



AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratie de conformitate CE_Onyx
I.2. Declarația de conformitate CE	Declaratie de conformitate CE_Proxy
I.2. Declarația de conformitate CE	Declaratie de conformitate CE_Nexus

Введите текст для поиска...										
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
						infimed	datacontrol			
DM000303246	MASĂ DE OPERAȚIE	FENIX	OT-01		Polonia	INFIMED SP. Z O.O.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000037	09-02-2021	
DM000303247	MASĂ DE OPERAȚIE	VIVAX	OT-02		Polonia	INFIMED SP. Z O.O.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000037	09-02-2021	
DM000303245	LAMPĂ DE EXAMINARE	ONYX	TL-01		Polonia	INFIMED SP. Z O.O.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000037	09-02-2021	
DM000303243	LAMPĂ CHIRURGICALĂ	NEXUS	OL-02		Polonia	INFIMED SP. Z O.O.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000037	09-02-2021	
DM000303244	LAMPĂ CHIRURGICALĂ	PROXY	OL-03		Polonia	INFIMED SP. Z O.O.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000037	09-02-2021	
DM000303242	LAMPĂ CHIRURGICALĂ	NEXUS	OL-01		Polonia	INFIMED SP. Z O.O.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000037	09-02-2021	
<input checked="" type="checkbox"/> Содержит('Reprezentant', 'datacontrol') И Содержит('Prodicatorul', 'infimed')										

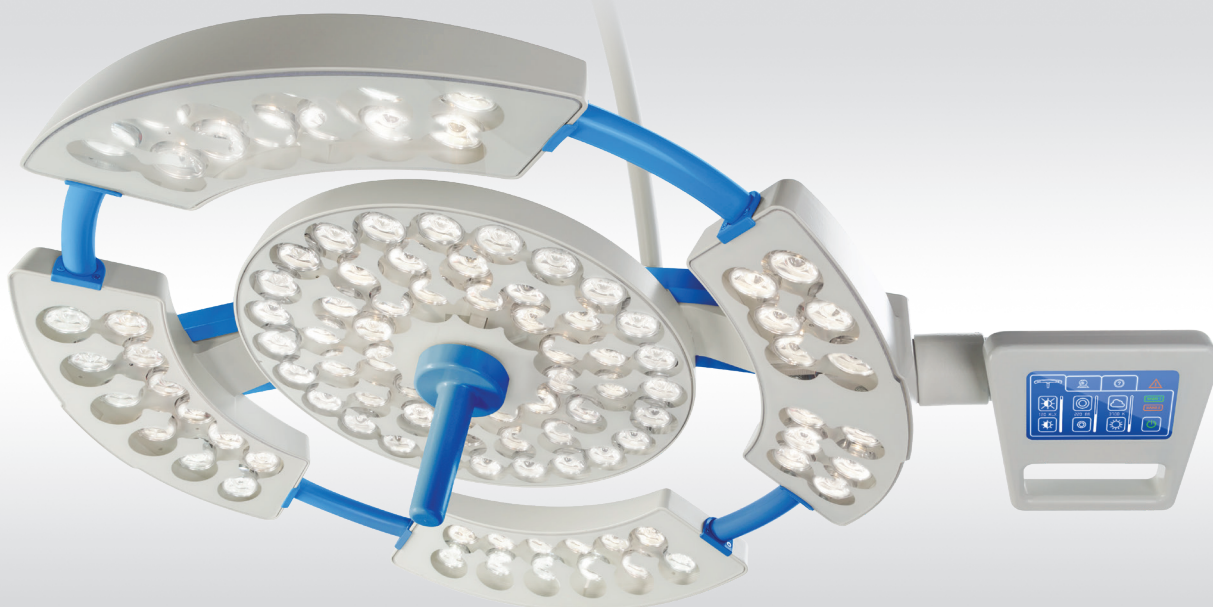


Operating and Treatment Lights

NEXUS OL-01/OL-02

PROXY OL-03

ONYX TL-01



NEXUS Operating light head

Modern Design

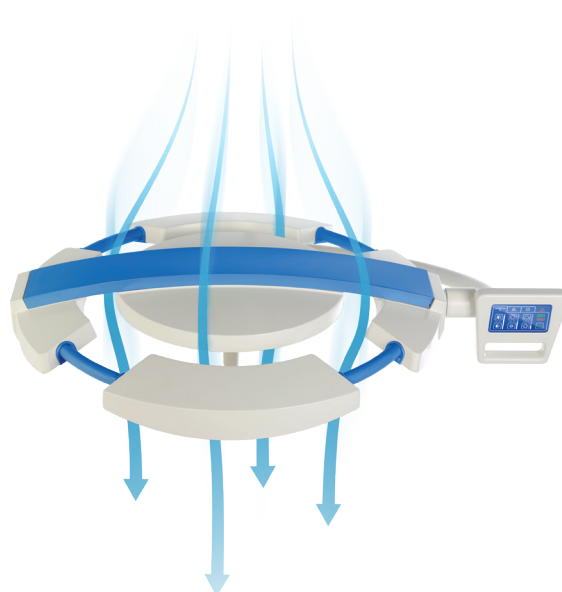
Operating lights INFIMED NEXUS and PROXY and treatment lights INFIMED ONYX with LED light source are distinguished by innovative technology and modern design.

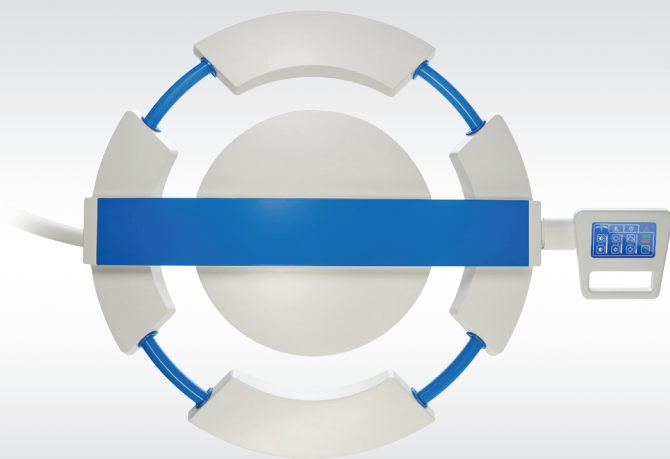
The little weight, ergonomic light heads as well as comfortable handles enable **easy and precise** set up and positioning of the operating light during surgery.

Waterproof, resistant to environmental factors design and smooth surfaces guarantees **ease of disinfection** and maintenance for perfect hygiene.

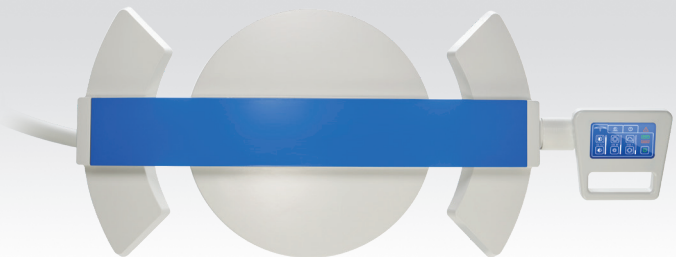
Ergonomic shape of the light minimizes disruption of **laminar airflow** in the operating theatre. The light head are closed construction, composed of solid, permanently assembled elements.

Flow-optimised light head

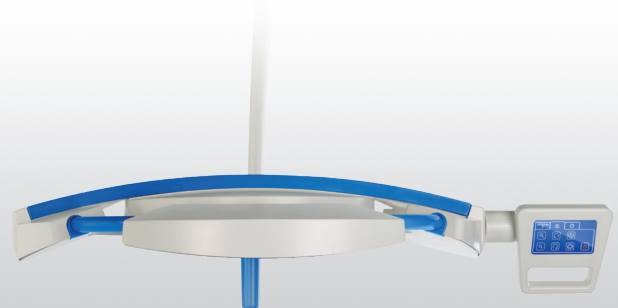




NEXUS Backside view

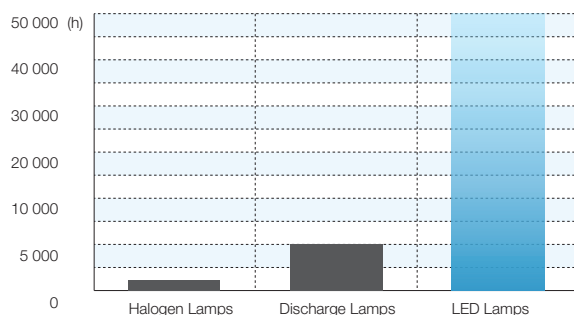


NEXUS Backside view



NEXUS Side view

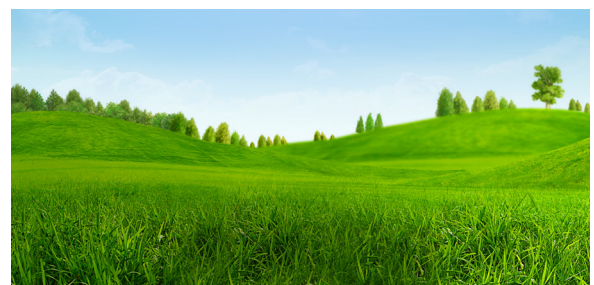
Economy



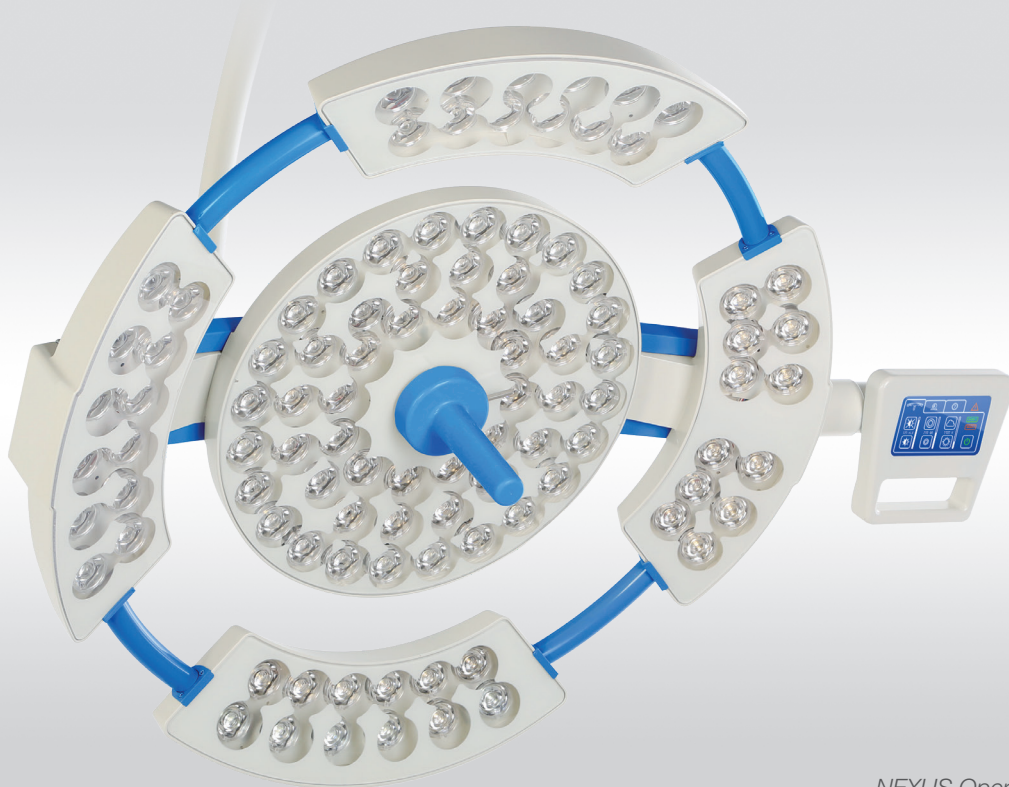
Low power consumption and high efficiency of LED light sources, provide measurable economic benefits by reducing maintenance costs of the operating theater.

Long lifetime of LED technology light sources, estimated at over 50,000 hours, several times exceeds conventional light sources. There is no frequent replacement of the light sources, significantly reducing maintenance and replacement costs.

Environmental Protection



LED light sources do not contain any heavy metals like lead or mercury which facilitate their future utilization. Aluminium, the main material of LED's can be efficiently recycled. LED light sources does not produce harmful UV radiation.



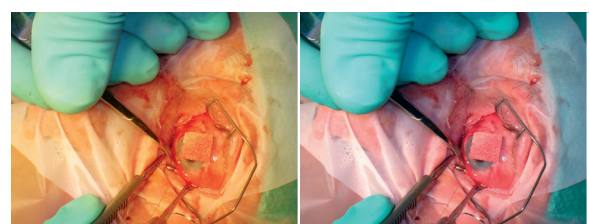
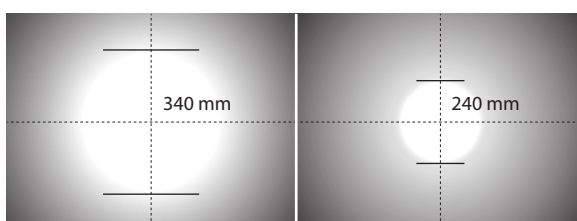
NEXUS Operating light head

Efficiency

LED technology ensures **consistent light distribution** and enables almost shadow-free conditions.

Low heat radiation minimize the temperature increase in the surgeon's head area to imperceptible level.

High light intensity and color rendering index facilitates surgeries of especially narrow and deep wounds. The illumination is electronically dimmed to provide optimum illumination of operating field. Together with wide range of **operating field size adjustment** optimal visual conditions are ensured.

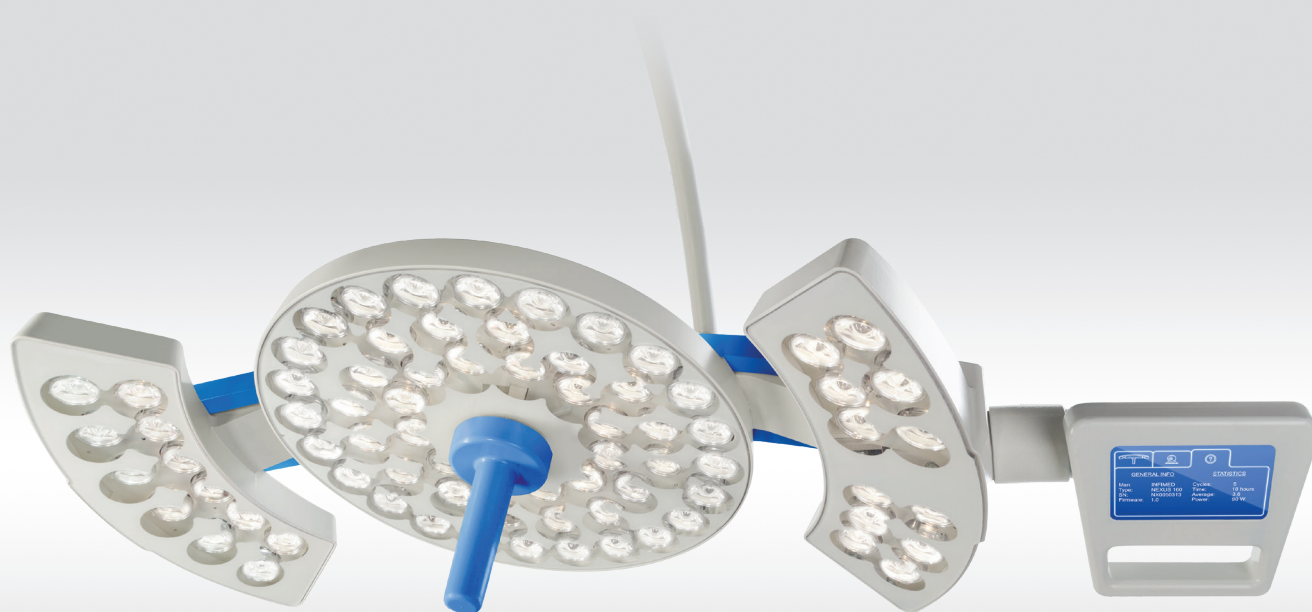


Colour temperature adjustment enables changing the contrast of the observed tissue and reduces fatigue of operating surgeon, which affects the comfort and ergonomics of the medical staff.



Adjustable **endo light** function reduces eye fatigue in case of endoscopic procedures and reflections on the monitors.

OL-01 / OL-02 / OL-03

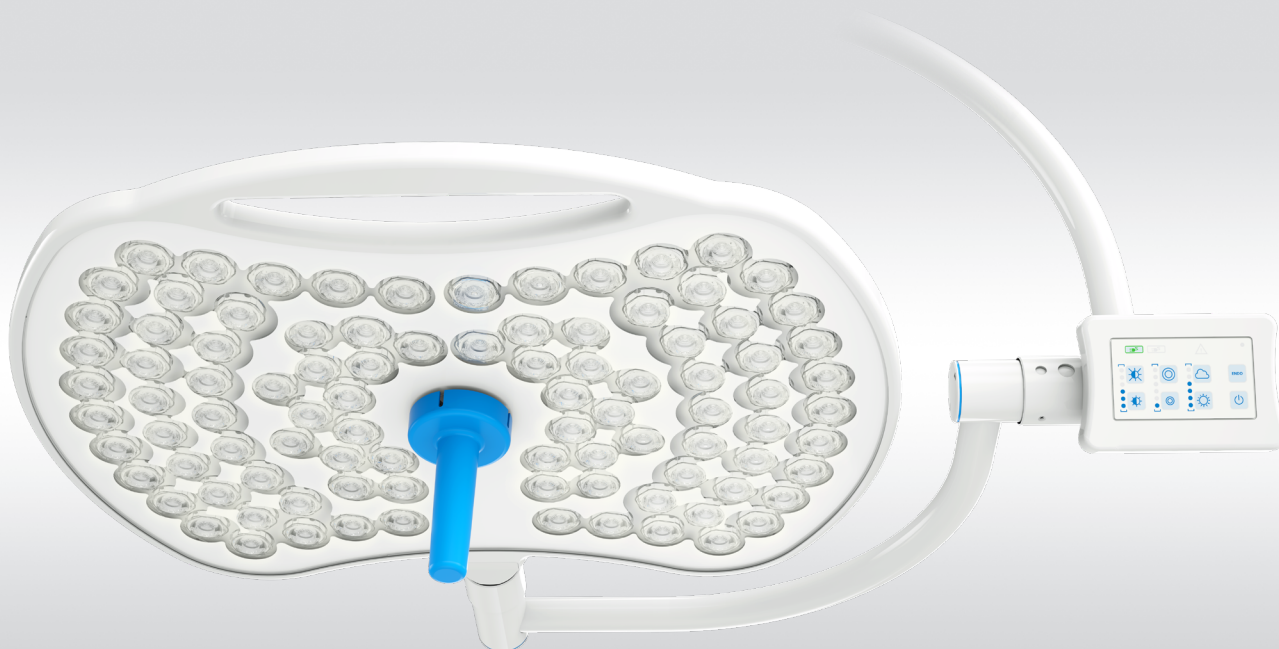


NEXUS Operating light head

Parameter of operating light INFIMED NEXUS	OL-01	OL-02
Light intensity Ec	160 000 lx	130 000 lx
Light intensity adjustment	5 – 100%	5 – 100%
Color temperature Tc (without adjustment)	4300K (4800 K)*	4300K (4800K)*
Color temperature Tc (with adjustment)	3800-4800 K (3700 – 5000 K)*	3800-4800 K (3700 – 5000K)*
Light field diameter d10 at Ec	240 – 340mm (200 - 360 mm)*	240 – 340mm (200 - 360 mm)*
Working range	600 – 1500 mm	600 – 1500 mm
Illumination depth (L1+L2)	1300 mm	1300 mm
Color rendering index [Ra(1-8)]	> 95 (> 97)*	> 95 (> 97)*
Red color rendering index [R9]	> 94	> 94
Endo lighting with adjustable intensity	Green light (white)*	Green light (white*)
Temperature of light surface after 60 min	< 40,00 ° C	< 40,00 ° C
Increase of temperature near doctor's head	< 1,00 ° C	< 1,00 ° C
Power supply	90 – 250 V AC	90 – 250 V AC
Power consumption	110W	80W
Luminary head voltage	24 – 28V DC	24 – 28V DC
Average service life of the LEDs (h)	> 60 000	> 60 000
Class of protection of light head	IP54	IP54

* additional options

Values are subject to a general industry tolerance of +/- 5%



PROXY Operating light head

Operating light PROXY

Is the smart solution of the modern operating light.

The light head ensures perfect light parameters and full functionality, providing adjustments of light intensity, light field diameter and color temperature.

The light head can be equipped with the additional functions (as per page 10) as well as the video camera fixed in the center (as per page 11).

All configurations mentioned on pages 8-9 are possible to implement.

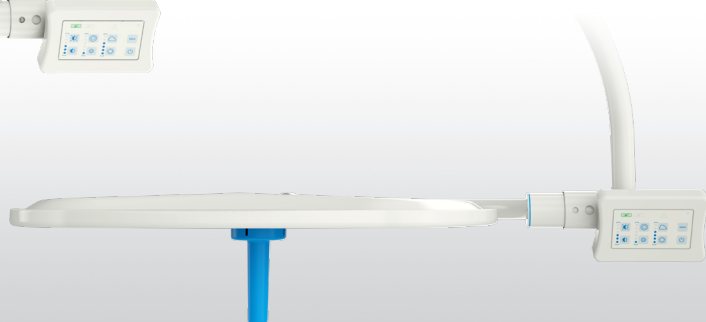


OL-03 / Operating light head with camera

OL-03



PROXY Backside view



PROXY Side view

Parameter of operating light INFIMED PROXY	OL-03
Light intensity E_c	160 000 lx
Light intensity adjustment	5 – 100%
Color temperature T_c (with adjustment)	3800 – 4800 K (3700-5000 K)*
Light field diameter d_{10} at E_c	240 – 340mm (200 - 360 mm)*
Working range	700 – 1400 mm
Illumination depth (L1+L2)	1200 mm
Color rendering index [Ra(1-8)]	>95 (>97)*
Red color rendering index [R9]	>93 (>95) *
Endo lighting with adjustable intensity	Green light (white)*
Temperature of light surface after 60 min	< 40,00 ° C
Increase of temperature near doctor's head	< 1,00 ° C
Power supply	90 – 250 V AC
Power consumption	80 W
Luminary head voltage	24 – 28V DC
Average service life of the LEDs (h)	> 60 000
Class of protection of light head	IP54

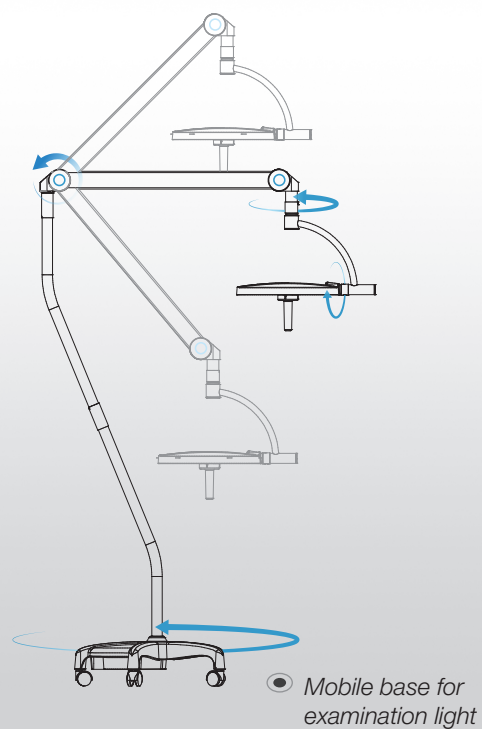
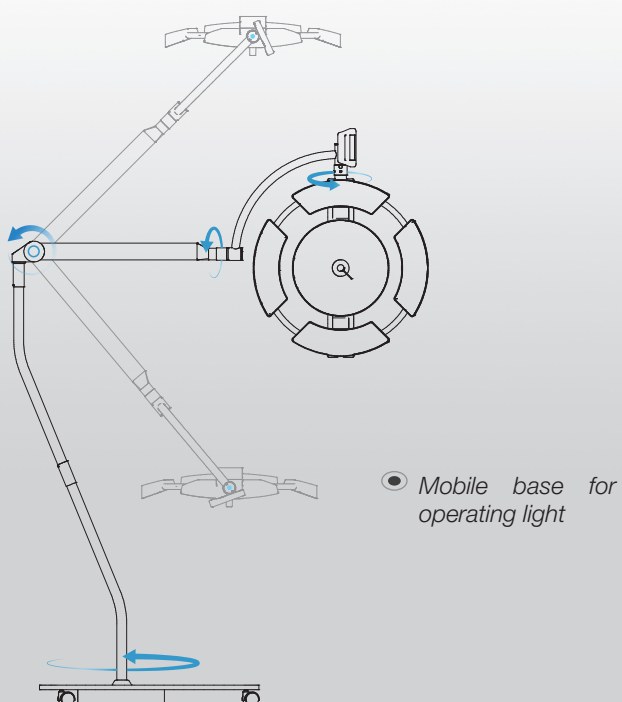
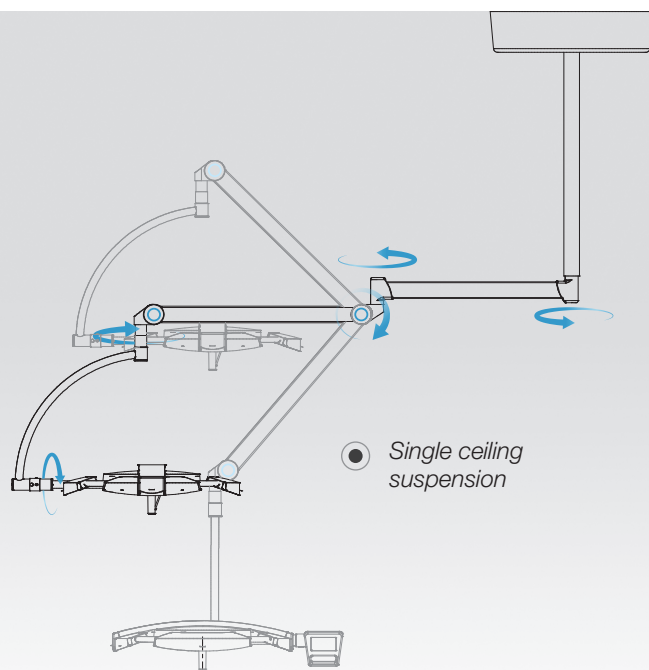
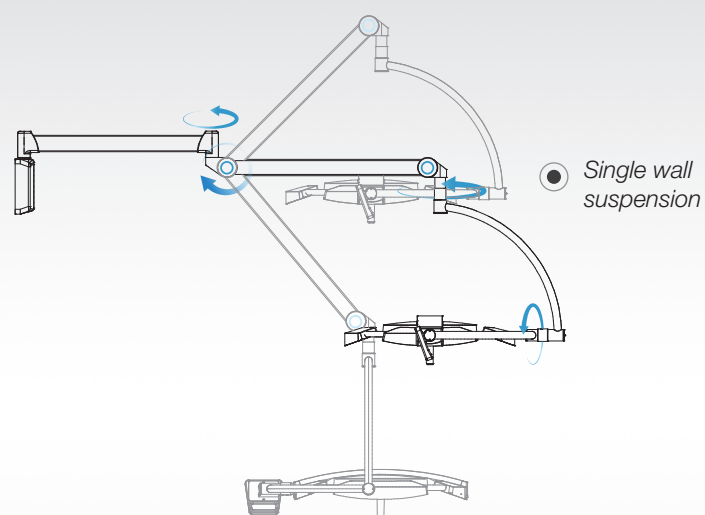
* Additional options

Values are subject to a general industry tolerance of +/- 5%

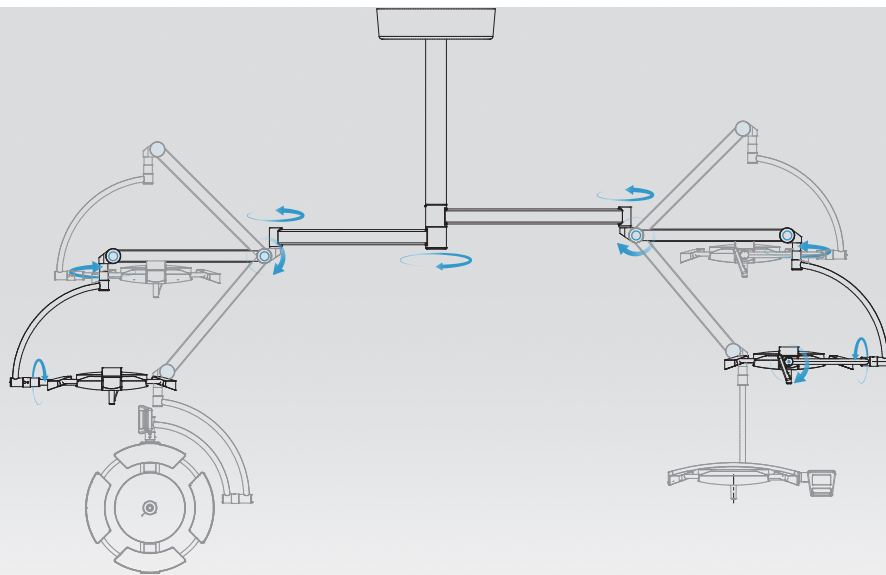
Configurations

Operating lights INFIMED are available in ceiling suspensions (single, double, triple), single wall suspension and the mobile version equipped with the battery.

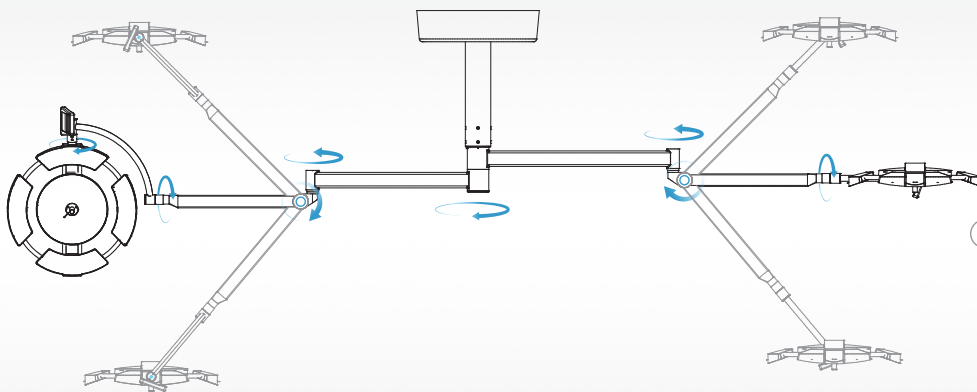
Examples of suspension configurations for operating lights:



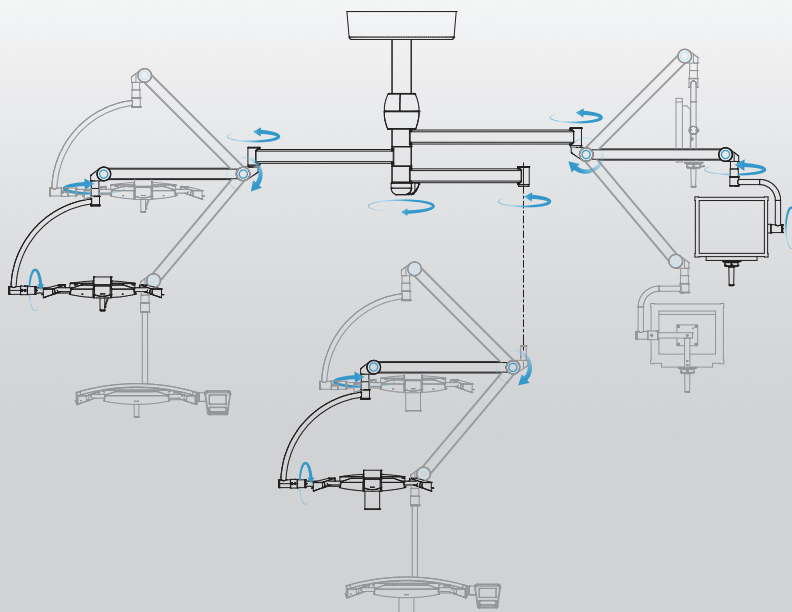
Configurations



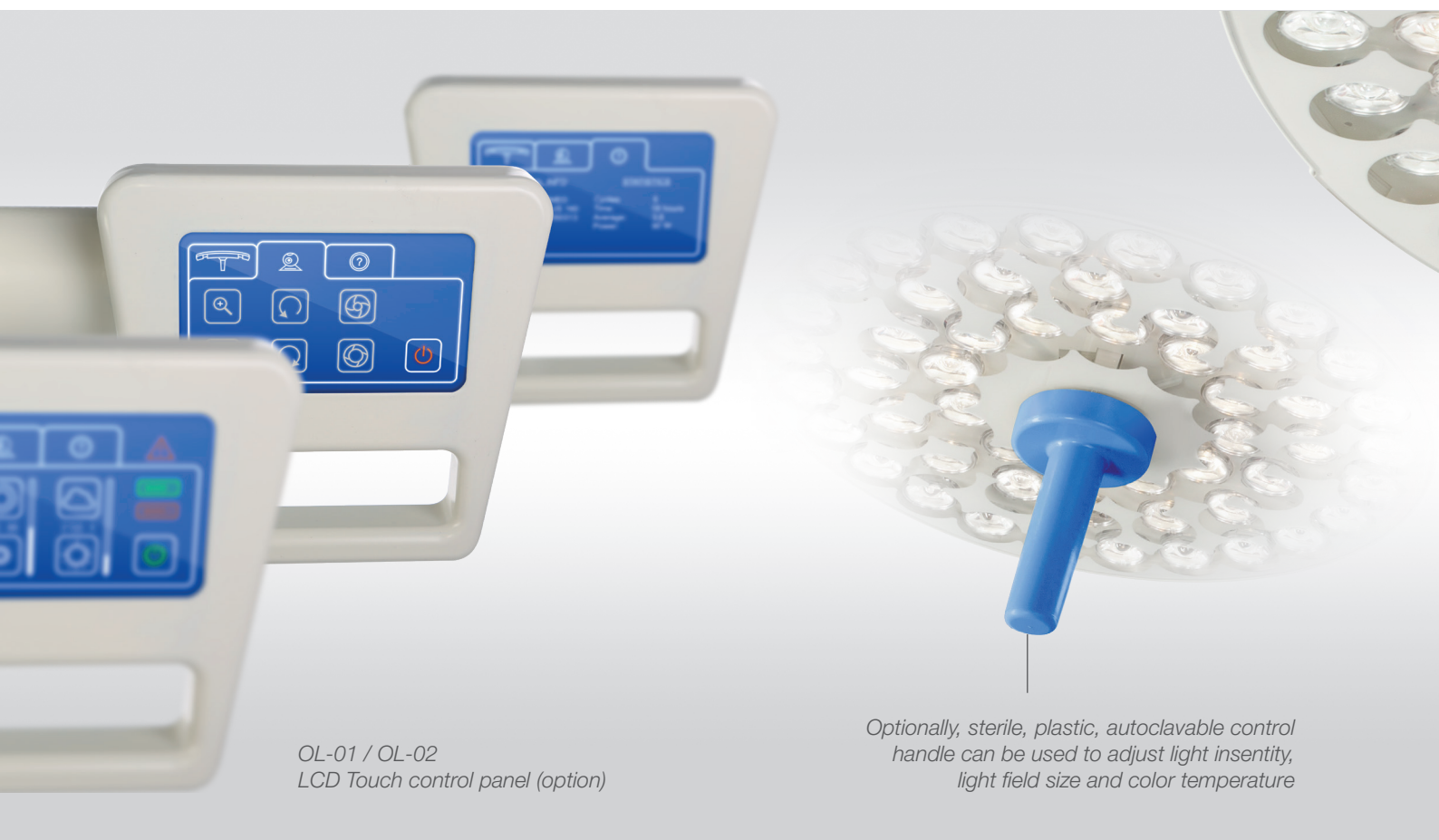
- Double ceiling suspension (>2700 mm) nx360°



- Double ceiling suspension for low height rooms (<2700 mm) nx360°



- Triple ceiling suspension, two arms $n < 360^\circ$, one arm nx360°



OL-01 / OL-02
LCD Touch control panel (option)

Optionally, sterile, plastic, autoclavable control handle can be used to adjust light intensity, light field size and color temperature

Controls And Communication

The sensor type control panel (standard) enables adjustment of:

- illumination intensity
- endoscopic illumination intensity
- switching ON/OFF
- light field size (option)
- color temperature adjustment (option)



The LCD type control panel (option) additionally enables adjustment of camera functions (zoom, iris manual, auto, focus manual and auto, stop image, rotation with lock >360 deg.) The LCD type control panel (option)

Additional functions

Measurement of the distance from operating area

The sensor in the light recognises the distance from the operating field and adjust the illumination intensity accordingly.

Intelligent shadow management

The sensor in the light perceives the surgeon head when it is directly under the light beam and brighten or dim specific LED's, in order to eliminate the shadows in the operating field.

Functions adjustment with sterile handle

Sterile, plastic, autoclavable control handle can be used to adjust 1-3 of following functions: light intensity, light field size and color temperature.

Synchronic adjustment of more light heads

Light heads adjustments can be synchronised: when adjusting any function of any light head, other light head (s) are adjusted simultaneously.

Infrared pointer

Infrared pointer shows the center of light beam.

Additional Equipment and Functions



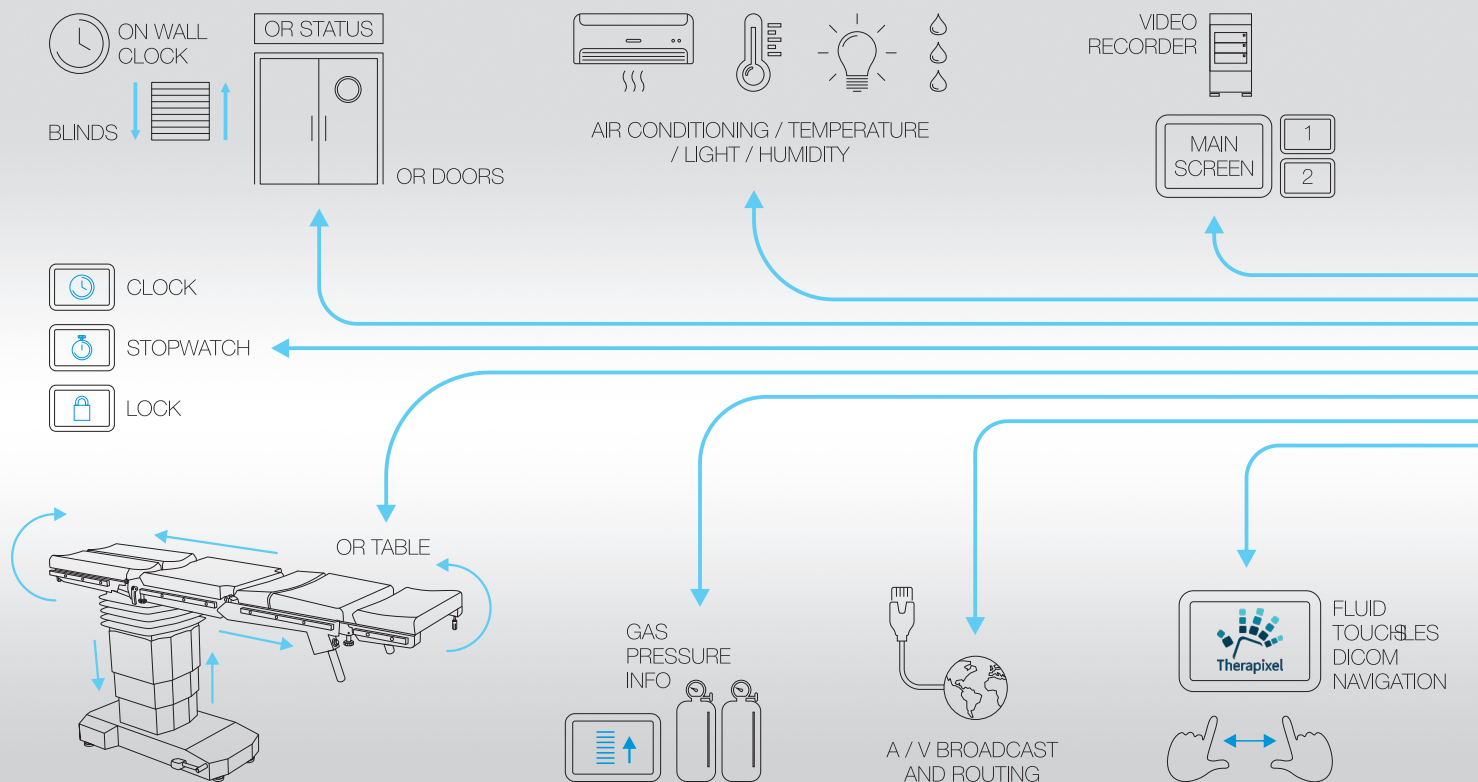
Integrated video system

Operating lights NEXUS OL-01 and OL-02 can be equipped with video camera, fixed in the center of the light. Optionally the lights can be delivered with standard sterile, plastic handle, to be exchanged into handle with camera in the future.

Sony camera, Full 1920 x 1080/30p High Definition, adjustable from keyboard.



Camera Specifications	Details
Image Device	1/2.8 type Exmor™ CMOS sensor
Effective Pixels	Approx. 2 million
Digital Zoom	20x (200x with optical zoom)
Horizontal Viewing Angle	54.1° (wide end) to 2.9° (tele end)
Sync System	Internal
Electronic Shutter	1/2 to 1/10,000 s, 21 steps
White Balance	Auto
Focus System	Auto
Exposure Control	AE Control: Auto, Manual, Priority (shutter priority and iris priority)
Video Output	Details
Lens Value	20x Optical Zoom, f=4.7 mm (wide) ~ 94.0 mm (tele), f1.6 to f3.5
S/N Ratio More	More than 50 dB
Signal System	Signal System HD: 1080p/29.97, 1080p/25, 1080i/59.94, 1080i/50, 720p/50, 720p/29.97, 720p/25 SD: NTSC/PAL



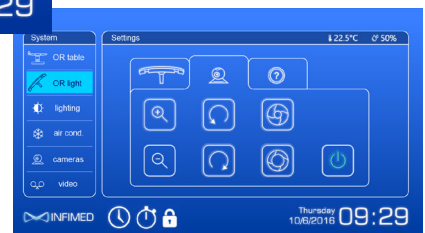
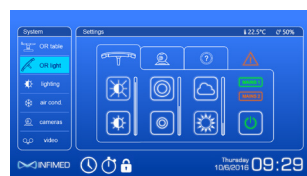
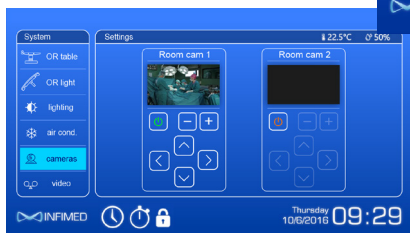
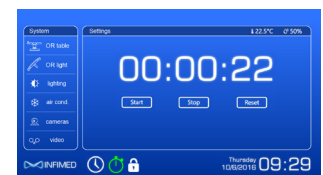
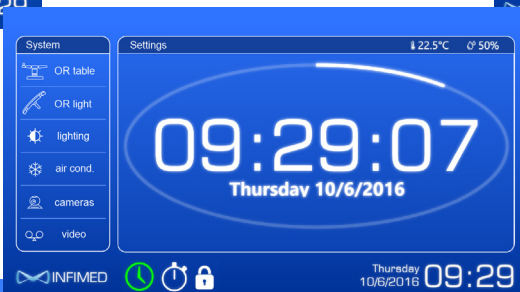
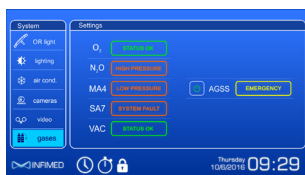
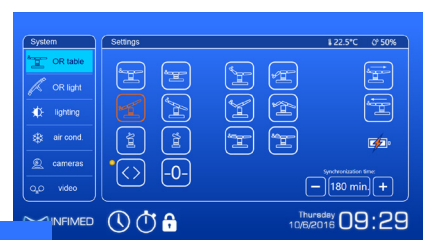
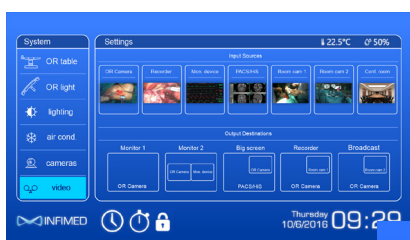
Opera control system

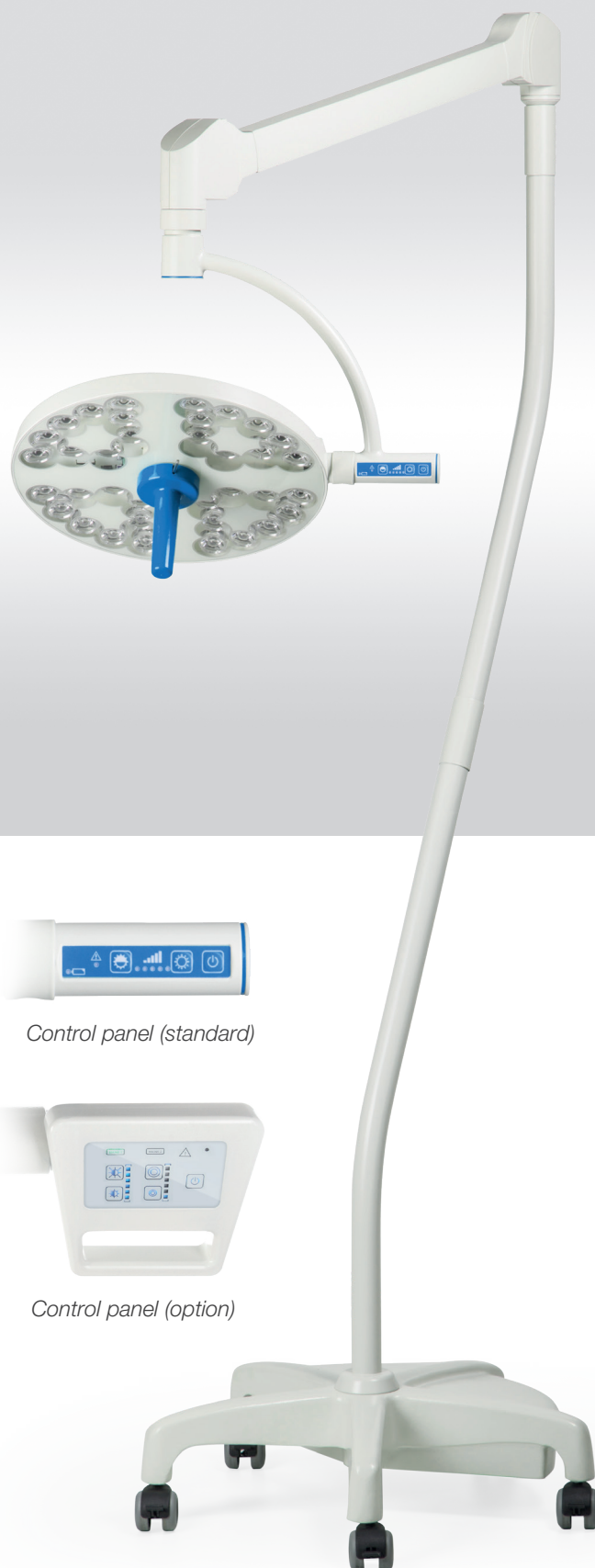
Provides better and easier control of the devices in the operating room from a single location. The system is very flexible, open, modular, can be adjusted to comply the client's expectations and requirements, accordingly to the above shown solutions. Can be operated from wall mounted control panel or wirelessly from mobile device.

The product is safe and secure and it is a certified Class I Medical Device manufactured in accordance with the ISO 9001, 13485 and other European standards. It provides a fully intuitive operation thanks to a simple and user-friendly interface, thereby minimizing the possibility of misuse and avoiding improper treatment operations.



Control System OPERA




Treatment light ONYX, 60 000 lx

Control panel (standard)
Control panel (option)

Lights INFIMED ONYX TL-01

Lights ONYX are usually used in operating and procedures rooms, intensive care, neonatology units, induction rooms, dentist, dermatology, gynecology cabinets, veterinary cabinets, dissection rooms. They are available with different levels of illumination intensity. Treatment lights can have 30 000 or 60 000 lx. The light having 100 000, 110 000, 120 000 lx optionally with field size adjustment can be used as minor operating light.

Light intensity and optional light field size adjustment are adjustable by control panel.

All configurations mentioned on pages 8-9 are possible to implement. Lights INFIMED ONYX can be also used in double ceiling system as satellite with NEXUS or PROXY operating lights.

TL-01



Minor operating light ONYX, 100 000, 110 000, 120 000 lx with field size adjustment.



Treatment light ONYX, 30 000 lx

Parameter	INFIMED ONYX 60 000/100 00 lx	INFIMED ONYX 30 000 lx
Light intensity Ec	60 000 lx / (100 000 - 120 000 lx)	30 000 lx
Dimming range	10 – 100%	10 – 100%
Color temperature Tc	4300K (4800K)*	4300K (4800K)*
Light field size d10 at Ec	260 mm / (240 – 340 mm)*	240 mm
Color rendering index [Ra(1-8)]	> 92 (> 95)*	>92 (>95)*
Red color rendering index [R9]	(>90) (> 92)*	(>90)*
Temperature of light surface after 60 min	< 40,00° C	< 40,00° C
Increase of temperature near doctor's head	< 1,00° C	< 1,00° C
Power supply	90 – 250 V AC	90 – 250 V AC
Power consumption (± 10%)	50W	20W
Luminary heads voltage	24 – 28V DC	24 – 28V DC
Life cycle of the lights	> 50 000	> 50 000
Class of protection of light head	IP54	IPX2

* additional options

Values are subject to a general industry tolerance of +/- 5%



**European
Funds**
Smart Growth



Polska

European Union
European Regional
Development Fund



For special requirement of the customer it is possible to produce the product with changed technical parameters which do not diminish its safety.

The details given in this catalogue are correct at the time of going to press. Infimed Sp. z o.o., however, reserves the right to improve shown equipment.

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email office@infimed.pl
www www.infimed.pl

NIP 553-251-29-67
REGON 243274947
KRS 0000463933

Sąd Rejonowy w Bielsku-Białej, VIII Wydział
Gospodarczy Krajowego Rejestru Sądowego.
Wysokość Kapitału Zakładowego: 500 000 PLN

bank Bank Spółdzielczy
w Węgierskiej Górze
SWIFT POLUPLPR

78 8131 0005 0016 2492 2000 0010 PLN
PL02 8131 0005 0016 2492 2000 0020 EUR
PL23 8131 0005 0016 2492 2000 0030 USD



www.infimed.pl



Declaration of conformityCompany: **INFIMED Spółka z ograniczoną odpowiedzialnością**

34-300 Żywiec, ul. Kabaty 1, Poland,

Tel/fax +48 33 861 40 96

e-mail: office@infimed.pl

SRN: PL-MF-000015633

We hereby declare for our own responsibility, that

Medical device: Operating Light

Name: NEXUS

Type: OL-01 and OL-02

Class: I, according to rule 13 in conformity with annex VIII of the EU Regulation 2017/745

Serial number:

covered by Technical file no 1.1, date 08.2021r.

Inspection documentation of device: Report of final inspection no 17.3.1.10

fulfills all the requirements of Regulation (EU) 2017/745 of the European Parliament and the Council that applies to this device.

List of all harmonized standards is indicated in Technical File.

Procedure of conformity assessment:

Annex VIII Of the EU Regulation 2017/745


INFIMED Sp. z o.o.
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tel./fax 33 861 40 96
NIP: 5532512967 REGON: 243274947
(4)
Prezes Zarządu
Piotr Kozbiat

Place and date: Żywiec

Name and surname:

Basic UDI-DI-PI Code

adres INFIMED Sp. z o.o.
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www www.infimed.plNIP 553-251-29-67
REGON 243274947
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Wysokość Kapitału Zakładowego: 500 000 PLNbank Bank Spółdzielczy
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SWIFT POLUPLPR78 8131 0005 0016 2492 2000 0010 PLN
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PL23 8131 0005 0016 2492 2000 0030 USD



Declaration of conformity

Company: **INFIMED Spółka z ograniczoną odpowiedzialnością**

34-300 Żywiec, ul. Kabaty 1, Poland,

Tel/fax +48 33 861 40 96

e-mail: office@infimed.pl

SRN: PL-MF-000015633

We hereby declare for our own responsibility, that

Medical device: Treatment Light

Name: ONYX

Type: TL-01

Class: I, according to rule 13 in conformity with annex VIII of the EU Regulation 2017/745

Serial number:

covered by Technical file no 1.1, date 08.2021r.

Inspection documentation of device: Report of final inspection no 17.3.1.11

fulfills all the requirements of Regulation (EU) 2017/745 of the European Parliament and the Council that applies to this device.

List of all harmonized standards is indicated in Technical File.

Procedure of conformity assessment:

Annex VIII Of the EU Regulation 2017/745



INFIMED Sp. z o.o.

34-300 Żywiec, ul. Kabaty 1

tel./fax 33 861 40 96

NIP: 5532512967 REGON: 243274947
(4)

Prezes Zarządu

Piotr Kozbiat
Piotr Kozbiat

Place and date: Żywiec

Name and surname:

Basic UDI-DI-PI Code



adres INFIMED Sp. z o.o.
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Gospodarczy Krajowego Rejestru Sądowego.
Wysokość Kapitału Zakładowego: 500 000 PLN

bank Bank Spółdzielczy
w Węgierskiej Górze
SWIFT POLUPLPR

78 8131 0005 0016 2492 2000 0010 PLN
PL02 8131 0005 0016 2492 2000 0020 EUR
PL23 8131 0005 0016 2492 2000 0030 USD

Certyfikat

Standard odniesienia **ISO 9001:2015**

Numer rejestracyjny 0198 100 13761

Posiadacz certyfikatu: **INFIMED Sp. z o.o.**
Kabaty 1
34-300 Żywiec
Polska

Zakres certyfikacji: Projektowanie i rozwój, produkcja, dystrybucja, instalowanie i serwisowanie opraw chirurgicznych i zabiegowych oraz opraw do diagnostyki, urządzeń do pozycjonowania i transportu pacjenta wraz z wyposażeniem, mebli medycznych, wyrobów wykonanych z metalu, modułowych systemów zabudowy sal operacyjnych, systemów sterowania wyposażeniem sal operacyjnych.

Na podstawie audytu potwierdza się spełnienie wymagań normy ISO 9001:2015.

Okres ważności: Certyfikat jest ważny od 20.10.2022 do 19.10.2025.

11.10.2022

Grzegorz Grabka

TÜV Rheinland Polska Sp. z o.o.
ul. Wolności 347, 41-800 Zabrze

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 0198 100 13761

Certificate Holder: **INFIMED Sp. z o.o.**
Kabaty 1
34-300 Żywiec
Poland

Scope: Design and development, production, distribution, installation and servicing of surgical and treatment luminaires, luminaires for diagnosis, devices for patient positioning and transport with related equipment, medical furniture and metal products, modular rooms systems for operating theatre, control systems of operating theatre equipment

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2022-10-20 until 2025-10-19.

2022-10-11

Grzegorz Guabka

TÜV Rheinland Polska Sp. z o.o.
ul. Wolności 347, 41-800 Zabrze

Zertifikat

Prüfungsnorm **ISO 9001:2015**

Zertifikat-Registrier-Nr. 0198 100 13761

Unternehmen: **INFIMED Sp. z o.o.**
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34-300 Żywiec
Polen

Geltungsbereich: Projektierung und Entwicklung, Herstellung, Vertrieb, Installierung und Service von Operations- und Behandlungsleuchten sowie Diagnostikleuchten, Geräten zur Patientenpositionierung und Patiententransport mit zugehöriger Ausrüstung, medizinischen Möbeln und Produkten aus Metall, modularen Raumsystemen für den Aufbau von Operationssälen, Steuerungssystemen für die Ausrüstung von Operationsräumen

Durch ein Audit wurde der Nachweis erbracht, dass die Forderungen der ISO 9001:2015 erfüllt sind.

Gültigkeit: Dieses Zertifikat ist gültig vom 20.10.2022 bis 19.10.2025.

11.10.2022

Grzegorz Guabka

TÜV Rheinland Polska Sp. z o.o.
ul. Wolności 347, 41-800 Zabrze

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1436359-1

Organization: INFIMED Sp. z o.o.
ul. Kabaty 1
34-300 Żywiec
Poland

Scope: Design and development, production, distribution, installation and servicing of surgical and treatment luminaires, luminaires for diagnosis, devices for patient positioning and transport with related equipment, medical furniture, modular room systems for operating theatre as well as software working in combination with related infrastructure for managing and integration of equipment and medical devices in operating room.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

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