

Operating instructions

ENG



D^{med}® **VISIANO** 10-1 P S10

Examination light

SYMBOLS

The warning symbol identifies all important instructions relating to safety. A failure to observe these can result in injury, damage to the luminaire or the equipment! In conjunction with the following signal words, the warning symbol stands for:



Can result in death or serious injury



Follow the operating instructions



CE conformity mark



On



Off



Protection class II device



Storage humidity



Storage temperature



Disposal



Manufacturer



Authorized Representative in the EU

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1 SAFETY INSTRUCTIONS

1.1 Intended use

The D^{med}® VISIANO 10 luminaire is an examination light. It is intended to illuminate the patient's body to support local diagnosis or treatment. Discontinuation of diagnosis or treatment because of a light failure may be possible at any time without risk to the patient. The luminaire is not intended for use in operating rooms.

1.2 User profile

Health Professional

All individuals who have completed medical training and work in the professional field they trained for.

Cleaning Specialist

Trained in national and workplace connected hygiene regulations.

Qualified Electrician

Trained in the areas of electronics and electrical engineering and knows the relevant standards and regulations.

Qualified Specialist

Qualified due to his technical training, knowledge and experience and knowledge of the rules, to carry out the assembly / demounting.



1.3 Safety instructions

- ▶ Operation by Health Professional
- ▶ The instructions form part of the product and must be stored and made available to all future users.
- ▶ All work on the luminaire (incl. repairs) may only be performed by a qualified electrician. The assembly may only be performed by a qualified specialist.
- ▶ The manufacturer or a service technician authorized by the manufacturer or a similarly qualified person may only replace the light source of this luminaire.
- ▶ The luminaire may not be altered or manipulated. Only approved genuine parts may be used. Any use other than the one intended with the genuine parts can lead to other technical values and life-threatening hazards.
- ▶ Operation in potentially explosive areas is prohibited. The current supply of the luminaire represents a potential ignition source.
- ▶ The luminaire may only be operated in dry and dust-free rooms.
- ▶ The luminaire should not be on without supervision.
- ▶ Do not use a damaged luminaire. Defective cord locations also represent a potential hazard. Do not place cord near heat sources or sharp edges.
- ▶ Damage to eyes: never look directly into the light cone.
- ▶ Replace damaged lenses before operating the luminaire again.
- ▶ Do not place extra loads on the luminaire head and the arm system.
- ▶ The luminaire must not be covered with a cloth or similar during operation.
- ▶ The ventilation openings (if available) must always be kept free during operation!
- ▶ The luminaire must not be operated near to external heat sources that exceed the maximum ambient temperature of the luminaire.
- ▶ The luminaire must not be used outside the specified ambient conditions.

- ▶ The luminaire may only be used for the intended use described here.

The manufacturer cannot be held responsible for any damages resulting from use deviating from its intended use, or the failure to observe the safety instructions and warnings.

1.4 Warning levels

 DANGER
Warning of hazards that can result in death or serious injury if there is a failure to follow the instructions.
 WARNING
Warning of hazards that can result in injury if there is a failure to follow the instructions.
CAUTION
Warning of hazards that can result in material damage if there is a failure to follow the instructions.

2 SCOPE OF DELIVERY

VISIANO 10-1 P S10

Included with delivery:



1x Luminaire

1x Power cable

3 ASSEMBLY

Workload data

Bending moment M_b	15 Nm
Vertical weight F_G	32 N



- ▶ Hook rail clamp (1) on the DIN rail (2) and tighten with a hand screw (3).
- ▶ Insert 16 mm pin (4) and secure it with the plastic screw (5).

⚠ DANGER

Danger to life through electric shock

- ▶ All poles of the luminaire must be separated by an external switch from the power (not included in the delivery).

⚠ DANGER

Danger to life through electric shock

- ▶ All poles of the voltage supply at the power connection must be secured via an overcurrent release (according to national assembly regulations) (not included in the delivery).

3 OPERATION

⚠ WARNING

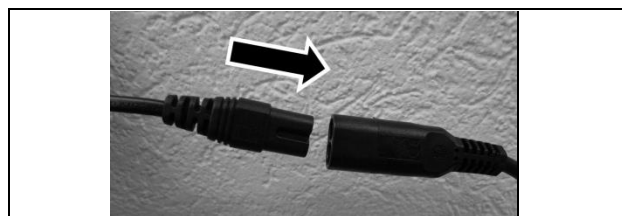
Warning against damage to eyes

- ▶ Never look directly into the beam of light.

⚠ DANGER

Danger to life through electric shock

- ▶ Do not plug in any damaged power cables.
- ▶ If there are any signs of damage to the power cable, immediately replace it with a new one.
- ▶ Connection voltage and frequency must match data on the type plate.



- ▶ Plug in cable
- ▶ Before each use: Perform a function test: all LEDs in the light cone must come on.



- ▶ Turn luminaire on/off

5 CLEANING

⚠ DANGER

Danger to life through electric shock

- ▶ Before cleaning disconnect the power connection from the power supply and secure against unintentional start.

CAUTION

Material damage due to incorrect cleaning

- ▶ For cleaning, only use agents which do not affect the functioning of the luminaire.
- ▶ For cleaning, do not use any solvent or chlorine based or abrasive detergents as they can, among other things, result in the cracking of plastic parts.
- ▶ The agents used must be approved for use on plastics such as PC, PMMA, PA and ABS.
- ▶ Damage to the luminaire due to concentrated disinfectant.
- ▶ For concentration and application times, please consult the information provided with the agent used.
- ▶ Scratches caused by incorrect cloths.

CAUTION

Dirt reduces the luminosity

- ▶ Keep cover clear through regular cleaning.
- ▶ Only disinfectant wipes allowed.



- ▶ Clean the PMMA clear cover with a suitable cleaning cloth and a suitable cleansing agent.

CAUTION

To minimize the risk of disease transmission, applicable health and safety regulations and the requirements of the national bodies responsible for hygiene and disinfection must be observed in addition to these instructions.

6 SAFETY INSPECTIONS

DANGER

Danger to life through electric shock

- ▶ Unplug the plug from the mains and turn switch to off position.
- ▶ Power supply cable must be checked at least once a year for damage.

CAUTION

- ▶ Maintenance and repairs can only be performed by qualified electricians.
- ▶ The corresponding user profile is in Section 1 Safety instructions.

7 DEMOUNTING

DANGER

Danger to life through electric shock

- ▶ Before demounting, disconnect from the power connection and secure against unintended switching on.

Disposal

Do not place the luminaire with the household waste. Bring the luminaire, according to local regulations, to a disposal site or give it to a dealer with the appropriate service offering. Cut the cable directly at the casing.



The products listed above are over 95% recyclable. In order for a high percentage of the used materials to either be physically re-used or used for energy after the end of their life cycle, the luminaires have been designed with recycling in mind. They do not contain hazardous or supervision-requiring substances.

8 ACCESSORIES

Table clamp (Art. No.: D14.228.000 - black)



Universal mount (Art. No.: D13.430.000 - pure white)



Rail clamp (Art. No.: D13.269.000)



Wall bracket (Art. No.: D13.231.000 - pure white)



Roller stand (Art. No.: D14.022.000)



9 ADDITIONAL INFORMATION

The luminaire itself is maintenance free.

Additional documents may be requested from the manufacturer for this product.

Using this luminaire does not present a risk to other equipment.

To save energy, the luminaire should only be switched on when it is actually needed.

10 TROUBLESHOOTING

Fault	Possible cause	Troubleshooting	User profile
Luminaire not working	Contact fault	Switch on again	All
Luminaire not working	No mains voltage	Check voltage, check all connections	Qualified Electrician
Luminaire not working	LED module defective	Contact manufacturer's service dept.	Only by manufacturer's service dept.
Luminaire will not stay in position	Foot joint does not have enough friction	Adjust the foot joint, until desired friction has been achieved	Qualified Specialist

11 TECHNICAL DATA


Electrical Data:	
Rated input voltage	100-240 VAC
Frequency range	50/60 Hz
Power consumption	10.5-13 W (11.2-17 VA)
Input current	0.08-0.12 A
Power factor	0.76
Photometric values:	
Central illuminance E_c at 0.5 m distance	50,000 lx *
Light field diameter d_{10} at 0.5 m distance	$\varnothing = 18$ cm
Light field diameter d_{50} at 0.5 m distance	$\varnothing = 10$ cm
Color temperature	4400K *
Color rendering Index R_a	> 93
Color rendering Index R_9	> 90
Ambient conditions for transport, storage and operation:	
Total irradiance E_e at max. intensity	< 210 W/m ² (* -10% / +20% Tol.)
Ambient temperature (storage and transport)	20°C to +70°C
Ambient temperature (operation)	+10°C to +35°C
Rel. humidity (non-condensing) (storage and transport)	max. 90%
Rel. humidity (non-condensing) (operation)	max. 75%
Weight:	
Visiano 10-1 P S10	1.1 kg
Operating mode:	
Operating mode	Continuous operation
Classification:	
Visiano 10 -1 P S10	Protection class II
Degree of protection according to IEC 60529	IP 20
Classification according to 93/42 ECC – Annex IX (Medical Device Class)	Class I
Classification according to 93/42 ECC – Annex IX (Medical Device Class)	Class I
Electrical safety testing and EMC according to:	EN/IEC 60601-1 EN/IEC 60601-2-41 EN/IEC 60601-1-2
Life cycle of the light source:	
Life cycle of LED	50,000 h (L70/B50)

12 ELECTROMAGNETIC COMPATIBILITY (EMC)

Guidelines - Electromagnetic disturbance emissions

The medical device is intended for operation in an electromagnetic environment such as described below. The user must ensure that it is operated in such an environment.		
Emissions	Correspond to	Electromagnetic environment
RF emissions (CISPR 11)	Group 1	The medical device uses RF energy only for its internal function. Therefore, its RF emissions are very low and it is unlikely that nearby electronic devices will be affected.
RF emissions (CISPR 11)	Class B	The medical device is intended for usage in all facilities including residential buildings and such facilities that are directly (without a transformer) connected to the same low voltage network as the residential building.
Harmonic emissions (IEC 61000-3-2)	Class C	
Voltage fluctuations / flicker emissions (IEC 61000-3-3)	Compliant	

Guidelines - Electromagnetic immunity

The medical device is intended for operation in an electromagnetic environment such as described below. The user must ensure that it is operated in such an environment.			
Immunity against	IEC 60601-1-2 test level	Conformance level of the medical device	Electromagnetic environment
Electrostatic discharge (ESD) (IEC 61000-4-2)	Contact discharge: ± 6 kV Air discharge: ± 8 kV	± 6 kV ± 15 kV	Floors are preferably made of wood, concrete or ceramic tiles. In the case of synthetic floor covering, the relative humidity should be at least 30%.
Fast transient electrical disturbances/bursts (IEC 61000-4-4)	Power cables: ± 2 kV Longer input and output power cables: ± 1 kV	± 2 kV Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Impulse voltage/surges (IEC 61000-4-5)	± 1 kV voltage outer conductor - outer conductor ± 2 kV voltage outer conductor - earth	± 1 kV n/a	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Magnetic field at the supply frequency (50/60 Hz) (IEC 61000-4-8)	3 A/m	100 A/m	Devices with strong line-frequency magnetic fields (transformer stations, etc.) should not be operated in the vicinity of the medical device.
Voltage dips and short interruptions of the supply voltage (IEC 61000-4-11)	Dip > 95 %, 0.5 Per. Dip 60 %, 5 Per. Dip 30 %, 25 Per. Dip > 95 %, 5 Sec.	Dip > 95 %, 0.5 Per. Dip 60 %, 5 Per. Dip 30 %, 25 Per. Dip > 95 %, 5 Sec.	The quality of the supply voltage should correspond to that of a business or hospital environment. If the user requires continued functioning during interruptions in the power supply, we recommend powering the medical device from an uninterruptible power supply or a battery.
Emitted RF disturbance (IEC 61000-4-3)	3 V/m 80 MHz - 2.5 GHz	10 V/m	Recommended separation distance from portable and mobile RF devices in transmission power PEIRP of the medical device including its cords: $d = 0.35\sqrt{P}$
Conducted RF interference (IEC 61000-4-6)	$3 V_{rms}$ 150 kHz - 80 MHz:	$10 V_{rms}$	Recommended separation distance from portable and mobile RF devices in transmission power PEIRP of the medical device including its cords: 80 MHz – 800 MHz: $d = 0.35\sqrt{P}$ 800 MHz - 2.5 GHz: $d = 0.7\sqrt{P}$
d = recommended separation distance [m], P = power of transmitter [W]. The field strength of stationary radio transmitters should be for all frequencies, in accordance with an on-site examination, less than the compliance level.			
In the vicinity of equipment marked with the following symbol, disturbances are possible: 			

Recommended safety distances to portable and mobile RF communications equipment

Power of transmitter [W]	150 kHz - 800 MHz	800 MHz - 2.5 GHz
0.01	0.035 m (0.11 ft)	0.07 m (0.23 ft)
0.1	0.11 m (0.36 ft)	0.22 m (0.72 ft)
1	0.35 m (1.15 ft)	0.7 m (2.30 ft)
10	1.11 m (3.64 ft)	2.21 m (7.25 ft)
50	2.47 m (8.10 ft)	4.95 m (16.24 ft)
100	3.5 m (11.48 ft)	7 m (22.97 ft)