INFIMED

User manual

OPERATING LIGHT ONYX

TL-01

Serial number .....

Edition 3.1

September 2024

Manufacturer:

INFIMED Spółka z ograniczoną odpowiedzialnością

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REGON 243274947

In accordance with Annex VIII to Regulation (EU) 2017/745 of the European Parliament and of the Council , the lamp has been classified as class I, according to rule 13.

The manufacturer declares that the product complies with the general safety and performance requirements contained in Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council and the Medical Devices Act.

The manufacturer declares that he is following the conformity assessment procedure set out in Article 52(7) of Regulation 2017/745, after drawing up the technical documentation set out in Annexes II and III of Regulation 2017/745.

CE

Dear Customer!

As a manufacturer, we congratulate you on the right choice and wish you many years of satisfaction with the use of the purchased lamp.

To ensure the longest possible trouble-free service life of the product, please read these instructions carefully and follow all manufacturer's recommendations for proper installation, use and maintenance of the product.

1. Safety

The product has been designed and manufactured in such a way as to ensure its safe use and handling. A prerequisite for the safe use of the lamp is to read, understand and follow the rules included in this manual.

This marking has been placed on parts and mechanisms whose handling contrary to the guidelines of the instructions may result in a hazard to the safety of the patient or the staff.

It is imperative that you read the user manual.

1.1. General safety remarks

- Do not use, operate or service the lamp in a manner inconsistent with these user manuals. This may lead to damage that is the responsibility of the user and for which the manufacturer is not responsible.

- The user may not make modifications or repair of the product on their own. Doing so will void your warranty. Repairs can be carried out by service personnel or the manufacturer's representative.

- The optical radiation emitted by this product complies with the exposure limits for reducing the risk of photobiological hazards set forth in IEC 60601-2-41.

- Any serious incident related to the device must be reported to the manufacturer and the competent authority of the Member State where the user or patient is resident.

1.2. General remarksconcerning the safe use of the product

- This product emits potentially dangerous optical radiation. Do not stare at the light emitted by the surgical frame, as it may injure the eye.

- The lamp must not be used when the shading glass or lens system indicates damage (unstable mounting, cracking, etc.). Temperature disturbance or change in light parameters may affect the course of the surgery.

- When moving the lamp arms, collisions between the arms or lamp heads should be avoided,

- To obtain a full range of illumination adjustment, the distance between the operated field and the lamp should be between 0.6 and 1.5 m.

- The lamp must be connected to power sources in accordance with the rating plate (indication of the source operation on the ceiling cover: main – green LED and emergency – orange).

- The lamp is not intended to work in potentially dangerous places, e.g. where there is a risk of explosion.

- Do not place foreign objects on the lamp components, as this may lead to loss of suspension stability or hazards during the operation.

- It is forbidden to store the lamp with discharged batteries.

- If the product is not used for more than a week, the mains switch should be turned off, and after a long period of non-use of the product, the batteries should be recharged – at least once every six months.

- Do not use bleaching agents for cleaning and disinfecting – containing active choir or oxygen.

- Do not use any agents whose ingredients damage their structure.

Failure to comply with the above requirements concerning, above all, cleaning and disinfection, will void the warranty for the product

1.3. Technical Parameters

Parameters of the ONYX TL-01 operating lamps:	TL-01 60/100klx	TL-01 30klx
Illuminance Ec	60 klx (100klx-120klx)*	30 klx
Adjustable illuminance	10 – 100%	10 – 100%
Color temperature Tc	4300K (4800K)*	4300K (4800K)*
Luminous field diameter d10 at Ec	260mm (240-340mm)*	240mm
Luminous depth (L1+L2) 60% and 20%	800mm and 1300	600mm and 1000
Color Rendering Index [Ra(1-8)]	> 92 (> 95)*	>92 (> 95)*
Red rendering index [R9]	> 90 (> 92)*	(> 90)*
Maximum irradiance E_{total} in DMI = 800 mm	< 500 W/m2	< 370 W/m2
Irradiance E in D_{Ref} = 1000 mm	< 383 W/m2	< 450W/m2
Light head housing temperature	< 40.00oC	< 40.00oC
Temperature rise in the operator's head area	< 1.00oC	< 1.00oC
Primary Side Supply Voltage	90-250V AC	90-250V AC
Power Consumption	50W	20W
Supply voltage of luminaire heads	24-28V DC	24-28V DC
Lamp life	> 60,000hrs	> 60,000hrs
Degree of protection of the luminaire head	IP54	IPX2

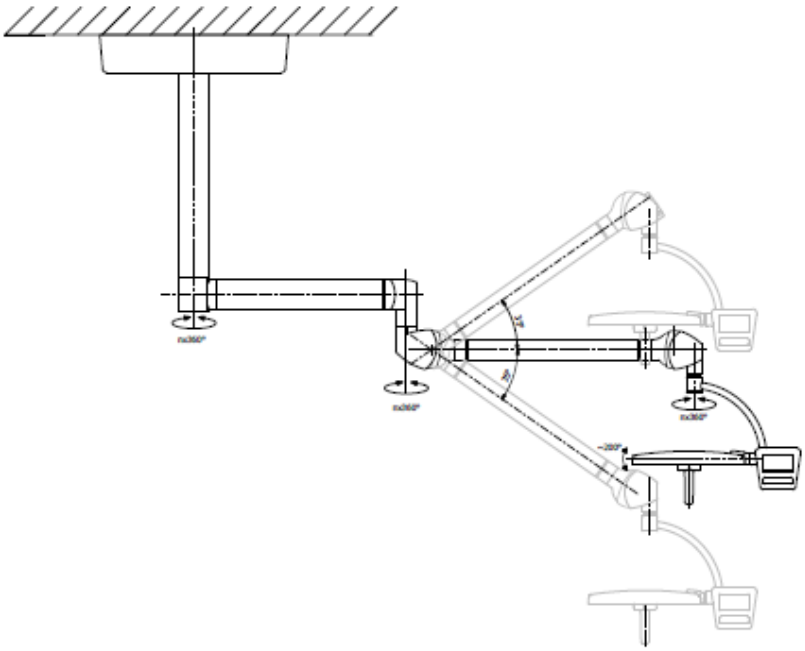
Reference point D_{ref} for measuring lamp luminous parameters is D_{Ref} = 1000 mm Lamp luminous parameter tolerance +/- 10 %

* - additional versions

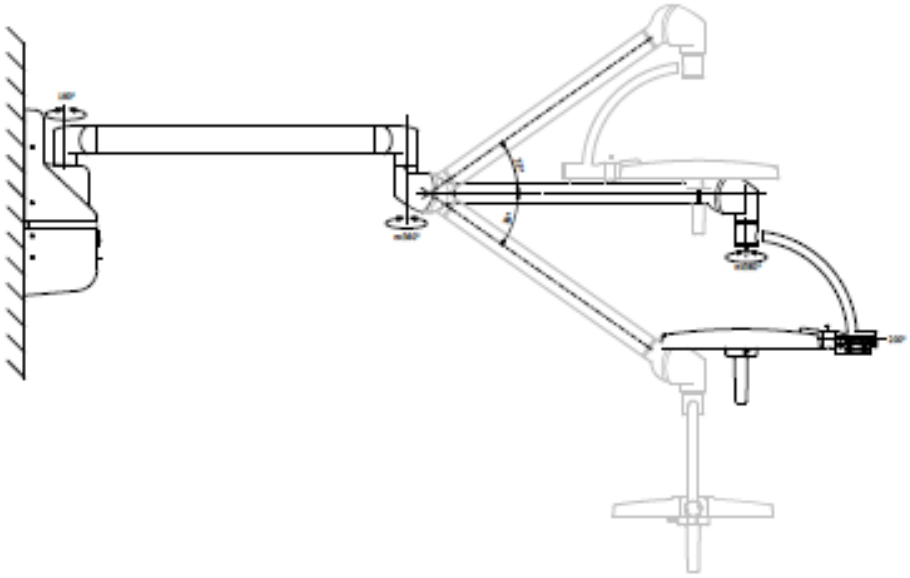
On special order of the customer, it is possible to make a product with changed technical parameters, which do not reduce its safety.

Configurations of ONYX TL-01 lamps

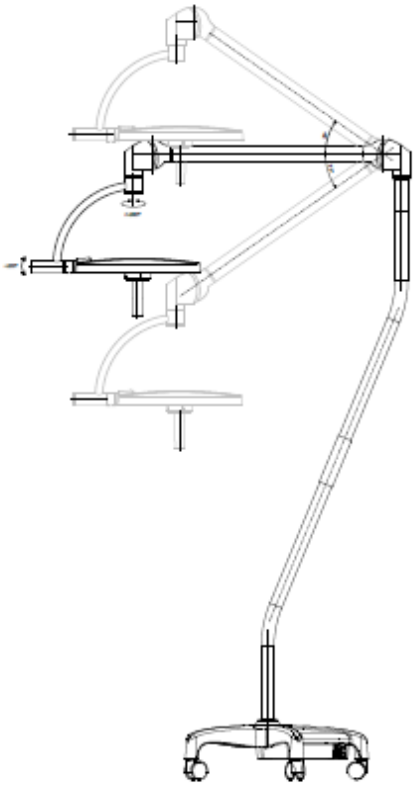
Single ceiling



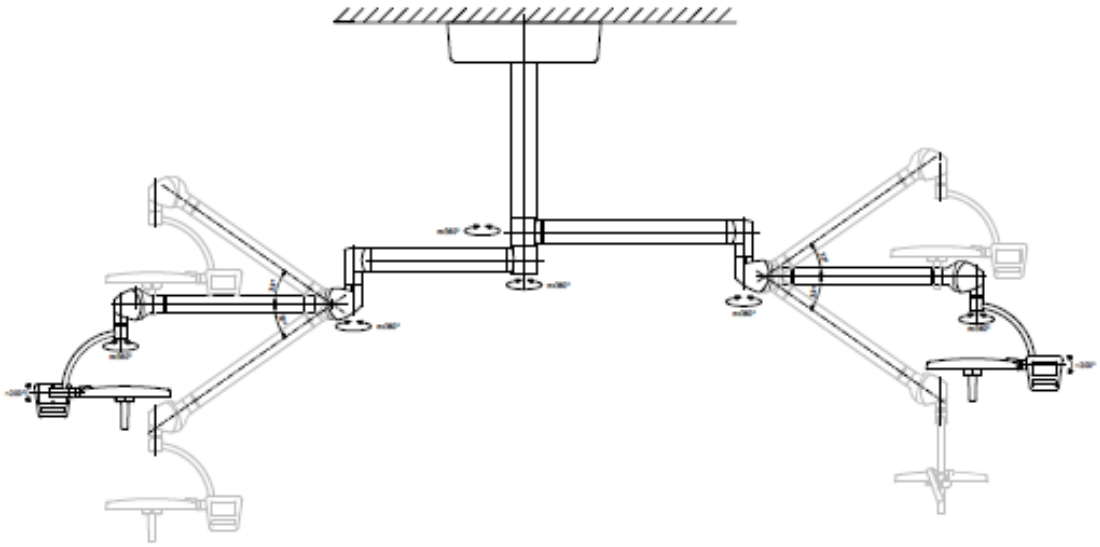
Wall-mounted version of the operating light:



A mobile version of the operating light:



Ceiling versions of the double suspension:



1.4. General requirements

The product should be used, operated and serviced in accordance with the rules of these instructions.

The lamp is intended to be installed and operated indoors only. **Using, operating and servicing the lamp contrary to the guidelines of the manual is strictly prohibited and may lead to danger and irreparable damage due to the fault of the user, for which the manufacturer is not responsible. Any interference with the lamp elements contrary to the instructions, the use of equipment other than those offered by the manufacturer may be allowed only on the basis of written consent from the manufacturer.** ***The user must ensure that all persons operating the product are familiar, understood and comply with these operating instructions***. In addition, the employee is obliged to ensure that the lamp is used only for its intended purpose and in conditions suitable for it. The user is obliged to guarantee all necessary measures to ensure safe and appropriate operation of the device, prevent any threats to the safety of life and health of himself, as well as patients and third parties.

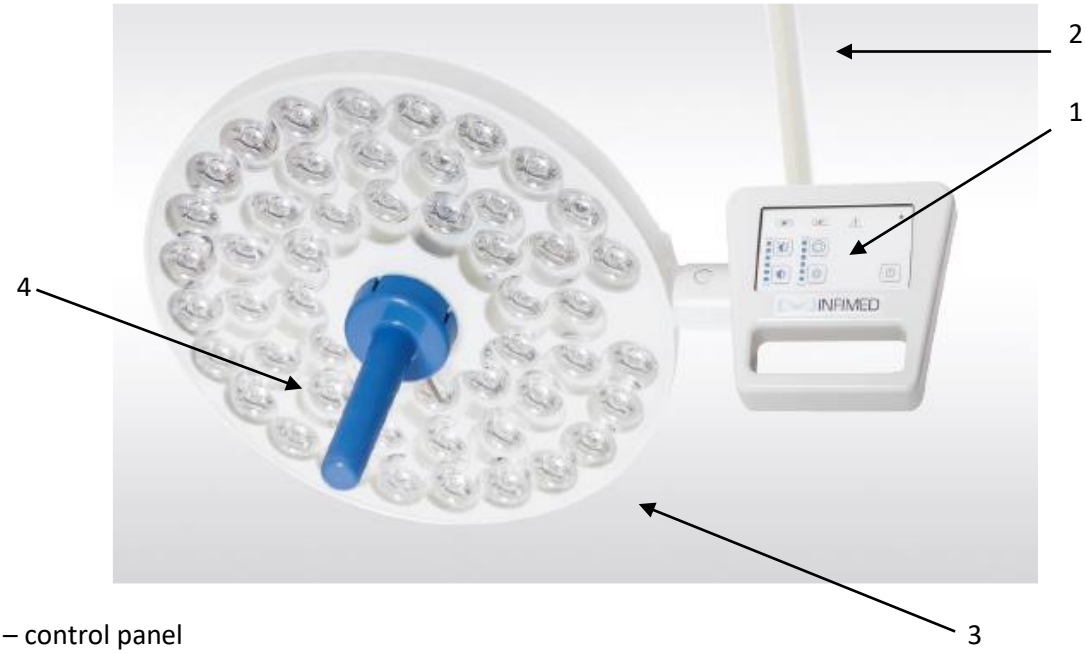
1.5. Description of the product

Infimed Onyx operating lamps are modern lamps made in LED technology, designed to illuminate the treatment area during diagnostic, therapeutic and cosmetic procedures. LED technology ensures low energy consumption, no harmful UW radiation and several times longer life of the operating lamp compared to traditional light sources – both halogen and discharge. LED light sources do not contain lead, mercury and other hazardous substances, which facilitates their future disposal. Infimed Onyx LED operating lamps are characterized by very good technical parameters, low heat radiation, as well as easy positioning of lightweight, ergonomic heads. The tight and resistant to mechanical damage aluminum structure guarantees easy disinfection and cleaning, as well as resistance to environmental factors. The control panel allows you to adjust selected parameters of the lamp – illuminance and, optionally, also light field adjustment. The sterile adjustment handle allows for precise positioning of the lamp and can be sterilized in an autoclave. As an additional option, it also allows you to adjust the size of the light field. The Infimed Onyx operating light is available in a single or double ceiling suspension version, a wall version and a mobile version optionally equipped with a battery system.

1.6. Description of the elements of the lamp construction

Example of light head construction:

Operating light TL-01 (60/100 kLux version)



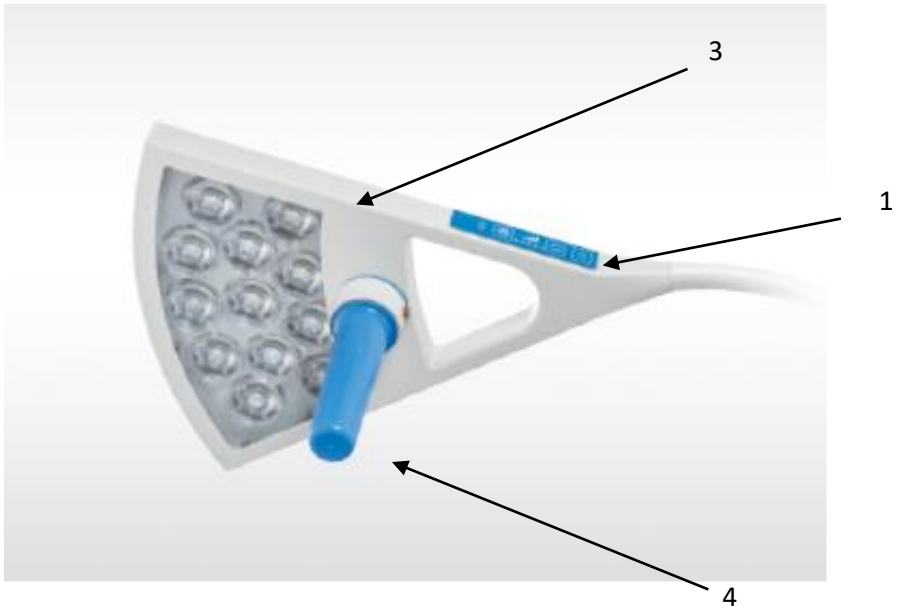
1 – control panel

2 – arrangement of the canopy arms

3 – canopy

4 – sterile handle

Operating light TL-01 (30klx version)



1.7 Electromagnetic compatibility

Medical device: **TL-01** is an electrical device. Electrical devices are a source of electromagnetic radiation and are themselves subject to its influence.

The use of an electrical appliance requires the use of proper precautions related to electromagnetic compatibility.

In the tables – point 7 Characteristics of the electromagnetic environment – the electromagnetic environment in which the medical device **TL-01** should be used is described. The user should follow the tips and warnings provided in the boards.

The use of accessories, accessories, cables, spare parts other than those offered and/or recommended by the manufacturer may result in increased emissions and/or reduced resistance of the product to electromagnetic phenomena in general.

Recommended distances between portable radio communication equipment and the product

Rated maximum transmitter output power in watts In	**150 kHz do 80 MHz** $d = 1{,}2\sqrt{P}$ **Distance in meters**	**150 kHz do 800 MHz** $d = 1{,}2\sqrt{P}$ **Distance in meters**	**800 MHz for 2.5 GHz** $d = 2{,}3\sqrt{P}$ **Distance in meters**
0.01	0,1	0,1	0,2
0.1	0,4	0,4	0,7
1	1,2	1,2	2,3
10	4	4	7
100	12	12	23
For transmitters whose maximum output power is not specified above, the separation distance should be calculated according to the given formulas. P is the power in watts (W) as declared by the transmitter manufacturer. REMARK The above guidance may not apply to all situations. The propagation of electromagnetic waves is subject to absorption and reflections from buildings, objects and people.			

2. Transport and start-up

2.1. Transport

The product can be transported by all generally available covered means of transport. During transport, the product must be protected against moisture and dust and immobilized. During transport and storage, the temperature should be in the range of -10 to +60 degrees C, and the humidity should be 20-60%. When unpacking the product, the temperature change must not be greater than 8-10°C per hour. Do not unpack the product before it has reached the temperature in the room intended for its installation. In the event of significant temperature differences between the transport temperature and the temperature of the room in which the product is to operate, it should be left for a minimum of 12 hours in order to equalize the temperature level. If there is no clear marking on the transport packaging, it is not allowed to layer the products.

In the case of transporting the lamp in specific conditions (low ambient temperature), the method of transport and protection should be agreed with the manufacturer.

2.2. Unpacking, storage and first start

The lamp is supplied by the manufacturer in a box. Do not unpack the lamp outside the building.

Preparing the lamp for work should be carried out in the following order:

a) Make sure that the transport packaging has been in the room where the lamp is to be used for a long time

b) Open the shipping case and remove the materials that protect the lamp parts

c) Attach the ceiling tile system to the existing ceiling in accordance with the Building Preparation Instructions for Infimed lamps

d) Attach the lamp mounting arm system, depending on the lamp version (installation according to the Installation Instructions of the arm manufacturer to the ceiling plate)

e) Attach the lamp to the arm holder

f) Connect the lamp to the power supply system, then connect the system to the mains

g) Read the user manual carefully

h) Check the operation of the mechanical suspension systems of the lamp

If the product is not completely functional, i.e. the obtained parameter values differ from those included in the manual, it must not be used. This fact should be reported to the manufacturer or its representative. The use of a faulty lamp may lead to damage that is the responsibility of the user and for which the manufacturer is not responsible.

If the product is not going to be used for an extended period of time, it should be stored under the following environmental conditions:

- temperatura: 25^{o}C (77^{o}F) ± 10^{o}C (18^{o}F)

- Relative humidity: 50% ± 25%

The product must be switched off during storage. The switch must be in the "0" position. For longer storage, plug it in every 6 months for 24 hours to recharge the batteries. The product must not be stored when the batteries are discharged (the red LED on the panel is on).

The product is intended to be installed and operated only in confined spaces with the following environmental conditions:

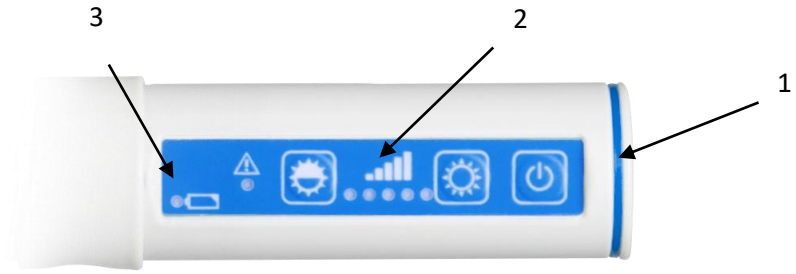
- temperatura: 25^{o}C (77^{o}F) ± 10^{o}C (18^{o}F)

- Relative humidity: 50% ± 25%

- atmospheric pressure 700 to 1060 hPa

3. Operation and operation

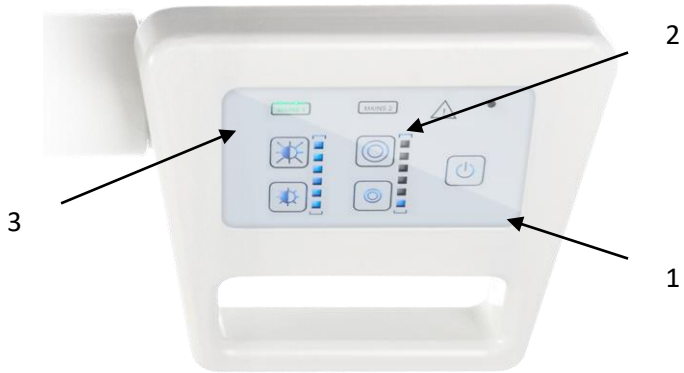
3.1. Control panel



The lamp is switched on and off by pressing button 1.

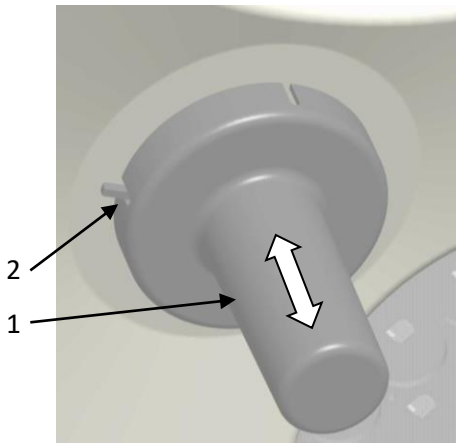
2 buttons adjust the parameters of the lamp head.

3 LEDs indicate a malfunction and the state of charge of the batteries or power supply.



3.2. Adjustment by means of an adjustment handle (optional extra)

The size of the light field is adjusted by turning clockwise or counterclockwise with the sterilizable adjustment handle.

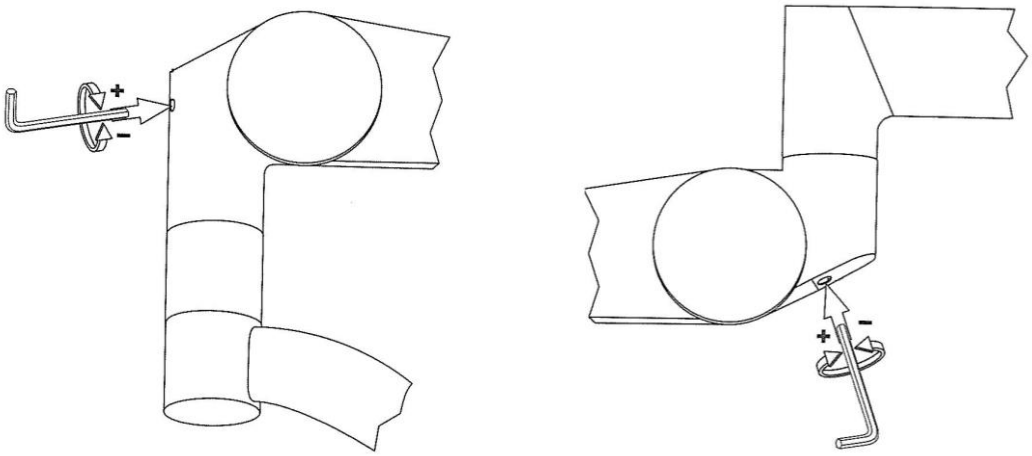


To remove the sterilizable handle, press the latch button (2) and, while holding it in the depressed position, pull the handle down.
To install the bracket, slide the handle (1) over the guide until the latch clicks (2).

3.3. Positioning of the light head depending on the spring arm

ONDAL arms

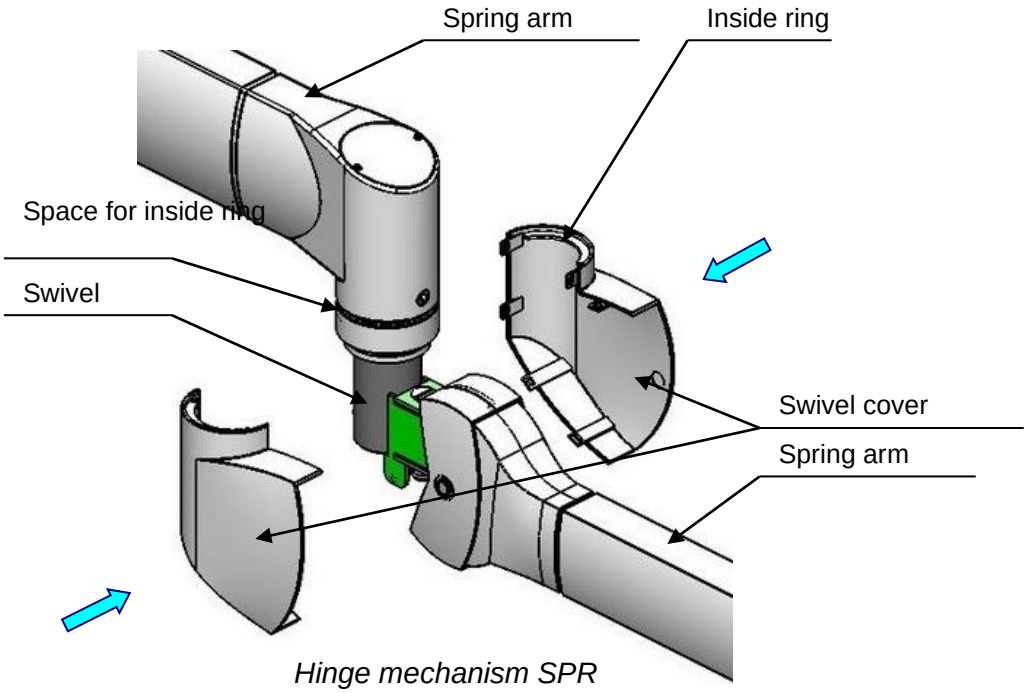
To position the lamp head, we use: a sterilizable adjustment handle and lamp positioning handles on the edges of the lamp head. The height of the lamp is determined using the movement capabilities of the arms to hang the lamps. It is possible to adjust the tension force of the tonearm. To limit the tension force (the tonearm rises automatically), place the adjusting rod (placed in the original packaging of the tonearm) in the hole and turn it clockwise (+). If the force is too low (the arm falls on its own), turn the adjusting rod counterclockwise (-).



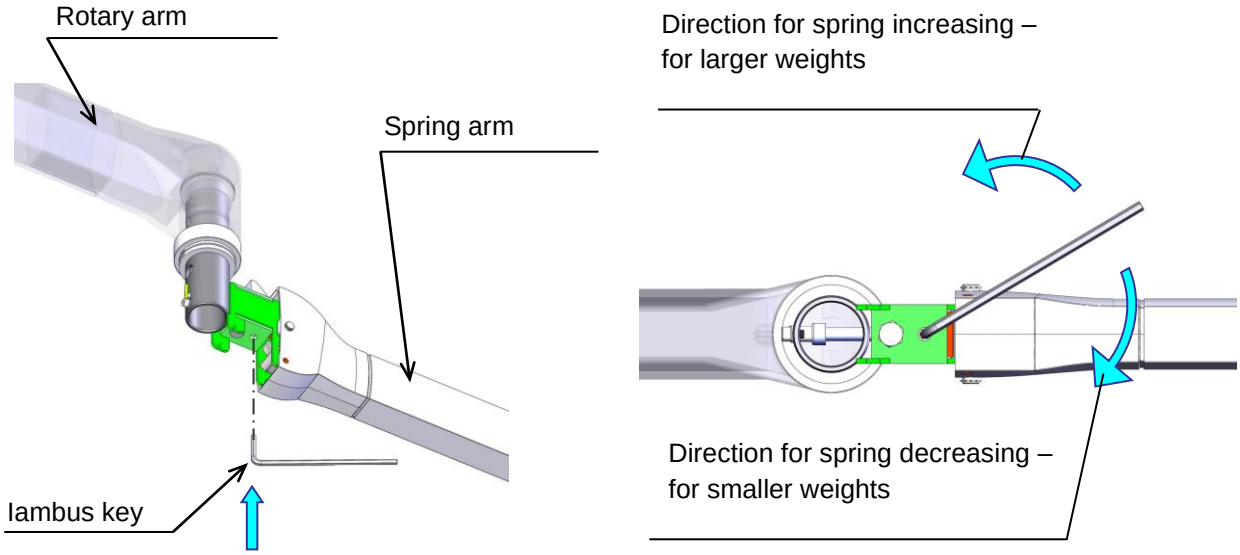
Way of adjusting the tension force and angle range of the spring arm

Liberec Arms

To position the lamp head, we use: a sterilizable adjustment handle and lamp positioning handles on the edges of the lamp head. The height of the lamp is determined using the movement capabilities of the arms to hang the lamps. It is possible to adjust the tension force of the tonearm. To limit the tension force, place the Allen key in the hole (from the bottom of the tonearm) and turn it in the direction of movement indicated below. If the force is too low, turn the Allen key in the opposite direction.

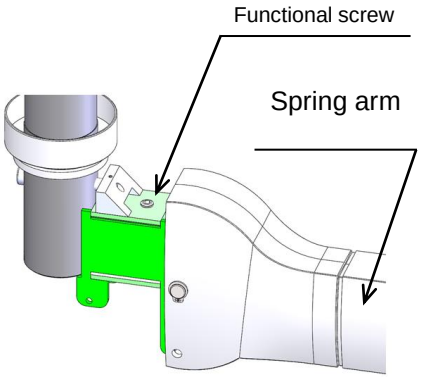


Hinge mechanism SPR parts



Adjustment of a spring arm

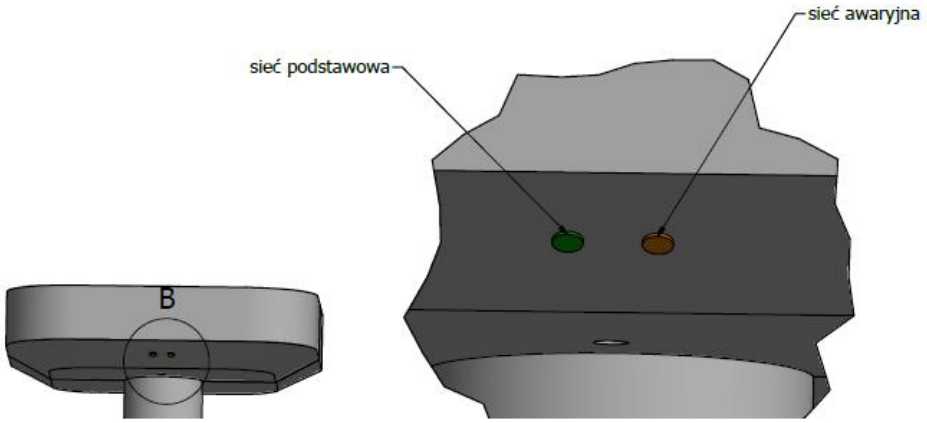
Do not adjust the function screw. It must be screwed in, it is not used for adjustment.



Place of functional screw

4. Mains power and battery charging

The mains power supply is indicated on the ceiling cover: green LED – operating main network, orange LED – operating emergency network.



If the lamp is equipped with a charger that allows you to charge the batteries in the lamp, it should be connected to the mains with the same power parameters as specified on the rating plate. The charging system is activated by inserting the appropriate end of the power cord into the socket located in the lamp housing, inserting the cable plug into the power socket and pressing the switch located in the lamp housing from the 0 to 1 position.

Do not perform operations while the batteries are charging.

A LED indicator is built into the control panel or power panel to indicate the charge status of the batteries. When the green LED is on, there is no need to recharge. The following indications may occur:

Green LED – Batteries Charged

Red LED – low battery state – absolutely **connect the power supply to the batteries**

When the power is connected, the green LED will light up. Batteries should be charged min. 6 hours. If the batteries are charged in a shorter time, the process will end automatically. If the user ends the

charging process earlier, after disconnecting the power supply, the LEDs that correspond to the level of battery charge will light up.

The nominal battery life is approx. 3 hours. However, this period may be shortened depending on the intensity of lamp use.

Do not store the lamp with discharged batteries.

When replacing batteries, always replace the set.

Charging batteries too often can lead to a shorter battery life.

Do not store the lamp with discharged batteries - if you do not use the product for more than a week, turn off the mains switch, and after a long period of non-use of the product, charge the batteries - at least once every six months.

5. Collision hazard

When moving the lamp arms, collisions between the arms or lamp heads, as well as with other devices in the operating room, should be avoided.

Operate the lamp consciously, with caution and full responsibility.

6. Assessement of correct operation

Before each first start-up and use of the lamp on a given day, it is necessary to assess its correct operation.

How to assess the correct state of operation:

- check the smoothness of movement by trying to move the lamp manually

- check for mechanical play by manually moving the lamps and the arm system

- check the functioning of the electronic system by performing all movements controlled from the control panel and the sterilized handle,

- check that the arms do not fall or rise on their own

If no inaccuracies or damage are detected during such a test and no disturbing sounds reached the user during the tests, the lamp can be used. Otherwise, please refer to the troubleshooting point.

If the lamp is not completely functional, it must not be used. This fact should be reported to the manufacturer or its representative. The use of a faulty lamp may lead to damage that is the responsibility of the user and for which the manufacturer is not responsible.

4. Defects and faults

Damage and defects detected in the product by the operating personnel should be immediately reported to the person responsible for the state of maintenance in a given facility. This person, after a thorough diagnosis of the possible defect and its cause, is obliged to contact the service or the

manufacturer for consultation and possible guidance on further actions. A product that cannot be used safely (mechanical or electrical damage) cannot be used until it has been repaired.

5. Cleaning and disinfection

For cleaning and disinfection, use cleaning agents that do not contain active oxygen or chlorine in their composition. After disinfection, the product should be washed with distilled water to eliminate stains. Use a dry, soft, sterile cloth to dry thoroughly.

It is imperative to unplug the power cord before disinfection. 

Do not use any agents to wash elements made of plastic, the ingredients of which destroy their structure.

The removable sterilizable adjustment handle is made of material that can withstand high-temperature sterilization conditions. The handle must be cleaned, disinfected and sterilized, both before the first use and before each subsequent use. The handle should be sterilized in an upright position, in an autoclave at a temperature of up to 134 degrees C for up to 5 minutes. The handles can be sterilized a maximum of 100 times, after this period the handles must be replaced with new ones.

The apertures of the lamp's diodes are made of polycarbonate, which can be cleaned with standard cleaning agents in the form of a solution at the concentrations specified by the manufacturer. Do not dry wipe polycarbonate, use scrubbing agents or use agents with an alcohol content of more than 20%. After cleaning, wipe the shutters with an antistatic agent.

The list of disinfectants can be found in *Appendix 1* to the manual.

Failure to comply with the above requirements will result in the loss of the product warranty.

6. Maintenance, inspections and repairs

All repairs are carried out in the product by the appropriate service or a direct representative of the manufacturer. The user has no right to make any modifications and repairs to the product himself without special training and authorization. After the customer has obtained the manufacturer's written consent for any repair to be carried out by the customer's technical personnel, the manufacturer will make available all necessary information needed to perform the repair.

To ensure long and trouble-free operation of the lamps, use only original parts provided by the manufacturer.

Due to the fact that the product contains elements that may pose a threat to the environment, the handling of used parts must comply with environmental protection regulations.

In the case of replacing batteries, the manufacturer is obliged to take them back.

All repairs, inspections and maintenance should be recorded in the Repair and Maintenance Completed Card attached to the product manual (Appendix 2).

7. Technical inspection and periodical inspection

In order to ensure that the proper technical condition of the product is maintained, during its use, the user is obliged to subject it to periodic technical inspections. Inspections are carried out by an authorized service center or by a direct representative of the manufacturer. The inspection is carried out at the expense of the user.

Only a positive result of the inspection can be the basis for further use of the lamp.

Every 12 months, the following should be performed:

- checking the general technical condition

- functionality check

- checking the electrical installation

To ensure the correct safe operation of the lamps, the user should check the technical condition of the device at least once every 6 months. In this case, proceed in the following order:

a) perform all functional movements of the suspension arms, checking the effectiveness of brakes, tension forces of the swivel arms, protection on the rotary nodes

b) check the condition of the sterilized handle and the operation of its attachment mechanism

c) check the condition of the lamp heads – the condition of the shutters, the functioning of the control systems, etc.

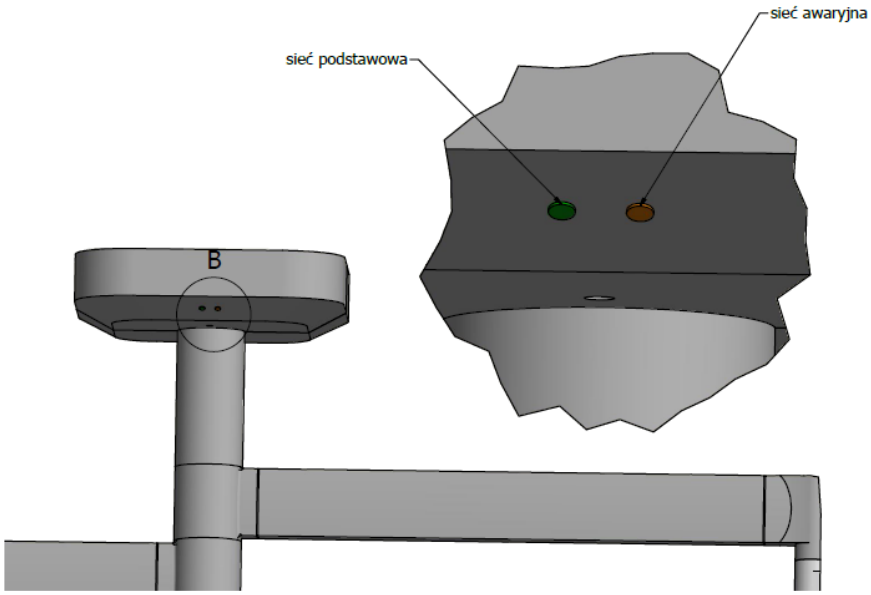
d) check the condition of the protective earth conductor

8. Removing of potential problems

a) the lamp does not light up

- check the charge level of the mobile batteries and the condition of the fuses,

- check the status of the power supply networks (indication of operation on the ceiling cover: main – green LED and emergency – orange) – LEDs do not light up, no power supply to both networks.



b) unsecure fixation of sterilizable handles

- replace the handle with a new one

If in doubt, contact the manufacturer for the necessary help and clarification.

9. Product liquidation

When making a decision to discontinue the use of the product, the user is obliged to disinfect it (a product that has not been disinfected in accordance with the applicable environmental protection regulations is hazardous waste). There are three options for proceeding:

1. Have the manufacturer of the device dispose of the product,
2. Have an enterprise that has the required permits to take back the equipment for decommissioning or disposal in a way that ensures the protection of human life, health and the environment,
3. Carry out on their own, if they have services that can disassemble the product.

The rules for dealing with waste are set out in the Waste Act of 14 December 2012

10. Electromagnetic emissions

Medical device: ***TL-01*** is intended for use in an electromagnetic environment with the following characteristics. The user should ensure that the medical device: ***TL-01*** will be used in such an environment.		
Type of issue	**Classification**	**Explanations and tips**
RF emissions CISPR 11	Group 1	Medical device: ***The TL-01*** produces radio frequency energy only for the internal needs of the device itself. The radio frequency energy emission value is very low and is not likely to cause interference to nearby electronic devices.
RF emissions CISPR 11	Class B	Medical device: ***TL-01*** is intended for use in residential premises and in rooms directly connected to the low-voltage network that supplies residential buildings.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations, flickering IEC 61000-3-3	Compatible	

Medical device: ***TL-01*** is intended for use in an electromagnetic environment with the following characteristics. The user should ensure that the medical device: ***TL-01*** will be used in such an environment.			
Immunity	**IEC 60601-1-2 Test Level**	**Resilience level**	**Explanations and tips**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV Air	± 6 kV contact ± 8 kV Air	The floor at the place where the column is used should be wooden, concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least 30%
Shocks IEC 61000-4-5	± 1 kV between the conductors of the power line ± 2 kV between the power line conductor and the ground	± 1 kV between the conductors of the power line ± 2 kV between the power line conductor and the ground	The mains power supply and interference should be the same as in a typical commercial or hospital environment
Fast transient series IEC 61000-4-4	± 2 kV power supply lines ± 1 kV signal lines	± 2 kV power supply lines ± 1 kV signal lines	The mains power supply and interference should be the same as in a typical commercial or hospital environment.
Voltage drops, dips, voltage changes on power lines IEC 61000-4-11	< 5% UT (>95% dip UT) for 0.5 cycles 40% UT (60% dip UT) for 5 cycles 70% UT (30% dip UT) for 25 cycles < 5% UT (>95% dip UT) for 5 seconds		The mains power supply and interference should be the same as in a typical commercial or hospital environment.
NOTE UT is the mains voltage before the test voltages are applied			

Medical device: ***TL-01*** is intended for use in an electromagnetic environment with the following characteristics. The user should ensure that the medical device: ***TL-01*** will be used in such an environment.

Immunity	IEC 60601-1-2 Test Level	Resilience level	Explanations and tips
Conducted disorders induced by radio frequency fields IEC 61000-4-6	3 Vrms 150 kHz do 80 MHz	3 Vrms	Portable radio communication equipment should not be used at a distance shorter than the recommended separation distance, determined according to the correct formula depending on the frequency of the transmitter. This distance is the distance between the transmitter and any part of the medical device and/or its wiring. **Recommended separation distance:** $d = 1{,}2\sqrt{P}$
Radio frequency electromagnetic field IEC 61000-4-3	3 V/m 80 MHz for 2.5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz do 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz for 2.5 GHz where: *P* is the maximum output power of the transmitter in watts (W) as declared by the transmitter manufacturer; *d* is the recommended distance in meters (m). The field strength from stationary radio frequency transmitters, determined by measurements at the installation site, should be lower than the resistance level of the product over the entire frequency range.[b] Disruptions in the functioning of the medical device may occur when the column is used in the vicinity of devices marked with the following symbol. The correct functioning of a medical device should be verified when the medical device is used in the vicinity of devices marked with this symbol

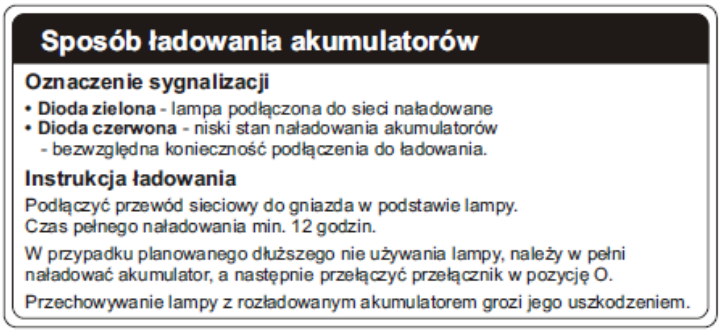
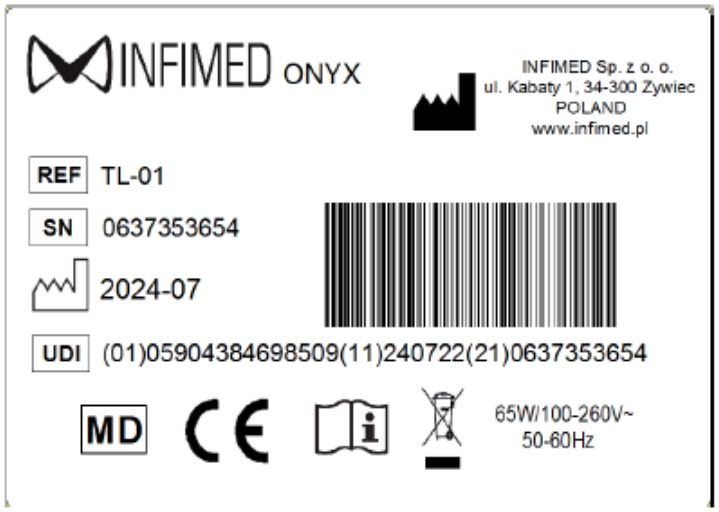
a Field strength from stationary transmitters, such as radio stations, telephone stations (telephony cellular, wireless), land mobile radio stations, amateur radio stations, AM FM broadcasting stations, television transmitters, cannot be estimated with sufficient accuracy. In order to assess electromagnetic radiation from stationary radio frequency transmitters, measurements should be carried out at the installation site of the medical device: ***TL-01 .*** If the value of the electromagnetic field intensity at the place of installation of a medical device exceeds its resistance level, the correct operation of the device should be verified. If the medical device is not working properly, it may be necessary to: perform additional measurements, reorient and/or relocate the medical device, and/or apply additional protective measures.

b Outside the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

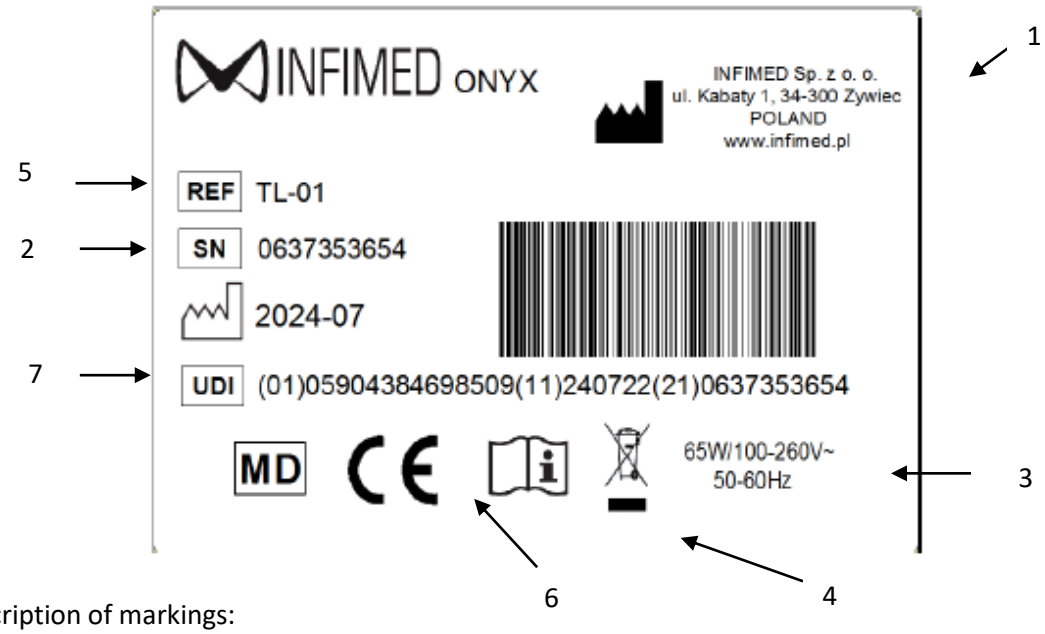
REMARK
The above explanations may not apply to all situations. The propagation of electromagnetic waves is subject to absorption and reflections from buildings, objects and people.

11. Lamp labels

Marking of the ONYX TL-01 operating light:

1		Safety instructions for rechargeable lamps
2		Plate ONYX TL-01
3		Potential equalization connector

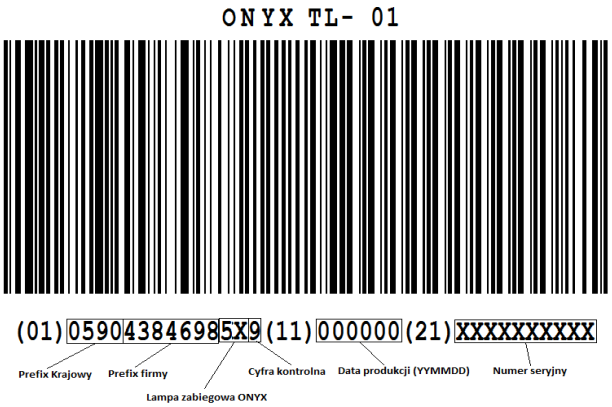
Plate



Description of markings:

1. Manufacturer's name, logo and address
2. Serial Number
3. Power parameters, power consumption
4. Additional markings, e.g. application parts, tightness classes, etc
5. Product symbol
6. CE Mark
7. Code UDI-DI-PI

UDI-DI-PI code explained



Data presented on the label:

Lp.	Element:	Pictogram to use
1.	Company logo	
2.	Manufacturer's name and address	
3.	Name	Operating lamp
4.	Part Number	
5.	CE mark – compliance of the product with the requirements of the MDR Regulation 2017/745	
6.	IP rating	IP-X4
7.	Serial Number	
8.	Production date	
9.	Read the Instructions for Use	
10.	Remark	
11.	Medical device	
12.	UDI code	

The manufacturer reserves the right to make changes to the design of the lamp in connection with the use of newer technological solutions to improve the functionality of the product.

Annex 1

Agents recommended for cleaning and disinfecting surfaces of products and elements made of aluminum, powder-coated steel and plastics

PREPARAT	STAL I ALUMINIUM	MATERIAL	DISTRIBUTOR/MANUFACTURER
MELISEPTOL	+	-	**Aesculap-Chifa Sp.z o.o.** Tysiąclecia 1464-300 Nowy Tomyśl tel: 061 4420100fax: 061 4437505
SPRAY	+	-	**Bochemie PL Sp. z o.o.** Jana III Sobieskiego 11/E640-082 Katowice tel:*+48694400019*
TRICHLOROL	+	+	**MEDILAB Sp. z o.o.** ul. Niedźwiedzia 6015-531 Białystoktel./fax: (85) 7479300tel./fax: (85) 7479301
SURFANIOS PREMIUM	+	+	
NEOFORM MED RAPID	+	-	**DR WEIGERT POLSKA Sp. z o.o.** Wybrzeże Gdyńskie 6D 01-531 Warsaw **phone:** +48 (22) 6160223, 6160231
INCIDIN ACTIVE	+	+	**Opolska** 114 31-323 Kraków Tel.: 48-12-2616 100 Fax: 48-12-2616 101
INCIDIN FOAM	+	+	
TERRALIN PROTECT	+	+	**Schulke Polska Sp. z o. o.** Rydygiera 801-793 Warsaw Tel : (022) 568-22-02(022) 568-22-03Fax: (022) 568-22-04
PERFORM	+	-	
UNCOOKED	+	-	**Antiseptica Dr. Hans-Joachim Molitor GmbH** Carl-Friedrich-Gaus-Strase 7, D-50259 Pulheimtel. +49 (0) 2234-98466-0 fax +49 (0) 2234-98466-11
ANTISEPTICA COMBI SPRAY	+	-	
BIG SPRAY OR	+	-	
VELOX SPRAY	+	+	**Medisept Sp. z o.o.** ul. Konopnica 193 c, 21-030 Motycz tel. +48815352222

Annex 2

Product Repair and Inspection Sheet

Lamp type .....Serial No. ..... Date of purchase .....

Review No.	Date of inspection or repair	Type of inspection (annual, semi-annual)	Person performing the inspection or repair	Signature of the person performing the inspection or repair	Comments found during inspection or repair
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					