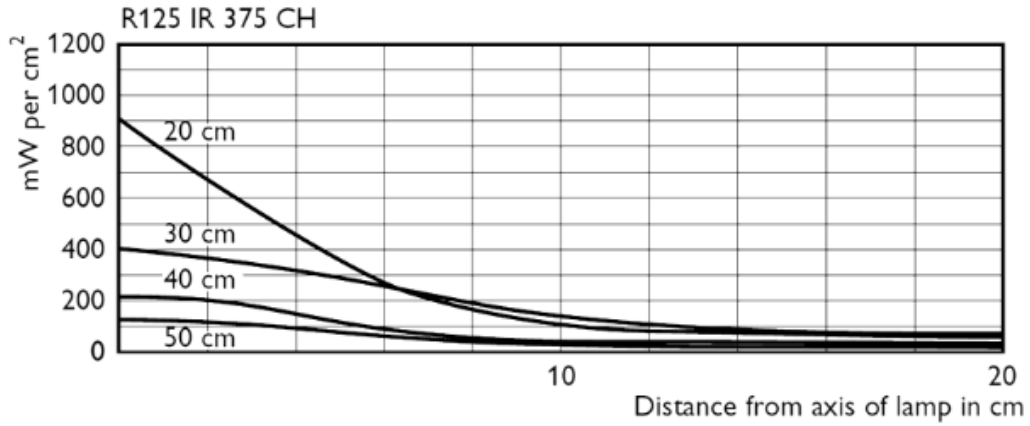


Figure 8-3 Radiation intensity at 20-30-40-50 cm from the front of the bulb – R125 IR375CH (Signify/Philips)

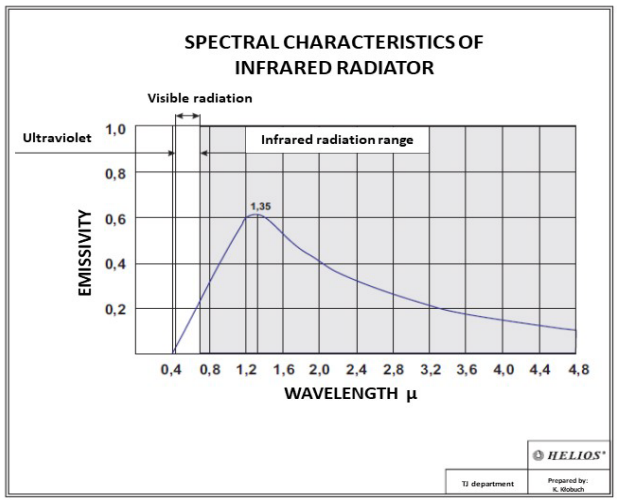


Figure 8-4 Spectral characteristics of infrared radiator (Helios)

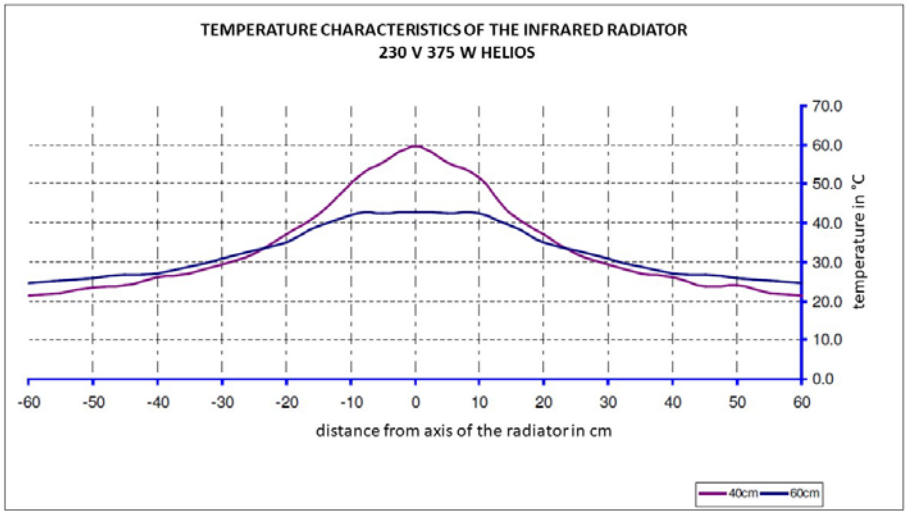


Figure 8-5 Temperature characteristics of the infrared radiator (Helios)

9. Indications and contraindications

9.1 Indications

The effects of infrared radiation therapy on tissues include:

- acceleration of healing,
- shortening of the disease period – stimulation of immune processes,
- relief of pain, reduction of inflammation,
- alleviation of disease side-effects, pain and symptoms,
- shortening of the convalescence period.

Therapeutic application:

- subacute and chronic joint inflammation conditions
- increased muscle tension
- subacute and chronic periarticular inflammations
- contractions, scars, adhesions
- myalgias
- subacute and chronic peripheral nerve inflammation conditions
- paresthesia
- frostbites
- zoster
- juvenile and erythematolosa acne
- conditions after burns
- maxillary sinusitis
- skin disorders, furuncles, sebaceous gland infection
- wounds which are difficult to heal

9.2 Contraindications

9.2.1 Absolute

- acute inflammatory conditions
- peripheral circulation disorders
- sensory disturbances
- predisposition for bleeding
- acute fever diseases, including the early stage of a cold disease
- chronic illnesses, such as tuberculosis, kidney and liver diseases, anemia
- neoplastic disease
- condition after radiotherapy
- thrombotic diseases (e.g. thrombophlebitis)
- epilepsy
- gestation
- edemas of undetermined etiology
- fresh injuries with predisposition to bleeding
- skin infections
- varicose veins
- irreversible damage to the skin and its vessels
- the risk of bleeding from the digestive tract, urinary tract, lungs and genitals (also during menstruation)
- atherosclerosis of blood vessels
- disturbance of internal secretion
- hypertension – II stage and higher, according to WHO
- the state of general exhaustion of the body

9.2.2 Irradiation limitations

- irradiation of patients with disturbed superficial sensation should be avoided
- avoid simultaneous exposure to infrared radiation, visible (red) radiation and ultraviolet

9.3 Possible side effects

Pay special attention to the correct methodology of the procedure. In case of non-observance, tissue overheating may occur in the area of the treatment. In this situation, appropriate help should be given immediately.

Burns are a potential risk when the irradiation intensity is high and the patient suffers from disturbed superficial sensation or communication with the patient is difficult.

The risk of burns can be reduced by:

- careful radiation application, including the assessment of the patient's feeling sensations during temperature change,
- providing information to the patient regarding the nature of the thermal effect and the intensity of the sensed temperature,
- moving the lamp at a safe distance in case of difficult communication,
- verification of the overheating level of the radiated area during the treatment.

Potential side effects should also include the risk of eye damage, however if you follow the instructions and use protective goggles dedicated for the therapist and patient, then the risk is negligible.

It should also be mentioned that with intense or prolonged exposure to the irradiation the patient may sweat.

10. Maintenance, cleaning, disinfection

NOTE: The warranty does not cover any damage due to a failure to adhere to the recommendations stated in this chapter.

NOTE: Before attempting to perform following operations isolate the unit from the mains supply!

The activities of maintenance, cleaning and disinfection of device components should be realized at:

- ambient temperature between +15°C to +30°C,
- relative humidity between 30% to 75%,
- atmospheric pressure between 700 hPa and 1060 hPa (70 – 106 kPa).

These conditions are identical to those defined in chapter 4.2 as operation conditions.

There are no limitations for the number of cleaning and disinfection cycles, procedures should be carried out during the entire device "life time".

10.1 Replacement of the bulb

NOTE:
Before proceeding to the further described operations disconnect the unit from the mains!

If the bulb burns out, users can easily replace it by their own.

Operation scheme:

Step	**Description** (Figure 10.1.)
1.	Disconnect the device from the mains.
2.	Disconnect the mains cable from the mains socket.
3.	Remove the filter from the front of the lamp (Figure 10.1. a).
4.	Unscrew the bulb (it is easier to do this after turning the tube down) - Figure 10.1. b.
5.	Screw a new bulb (Figure 10.1. c).
6.	Clean the front part of the bulb with soft cloth soaked in alcohol to remove dirt and fat (the contamination may result in quicker bulb consumption or burning).
7.	Put the filter into the front of the lamp (Figure 10.1. d).
8.	Connect the mains cable – firstly to the socket placed in the rear panel of the lamp tube and then to the mains.

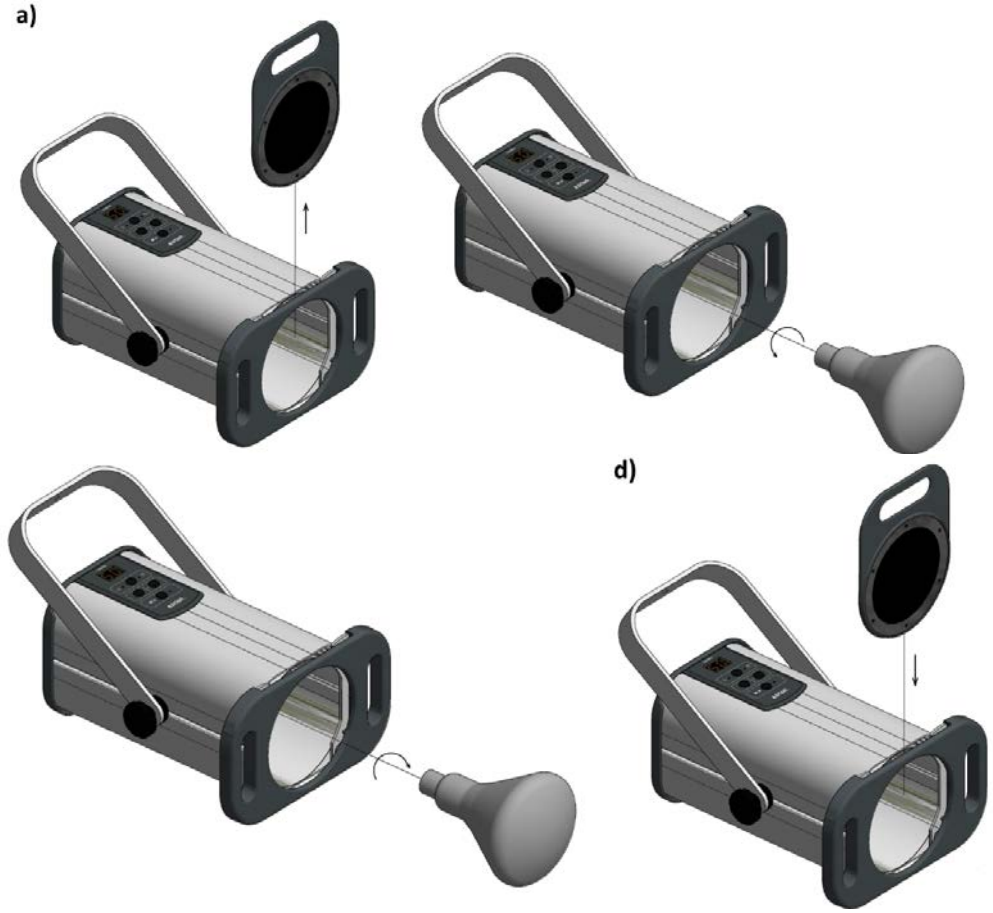


Figure 10.1. Filter and bulb replacement

10.2 Fuse replacement

NOTE:
Before proceeding to the further described operations disconnect the unit from the mains!

In case of blown fuses, they must be replaced. Their parameters are given in section **„Specification and accessories”** and on the name plate.

Operation scheme:

Step	Description
1.	Disconnect the device from the mains.
2.	Disconnect the mains cable from the mains socket.
3.	With flat screwdriver lever the fuse socket.
4.	With your fingers, remove the socket, replace the fuses.
5.	Put the socket back into the housing, press it firmly.
6.	Connect the mains cable.
7.	Check the device operation.

10.3 Cleaning and disinfection – lamp

NOTE: The warranty does not cover any damage due to a failure to adhere to the recommendations stated in this chapter.

NOTE: Before proceeding to the further described operations disconnect the unit from the mains!

The activities of maintenance, cleaning and disinfection of device components should be realized at:

- ambient temperature between +15°C to +30°C,
- relative humidity between 30% to 75%,
- atmospheric pressure between 700 hPa and 1060 hPa (70 – 106 kPa).

These conditions are identical to those defined in chapter 4.2 as operation conditions.

There are no limitations for the number of cleaning and disinfection cycles, procedures should be carried out during the entire device "life time".

Cleaning of the lamp tube, stand with base, table base and cables shall be performed with lightly humid sponge or soft cloth with delicate soap solution or mild detergent. The sponge/cloth should be drained so that there is no dripping water.

It is recommended to use a microfiber cloth, preferably designated for cleaning mirrors or glass because they thoroughly remove dirt.

Do not use solvents for paints and lacquers. Do not use excessively dampened sponges either, which can lead to water penetration inside the unit.

Then all cleaned accessories shall be wiped with dry cloth and left for complete drying. Do not use wet or moist leads!

Casing of the unit shall not be sterilized or disinfected. Disinfection of accessories, which are not intended for contact with patient's body (for example cables), shall be carried out with liquid or spray agents dedicated to that purpose at least once a week.

10.4 Cleaning and disinfection – accessories

In case of dirty glass surface of:

- filters,
- therapist's goggles,
- patient's goggles,

use a cloth (preferably a non-dusting material) soaked with isopropyl alcohol or lens (or optical components) cleaner and thoroughly clean it. Eyewear cleaning agents from Chemax, Uvex, Carl Zeiss, Bausch & Lomb, and Alpro can be used.
Items that come into contact with the patient's body, such as goggles, should be disinfected after each treatment.

10.5 Errors

Errors detected during or after the self-test procedure are presented on the display screen. Errors are not deleted – switching the unit off and on is required. The procedure in case of errors occurrence is presented in point 10.6.

Table 10-1 Error description

Error code	Error description
E1	Synchronization error (wrong mains frequency)
E2	CRC memory flash error

10.6 Troubleshooting

Problem	Undertaking action
After switching on the power supply, none of the controller indicators is lit.	Check whether the device is connected to the mains. Check, if the mains cable is working properly. If you have the opportunity, try to connect another cable of **the same type**. Check fuses. In case when the fuses are blown, replace them according to instructions given in this user manual (see section 10.2).
After pressing the START/STOP key, the lamp is off.	Check, if the bulb is not burnt – If it is burnt, replace it with a new one (see section 10.1).
After pressing the START key, the fan does not operate while the bulb is on.	Check whether any object does not block the operation of the fan.
After the end of a treatment the fan is still working.	This is normal situation, the fan stops working after three minutes from the end or interruption of the operation.
It is difficult to change the position of the lamp.	Unlock the brakes, then set the position of the lamp. Re-lock the brakes.
The bulb stops working during the procedure.	Check, if only the radiation emission has been stopped, but you can hear the fan running and the treatment time is counted down. If so, it means that the thermal protection has worked. Emissions have been stopped to avoid damaging the controller due to overheating. Wait until the temperature inside the unit drops to continue working. **Do not turn off the unit during cooling down.** If the lamp does not resume operation automatically, check that the bulb is not burnt out. If so, replace it with a new one (see section 10.1). If the problem persists or occurs frequently, contact with the manufacturer's authorized service.
Error E1 displayed on the screen	Switch the unit off and wait 10 seconds before you switch it on again. If the problem persists or occurs frequently, contact with the manufacturer's authorized service.
Error E2 displayed on the screen	

In the event that the indicated actions do not help, contact the authorized service provider to determine how to perform service action. Describe the malfunction during the conversation.

11. Specification and accessories

11.1 Specification

Classification:

Medical device class:	IIa
Rule:	9
Electrical safety class:	I
Application type:	B
Classification in compliance with IEC 60601-2-57:	Exempt Group
Degree of protection provided by enclosures:	IP20
Pollution degree	2
Material group	IIIb
Operating altitude	<2000m

Operation mode:

The Lumina lamp is intended for continuous operation.

Treatment parameters:

Described in section 8.1

Accuracy of operation parameters:

Treatment time:	±10%
Brightness level:	±20%

General:

Mains supply:	230 V ±10%, 50/60 Hz
Power consumption:	max. 450 W
Fuse:	size 5x20mm, T3, 15L250V; 3,15 A, 250 V
Lamp weight (with bulb and filter):	max. 13.7 kg
Lamp weight with the packaging:	max. 15kg
Lamp height:	min. 1,2 m ± 0,05 m max. 1,9 m ± 0,05 m
Lamp base dimensions:	max. 0,5 x 0,6 m
Permissible working height above sea level	2000 m

Storage conditions:

Temperature range:	+5 ÷ +45 °C
Relative humidity:	30 ÷ 75 %
Pressure range:	700÷1060 hPa (70 ÷ 106 kPa)

Operation conditions:

Temperature range:	+15 ÷ +30 °C
Relative humidity:	30 ÷ 75 %
Pressure range:	700÷1060 hPa (70 ÷ 106 kPa)

Transport conditions:

Temperature range:	-10 ÷ +45 °C
Relative humidity:	20 ÷ 95 %
Pressure range:	700÷1060 hPa (70 ÷ 106 kPa)

11.2 EMC parameters

In compliance with IEC 60601-1-2:2014

Guidance and manufacturer's declaration – electromagnetic emissions

Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies

Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±2, 4, 6, 8kV contact ±2, ±4, ±8, ±15 kV air	±2, 4, 6, 8kV contact ±2, ±4, ±8, ±15 kV air
Recommendation: Floor should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.		

Immunity test	IEC60601 test level	Compliance level
Radiated RF IEC 61000-4-3	10 V/m 80MHz do 2,7 GHz	10 V/m
Field strengths from fixed transmitters, such 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 the Lumina lamp is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Lumina lamp. Applied compliance level is suitable for home healthcare environment. It means the device may be connected to the public low-voltage power supply network.		

Immunity test	IEC60601 test level	Compliance level
Electric fast transient / burst IEC 61000-4-4	±2 kV	±2 kV

Immunity test	IEC60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz
	6 Vrms in ISM and amateur radio bands between 150 kHz – 80 MHz	6 Vrms in ISM and amateur radio bands between 150 kHz – 80 MHz
Field strengths from fixed transmitters, such 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 the Lumina lamp is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Lumina lamp. Applied compliance level is suitable for home healthcare environment. It means the device may be connected to the public low-voltage power supply network.		

Immunity test	IEC60601 test level	Compliance level
Magnetic field power frequency (50 and 60 Hz) IEC 61000-4-8	30 A/m	30 A/m

Immunity test	IEC60601 test level	Compliance level
Voltage dips IEC 61000-4-11	0% U_T 0,5 cycle, phase angles of synchronization with AC power supply voltage 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	Complies
	0% U_T 1 cycle, phase angle of synchronization with AC power supply voltage 0°	Complies
	70% U_T 25 cycles for 50 Hz 30 cycles for 60 Hz phase angle of synchronization with AC power supply voltage 0°	Complies
Voltage interruptions IEC 61000-4-11	0% U_T 250 cycles for 50 Hz 300 cycles for 60 Hz	Complies

Immunity test	Compliance level
Proximity fields from RF wireless communications equipment according to 8.10 IEC 60601-1-2:2014	Complies

11.3 Standard accessories

Therapeutic lamp Lumina defined as a medical device contains the unit and accessories.
Accessory – is an attached or accompanying component necessary for a medical device to achieve its intended purpose. It is not a separate medical device and works only with controllers manufactured by Astar. It meets the definition of the 'accessory for a medical device' (see MDR 2017/745, Article 2, def.2).

No.	Name	REF	Quantity
1.	Lumina lamp	A-UO-A-AST-LUMINAV5PS	1
2.	Red filter	A-AO-ASTFILTR_CE_V5.0	1
3.	Blue filter	A-AO-ASTFILTR_NB_V5.0	1
4.	Bulb manufactured by Signify/Philips infrared lamp emitter R-125 IR375 CH 230V 375W	-	1
5.	Mains cable	-	1
6.	Fuse T3,15L250 (3,15 A, 250 V)	-	2
7.	Instructions for use	-	1
8.	Electrical safety test – inspection report	-	1

11.4 Optional accessories

Name	REF
Bulb manufactured by Signify/Philips infrared lamp emitter IR-250CH 230V 250W	-
Bulb manufactured by Helios infrared lamp emitter R-125 E27, 230V 375W	-
Front safety mesh without glass filter	A-AO-AST-NET_NF_V5.0

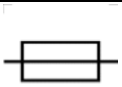
Other	
Name	
Safety goggles for the patient	Safety goggles for the therapist
Allen key (size 4)	-

12. Appendix A. Symbol description

Recommendation for the operator's position to ensure the legibility of markings and information on the controller and accessory labels:

- visual distance – shall be 30 cm due to the applied technologies,
- lighting – 500 lx, which corresponds to normal room lighting conditions.

12.1 Controller, accessories, packaging

Symbol	Explanation
	Caution, see the ASSOCIATED DOCUMENTS, symbol ISO 7000-0434A
	B type equipment, symbol IEC 60417-5840
	Date of production: year and month, symbol ISO 7000-2497, GS1
	Manufacturer, symbol ISO 7000-3082
IP20	Degree of protection provided by enclosures (IP code), symbol IEC 60529
	Fuse, symbol IEC 60417-5016
VER	Device version
	Serial number, symbol ISO 7000-2498
	Batch code, symbol ISO 7000-2492
	Catalogue number, symbol ISO 7000-2493
	Medical device, symbol 5.7.7. of ISO 15223-1 standard
	Unique Device Identifier, symbol 5.7.10. of ISO 15223-1 standard
	Disposal of used devices together with other waste is prohibited, complied with the requirements of WEEE

Symbol	Explanation
	Operator's manual, symbol ISO7000-1641
	Non-ionizing electromagnetic radiation, symbol IEC 60417-5140 Indication of equipment in the medical electrical area that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	Follow operating instructions, symbol ISO 7010-M002 Background color: blue
	No sitting, symbol ISO 7010-P018 Background color: white Circular band and slash Symbol/ text: black
	No stepping on surface, symbol ISO 7010-P019 Background color: white Circular band and slash Symbol/ text: black
	No pushing, symbol ISO 7010-P017 Background color: white Circular band and slash Symbol/ text: black
	Weight
	Packaging size
	Temperature limit, symbol ISO 7000-0632
	Keep away from rain, symbol ISO 7000-0626
	Fragile; handle with care, symbol ISO 7000-0621
	This way up, symbol ISO 7000-0623
CE 0197	The marking of conformity with legal regulations for medical devices applicable in the European Union along with the number of the Notified Body taking part in the conformity assessment.

12.2 UDI code

Regulation (EU) 2017/745 of The European Parliament and of The Council defines “Unique Device Identifier” (‘UDI’) as a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market (def.15). The code development process is supported by entities designated by Commission (EU) Implementing Decision. The manufacturer has chosen to cooperate with the GS1 organization.

Figure 12-1. UDI code – example

ID	Symbol	Description	UDI code part
(01)	GTIN	Unique GTIN code assigned by GS1 organization	UDI-DI
(11)	PROD DATE	Production date format: RRMMDD A record limited to the year and month is acceptable in the format: RRMM00	UDI-PI
(21)	SERIAL	Serial number	