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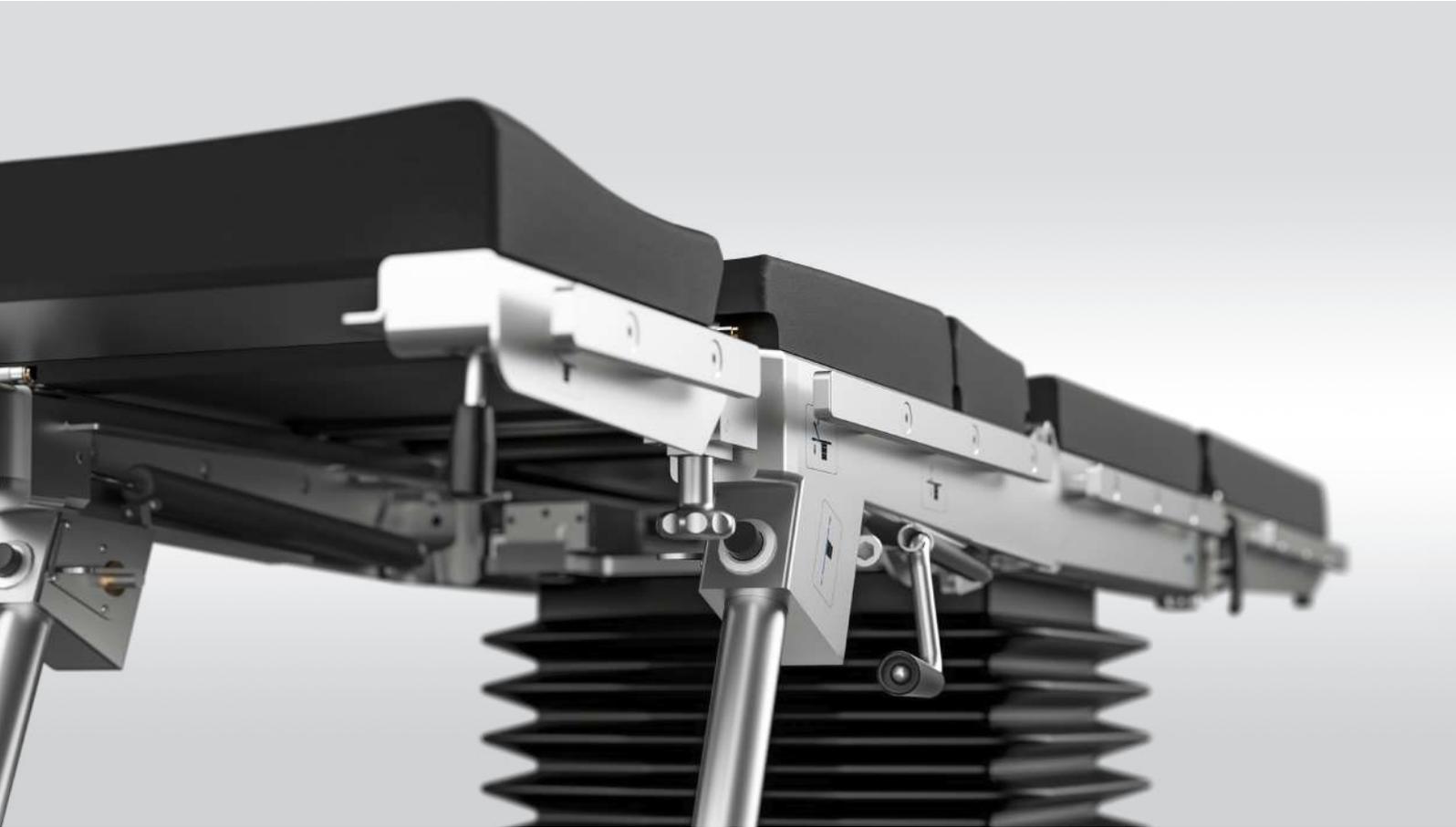
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DM000303246	MASĂ DE OPERAȚIE	FENIX	OT-01		Polonia	INFIMED SP. Z O.O.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000037	09-02-2021	
DM000303247	MASĂ DE OPERAȚIE	VIVAX	OT-02		Polonia	INFIMED SP. Z O.O.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000037	09-02-2021	
DM000303245	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	



# Operating Tables

FENIX OT-01

VIVAX OT-02



**Quality**  
**Cost Effectiveness**  
**Versatility**

Outstanding quality for reasonable price, versatility and functionality ensure operational comfort for everyday surgical work. Optional table tops and bases, together with wide range of additional accessories make it suitable for general and specialist surgical procedures.

Adjustment possibilities and ranges meets the requirements demanded by a modern universal operating tables.



# OT-01 / OT-02



Operating table VIVAX with optional "Super mobile" base



Operating table VIVAX with standard "T" base

## Design

Standard "T" base with 5 antistatic castors, (4 rear castors in 2 pairs and directional one in the front), with foot operated central brake.

Optionally available base "Super mobile" for enhanced manoeuvrability and better access to the operating field, thanks to 4 antistatic castors diam. 125 mm. Driving system with foot operated central brake and directional castor.

The elements of the table top, base and column covers are made of matt polished stainless steel, which makes the surfaces smooth and hygienic. The covers are impact resistant, easy to clean, prevent fluid ingress, minimizing infection risk.

High quality, ergonomically profiled, antistatic mattresses made of polyurethane foam of thickness 50 mm. Easy removable, with antibacterial protection, seamless, ensure maximum hygiene and prevent against cross contamination.

Table tops for general surgeries:



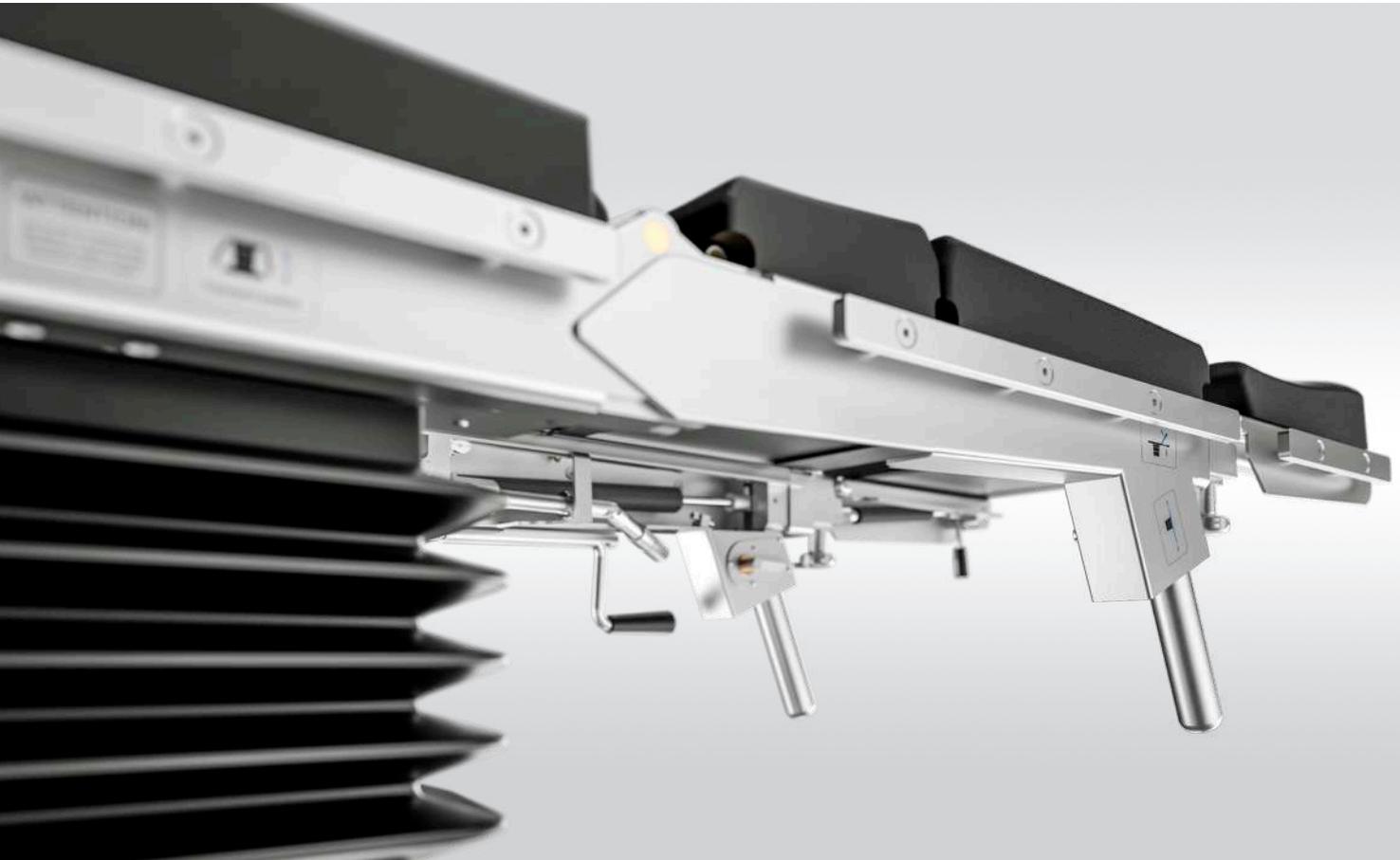
Modular table top



5 section table top



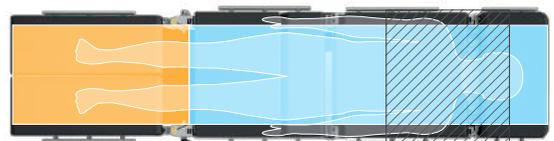
4 section table top



### Imaging Flexibility

Multisectional (4,5 or 6 sectioned) table tops, full-length C-Arm radio translucent.

Superior imaging is ensured by full length X-ray cassette tunnel (except foot sections), with possibility of inserting the cassette from both sides, head rest and foot rests interchange and longitudinal slide (350 mm).



- X-ray cassette tunnel and access to C-arm
- Access to C-arm only
- Table column - no access to C-arm

Schemes description

Table top moved to the head side, interchanged head and foot sections

# OT-01 / OT-02

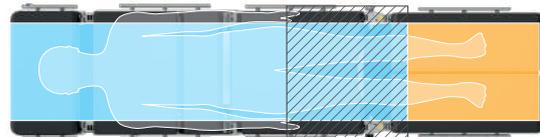
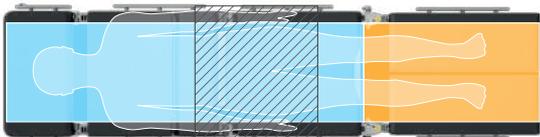


Table top moved to the foot side

Table top moved to the head side



*Trendelenburg position*



*Elevated backrest, lowered footrests position*

**Features**

- Battery powered, with charger built-in the base.
- Unique software providing smooth and precise table movements.
- Superior electro- hydraulic system, with technical solutions of the world leading micro-hydraulics provider.



INFIMED OPERA Control System

**Controls**

- Robust wire controller with visual battery level indication, ideal for simple, intuitive control (standard)
- Wire controller with LCD screen (option)
- Wireless controller (option)
- Sensor side control panel on the table column (option)
- LCD side control panel on the table column (option)
- Foot controller.
- Wall control panel (OPERA system).



Wire controller



Wire controller with LCD screen

# OT-02



*Kidney bridge position*



*Beach chair position*

- Optional override control system, mechanic-hydraulic, used in case of corded hand control damage, failure of drive or main control system.
- Range of table movements controlled via electro-hydraulic drive:
  - Height adjustment,
  - Table top tilts: lateral and longitudinal (Trendelenburg and Rev- Trendelenburg),
  - Back rest section and kidney bridge (option),
  - Longitudinal slide (option)
  - Central brake (option).
- Adjustment angles of 40° Trendelenburg/ Rev Trendelenburg and and 30° tilt make it ideal solution for minimally invasive procedures.
- Range of table movements controlled mechanically or gas spring supported:
  - Backrest section and kidney bridge,
  - Footrest sections,
  - Headrest sections,
  - Longitudinal slide.



Sensor side control panel



LCD side control panel



## Specialized angiography operating table VIVAX OT-02

### Application:

Operations with simultaneous radiolucency of the operating field: intraoperative radiology and angiography, heart and vascular surgery.

### Main Features:

- Standard "T" base with central brake.
- Carbon fibre table top, ensuring maximum X-ray transparency and unrestricted access for C-arm
- Range of table movements controlled via electro-hydraulic drive:
  - Height adjustment
  - Table top tilts: lateral and longitudinal (Trendelenburg and Rev-Trendelenburg)
  - Longitudinal slide (option)
  - Lateral slide (option)

- Range of table movements controlled mechanically or gas spring supported:

- Central brake

### Controls

- standard wire controller
- joystick (option)



Joystick

# OT-02



## Specialized bariatric operating table VIVAX OT-02

**Application:** Bariatric operations of patients weighing up to 450 kg.

### Main Features:

- Standard "T" base with central brake.
- Table-top with increased width, using special extensions, in order to support heavy patients.
- Range of table movements controlled via electro-hydraulic drive:
  - Height adjustment
  - Table top tilts: lateral and longitudinal (Trendelenburg and Rev-Trendelenburg)
  - Back rest section
  - Longitudinal slide
  - Kidney bridge (for 5,6 sections table-tops),
  - Central brake

- Range of table movements controlled mechanically or gas spring supported:
  - Foot rest sections
  - Head rest section





## Specialized orthopaedic operating table VIVAX OT-02

**Application:** Orthopaedic, traumatology, shoulder surgeries.

### Main Features:

- Standard "T" base with central brake.
- Table-top with fully detachable shoulder sections for unrestricted surgical access, with horseshoe headrest.
- Orthopaedic attachment fixed in place of the foot rest sections.
- Range of table movements controlled via electro-hydraulic drive:
  - Height adjustment
  - Table top tilts: lateral and longitudinal (Trendelenburg and Rev-Trendelenburg)
  - Back rest section and longitudinal slide (options)

- Range of table movements controlled mechanically or gas spring supported:
  - Back rest section
  - Headrest section
  - Central brake





## Features

- Powered by hydraulic system, operated via foot position selector and foot levers,
- Height and table top tilts adjustment available from head end enabling easy operation by the hospital staff



## Controls

- Range of table movements controlled hydraulically:
  - Height adjustment,
  - Table top tilts: lateral and longitudinal (Trendelenburg and Rev-Trendelenburg).
- Range of table movements controlled mechanically or gas spring supported:
  - Back rest section and kidney bridge,
  - Footrest sections,
  - Headrest sections,
  - Longitudinal slide (option).

Examples of additional accesories for opearating tables *			
			
EB-01 One position clamp	EB-02 Multi position clamp	EB-03 Knee support	EB-04 Angle arm support
			
EB-05 Arm support	EB-06 Thigh holder	EB-07 Side-shoulder support	EB-08 Side support
			
EB-09 Anesthetic frame	EB-10 Anesthetic frame with adjustable width	EB-11 Infusion holder	EB-12 Hand/shank holder
			
EB-13 Support for meniscus operation	ES-01 Leg strap ES-02 Thigh strap	ES-03 Abdominal strap	ES-04 Hand/wrist strap

# Additional Accesories

Examples of additional accesories for opearating tables *			
			
ES-05 Gynecological bowl	ES-06 Urological bowl	ES-07 Holder for additional equipment	ES-08 Holder for arm operations
			
ES-09 Holder for tubes	ES-10 Tray for additional accessories	ES-11 X-ray tray	ES-12 Chest support
			
ES-13 Attachment for knee operations	ES-14 Pubic support	ES-15 Leg support, not-divided ES-21 Leg support, divided	ES-16 Proctological attachment
			
ES-20 Side extension for bariatric tabletop	EN-01 Specialistic head rest with adjustable track	EN-02 Specialistic head rest, horseshoe	DORO neurosurgical attachment

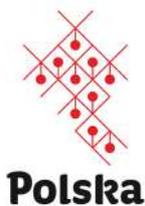
Examples of additional accesories for opearating tables *			
			
EO-01 Orthopaedic attachment with two extension devices and support roll		EO-02 Bar suport	EO-03 Leg support
	 		
EO-04 Support for plastering	EO-05 Heel holder EO-06 Foot support	EO-07 Clamp for orthopaedic attachment supports	EO-08 Knee operation attachment for orthopedic attachment
			
EO-09 Hip support for lateral decubitus position	EO-10 Support for orthopedic attachment arms	EO-11 Knee support for side positions	EO-12 Trolley for installation of orthopedic attachment
			
EO-13 Mobile stand for orthopedic accesories	EO-14 Leather shoes for orthopedic attachment	EO-20 Attachment for hand operating	EO-30 Attachement for shoulder operations with head rest EN-02

# Technical parameters

Technical parameters of operating tables INFIMED VIVAX	OT-02 standard	OT-02 angiography version	OT-02 bariatric version
Total length of the table with 4, 5 sections, modular, orthopedic and bariatric table tops	2100 mm	----	2100 mm
Total length of the table with 6 sections table top	2300 mm	----	2300 mm
Total length of the table carbon fibre table top	----	2200 mm	----
Table top width (without / with side rails)	500 mm / 560 mm	600 mm	800 mm/ 860 mm **
Standard height adjustment, with mattress 50 mm (electro-hydraulic)	730 mm – 1080 mm	----	730 mm – 1080 mm
Extended height adjustment, with mattress 50 mm (electro-hydraulic)	700 mm – 1150 mm	----	700 mm – 1150 mm
Height adjustment, without mattress (electro-hydraulic), with longitudinal and lateral slide	----	800 mm – 1150 mm	----
Height adjustment, without mattress (electro-hydraulic), with longitudinal slide	----	730 mm – 1080 mm	----
Height adjustment, without mattress (electro-hydraulic), fixed	----	660 mm – 1010 mm	----
Lateral tilts adjustment (electro-hydraulic)	± 30°	± 20°	± 30°
Trendelenburg / reverse-Trendelenburg adjustment (electro-hydraulic)	± 40°	± 20°	± 40°
Backrest adjustment (pneumatic)	- 45° ; +85°	----	----
Optional backrest adjustment (electro-hydraulic)*	- 35° ; +85°	----	- 35° ; +85°
Footrest adjustment (pneumatic)	- 90° ; +25°	----	- 90° ; +25°
Footrest abduction (mechanic)	180°	----	180°
Headrest adjustment (pneumatic)	± 45°	----	± 45°
Kidney bridge adjustment (mechanic) Optional kidney bridge adjustment (electro-hydraulic)*	~120 mm	----	~120 mm
Longitudinal slide (mechanic) Optional longitudinal slide (electro-hydraulic)*	350 mm	350 mm	350 mm
Lateral slide (electro-hydraulic)*	----	210 mm	----
Table mass	280 kg +/- 10%	280 kg +/- 10%	2.... kg +/- 10%
Maximum dynamic / static working load	250 / 300 kg	250 kg	450 / 540 kg
Built in battery power Built in charger power	24 V 230V ~ 50/60Hz	24 V 230V ~ 50/60Hz	24 V 230V ~ 50/60Hz
Working time between battery charging	Up to 65 operations	Up to 65 operations	Up to 65 operations
Lifetime	10 years	10 years	10 years
Degree, class of protection, application part type	IP-X4 / I / B	IP-X4 / I / B	IP-X4 / I / B
Technical parameters of operating tables INFIMED FENIX		OT-01	
Total length of the table with 4 and 5 sections tabletop	2100 mm		
Total length of the table with 6 sections tabletop	2300 mm		
Table top width (without / with side rails)	500 mm / 560 mm		
Standard height adjustment (hydraulic), with mattress 50 mm	680 mm – 1030 mm		
Height adjustment (hydraulic), longitudinal slide, with mattress 50 mm	730 mm – 1080 mm		
Lateral tilts adjustment (hydraulic)	± 30°		
Trendelenburg / reverse-Trendelenburg adjustment (hydraulic)	± 40°		
Backrest adjustment (pneumatic )	- 45° ; +85°		
Footrest adjustment (pneumatic)	- 90° ; +25°		
Footrest abduction (mechanic)	max 180°		
Headrest adjustment (pneumatic)	± 45°		
Kidney bridge adjustment (mechanic), available in 5 or 6 section tabletop	~120 mm		
Optional longitudinal slide (mechanic)	350 mm		
Table mass	250 kg		
Maximum dynamic / static working load	200 /250 kg		

\* additional options

\*\* width including side extension for bariatric tabletop ES-20



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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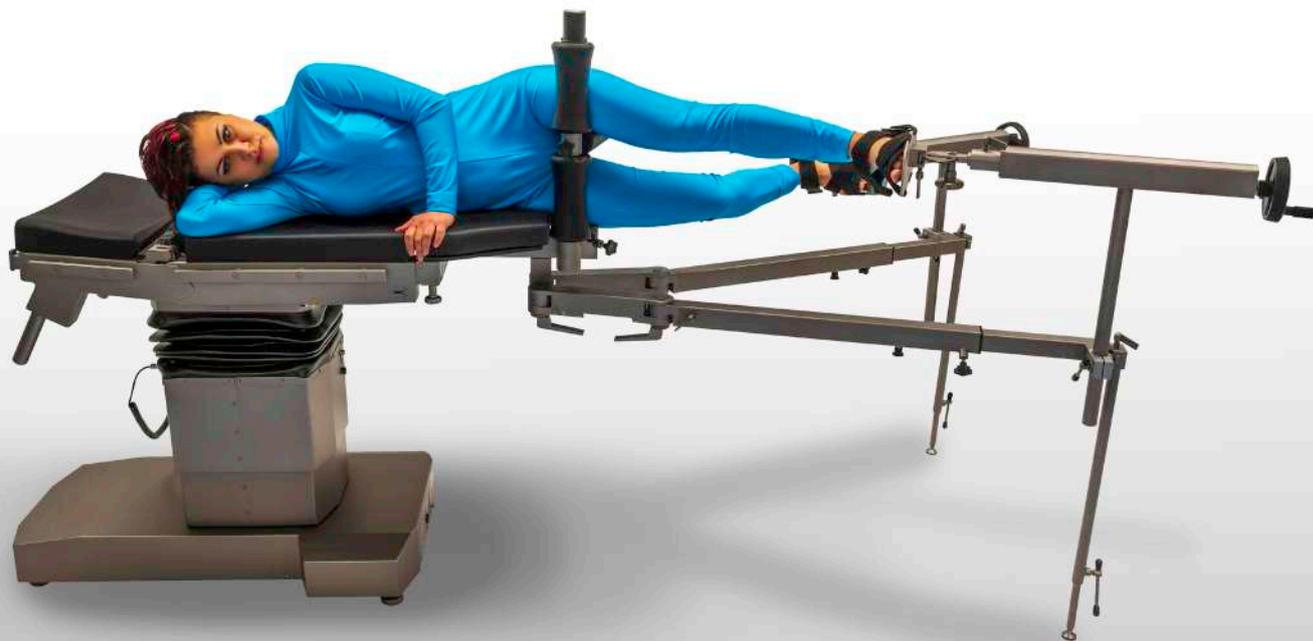
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## Accesories for Operating Tables

FENIX OT-01

VIVAX OT-02

## **ACCESORIES FOR OPERATING TABLES**

This catalogue presents the wide range of accessories available for INFIMED operating table.

They were created basing on long experience in designing of medical equipment, hours spent on consultation with medical staff and functional and ergonomy testing.

The accessories haven been sorted according to practical use and surgical disciplines.

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# General surgery positions



**SUPINE POSITION**



**BEACH CHAIR POSITION**

**LATERAL POSITION AND FLEX**



## EB-01 One position clamp

### TECHNICAL INFORMATION:

For fixation of the various accesories with rods of 16 mm diameter to the side rail

Made of stainless steel, with a matt finish



## EB-02 Multi position clamp

### TECHNICAL INFORMATION:

For fixation of the various accesories with rods of 16 mm diameter to the side rail

Allows radial adjustment of the accesories

Made of stainless steel, with a matt finish



## EB-04 Angle arm support

### TECHNICAL INFORMATION:

Height adjustment: 300mm

Distance from table top adjustment: 200mm

Tilting adjustment by ball joint

Made of stainless steel with matt finish and polyurethane foam, with two fixing velcro straps

To be fixed with EB-02 clamp



## EB-05 Arm support

### TECHNICAL INFORMATION:

Height adjustment: 100mm

Made of stainless steel with matt finish and polyurethane foam, with two fixing velcro straps

To be fixed with EB-01 clamp

## General Basic Accesories



### **EB-06 Thigh holder**

TECHNICAL INFORMATION:

Height adjustment: 300mm

Made of stainless steel with matt finish and polyurethane foam

To be fixed with EB-01 clamp



### **EB-07 Side-shoulder support (side support position)**

TECHNICAL INFORMATION:

Height adjustment: 230mm

Distance from table top adjustment: 150mm

Made of stainless steel with matt finish and polyurethane foam

To be fixed with EB-01 clamp



### **EB-07 Side-shoulder support (shoulder support position)**

TECHNICAL INFORMATION:

Height adjustment: 230mm

Distance from table top adjustment: 150mm

Made of stainless steel with matt finish and polyurethane foam

To be fixed with EB-01 clamp



### **EB-08 Side support**

TECHNICAL INFORMATION:

Height adjustment: 150mm

Distance from table top adjustment: 150mm

Made of stainless steel with matt finish and polyurethane foam

To be fixed with EB-01 clamp

**EB-09 Anesthetic frame**

TECHNICAL INFORMATION:

Height adjustment: 600mm

Made of stainless steel with matt finish

To be fixed with EB-01 clamp

**EB-10 Anesthetic frame with adjustable width**

TECHNICAL INFORMATION:

Height adjustment: 500mm

Both side width adjustment 200mm  
Made of stainless steel with matt finish

To be fixed with EB-01 clamp

**EB-11 Infusion holder**

TECHNICAL INFORMATION:

Height adjustment: 200mm

Made of stainless steel with matt finish

To be fixed with EB-01 clamp

**EB-12 Hand (shank holder)**

TECHNICAL INFORMATION:

Height adjustment: 300mm

Made of stainless steel with matt finish and polyurethane foam

To be fixed with EB-01 clamp

# General Basic Accesories

## EB-13 Support for meniscus operation

TECHNICAL INFORMATION:

Height adjustment: 600mm

Made of stainless steel with matt finish and polyurethane foam

To be fixed with EB-02 clamp



## EB-14 Arm support, with horizontal movement

TECHNICAL INFORMATION:

Height adjustment: 300mm

Distance from tabletop adjustment: 200mm

Tilting adjustment by ball joint

Made of stainless steel with matt finish, HPL, foam mattress covered with antistatic artificial leather, fixing velcro straps  
To be used with EB-01 clamp



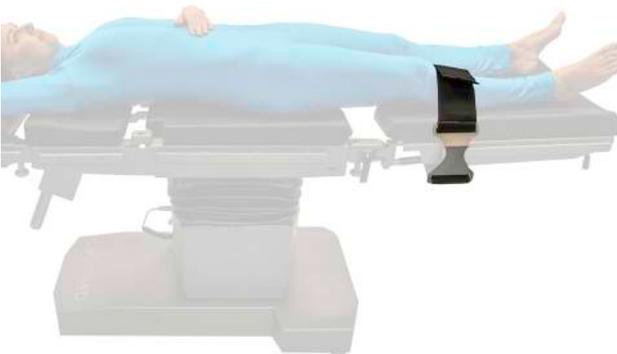
## ES-01 Leg strap ES-02 Thigh strap

TECHNICAL INFORMATION:

Adjustment by velcro: 400mm

Strap width: 100mm

Made of stainless steel with matt finish and polyamide strap



## ES-03 Abdominal strap

TECHNICAL INFORMATION:

Adjustment by velcro: 400mm

Strap width: 100mm

Made of stainless steel with matt finish and polyamide strap





**ES-04 Hand strap**

TECHNICAL INFORMATION:

Adjustment by velcro: 400mm

Strap width: 100mm

Made of stainless steel with matt finish and polyamide strap



**ES-07 Holder for additional equipment, mobile**

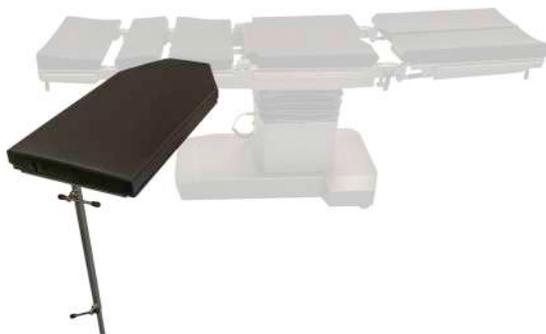
TECHNICAL INFORMATION:

Non-marking wheels with brakes

Hooks and rails for assembly of accessories on rack

Basket in basis

Made of stainless steel with matt finish



**ES-08 Holder for arm operations**

TECHNICAL INFORMATION:

Fixed to side rails of operating table

Vertical adjustment of angle against tabletop  
Distance from tabletop adjustment: 100mm

Height adjustable feet

X-Ray permeable tabletop, dimensions 800x400mm

Made of stainless steel with matt finish, foam mattress covered with antistatic artificial leather



**ES-09 Holder for tubes**

TECHNICAL INFORMATION:

Height adjustment: 200mm

Distance from tabletop adjustment: 200mm

Made of stainless steel with matt finish and HPL

To be fixed with EB-01 clamp

## General Basic Accesories



### ES-10 Tray for additional accessories

TECHNICAL INFORMATION:

Height adjustment: 400mm

Tray dimensions: 450x250mm

Made of stainless steel with matt finish

To be used with EB-01 clamp



### ES-11 X-ray tray

TECHNICAL INFORMATION:

Height adjustment: 400mm

To be used with X-Ray cassette of width381mm

Installation from head or side

Made of stainless steel with matt finish



### ES-12 Chest support

TECHNICAL INFORMATION:

Height adjustment: 150mm

Distance from tabletop adjustment: 150mm

Made of stainless steel with matt finish and polyurethane foam

To be fixed with EB-01 clamp



### ES-13 Attachement for knee operation

TECHNICAL INFORMATION:

Height adjustment: 200 mm

Knee holder adjustment

Made of stainless steel with matt finish and polyurethane foam

To be fixed with EB-01 clamp



### ES-14 Pubic support

TECHNICAL INFORMATION:

Height adjustment: 150 mm

Distance from tabletop adjustment: 150 mm

Made of stainless steel with matt finish and polyurethane foam

To be fixed with EB-01 clamp



### ES-15 Leg support, not-divided

TECHNICAL INFORMATION:

To be fixed to siderails

Made of stainless steel with matt finish and foam mattress covered with antistatic artificial leather

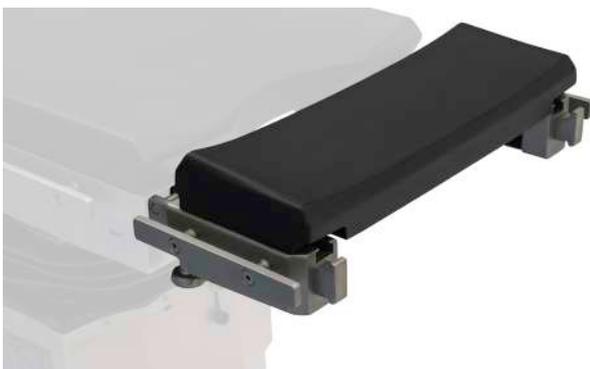


### ES-17 Side rail extension

TECHNICAL INFORMATION:

Extension for side rail for mounting side rail accessories

Made of stainless steel with matt finish



### ES-18 Tabletop extension

TECHNICAL INFORMATION:

To be fixed to siderails

Made of stainless steel with matt finish, HPL and polyurethane foam

## General Basic Accesories



### ES-19 Strap for anesthetic frame

TECHNICAL INFORMATION:

To be fixed to anesthetic frame EB-09 or EB-10

Made of polymide strap



### ES-20 Side extension for bariatric table-top

TECHNICAL INFORMATION:

To be fixed to siderails

Made of stainless steel with matt finish, HPL and polyurethane foam with artificial leather



### ES-21 Leg support, divided

TECHNICAL INFORMATION:

To be fixed to siderails

Made of stainless steel with matt finish and polyurethane foam



**GYNEACOLOGICAL SURGERY**



**PROCTOLOGICAL (KNEEL) SURGERY**

# Gynaecology Urology Proctology Accesories



## EB-03 Knee support

TECHNICAL INFORMATION:

Height adjustment: 100mm

Made of stainless steel with matt finish and polyurethane foam

To be fixed with EB-02 clamp



## ES-05 Gyneacological bowl

TECHNICAL INFORMATION:

Fixed instead of the leg supports

Adjustable horizontal position and rotation

Bowl capacity: 4 litres

Made of stainless steel with matt finish



## ES-06 Urological bowl

TECHNICAL INFORMATION:

Fixed instead of the leg supports

Adjustable horizontal position and rotation

Bowl capacity:4 litres, with rubber outflow

Made of stainless steel with matt finish



## ES-16 Proctological attachment

TECHNICAL INFORMATION:

Height adjustment: 200mm

Kneeling chair, without clamp, fixed to side rails

Abdominal support to be used with 2 pcs of EB-02 clamps

Made of stainless steel with matt finish, HPL and polyurethane foam



**NEUROSURGICAL SURGERY - SUPINE POSITION (WITH DORO NEUROSURGICAL ATTACHEMENT)**



**NEUROSURGICAL SURGERY - SITTING POSITION (WITH DORO NEUROSURGICAL ATTACHEMENT)**

# Neurosurgery Laryngology Ophthalmology Accesories



## EA-01 Adapter for specialistic head rest

### TECHNICAL INFORMATION:

Neccesary to fix to the operating table to use DORO neurosurgical attachement or any of specialistic head rest

Made of stainless steel with matt finish



## EN-01 Specialistic head rest with adjustable track

### TECHNICAL INFORMATION:

Fixed to the adapter EA-01

Height adjustment 150mm, angle adjustment to the table top

Adjustment of the distance from the tabletop: 250mm

Made of stainless steel with matt finish and polyurethane foam



## EN-02 Specialistic head rest, horseshoe

### TECHNICAL INFORMATION:

Fixed to the adapter EA-01

Height adjustment 150mm, angle adjustment to the table top

Adjustment of the distance from the tabletop: 250mm

Made of stainless steel with matt finish and polyurethane foam



## EN-05 Arm support

### TECHNICAL INFORMATION:

Height adjustment: 300mm

Distance from tabletop adjustment: 200mm

Tilting adjustment by ball joint

Made of stainless steel with matt finish, HPL, foam mattress covered with antistatic artificial leather, fixing velcro straps  
To be used with EB-01 clamp



### **DORO neurosurgical attachment for laying position**

TECHNICAL INFORMATION:

To be fixed to adapter EA-01

Including:

- Adjustable Base Unit 3001-00
- Swivel Adaptor 3002-00
- QR3 Skull Clamp 1001.001
- Reusable Skull Pins Pediatric 3004-00 (3 pcs)
- Reusable Skull Pins Adult 3005-00 (3 pcs)



### **DORO neurosurgical attachment for sitting position**

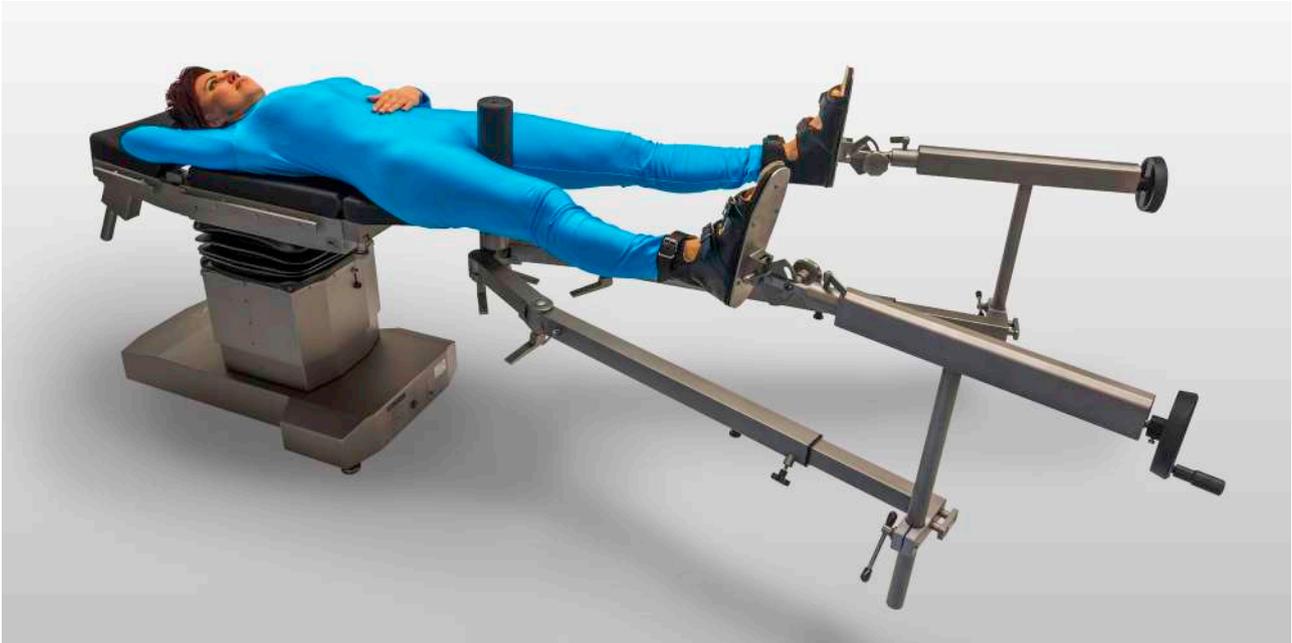
TECHNICAL INFORMATION:

To be fixed to side rails using EB-02 multiposition clamps

Including:

- Adjustable Base Unit 3001-00
- Swivel Adaptor 3002-00
- QR3 Skull Clamp 1001.001
- Reusable Skull Pins Pediatric 3004-00 (3 pcs)
- Reusable Skull Pins Adult 3005-00 (3 pcs)
- Crossbar Adaptor

## Orthopaedics Traumatology Positions



**ORTHOPAEDIC SURGERY - SUPINE POSITION (ORTHOPAEDIC ATTACHEMENT EO-01)**



**ORTHOPAEDIC SURGERY - SUPINE POSITION  
(ORTHOPAEDIC ATTACHEMENT EO-01 WITH SUPPORTS EO-10 AND BAR SUPPORT EO-02)**



**ORTHOPAEDIC SURGERY - LATERAL DECUBITUS POSITION  
(ORTHOPAEDIC ATTACHEMNT EO-01 WITH SUPPORTS EO-10 AND HIP SUPPORT EO-09)**



**Ortopaedic attachemnt EO-01 (with EO-10 supports)**

**TECHNICAL INFORMATION:**

- Includes 2 extension devices with foot plates and straps
- Additional accessories (EO-02...EO-11) are to be ordered seperately
- Fixed to leg rests sockets
- Adjustment of extensions devices height: 350mm
- Distance between support roll and extensions devices: 300-1300mm
- Adjustment of rotation arms position: 0-180
- Adjstment of length of ortropaedic attachments arms: 600mm
- Support roll X-Ray permeable
- Made of stainless steel with matt finish, foam mattress covered with artificial leather, polyurethane

# Orthopaedics Traumatology Accessories



## EO-02 Bar support

### TECHNICAL INFORMATION:

To be fixed to the arms of the orthopaedic attachment EO-01 with EO-07 clamp

Height adjustment 400mm

Made of stainless steel with matt finish and leather strap



## EO-03 Leg support

### TECHNICAL INFORMATION:

To be fixed to the arms of the orthopaedic attachment EO-01 with EO-07 clamp

Height adjustment 400mm

Made of stainless steel with matt finish and leather strap / polyurethane foam



## EO-04 Support for plastering

### TECHNICAL INFORMATION:

To be fixed to the socket of the orthopaedic attachment EO-01

Made of stainless steel with matt finish and leather strap / polyurethane foam



## EO-05 Heel holder

### TECHNICAL INFORMATION:

To be fixed to orthopaedic attachment EO-01 instead of plate supports

Made of stainless steel with matt finish



### EO-06 foot support

**TECHNICAL INFORMATION:**

To be fixed to the orthopaedic attachment EO-01 instead of plate supports

Made of stainless steel with matt finish and leather straps



### EO-07 Clamp for orthopaedic attachment supports

**TECHNICAL INFORMATION:**

Used to fix the following accessories: EO-02, EO-03, EO-08, EO-11, to the orthopaedic attachment EO-01

Made of stainless steel with matt finish



### EO-08 Knee operation attachment for orthopaedic attachment

**TECHNICAL INFORMATION:**

Without extension device

To be fixed to the arms of the orthopaedic attachment EO-01 with EO-07 clamp Height adjustment: 200mm

Adjustment of distance between support roll and extension device: 800mm

Angle adjustment against tabletop

Made of stainless steel with matt finish and polyurethane foam



### EO-09 Hip support for lateral decubitus position

**TECHNICAL INFORMATION:**

To be fixed to the socket of the orthopaedic attachment EO-01

Adjustment left/right

Adjustment of support roll rotation

Made of stainless steel with matt finish and polyurethane foam

## Orthopaedics Traumatology Accessories



### EO-10 Support for orthopedic attachment arms

#### TECHNICAL INFORMATION:

To be fixed to the arms of the orthopaedic attachment EO-01

Height adjustment: 400 mm

Made of stainless steel with matt finish



### EO-11 Knee support for side positions

#### TECHNICAL INFORMATION:

To be fixed to the arms of the orthopaedic attachment EO-01 with EO-07 clamp

Made of stainless steel with matt finish and polyurethane foam



### EO-12 Trolley for installation of orthopaedic attachment

#### TECHNICAL INFORMATION:

Used to transport and assembly the orthopaedic attachment EO-01 to the operating table

Non-marking castors with individual brakes

Basket for accessories in the base

Made of stainless steel with matt finish



### EO-13 Mobile stand for additional equipment of orthopaedic attachment

#### TECHNICAL INFORMATION:

Non-marking castors with individual brakes

Hooks and rails for storage of orthopaedic accessories

Basket in the base

Made of stainless steel with matt finish and HPL



### **EO-14 Leather shoes for orthopedic attachment**

**TECHNICAL INFORMATION:**

To be fixed to the orthopedic attachment EO-01 instead of plate supports

Made of stainless steel with matt finish and leather



### **EO-20 Attachment for hand operating**

**TECHNICAL INFORMATION:**

To be fixed with 2 pcs of clamp EB-01

Height adjustment: 200mm

Adjustment of extension device length: 350mm

Adjustment of tilt and rotation of hand fixing

Made of stainless steel with matt finish and polyurethane foam



### **EO-30 Attachement for shoulder operations head rest EN-02**

**TECHNICAL INFORMATION:**

To be fixed to legrests sockets

Includes EN-02 head rest

Removable right and left shoulder sections

Made of stainless steel with matt finish, polyurethane foam and HPL

## Angiography table



**VIEW FROM THE SIDE, WITH MAX LONGITUDINAL SLIDE**



**VIEW FROM THE BACKSIDE, WITH MAX LATERAL SLIDE**

**ER-01.0**

## TECHNICAL INFORMATION:

To be fixed on carbo fibre tabletop

Allows to fix heavier additional accesories on the side rails

Made of stainless steel with matt finish.

**ER-01.1**

## TECHNICAL INFORMATION:

To be fixed on carbo fibre tabletop

Allows to fix lighter additional accesories on the side rails

Made of stainless steel with matt finish.

**ER-02.0**

## TECHNICAL INFORMATION:

To be fixed on carbo fibre tabletop

Allows to fix heavier additional accesories on the side rails

X-ray permeable

Made of carbon fibre and stainless steel with matt finish.

**ER-02.1**

## TECHNICAL INFORMATION:

To be fixed on carbo fibre tabletop

llows to fix lighter additional accesories on the side rails

X-ray permeable

Made of carbon fibre and stainless steel with matt finish.

## Positioning pads

### EM-01 Mattress for spine surgeries

TECHNICAL INFORMATION:

For positioning the patient, especially during surgical procedures on the spine

Made of polyurethane foam with artificial letter



### EM-02 Mattress for sitting position

TECHNICAL INFORMATION:

For positioning the patient, especially during procedures requiring sitting position

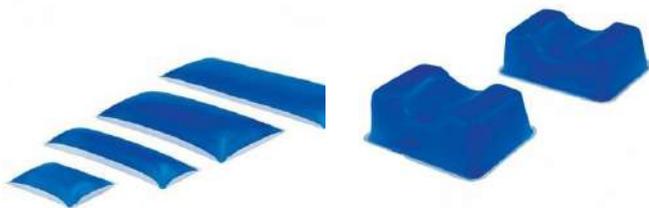
Made of polyurethane foam with artificial letter

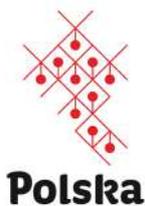


### Gel patient body positioners

TECHNICAL INFORMATION:

Thick layered gel patient body positioners for patient on operation table: arm, chest, heel, head positioners and table pads





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.

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## Operating and Treatment Lights

**NEXUS** OL-01/OL-02

**PROXY** OL-03

**ONYX** TL-01



*NEXUS Operating light head*

## Modern Design

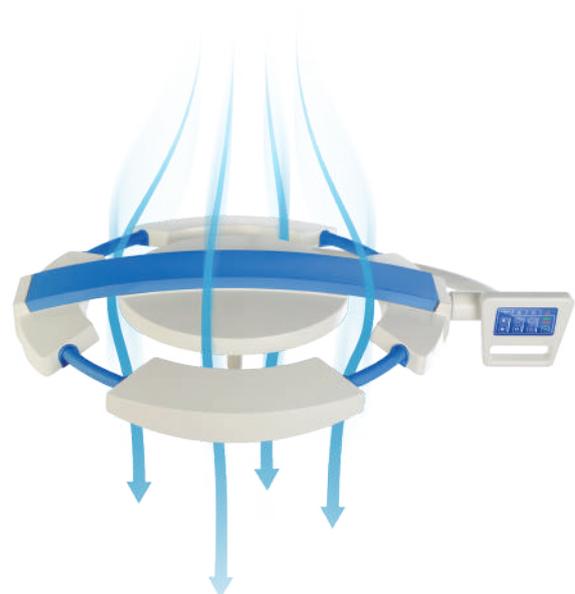
Operating lights INFIMED NEXUS and PROXY and treatment lights INFIMED ONYX with LED light source are distinguished by innovative technology and modern design.

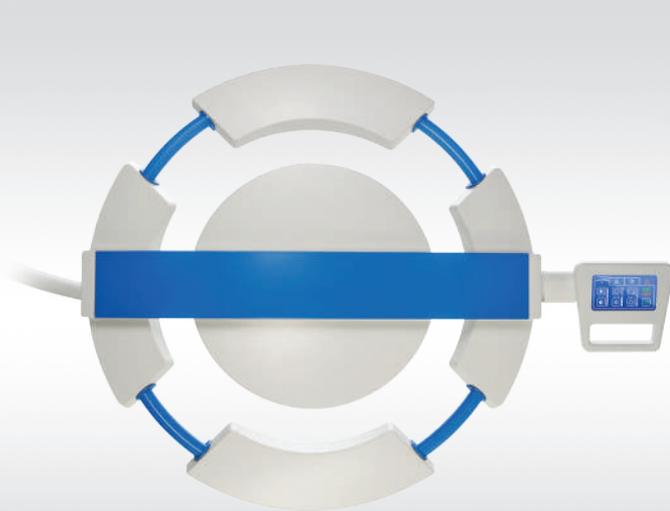
The little weight, ergonomic light heads as well as comfortable handles enable **easy and precise** set up and positioning of the operating light during surgery.

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

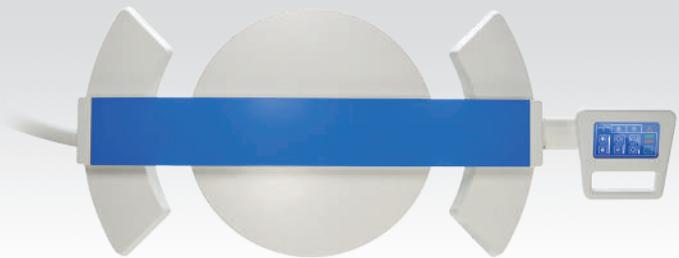
Ergonomic shape of the light minimizes disruption of **laminar airflow** in the operating theatre. The light head are closed construction, composed of solid, permanently assembled elements.

Flow-optimised light head

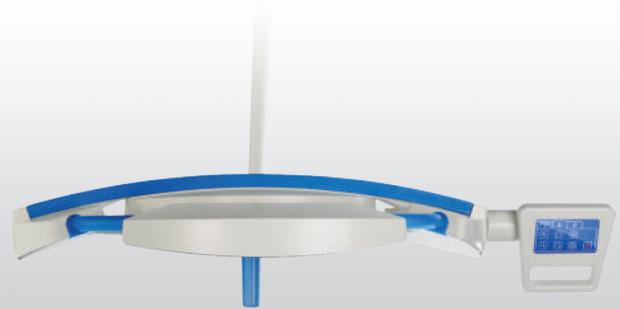




NEXUS Backside view

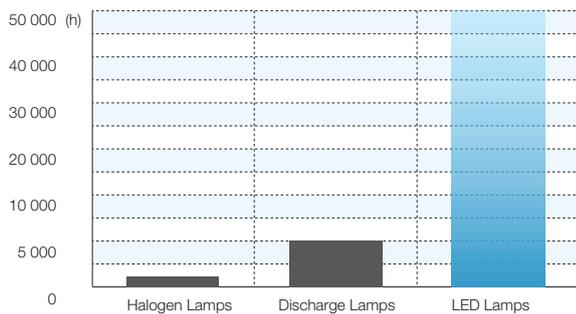


NEXUS Backside view



NEXUS Side view

## Economy



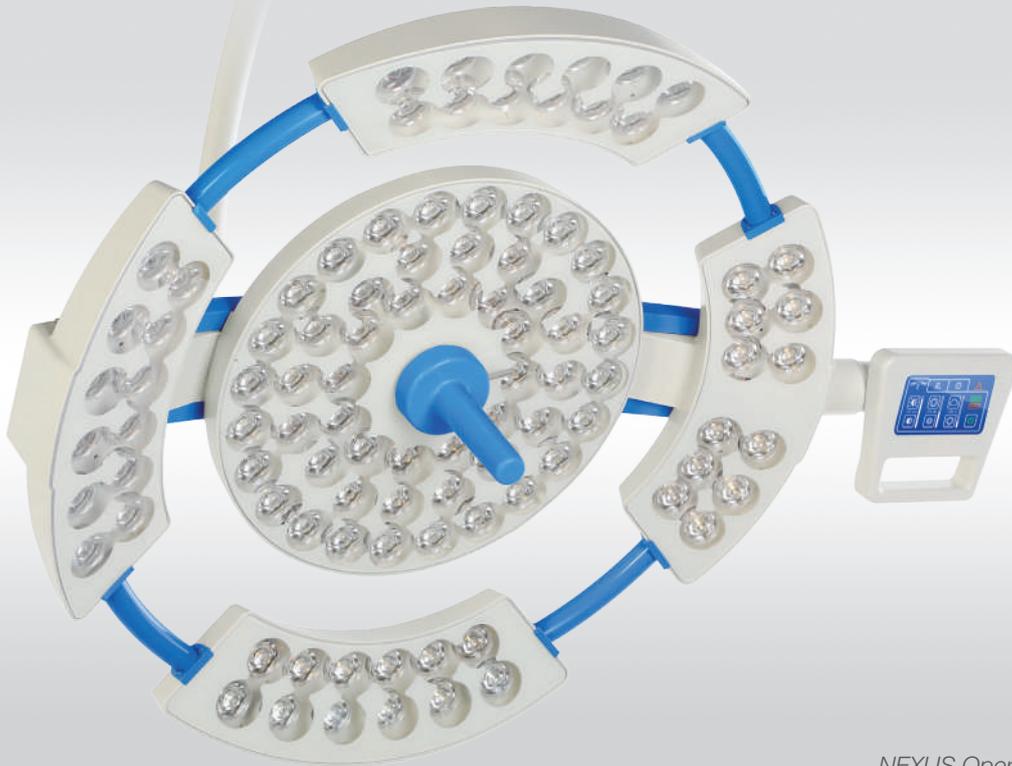
**Low power consumption** and high efficiency of LED light sources, provide measurable economic benefits by reducing maintenance costs of the operating theater.

**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.



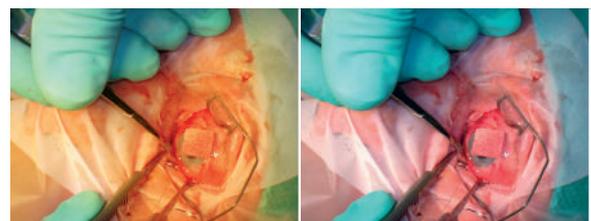
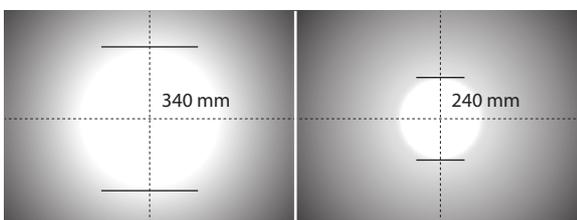
*NEXUS Operating light head*

## 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** facilities 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 E <sub>c</sub>	160 000 lx	130 000 lx
Light intensity adjustment	5 – 100%	5 – 100%
Color temperature T <sub>c</sub> (without adjustment)	4300K (4800 K)*	4300K (4800K)*
Color temperature T <sub>c</sub> (with adjustment)	3800-4800 K (3700 – 5000 K)*	3800-4800 K (3700 – 5000K)*
Light field diameter d <sub>10</sub> at E <sub>c</sub>	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.

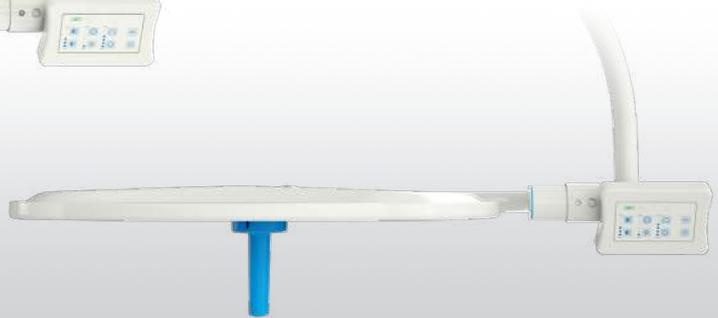


OL-03 / Operating light head with camera

# 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

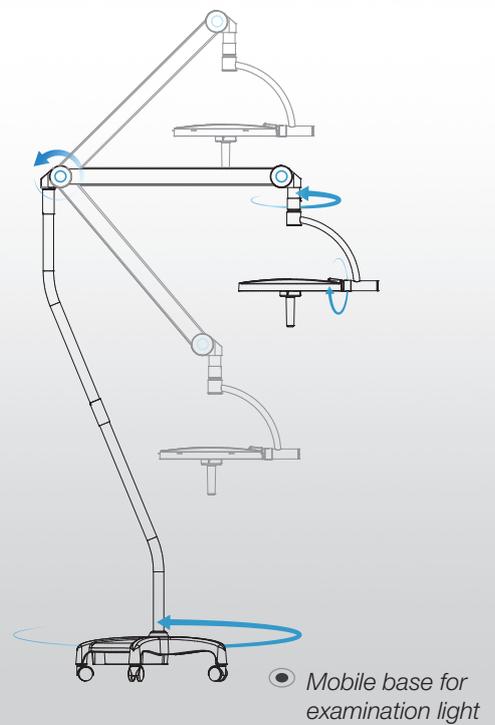
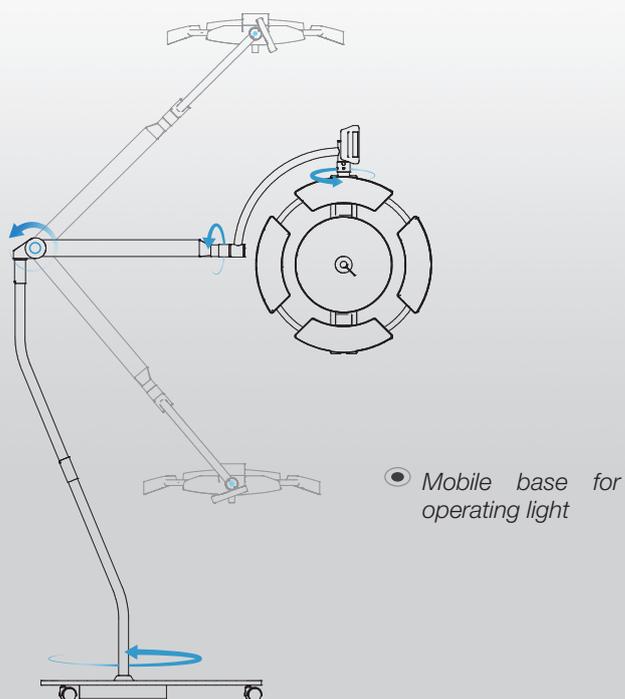
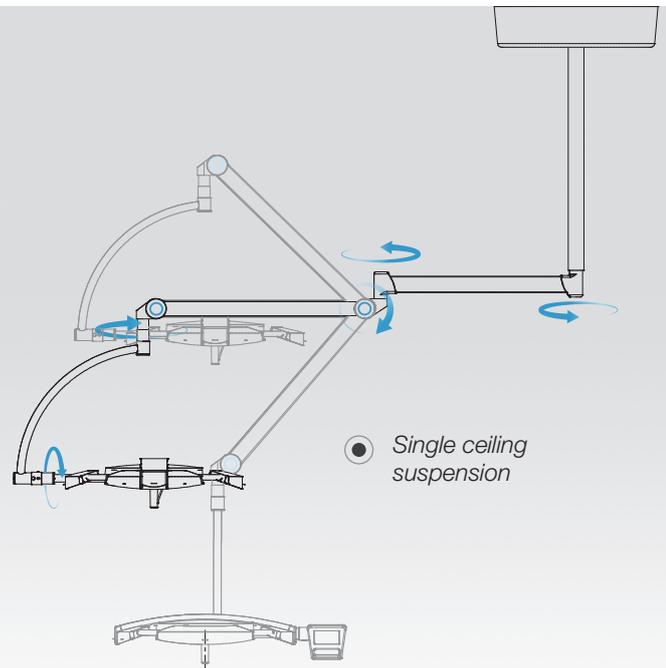
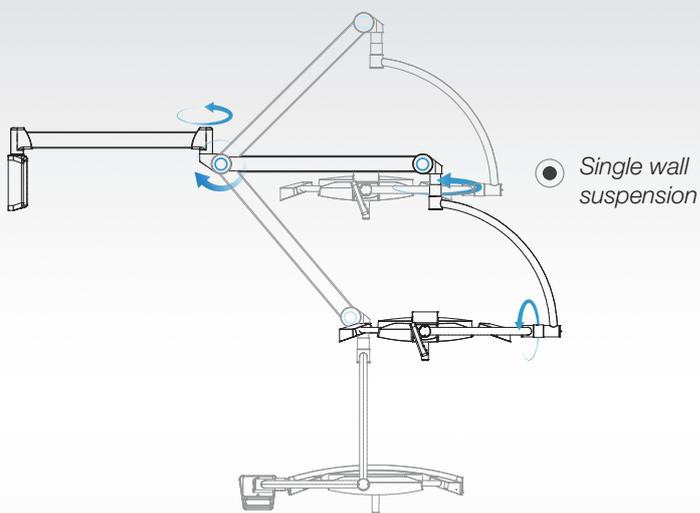
\* Additional options

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

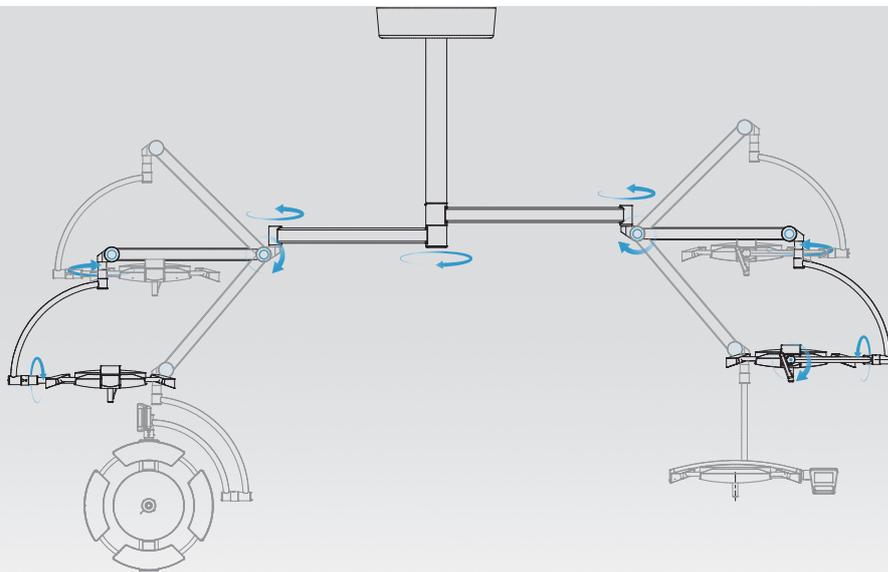
**Configurations**

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

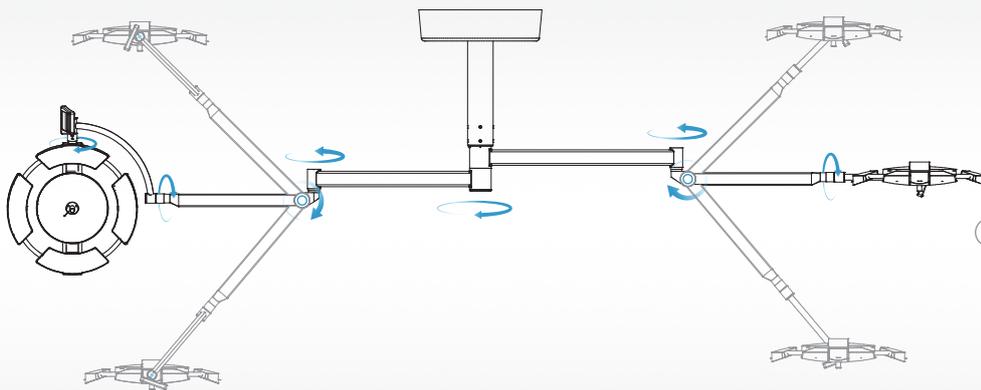
Examples of suspension configurations for operating lights:



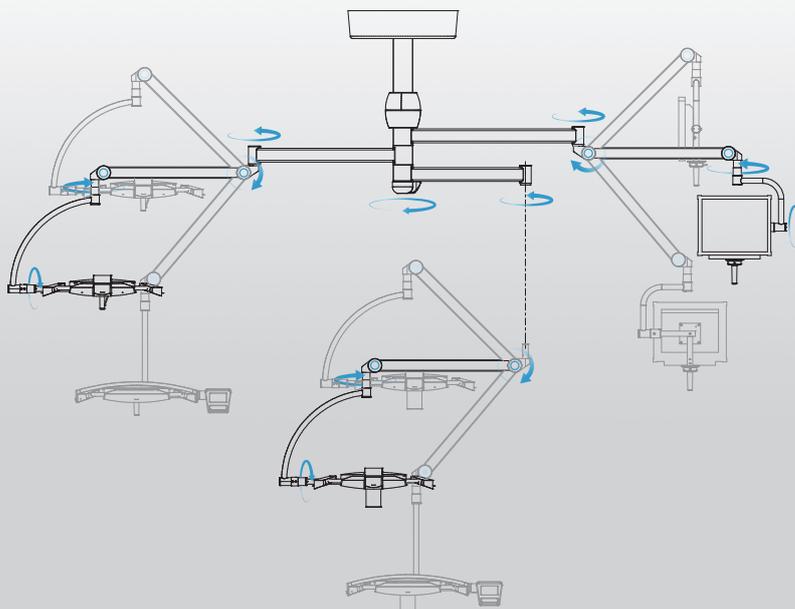
# Configurations



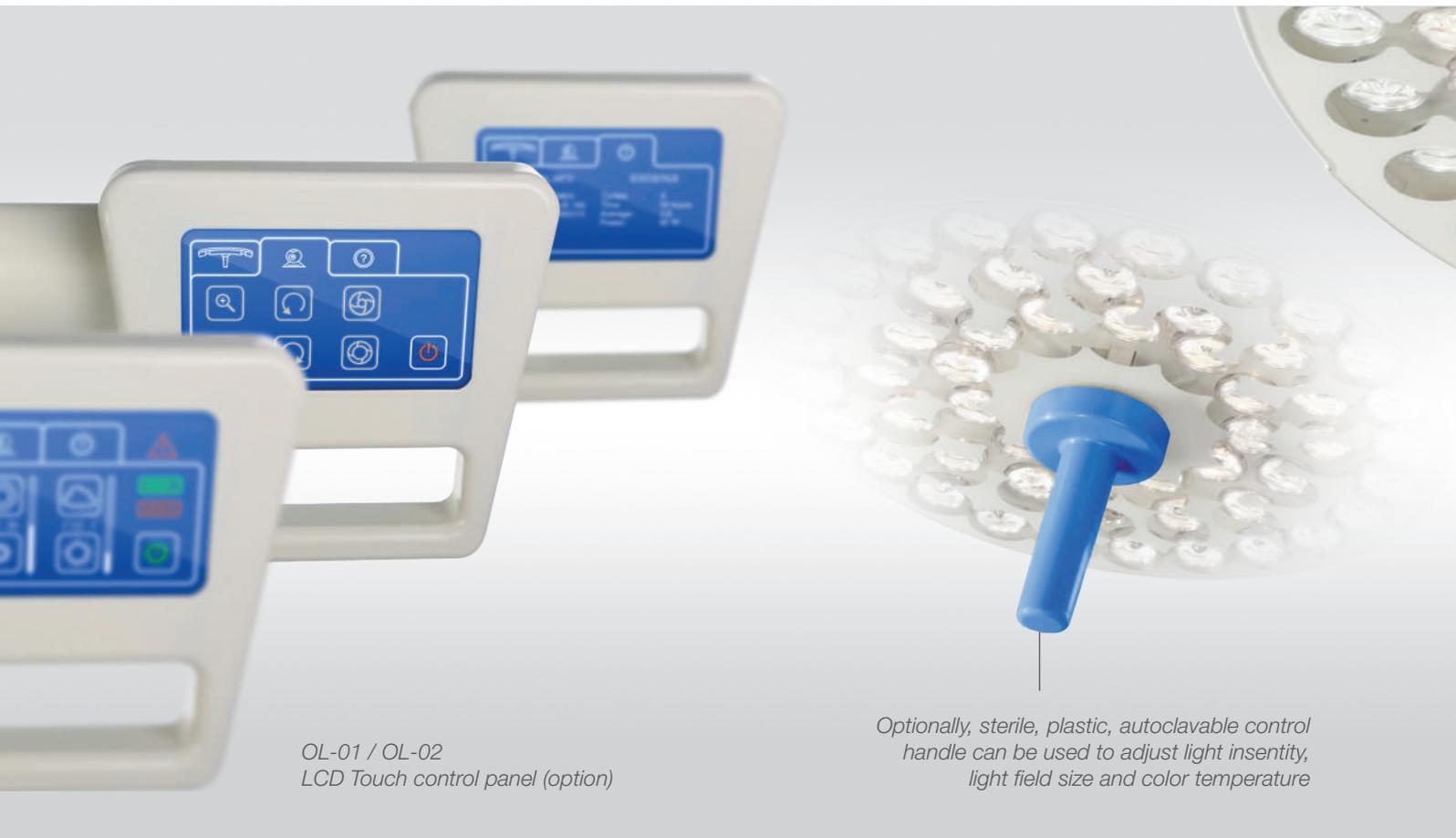
● Double ceiling suspension (>2700 mm) nx360°



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



● Triple ceiling suspension, two arms n<360°, 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



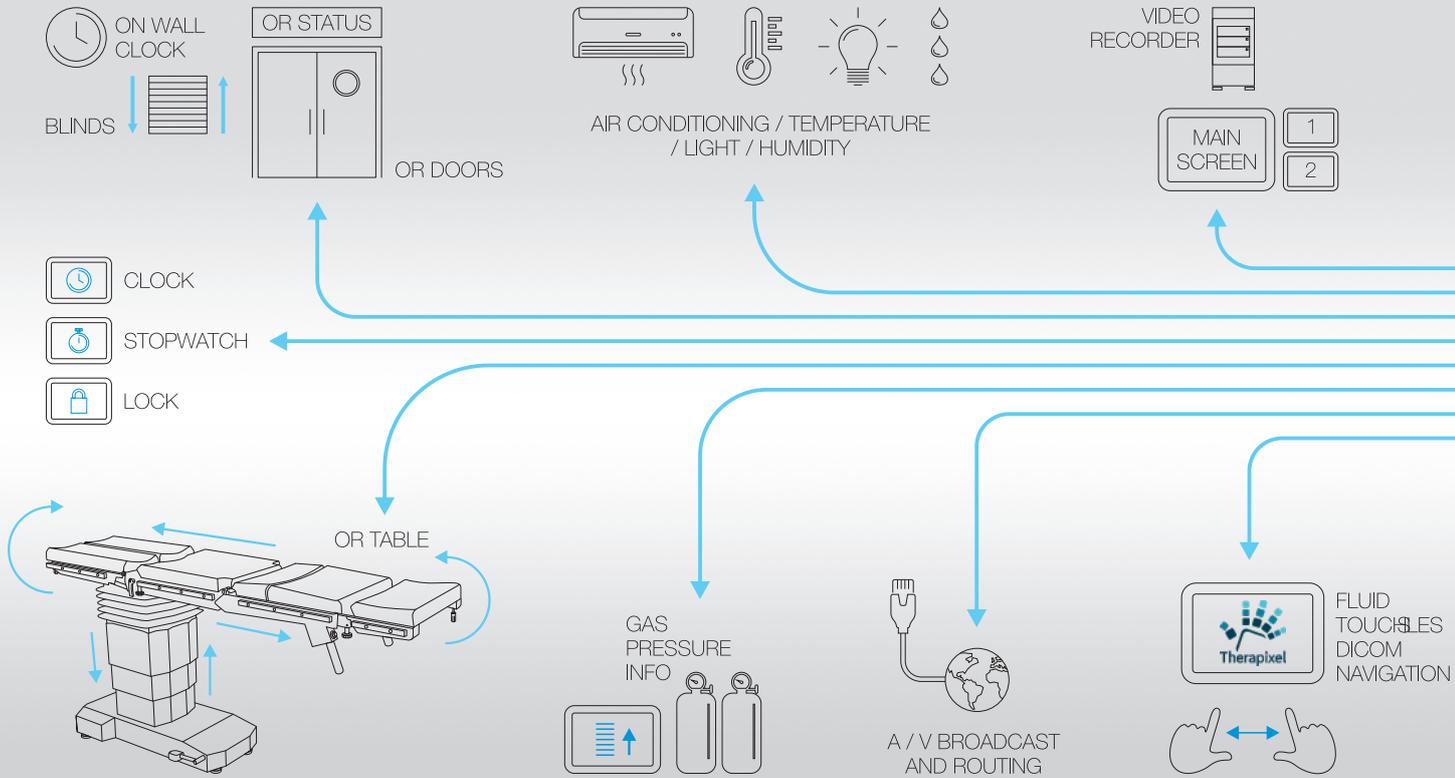
Medical monitor



## 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



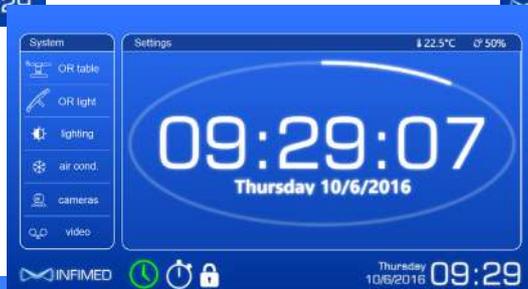
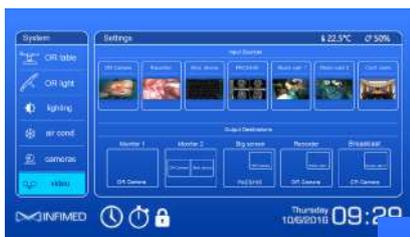
### Opera control system

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.

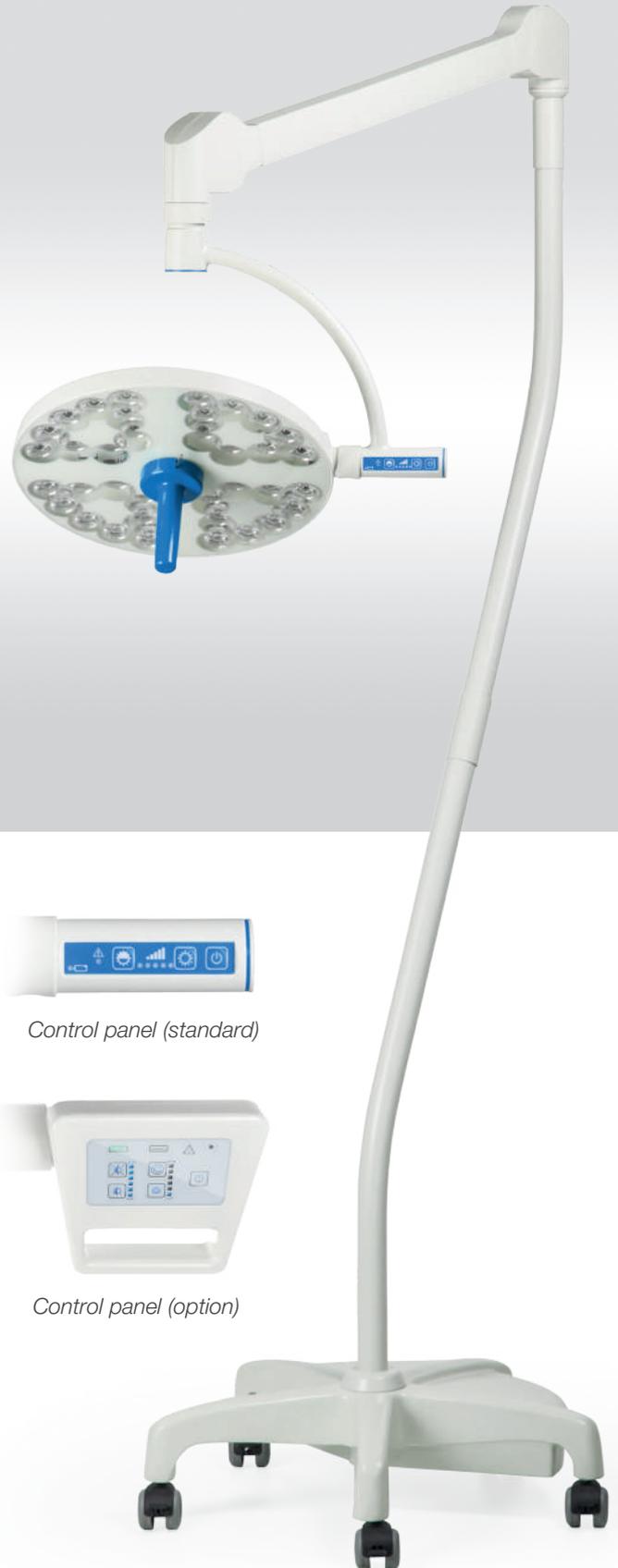


# Control System OPERA





*Treatment light ONYX, 60 000 lx*



### 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.



*Control panel (standard)*



*Control panel (option)*

# TL-01



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



Treatment light ONYX, 30 000 lx

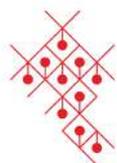
Parameter	INFIMED ONYX 60 000/100 00 lx	INFIMED ONYX 30 000 lx
Light intensity E <sub>c</sub>	60 000 lx / (100 000 - 120 000 lx)	30 000 lx
Dimming range	10 – 100%	10 – 100%
Color temperature T <sub>c</sub>	4300K (4800K)*	4300K (4800K)*
Light field size d10 at E <sub>c</sub>	260 mm / (240 – 340 mm)*	240 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%



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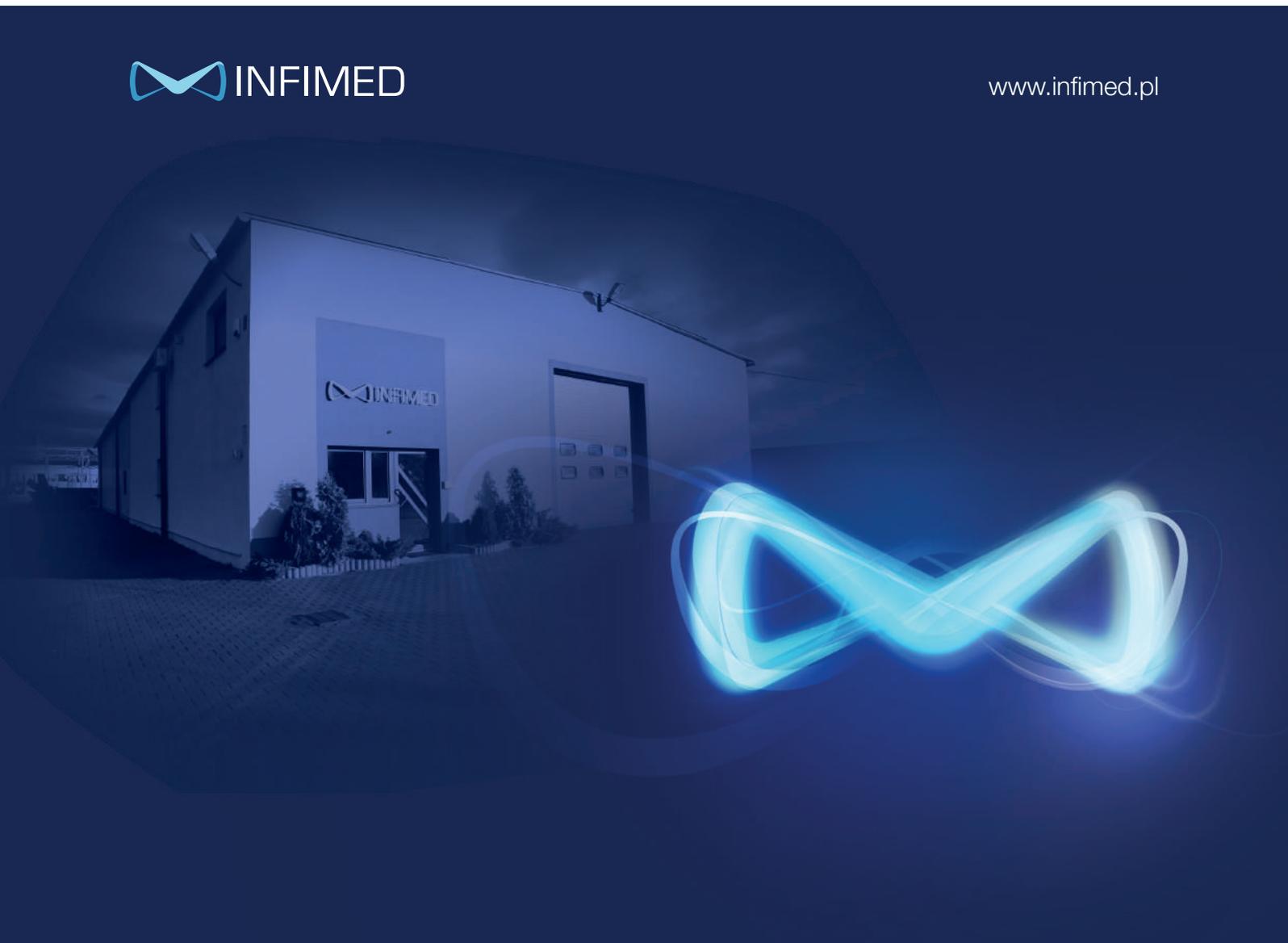
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EN ISO 9001:2008

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**Declaration of conformity**Company: **INFIMED Spółka z ograniczoną odpowiedzialnością**

34-300 Żywiec, ul. Kabaty 1, Polska,

Tel/fax +48 33 861 40 96

e-mail: [office@infimed.pl](mailto:office@infimed.pl)**We hereby declare for our own responsibility, that**

Medical device: Operating light

Name: NEXUS

Type: OL-01, OL-02

Class: I, according to rule 12 in conformity with annex IX of Directive 93/42/EEC

covered by Technical file no 1.0, date 08.2013

Inspection documentation of device: Report of final inspection no 17.3.1.10

**fulfills all requirements of Medical Directive 93/42/EEC that applies to this device.**

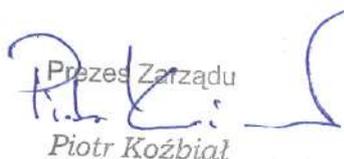
Procedure of conformity assessment:

Annex VII Of Council Directive no 93/42/EEC



Place and date: Żywiec 02.12.2016

Name and surname:



Prezes Zarządu  
*Piotr Koźbiał*



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(4)



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**List of all harmonised standards required by Directive 93/42/EEC:**

EN ISO 13485:2012 + AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009 + AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-10:2009	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
EN ISO 10993-15:2009	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
EN 60601-1:2006 + AC:2010	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
EN 60601-1-2:2007 + AC:2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007 (Modified))
EN 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)
EN 60601-1-8:2007 + AC:2010	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006)
EN 60601-2-41:2009 + A11:2011	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN 62304:2006 + AC:2008	Medical device software - Software life-cycle processes (IEC 62304:2006)
EN 62366:2008	Medical devices - Application of usability engineering to medical devices



## Declaration of conformity

Company: **INFIMED Spółka z ograniczoną odpowiedzialnością**

34-300 Żywiec, ul. Kabaty 1, Polska,

Tel/fax +48 33 861 40 96

e-mail: [office@infimed.pl](mailto:office@infimed.pl)

### We hereby declare for our own responsibility, that

Medical Device: Treatment light

Name: ONYX

Type: TL-01

Class: I, according to rule 12 in conformity with annex IX of Directive 93/42/EEC

Covered by Technical file no. 1.0, date 08.2013

Inspection documentation of device: Report of final inspection no 17.3.1.12

**fulfills all requirements of Medical Directive 93/42/EEC that applies to this device.**

Procedure of conformity assessment:

Annex VII Of Council Directive no 93/42/EEC



Prezes Zarządu  
*Piotr Kozbial*  
Piotr Kozbial

Place and date: Żywiec 02.12.2016

Name and surname:



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www [www.infimed.pl](http://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

**List of all harmonised standards required by Directive 93/42/EEC:**

EN ISO 13485:2012 + AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009 + AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-10:2009	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
EN ISO 10993-15:2009	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
EN 60601-1:2006 + AC:2010	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
EN 60601-1-2:2007 + AC:2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007 (Modified))
EN 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)
EN 60601-1-8:2007 + AC:2010	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006)
EN 60601-2-41:2009 + A11:2011	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN 62304:2006 + AC:2008	Medical device software - Software life-cycle processes (IEC 62304:2006)
EN 62366:2008	Medical devices - Application of usability engineering to medical devices



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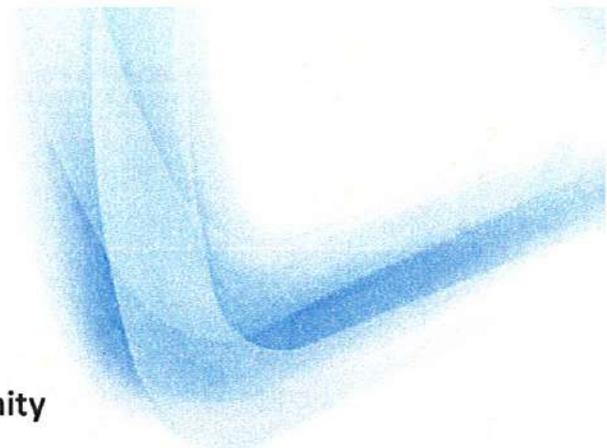
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### Declaration of conformity

Company: **INFIMED Spółka z ograniczoną odpowiedzialnością**

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e-mail: [office@infimed.pl](mailto:office@infimed.pl)

**We hereby declare for our own responsibility, that**

Medical device: Operating light

Name: PROXY

Type: OL-03

Class: I, according to rule 12 in conformity with annex IX of Directive 93/42/EEC

covered by Technical file no 1.0, date 12.2016

Inspection documentation of device: Report of final inspection no 17.3.1.10

**fulfills all requirements of Medical Directive 93/42/EEC that applies to this device.**

Procedure of conformity assessment:

Annex VII Of Council Directive no 93/42/EEC



Prezes Zarządu  
*Piotr Koźbial*  
Piotr Koźbial

Place and date: Żywiec 02.12.2016

Name and surname:



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

bank Bank Spółdzielczy  
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SWIFT POLUPLPR

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PL23 8131 0005 0016 2492 2000 0030 USD

**List of all harmonised standards required by Directive 93/42/EEC:**

EN ISO 13485:2012 + AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009 + AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-10:2009	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
EN ISO 10993-15:2009	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
EN 60601-1:2006 + AC:2010	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
EN 60601-1-2:2007 + AC:2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007 (Modified))
EN 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)
EN 60601-1-8:2007 + AC:2010	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006)
EN 60601-2-41:2009 + A11:2011	Medical electrical equipment - Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
EN 62304:2006 + AC:2008	Medical device software - Software life-cycle processes (IEC 62304:2006)
EN 62366:2008	Medical devices - Application of usability engineering to medical devices



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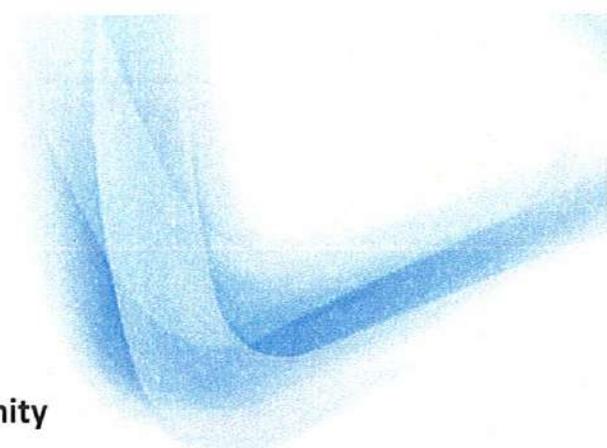
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### Declaration of conformity

Company: **INFIMED Spółka z ograniczoną odpowiedzialnością**

34-300 Żywiec, ul. Kabaty 1, Polska,

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e-mail: [office@infimed.pl](mailto:office@infimed.pl)

#### We hereby declare for our own responsibility, that

Medical device: Operating table

Name: VIVAX

Type: OT-02

Class: I, according to rule 12 in conformity with annex IX of Directive 93/42/EEC

covered by Technical file no 1.0, date 08.2013

Inspection documentation of device: Report of final inspection no 17.3.1.02

**fulfills all requirements of Medical Directive 93/42/EEC that applies to this device.**

List of all harmonised standards required by Directive 93/42/EEC is indicated in Technical File.

Procedure of conformity assessment:

Annex VII Of Council Directive no 93/42/EEC



Prezes Zarządu  
*Piotr Koźbial*  
Piotr Koźbial

Place and date: Żywiec 02.12.2016

Name and surname:



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Sąd Rejonowy w Bielsku-Białej, VIII Wydział  
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Wysokość Kapitału Zakładowego: 500 000 PLN

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PL02 8131 0005 0016 2492 2000 0020 EUR  
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**List of all harmonised standards required by Directive 93/42/EEC:**

EN ISO 13485:2012 + AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009 + AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
EN ISO 10993-10:2009	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
EN ISO 10993-15:2009	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
EN ISO 19054:2006	Rail systems for supporting medical equipment (ISO 19054:2005)
EN 60601-1:2006 + AC:2010	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
EN 60601-1-2:2007 + AC:2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007 (Modified))
EN 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)



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PL23 8131 0005 0016 2492 2000 0030 USD

EN 60601-1-8:2007 + AC:2010	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006)
EN 60601-2-46:1998	Medical electrical equipment -- Part 2-46: Particular requirements for the safety of operating tables
EN 62304:2006 + AC:2008	Medical device software - Software life-cycle processes (IEC 62304:2006)
EN 62366:2008	Medical devices - Application of usability engineering to medical devices



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PL02 8131 0005 0016 2492 2000 0020 EUR  
PL23 8131 0005 0016 2492 2000 0030 USD

# 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.

Report No.: 84956996-20  
Effective date: 2022-02-18  
Expiry date: 2025-01-30  
Issue date: 2022-02-18



Jarosław Pyclik  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany