USER MANUAL

SOLMED

Irradiation lamp

Model: UNO, DUO, TRIO

CE 0197

Manufacturer:
„Meden-Inmed", Sp. z o.o.
ul. Wenedów 2
75-847 Koszalin
tel. +48 94 347 10 40
fax. +48 94 347 10 41

Distribution and service in Poland:
„Meden-Inmed", Sp. z o.o.
ul. Wenedów 2
75-847 Koszalin
tel. +48 94 347 10 40
fax. +48 94 347 10 41

TABLE OF CONTENTS

1. INTRODUCTION 3

1.1. PURPOSE OF THE UNIT 4
1.2. INTENDED USERS 4
1.3. FUNCTIONS 4
1.4. INDICATIONS 5
1.5. CONTRAINDICATIONS 5
1.5.1. SIDE EFFECTS 5
1.6. CLASSIFICATION 5

2. TECHNICAL CHARACTERISTICS 6

2.1. DIMENSIONS 6
2.2. POWERING 7
2.3. PACKAGE CONTENTS 7
2.3.1. ADDITIONAL EQUIPMENT 8
2.4. CONDITIONS OF STORAGE, WORK AND TRANSPORT 8

3. SAFETY OF USE 9

3.1. SYMBOLS 9

4. UNIT DESIGN 10

4.1. DESCRIPTION OF THE OPERATION 10
4.2. LAMP DESIGN 10
4.3. CONTROL PANEL 11
4.4. POWER SOCKET WITH FUSES AND POWER SWITCH 12
4.5. THE CLASSIFICATION LABEL 13

5. INSTALLATION OF THE DEVICE 13

6. GENERAL WARNINGS AND SAFETY FEATURES 14

6.1. FILTER INSTALLATION 15
6.2. POSITION REGULATION 15
6.3. WORK PARAMETERS SETTING 16
6.4. INCLUSION OF THE TREATMENT AND LAMP OPERATING PARAMETERS MODIFICATION DURING THE OPERATION 17
6.5. LAMP TREATMENT PROGRAMS AND SEQUENCES 17
6.5.1. CHOICE OF THE PROGRAM 17
6.5.2. USER PROGRAM EDITING 18
6.5.3. SETTINGS PRE-SAVED IN USER PROGRAMS 19
6.6. SLEEP MODE 19
6.7. RELOCATION OF SOLMED LAMP 19

7. MAINTENANCE AND CLEANING 20

7.1. CLEANING 20
7.2. PERMEABILITY OF VENTILATION VENTS 20
7.3. FUSES REPLACEMENT 20
7.4. BULB EXCHANGE 21
7.5. REQUIRED LIGHT SOURCES 22
7.6. FILTER PARAMETERS 23

8. TECHNICAL CONDITIONS FOR USING THE UNIT 24

8.1. TROUBLESHOOTING 24
8.2. MANUFACTURER'S RESPONSIBILITY 25
8.3. CONTACT WITH THE SERVICE 25

9. ELECTROMAGNETIC COMPATIBILITY 26

10. WARRANTY CARD 29

11. CARD OF PERIODIC TECHNICAL TESTS 30

1. INTRODUCTION

The User's compliance with the recommendations from this instruction manual and use of the information contained enables safe, long-term and failure-free use of the SOLMED irradiation lamp. All comments and observations regarding making of the unit and contents of this manual should be sent to our address:

Meden-Inmed Sp. z o.o.
ul. Wenedów 2
75-847 KOSZALIN
tel. +48 94 347-10-40
fax: +48 94 347-10-41
e-mail: meden@meden.com.pl

General notes

1. The unit should be operated by qualified personnel who have read the contents of these operating instructions.
2. The use, operation and servicing of the product in a manner inconsistent with this manual is not permitted and may lead to damage that are responsibility of the user and for which the manufacturer is not responsible.
3. The unit manufacturer prohibits any modifications to the used unit.
4. If the operation and parameters of the product are inconsistent with the description in this instruction manual, the product may not be used. Please immediately report this fact to the manufacturer or supplier.
5. The warranty covers all material and manufacturing defects.
6. Every repair of the product must be made by a manufactory or authorized service center and registered in the list of repairs attached to the guarantee card. Failure to comply with this requirement will void the guarantee on the product.
7. The guarantee conditions will not be respected if the user will use the product contrary to the intended purpose or will not follow the rules of use in these operating instructions.
8. Technical description of the unit together with a list of spare parts and the instructions of their replacement (including the non-detachable power cord) is available from the manufacturer on demand.
9. Any serious SOLMED irradiation lamp incident shall immediately be reported to the manufacturer and to the competent authority of the Member State where the user or patient is resident.

1.1. PURPOSE OF THE UNIT

The SOLMED lamp is intended for therapy consisting in the treatment of skin tissue warming by means of thermal energy of infrared radiation emitted by the source - one, two or three light bulbs. In addition, depending on the intended effect treatment effect, you can use a red or blue color filter that changes the radiation pattern. The manufacturer also offers an optional orange and green filter. Parameters of filters are presented in point 7.6 of the instructions. The SOLMED irradiation lamp can be equipped with one, two or three tubes. In the version with two tubes, bulbs work independently, which allows simultaneous exposure of larger body areas or parts of the body separated from each other (e.g., knees). The design of the tube suspension allows easy adjustment of the height and distance of the light source from the patient. The SOLMED lamp, in order to facilitate the change of location, is placed on a chassis, equipped with four steering wheels. The program controlling the work of the lamp allows you to determine the parameters of the device, such as power and time exposure time.

1.2. INTENDED USERS

Patients are referred for treatment with the use of the SOLMED lamp upon the recommendation of their attending physician who decides whether they are qualified for the treatment.
The manufacturer does not recommend SOLMED lamp therapy for underage patients. Underage patients should be referred for treatment only upon the clear order of the attending physician.
The SOLMED irradiation lamp does not require installation. The device should be operated by qualified personnel who have read the contents of this instruction manual, paying particular attention to the following:

- intended use of the device,
- indications and contraindications for the use of the lamp,
- information on safety at work,
- information on the construction of the lamp,
- information on available operating settings,
- instructions on how to operate and output messages,
- information on recommended maintenance, cleaning and disinfection,
- what to do in the case of a technical fault.

The patient's treating physician and/or the qualified personnel carrying out the SOLMED lamp treatment determines the initial parameters, such as treatment duration, intensity and frequency of repetitions. During the treatment, it may be necessary to correct the set values resulting from the assessment of the patient's condition (heat sensation, skin redness, etc.). The literature on the subject emphasizes the impossibility of precise specification of IR parameter values due to their connection with individual patient characteristics (threshold level of heat sensation, radiation absorption, etc.). For this reason, the manufacturer recommends the necessity of constant control of the patient's condition during the procedure.

1.3. FUNCTIONS

- irradiating (heating),
- irradiating (heating) intensity regulation,
- treatment time regulation,
- tube (tubes) position regulation,
- using replaceable tube filters possibility.

1.4. INDICATIONS

The lamp is used for:

- preparing the patient's body before massage, manual therapy, iontophoresis, kinesitherapy, electrotherapy,
- chronic inflammatory conditions and pain syndromes of the spine,
- pain in the course of degenerative diseases of the cervical spine,
- chronic pain in the lower part of the spine,
- neuralgia and pain in the course of degenerative diseases of the spine and joints,
- conditions after injuries and degenerative changes in the joints,
- degenerative joint disease of the hip and knee,
- rheumatoid arthritis,
- delayed myalgia syndrome,
- facial nerve palsy (Bell's palsy),
- relief of the sequelae of epistomies.

The target place of application are physiotherapy, rehabilitation and sanatoriums.

1.5. CONTRAINDICATIONS

The main contraindications for the use of lamp irradiation:

- subfebrile states and fever,
- malignant disease,
- acute inflammation of the skin and soft tissues,
- hypersensitivity to thermal stimuli,
- sensory disturbances,
- pregnancy,
- circulatory insufficiency.

1.5.1. Side effects

- cataract,
- erythema on the skin,
- collagen degradation.

1.6. CLASSIFICATION

CE 0197

The SOLMED irradiation lamp is manufactured in accordance with Medical Device Regulation 2017/745 (class IIa, 9 rule) and has a CE marking, according to the manufacturer declaration.

2. TECHNICAL CHARACTERISTICS

WARNING!

The manufacturer reserves the right to make changes to the design of the lamp that do not violate the basic requirements of functionality and safety.
The illustrations in this manual are for reference only and the design variants result from the specifications of the order.

Model		UNO	DUO	TRIO
Supply voltage		220-230 V ~ 50/60 Hz		
The maximum power of the bulb		375 W		
Power consumption		max. 395 W (with one bulb)	max. 770 W (with two bulbs)	max. 1140 W (with three bulbs)
Net weight [kg]		23	28	30
Weight in transport packaging [kg]		26	31	34
Fuses		2 x T8AH / 250 V		
Dimensions [mm]	height	1170	1170	1170
	length	740	670	740
	width	480	480	610
Electrical safety		protection class I		
Security level		IP20		
Tube tilt angle range [°]	vertical	178		
	horizontal	60		
Tube height adjustment range [mm]		580		
Manufacturer		Meden-Inmed, sp. z o.o., ul. Wenedów 2, 75-847, Koszalin tel. +48 94 3471040, fax. +48 94 3471041, service: 94 3471048		

2.1. DIMENSIONS

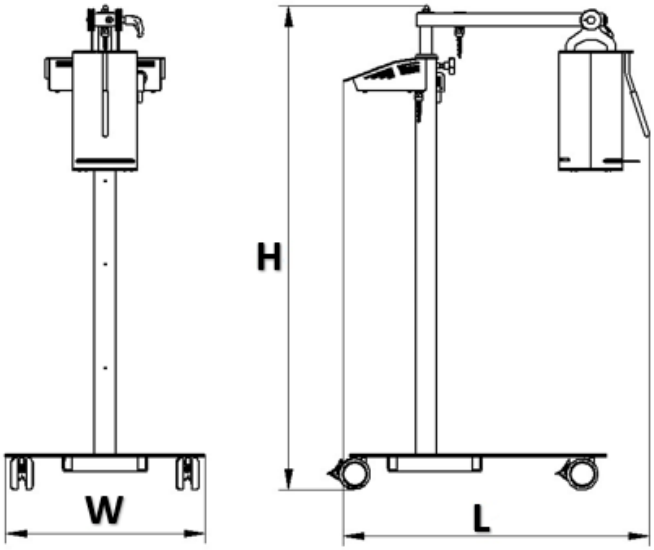


Figure 1 - Dimensions of SOLMED model UNO

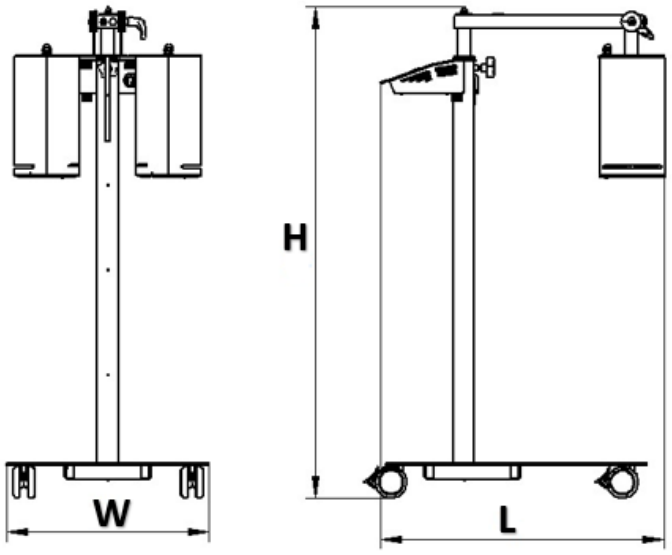


Figure 2 - Dimensions of SOLMED model DUO

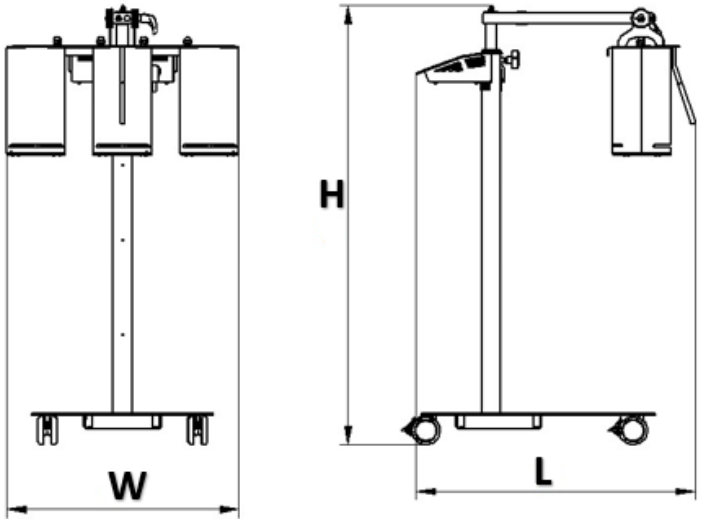


Figure 3 - Dimensions of SOLMED model TRIO

2.2. POWERING

The device requires powering from an alternative current mains socket with a rated voltage of 220-230V ~ 50H/60 Hz, equipped with a protective earth point of contact.

2.3. PACKAGE CONTENTS

Standard equipment	**Model**		
SOLMED lamp	**UNO**	**DUO**	**TRIO**
Light bulbs, pcs.	1	2	3
Filter set (red 1pc + blue 1pc), set.	1	2	3
Operators' safety glasses	1 pc.		
Protective goggles for the patient	1 pc.		
Power cord	1 pc.		
Allen key no. 3	1 pc.		
Instructions for use with the Warranty Card and the Periodic Technical Test Card	1 set		

2.3.1. Additional equipment

- Orange (amber) filter - not part of standard equipment and not supplied with the lamp,
- Green filter - not included in standard equipment and not supplied with the lamp.

2.4. CONDITIONS OF STORAGE, WORK AND TRANSPORT

WARNING!

The lamp during transport should be folded and packed so as to prevent accidental damage.

WARNING!

After unpacking the lamp from the transport packaging, wait 1 hour before starting the lamp.

WARNING!

When moving the lamp, especially after unevenness, remove the filter from the tube (also applies to the lamp with two and three tubes).

The device can work in the following conditions:

- Temperature from 15^{o}C to 30^{o}C
- Relative humidity in the range of 30% to 75% without condensation,
- Atmospheric pressure in the 700-1060 hPa range.

Permanent operation of the device is permissible.

The device should be stored under the following conditions:

- Temperature within + 5^{o}C to + 45^{o}C,
- Relative humidity does not exceed 75% without condensation,
- Atmospheric pressure in the 700-1060 hPa range,
- Indoor room.

Recommended conditions during transport:

- Temperature within -10^{o}C to + 45^{o}C,
- Relative humidity in the range of 20% to 95% without condensation,
- Atmospheric pressure in the 700-1060 hPa range.

3. SAFETY OF USE

3.1. Symbols

WARNING!

In this way, activities that may not be carried out in accordance with the contents of these Operating Instructions may result in deterioration of conditions or safety risk for the user and / or personnel operating the SOLMED irradiation lamp. A similar marking has been used on the device where it is essential to read the Operation Manual and follow its instructions when using the device.

Please read the Operation Manual
The mark is located on the device casing.

Wear protective goggles when using the device.
The mark is located on the device casing.

The device emits non-ionizing radiation!
The mark is located on the device casing.

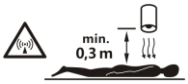
The device emits optical radiation!
The mark is located on the device casing.

Warning: Hot surface.
The mark is located on the device casing.

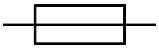
It is prohibited to push, tilt, lean, etc. (applies to a lamp with two tubes).
The mark is located on the device casing.

It is forbidden to enter the surface.
The mark is located on the device casing.

Do not cover the fan.
The mark is located on the device casing.



Minimum distance between the tube and the patient's body.
The mark is located on the device casing.



Fuse marking

Medical device

Catalogue number (UNO, DUO, TRIO)

Serial number

Lot ID (applies to filters)

IP20	Protection level provided by the enclosure
max. 23 kg	Device weight (model UNO)
max. 28 kg	Device weight (model DUO)
max. 30 kg	Device weight (model TRIO)
YYYY	Manufacturer, YYYY – year of production
	Pursuant to the provisions of the Act on waste electrical and electronic equipment, it is forbidden to throw away used equipment with the symbol of a crossed out basket. Waste electrical and electronic equipment should be taken to the appropriate collection point. The above statutory duties were introduced in order to limit the amount of waste generated from waste electrical and electronic equipment and to ensure an appropriate level of collection, recovery and recycling of used equipment. Proper implementation of these duties is important especially when there are hazardous components in the used equipment, which have a particularly negative impact on the environment and human health.
UDI	Unique Device Identification

4. UNIT DESIGN

4.1. DESCRIPTION OF THE OPERATION

SOLMED lamp works on the principle of emitting thermal energy of infrared radiation, the source of which is one or two light bulbs. The intensity of irradiation (heating) can be adjusted by means of the control panel, as well as by adjusting the position of the tube. In addition, you can adjust the treatment time and radiation characteristics by changing the filter in the tube.

4.2. LAMP DESIGN

The lamp consists of three basic parts:

A – support stand with height adjustment,

B – mobile base on wheels,

C - movable head with one, two or three tubes.

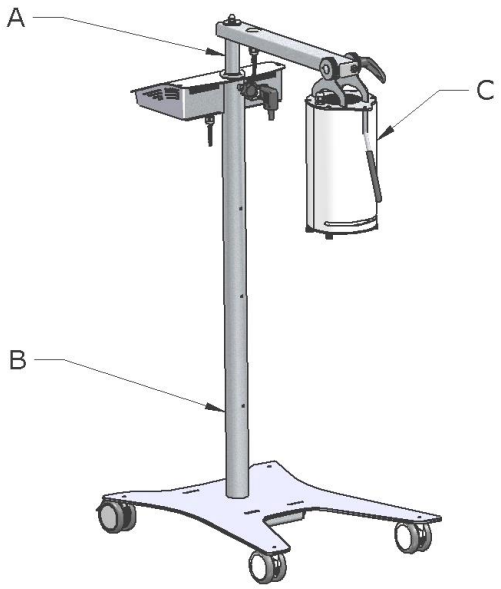


Figure 4 - View of the assembled SOLMED lamp in the version with 1 tube on the mobile base

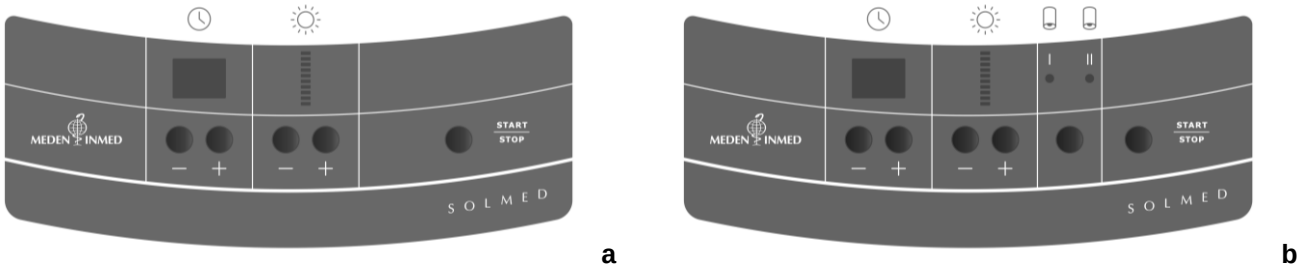
Support stand (A) - consists of a pipe to which the arm is attached with the tube. There is a gas spring in the pipe that allows you easily change the height of the lamp. A tube is attached to the arm by means of a joint, which allows adjusting the angular position of the tube. Report of the techniques to adjust the lamp position is included in the further part of the Operation Manual.

Base (B) - it consists of a base plate to which the pipe (lamp stand) and wheels have been fixed. The wheels ensure the mobility of the lamp. For safety, all wheels (four) have been equipped with brakes to prevent the lamp from moving uncontrolled. A control panel was attached to the lamp stand. The operation of the desktop will be described later in the Operation Manual.

Head (C) - it consists of one or two tubes, each tube is equipped with its own cooling fan and filter fixing system, as well as a handle for adjusting the tube position. The power cables and the fan control are connected to the tubes.

4.3. CONTROL PANEL

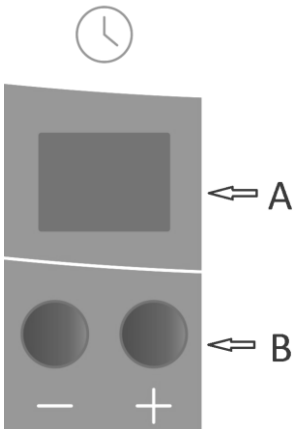
In this chapter, the components of the control panel will be presented with a description of their functions. They are described in detail in the chapter on the use of the lamp.



a **b**

Figure 5 - View of the SOLMED control desk with one (a) and two or three tubes (b).

Buttons for changing the time of the treatment



A – Display

It displays the lamp's working time and dot. The time and dot is displayed in green. The time is displayed in minutes.

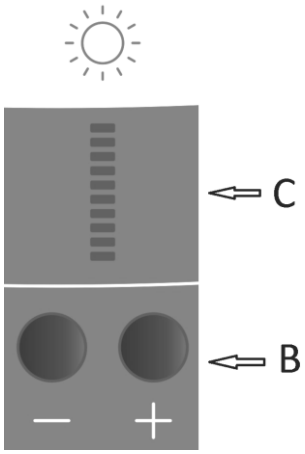
B – Buttons for changing work parameters

Placed under the display, change the time of the treatment.
The treatment time can be changed every 1 minute in the range from 1 minute to 30 minutes

Buttons for changing work parameters

Correspondingly, the button  **increases**, and the button  **decreases** the set value.

Light bulb power buttons



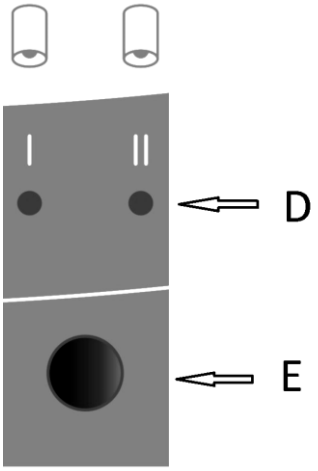
C - Bulb power setting indicator (green).
10 bulb power levels are displayed

B - Buttons for changing work parameters,
placed under the indicator, change the power of the bulb.

START/STOP button

The START / STOP button is used to activate the treatment, turn off and stop it (PAUSE).
The START / STOP button is also used to exit the sleep mode.

Bulb selection button *



D - LEDs (2xLED green) indicate the choice of light bulb.

E - Select button * of the bulb that you want to turn on.
* (only in the case of two or three tubes)

4.4. POWER SOCKET WITH FUSES AND POWER SWITCH

The power socket (fig. 6 item 1) together with the fuses (fig. 6 item 2) and the power switch (fig. 6 item 3) is located in the rear part of the control panel housing (fig. 6):

1- power socket,
2- fuses,
3- power switch.

A power cord is connected to the jack. Description of the fuse replacement can be found further in the Operation Manual.

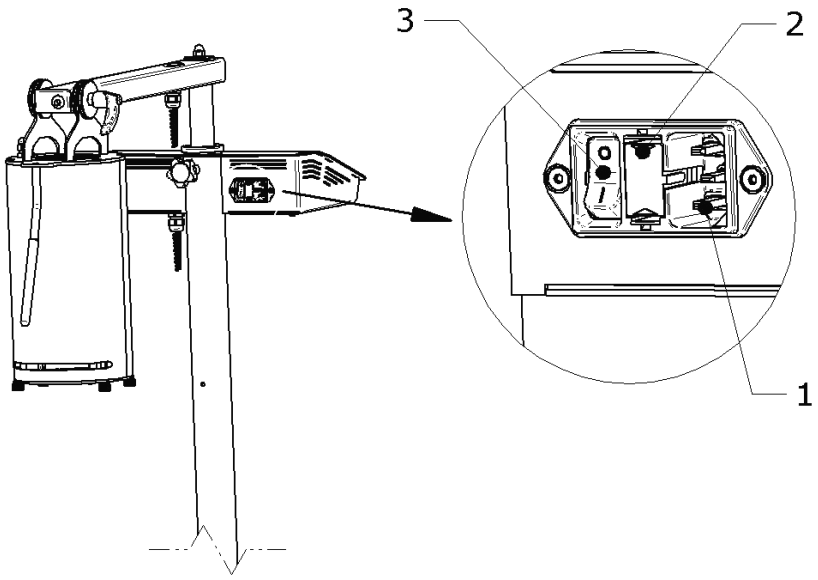


Figure 6 - Position of the power switch, socket and fuses

4.5. THE CLASSIFICATION LABEL

Figure 7 - View of the classification label

5. INSTALLATION OF THE DEVICE

The lamp is delivered to the User in a cardboard box in a folded condition.

6. GENERAL WARNINGS AND SAFETY FEATURES

WARNING!

To avoid hazards caused by the electromagnetic radiation emission, avoid using the device near life support devices.

WARNING!

To avoid the electric shock risk, this device must only be connected to a mains socket with a protective earth pin.

WARNING!

For secure disconnection from the mains, disconnect the mains plug of the lamp power cord from the mains socket.

WARNING!

Only the power cord provided by the manufacturer may be used with the lamp.
The SOLMED lamp should be placed so as not to obstruct its disconnection from the mains socket.

WARNING!

The safe distance for the eyes from the emission surface of optical radiation is 50 cm.
The operator should always wear safety glasses when operating the device! Patient goggles are provided for use when irradiating the face and face area from a distance of less than 50 cm**.**

WARNING!

Before the first use, check the general condition of the device, in particular the condition of the power cord, the condition of filters and light bulbs, and the condition of mechanical and electrical connections.

WARNING!

In order to maintain proper air cooling inside the tube, do not cover the ventilation opening in the upper part of the housing or insert any objects into it. Also, do not allow the ventilation hole to become blocked by a dust layer. Periodically check and clean the ventilation openings. Lack of cooling can cause damage to the device, which is not covered by the warranty conditions.
It is forbidden to insert any elements or approach the garment near the ventilation holes of the lamp (e.g. chains, earrings).

WARNING!

If the ventilator blades are mechanically blocked, the bulb power system will shut down.

WARNING!

The lamp is not designed for use in rooms with an atmosphere of enriched oxygen and flammable gases. It is recommended to avoid flammable anesthetic or oxygen-related gases such as nitrous oxide (N2O) and oxygen. When oxygen is saturated, some materials, such as cotton wool, can be ignited at the high temperatures generated by normal use of the equipment. It is recommended that adhesive solutions and flammable solvents used for cleaning. It is recommended that adhesive solutions and flammable solvents used for cleaning and decontamination be vaporized before the instrument is used. It is also recommended to pay attention to the danger of ignition of endogenous gases. The unit must be disconnected from the mains supply before disinfecting the room in which it is installed.

WARNING!

Use of controls, adjustments, or performance of procedures other than those specified herein may result in exposure to IR radiation, which may burn the patient.

WARNING!

Appropriate selection of treatment parameters, providing the patient with information on the character of perceptible heat and checking the degree of heating of the skin during the treatment, reduces the risk of burns.

WARNING!

Operation of the SOLMED lamp by unauthorized personnel may result in danger to the patient and/or user.

WARNING!

In the SOLMED lamp IR radiation is emitted through the surface of the hole in the lower part of the tube.

In order to start the device, it should be connected to the power network by means of a cable previously inserted in the 220-230 V ~ 50/60 Hz power socket.

6.1. FILTER INSTALLATION

WARNING!

During operation, the filter becomes very hot, so avoid touching the glass and metal part of the filter. The filter can be picked up only by the plastic holder provided for this purpose.

WARNING!

Do not perform any manipulations during the irradiation treatment to change filters!

WARNING!

Use only the original filters provided by the manufacturer.
In the event of damage to the filter (s), please contact the manufacturer for replacement.

Applying filters (fig. 8 item 1) is done by inserting them into the slit (fig. 8 item 2) in the front part of the tube. The filter is automatically immobilized, which prevents it from falling out.

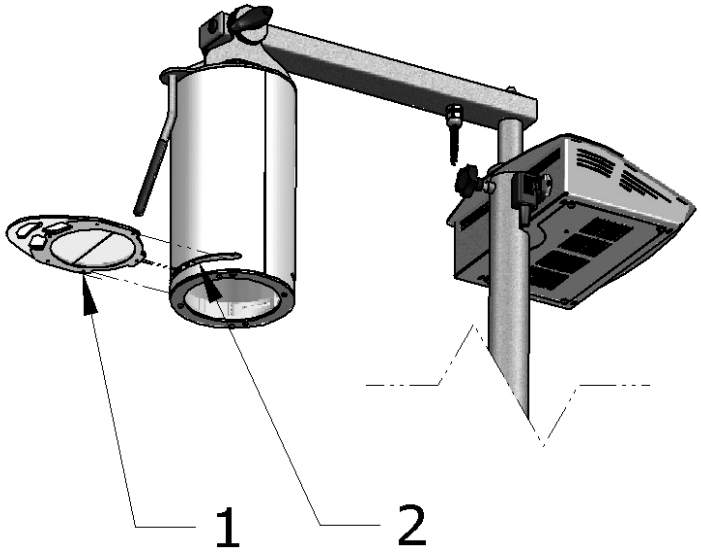


Figure 8 - The method of setting filters

6.2. POSITION REGULATION

WARNING!

The minimum distance from the front of the tube to the patient's body should not be less than 30 cm! A shorter distance can contribute to overheating and / or burns to the patient.

WARNING!

When adjusting the height or rotation of the tube, hold the tube mounting arm so that the tube stand does not fall down or protrude in an uncontrolled way.

WARNING!

To position the tube in the correct position for treatment, use only the adjustment elements described below.

After start-up, place the unit in the correct position for irradiation relative to the patient's body. The first step is to set the correct height with the help of a knob placed on the bottom of the lamp stand (fig. 9 item 1). In addition, you can adjust the rotation angle of the tube relative to the tripod axis in the range of 60°.
After adjusting the height, you can set the angle of the tube in the range of 178°. To do this, grasp the handle on the tube (fig. 9) and use the other hand to unlock the tube using the handle knob, located on the side of the tripod (fig. 9 item 2). After completing the adjustment, lock the joint by tightening the knob.

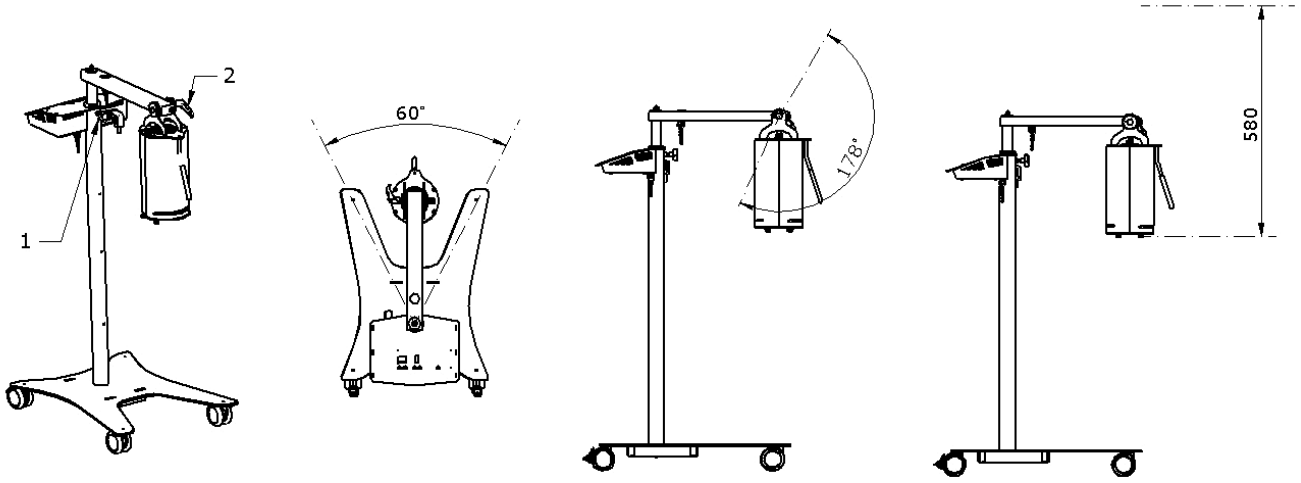


Figure 9 - Adjusting the position

6.3. WORK PARAMETERS SETTING

WARNING!

To avoid overheating and / or burns of the patient, the operator should monitor the course of the operation and pay attention to the patient's condition during operation.

WARNING!

The housing of the tubes heats up while working, avoid touching it.

Before setting the operating parameters, a suitable filter should be installed.
Maximum radiation power at setting of the 10th light level is 375 W.
The surface to be irradiated at the minimum distance of 30 cm from the tube is a circle with diameter of 32 cm.
The maximum irradiance, measured in accordance with the requirements of EN 60601-2-57:2011, regardless of the configuration of the SOLMED exposure lamp (with 1, 2 or 3 tubes) at a distance of 20 cm from the surface of optical radiation emission does not exceed 1 000 W/m2.

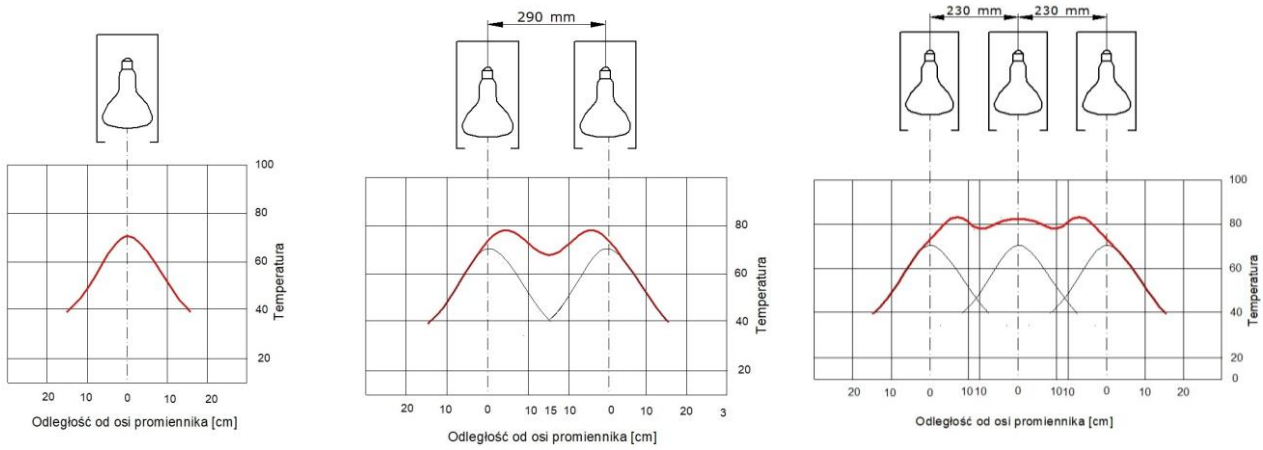


Figure 10 - Temperature changes on the irradiated surface at a distance of 30 cm from the tube

The operation parameters are set using the buttons on the control panel. The values of the work parameters depend on the purpose of the exposure - the treatment time is set, the power and the version with two tubes, the number (1 or 2) of working bulbs. The parameters of the treatment are remembered at the time the procedure is started. The memory is stored when the START / STOP button is pressed during the procedure.

6.4. INCLUSION OF THE TREATMENT AND LAMP OPERATING PARAMETERS MODIFICATION DURING THE OPERATION

After setting the parameters of the lamp operation, the procedure can be activated.

To do this, press the START / STOP button. The bulb (s) will light up and the treatment time will start. The time remaining until the end of the treatment will be displayed. During the operation of the lamp, the following parameters are displayed: the time of the treatment and the power level with which the bulbs shine and the dot of the time display blinks. If the lamp is with two tubes, the LED (s) for selecting the bulbs are also on. After the set exposure time has elapsed, the bulb (s) will turn off and the device will emit an intermittent sound signal. To turn it off, press any button. The fans will work for 1 minute after switching off the bulbs.

To change the treatment time during operation, press START / STOP. This will turn off the bulbs, stop the countdown of time until the end of the treatment and allow you to change the time of the procedure. After entering the new value, press START / STOP again to turn on the light bulbs and continue the countdown.

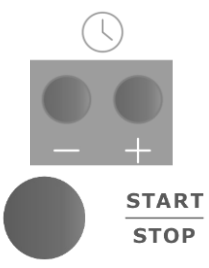
To change the number of working bulbs or power level you can do it with the appropriate buttons even during the procedure.

6.5. LAMP TREATMENT PROGRAMS AND SEQUENCES

There are 10 user programs numbered P0 ... P9. Each program is a sequence of 1 to 6 stages with a given duration and power level.

6.5.1. Choice of the program

- Hold down the "+" and "-" change buttons together. Select the desired program using the change time buttons.



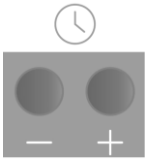
- Confirm the selection with the START / STOP button.

- After selecting a program, the display shows the program number and its total duration alternately. The regulation of time and power level is blocked.
- After starting the treatment, the display shows the program number alternately and the total time remaining until the end of the procedure.

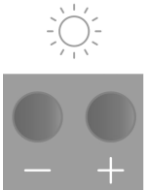
To return to manual adjustment of treatment settings, select the item displayed as "-" instead of one of the programs when selecting a program.

6.5.2. User program editing

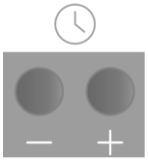
- Hold down the "+" and "-" change buttons together. Select the program number to be edited using the time change buttons. Confirm the selection with the START / STOP button.



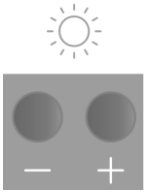
- Then hold the "+" and "-" power buttons together.



- The number of the first stage of the edited program will appear on the display, e.g. for the P2 program it will be "2.0".
- Use the time change buttons to set the duration of the stage.



- Set the power level using the power change buttons.



- Confirm the settings with the START / STOP button, the next step number will be displayed, e.g. "2.1”.

- Program in the above manner the subsequent stages of the desired treatment sequence.
- Setting the duration of the step equal to 0 or achieving the maximum total treatment time (30 min) results in the early completion of the program edition.

6.5.3. Settings pre-saved in user programs

Program	Stages					
P0	15 min. level 10					
P1	15 min. level 7					
P2	15 min. level 4					
P3	10 min. level 10					
P4	2 min. level 5	3 min. level 7	10 min. level 10			
P5	5 min. level 5	5 min. level 10	5 min. level 5			
P6	5 min. level 5	10 min. level 7	15 min. level 10			
P7	2 min. level 5	3 min. level 8	5 min. level 10	5 min. level 8		
P8	5 min. level 4	5 min. level 6	5 min. level 8	5 min. level 6		
P9	5 min. level 5	5 min. level 6	5 min. level 7	5 min. level 8	5 min. level 9	5 min. level 10

6.6. SLEEP MODE

If the treatment is not carried out and 15 minutes have passed since the last button was pressed, the device goes into sleep mode. When in sleep mode, only the dot lights up on the display. To leave the sleep mode, press any button.

6.7. RELOCATION OF SOLMED LAMP

WARNING!

The lamp should only be transported in the transport position.

WARNING!

Before changing the location of the SOLMED lamp, disconnect the mains supply cord and place it in a place where it cannot be crushed or damaged.

If case of relocation, prepare SOLMED for the transport position:

- remove the filters,
- drop the tube down and block the tube knob,
- lower the arm to the lowest position and lock it with the knob,
- unlock the wheels,
- you can transport the lamp by holding the arm.

7. MAINTENANCE AND CLEANING

WARNING!

When performing the following operations, it is absolutely necessary to disconnect the device from the mains by removing the mains plug from the mains socket.

7.1. CLEANING

WARNING!

Before starting the following operations, the device must be disconnected from the power supply and allow the tubes to cool down.

WARNING!

Too much water on the cloth may cause water to get inside the device, which is a danger to people and the device. If liquids get inside the device, please contact the service

WARNING!

Do not turn on the device if the casing or ducts are moist or wet.

Do not use strong detergents and solvents for cleaning. It is permissible to clean with soapy water or a mild detergent using a damp cloth, and then dry the device with a dry cloth.

7.2. PERMEABILITY OF VENTILATION VENTS

WARNING!

In order to maintain proper cooling inside the tube (s), do not cover the ventilation opening in the upper part of the casing or insert any objects into it. Also, do not allow the ventilation hole to become blocked by a dust layer. Periodically check and clean the ventilation openings. As a result of the lack of cooling and the activation of the thermal switch, the operation of the IR illuminator may be interrupted.

WARNING!

Lack of cooling can cause damage to the device, which is not covered by the warranty conditions.

7.3. FUSES REPLACEMENT

WARNING!

Before replacing the fuses, the device must be disconnected from the mains supply.

WARNING!

The fuse parameters are given in section 2 of this Operation Manual and on a plate next to the power socket**.**

The fuses are located in the power supply socket (see Fig. 6). To replace them, unplug the power cord, then press the lock lever and pull out the fuse socket. Use fuses with given parameters.

After replacing the fuses, insert the socket with the fuses until you hear the characteristic "click", connect the power cable and check if the device works.

7.4. BULB EXCHANGE

WARNING!

Before replacing the bulb, the device must be disconnected from the power supply.

WARNING!

The device gets very hot during operation, therefore the replacement of bulbs should be made after the heating elements are cooled.

WARNING!

Replacement of bulbs should be done by service personnel.

WARNING!

The lamp protection grid (fig. 11 item 3) protects the patient and staff from the hazards associated with a broken glass of the bulb or filter.

WARNING!

Use only bulbs specified by the manufacturer of the SOLMED lamp.

In order to insert or remove a light bulb, remove the filter (fig. 11 item 1), unscrew the two M5x12 screws from the front of the tube using a 3 size Allen key (fig. 11 item 2) and remove the front ring (fig. 11 item 3).

After screwing or removing the light bulb, attach the front ring and screw it to the face of the tube with two screws M5x12.

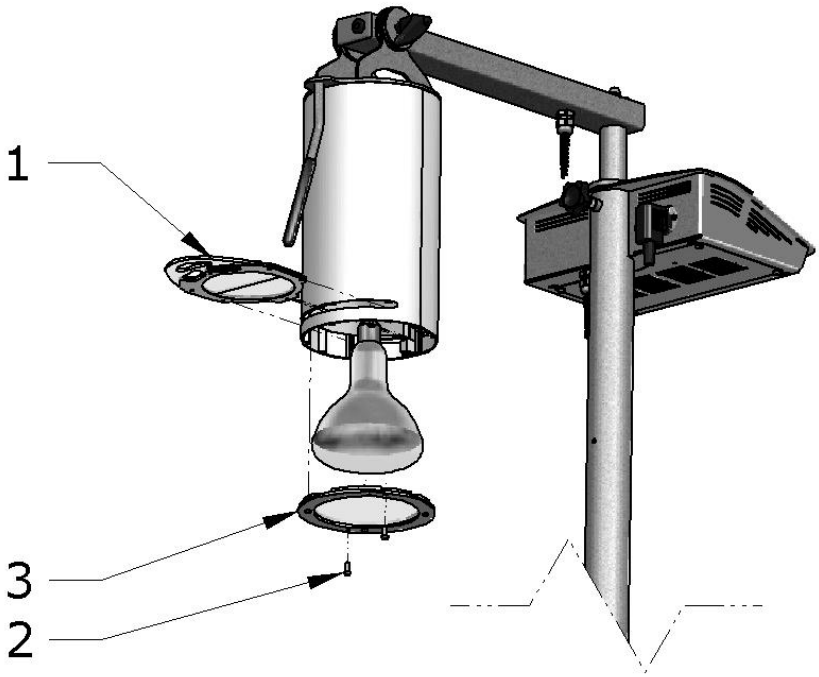


Figure 11 - How to change a light bulb

7.5. REQUIRED LIGHT SOURCES

WARNING!

The maximum power of the bulb for which the SOLMED lamp achieves the described operating parameters is 375 W.

WARNING!

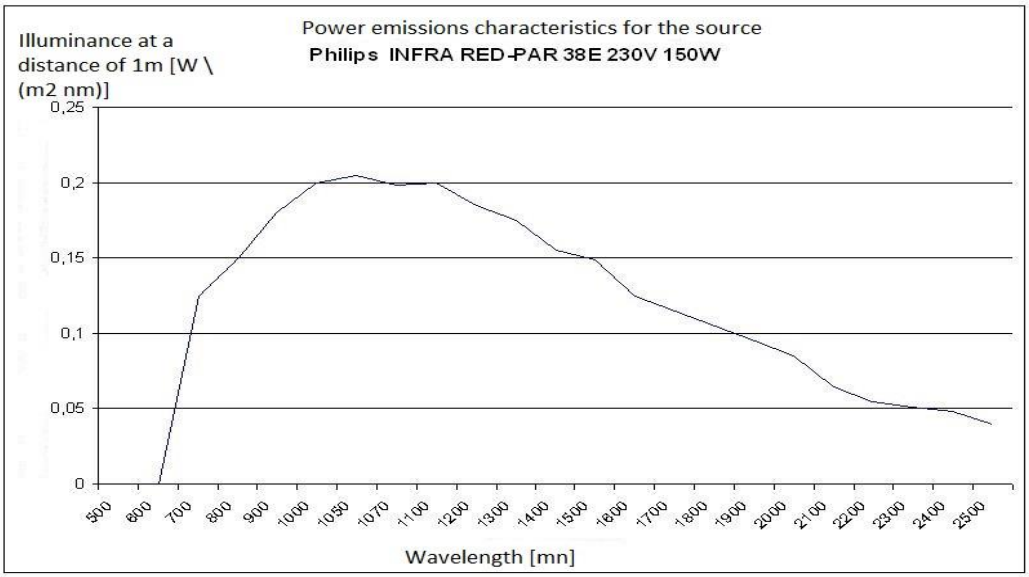
The manufacturer is not liable for using incandescent light bulbs.

WARNING!

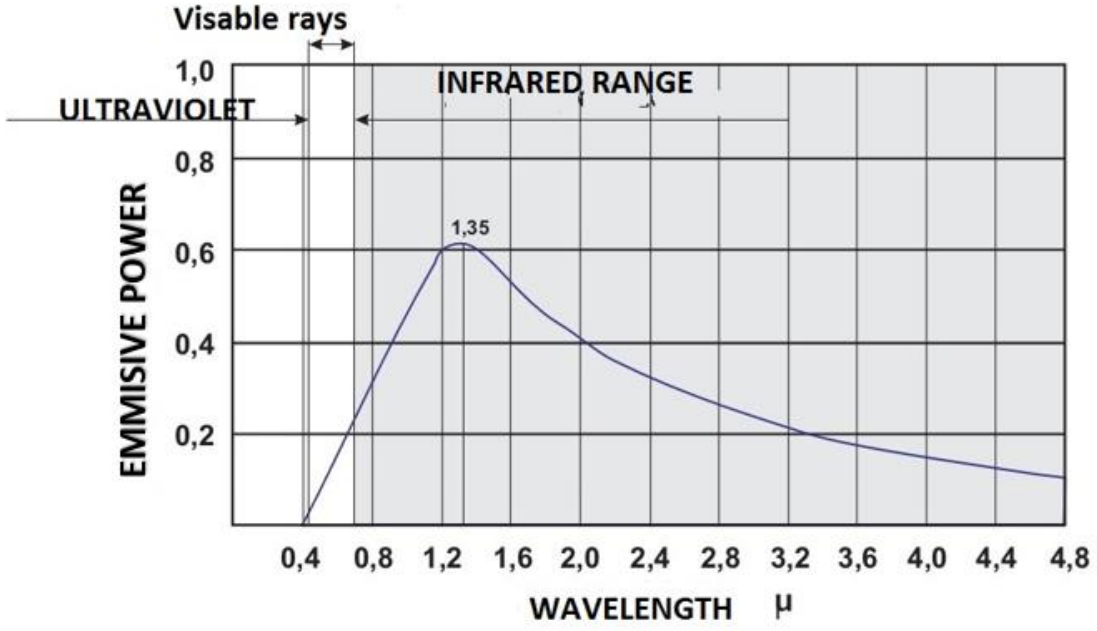
Use only bulbs indicated by the manufacturer of SOLMED irradiation lamps.

Sources of light for SOLMED lamps are available from Meden-Inmed.

- Philips production, infrared heater R-125 IR375 CH, 230V-375W.

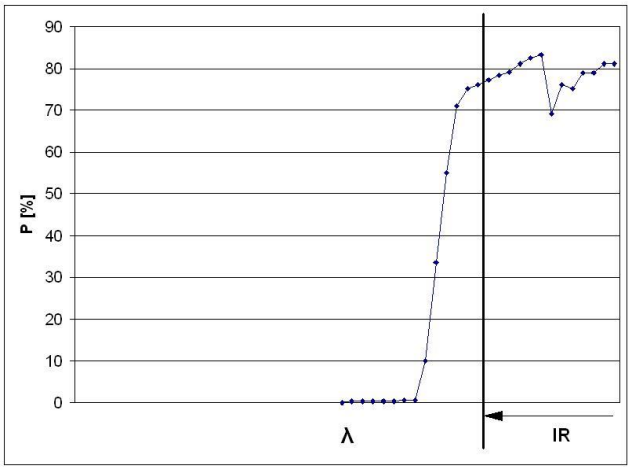


- Helios production, infrared heater R-125 E27, 230V-375W.

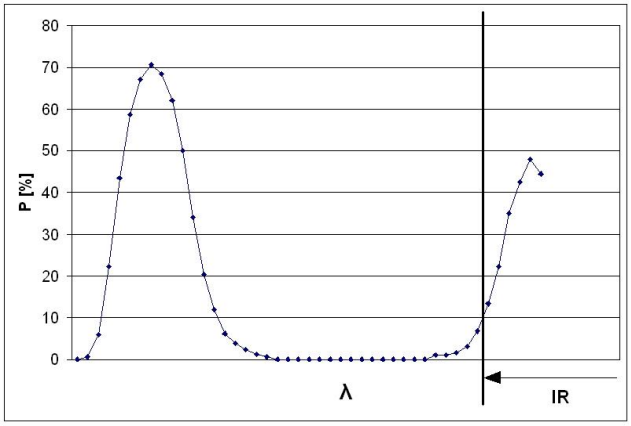


7.6. FILTER PARAMETERS

- red filter

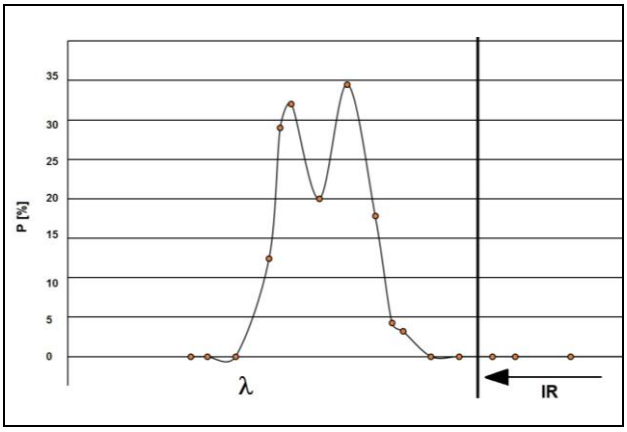


- blue filter



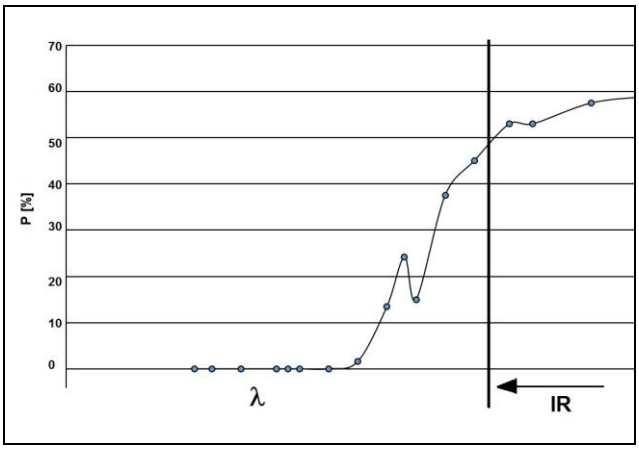
- orange (amber) filter

  (it is not included in the standard equipment and not supplied with the lamp)



- green filter

  (it is not included in the standard equipment and not supplied with the lamp)



Markings in the graphs above: P - transmission, λ - wavelength, IR - infrared range.

8. TECHNICAL CONDITIONS FOR USING THE UNIT

WARNING!

Under no circumstances can you open the desktop housing on the support stand.

WARNING!

Any mechanical or electrical damage to the SOLMED lamp should be strictly reported to the manufacturer's service.

WARNING!

The manufacturer will make available on request circuit diagrams, parts lists, descriptions helpful in the repairs of those parts that are allowed by the manufacturer to repair.

8.1. TROUBLESHOOTING

This section explains the basic problems that can occur when using a SOLMED lamp and how to solve them.

Symptoms	Troubleshooting
After connecting to the mains, the display on the desktop does not light up, no reaction to the buttons.	Check that the power cord is properly connected and that the switch is on. If this does not solve the problem, check the fuses (see p.7.3 "Fuses replacement").
A dot is on the desktop, the bulbs are not working.	The device has probably gone into sleep mode (see p.6.6 "Sleep mode") press any button to exit it.
After setting the operating parameters and pressing the START / STOP button, the bulb (s) will not light up.	Check that the bulb (s) are not blown (see p.7.4 "Bulb exchange").
The bulb went off during treatment.	Switch off the power supply and check the patency of the tube vents. Wait 30 minutes for the tube to cool down, switch on the power and restart the unit. Check that the bulb is not burnt out.
The device does not respond to commands and the display shows "E1" or “E2”.	Switch off the power supply and check the patency of the tube vents. Wait 30 minutes for the tube to cool down, switch on the power and restart the unit. Check that the bulb is not burnt out.
The device does not respond to commands, and the display shows "E3, E4, E5, E6"	Check if some external object is blocking the fan blades.
Frequent shutdown of the device during operation, resetting the controller and other unusual behavior.	Make sure that the lamp is not placed near devices that emit strong electromagnetic fields and possibly change its location. If there are no effects, disconnect the device from the mains and contact the manufacturer's service.

In any case, when the recommended solutions do not remove the signs of damage, disconnect the device from the mains and contact the manufacturer's service.

8.2. MANUFACTURER'S RESPONSIBILITY

After 10 years from the date of manufacture of the device (and its equipment) the manufacturer is not responsible for the defects of the device and its equipment and the resulting consequences. The manufacturer also does not bear any responsibility for the consequences to which the user or patient has been exposed, for example due to improper installation of the device or due to misdiagnosis, improper use of the device and its equipment, misinterpretation or non-compliance with the operating instructions and repairs by persons without rights.

8.3. CONTACT WITH THE SERVICE

Meden-Inmed Sp. z o.o.
ul. Wenedów 2
75-847 Koszalin
tel. (94) 344 – 90 – 48
e-mail: service@meden.com.pl

If you purchase the device from a distributor, we kindly ask you to provide information about the serial number and place of use of the device. These data will be placed in our service database, which will allow us to efficiently fulfill the terms of warranty and service.

9. ELECTROMAGNETIC COMPATIBILITY

WARNING!

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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!

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

WARNING!

Device may be susceptible to electromagnetic disturbances, but Basic Safety and Essential Performance are maintained.

Essential performance - documentation of the risk management process shows that there are no essential performance characteristics for the product * „SOLMED irradiation lamp”.

Guidance and manufacturer’s declaration – electromagnetic emissions		
The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The equipment* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The equipment* is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV (contact) ± 2/4/8/15 kV (air)	± 8 kV (contact) ± 2/4/8/15 kV (air)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines 100 kHz	±2 kV for power supply lines 100 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles (50/60Hz) 1 phase: at 0° 0 % U_T; 250/300 cycles (50/60Hz)	0 % U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles (50/60Hz) 1 phase: at 0° 0 % U_T; 250/300 cycles (50/60Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment* requires continued operation during power mains interruptions, it is recommended that the equipment* be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment* should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	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 equipment*, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Radiated RF IEC 61000-4-3	3 V/m 80MHz do 2,7GHz	3 V/m 80MHz do 2,7GHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	EN 60601-1-2:2015, Table 9 *(see below)* ☒ *Professional healthcare facility environment*	Complies ☒ *Professional healthcare facility environment*	

Proximity fields from RF wireless communications equipment						
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum power (W)**	**Distance (m)**	**Immunity test level (V/m)**
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

10. WARRANTY CARD

1. The seller (authorised representative, distributor) offers a 24-month warranty, starting from the date of purchase of the equipment, as indicated in a proof of purchase.
2. The seller (authorised representative, distributor) is responsible for any faults whether in quality or quantity occurring immediately after unpacking the product from its original shipment packaging only if they have been reported in a written form within 2 working days following the delivery.
3. The warranty will be fulfilled only by the authorised service team of the seller (authorised representative, distributor) or other technical service authorised by the manufacturer.
4. A repair time exceeding 3 days shall result in the extension of the warranty period by a time equivalent to the total time during which the device was out of order.
5. In case a faulty subassembly has already been repaired three times, the manufacturer shall be obliged to replace a faulty subassembly with a new one.
6. The user must ensure all the maintenance service described in the manual in order to benefit from the warranty coverage.
7. In case the installation and operation instructions have not been observed, the manufacturer shall bear no responsibility for the safety of the user or patient during the use of the unit.
8. The warranty does not cover faults of parts and materials resulting from natural wear and tear, which means faults other than material or workmanship, as well as faults resulting from poor or no maintenance (e.g. valves, bearings, guides, fans etc.).
9. The seller (authorised representative, distributor) shall bear no responsibility for any loss, whether consequential or incidental, including loss of profits or costs incurred that result from a failure to follow the instructions set out in the installation and user manual.
10. The seller (authorised representative, distributor) shall bear no responsibility resulting from this warranty for any loss, whether consequential or incidental, including loss of profits or costs incurred by failure of the equipment.
11. Faults that occur within the warranty period and are not reported to the authorised service are not covered by the warranty.
12. Costs resulting from an unfounded claim shall be borne by the user.
13. The warranty shall not cover equipment:
    - damaged as a result of fire and lightning or force majeure,
    - with a name plate and/or serial number or factory seals removed or damaged,
    - damaged due to its use in a manner other than defined in the operation manual,
    - where repairs or modifications have been done by unauthorized personnel,
    - damaged mechanically due to improper handling or transportation.
14. In case the equipment covered by the warranty has been re-sold, no new warranty document will be issued.
15. The warrantor shall not issue a duplicate of the Warranty Card.
16. This warranty does not exclude, limit or suspend your consumer statutory rights.

The serial number of the SOLMED unit:	
Date of production:	
Producer's seal and signature:	
Sale date:	
Salesperson's stamp and signature:	

11. CARD OF PERIODIC TECHNICAL TESTS

WARNING!

Every 12 months and each time after a failure / repair of the lamp, it is necessary to perform or commission electrical safety tests in accordance with applicable regulations. The tables of measurements are presented below.

SOLMED, irradiation lamp - manufacturing**.....**[1)]	**SN:**						–				

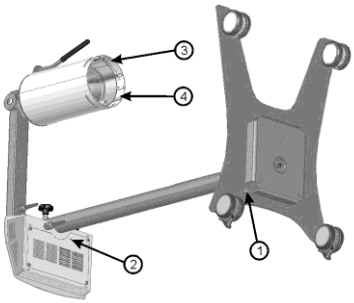
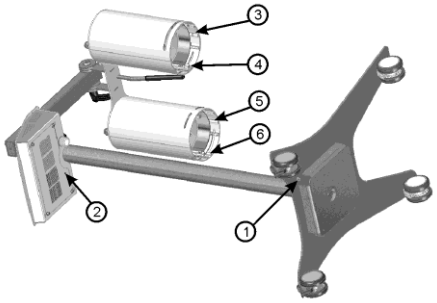
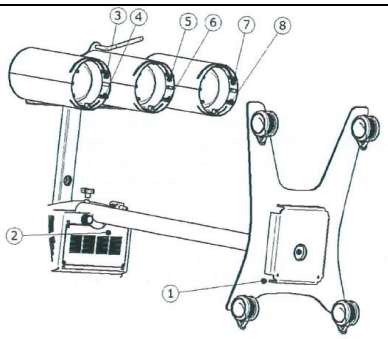
Measuring equipment: [1)]	
– *Separation transformer, id:*	
– *Electrical safety parameters tester, id:*	
– *Multimeter / voltmeter, id:*	
–	
–	
–	

Impedance and current strength of protective earth connections (PE)	

Measurement of impedance and current strength performed by a current of 25 A between the protective ground contact in the apparatus socket and the designated measuring point on the earthed part of the tested device.

Measure the tube on its inside (see drawings below). The probe should be applied to the surface of the tube not covered with paint (if necessary - clean the necessary surface from the paint).

Measurements acc: PN-EN 60601-1 (2011) - 8.6.4				Measurements acc: PN-EN 60601-1 (2011) - 8.6.4	
Measurement point	**measured voltage drop** U [mV]	**measured test current** I [A]	**Calculated resistance** R = U/I [mΩ]	**Permissible resistance** R_{MAX} [mΩ]	**Fulfills** Y / N
1- lamp base				≤ 100	
2 - the bottom sheet of the desktop (test hole)				≤ 100	
3 - tube 1 - left part of the cover				≤ 100	
4- tube 1 - the right part of the cover				≤ 100	
5 - tube 2 - left part of the cover				≤ 100	
6 - tube 2 - the right part of the cover				≤ 100	
7- tube 3 - left part of the cover				≤ 100	
8- tube 3 - the right part of the cover				≤ 100	

		
Location of measurement points for a 1-tube lamp	Location of measurement points for a 2-tube lamp	Location of measurement points for a 3-tube lamp

Earth leakage current

Measurements acc: PN-EN 60601-1 (2011) – 8.7.4.5	Requirements acc: PN-EN 60601-1 (2011) – 8.7.3 d)

Measurement [2), 3), 4)]	**Power voltage** U_Z [V]	**Leakage current**			
		measured I_P [mA]	**standardized for U_Z=253V** $I_U = I_P * 253 / U_Z$ [mA]	**acceptable for U_z=253V** I_{U_MAX} [mA]	**fulfills** Y / N
SN				≤ 0,5 [5)]	
SN*				≤ 0,5 [5)]	
SPU-L				≤ 10	
SPU-L *				≤ 10	

Remarks:

1) Complete the data and/or delete as appropriate.
2) The tests should be performed in a system with a separation transformer. In the case of testing WITHOUT SEPARATION TRANSFORMER, SAVE SPECIAL PRECAUTION due to the increased risk of electric shock!
   The system should also separate all parts of the tested device from the ground, except for the power connection, that the unintentional contact of any part of it with the ground does not disturb the measurement results.
3) Conditions for measuring leakage currents:
   - Measurements of leakage currents should be carried out with the power switch turned on.
   - Set the maximum brightness of the lamp.
   - Measurements in the normal state of MV / MV * should be performed with the treatment on (irradiation)).
4) Marking: SN - measurement in the normal state; SPU-L - measurement in the state of single fault with a break in one power cable; SN *, SPU-L * - measured as SN, SPU-L, respectively, but in the system with reversed (swapped) order of power wires L and N.
5) The limit results from limitations of the touch leakage current in the state of single fault with an interruption in the PE protective earth conductor.