INFIMED

User Manual

INTEGRATION SYSTEM OPERA

IS-01

Serial number …….

Edition 3.1

September 2024

PROJECT……

Manufacturer:

INFIMED Spółka z ograniczoną odpowiedzialnością

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VAT id no.: PL 553 251 29 67
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In accordance with Annex VIII to Regulation (EU) 2017/745 of the European Parliament and of the Council , the product has been classified as class I, according to rule 13.

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

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

CE

Dear Customer!

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

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

This document replaces all versions with an older release date. This version is not updated automatically. The data contained in this document was created with the utmost care. However, we cannot guarantee that the actual product interface will not differ from the form contained in this document.

Infimed Sp. z o. o. is not liable for damages that result directly or indirectly from improper use of this document.

General safety considerations:

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

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

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

Contents:

1. Description of INFIMED Opera system

The system enables control of equipment and devices located in the operating room. It is also able to transmit and manage video signals, and its open architecture allows for further expansion at the customer's request.

Depending on the configuration, the system enables control of the following equipment in the Operating Room:

- Tables and operating lamps,
- General lighting,
- Air conditioning, laminar air supply,
- Cameras placed in operating lamps and in the operating room,
- X-Ray viewers,
- Monitors, splitters and video recorders,
- Doors and curtains,
- Allows access to HIS and display of DICOM files.

The basic set of the Opera system consists of:

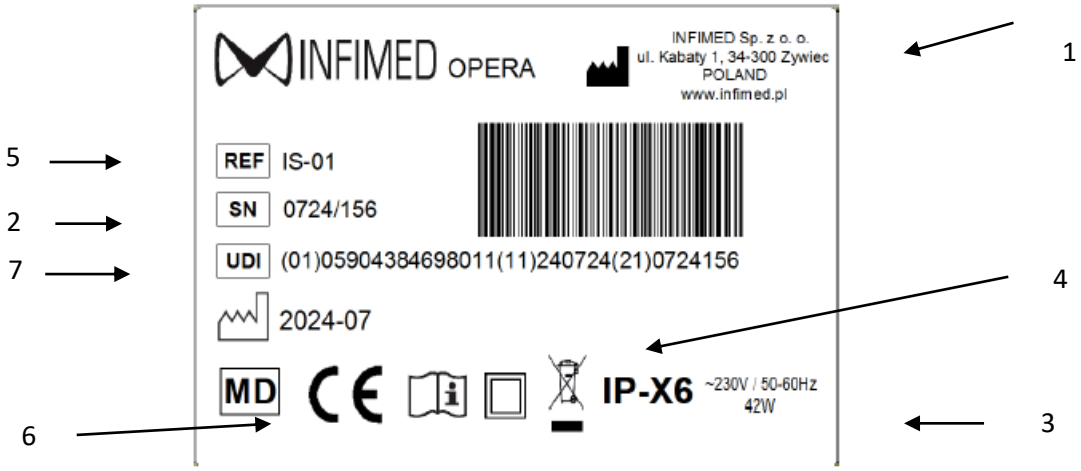
- Control unit, consisting of a touch glass flush with the wall, an integrated LCD display and a device hosting the control application. The connection between the glass and the panel guarantees tightness and facilitates disinfection.

- Infimed Opera IO input/output module, which provides communication between the control unit and other devices. Depending on the configuration, the system may be based on several such modules with power supplies, placed in plastic housings.

- Communication interfaces provided by third parties to control their devices or other additional peripherals.

- Wiring.

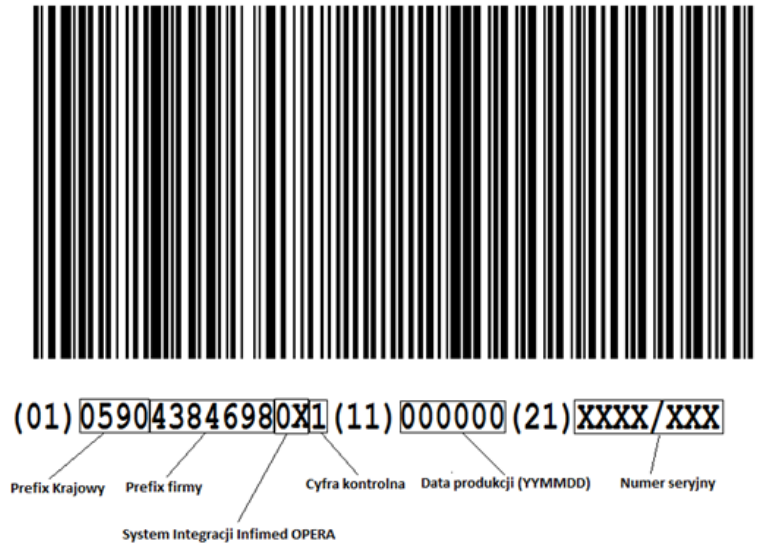
There is a nameplate on the device (on the OperaIO I/O module and control panel):



Description of markings:

1. Manufacturer's name, logo and address
2. Serial number
3. Power supply parameters, power consumption
4. Additional markings, e.g.: applied parts, tightness classes, etc.
5. Product symbol
6. CE mark
7. UDI-DI-PI code

Explanation of the UDI-DI-PI code



Data presented on the label:

No.	Element:	Pictogram to be used
1.	Company logo	INFIMED
2.	Manufacturer's name and address	
3.	Product name	Integration system
4.	Catalog number	REF
5.	CE mark – product compliance with the requirements of the MDR 2017/745 Regulation	CE
6.	IP protection class	IP-X4
7.	Second class of protection against electric shock	
8.	Serial number	SN

No.	Element:	Pictogram to be used
9.	Date of production	
10.	Read the Instructions for Use	
11.	Note	
12.	Medical device	
13.	UDI code	

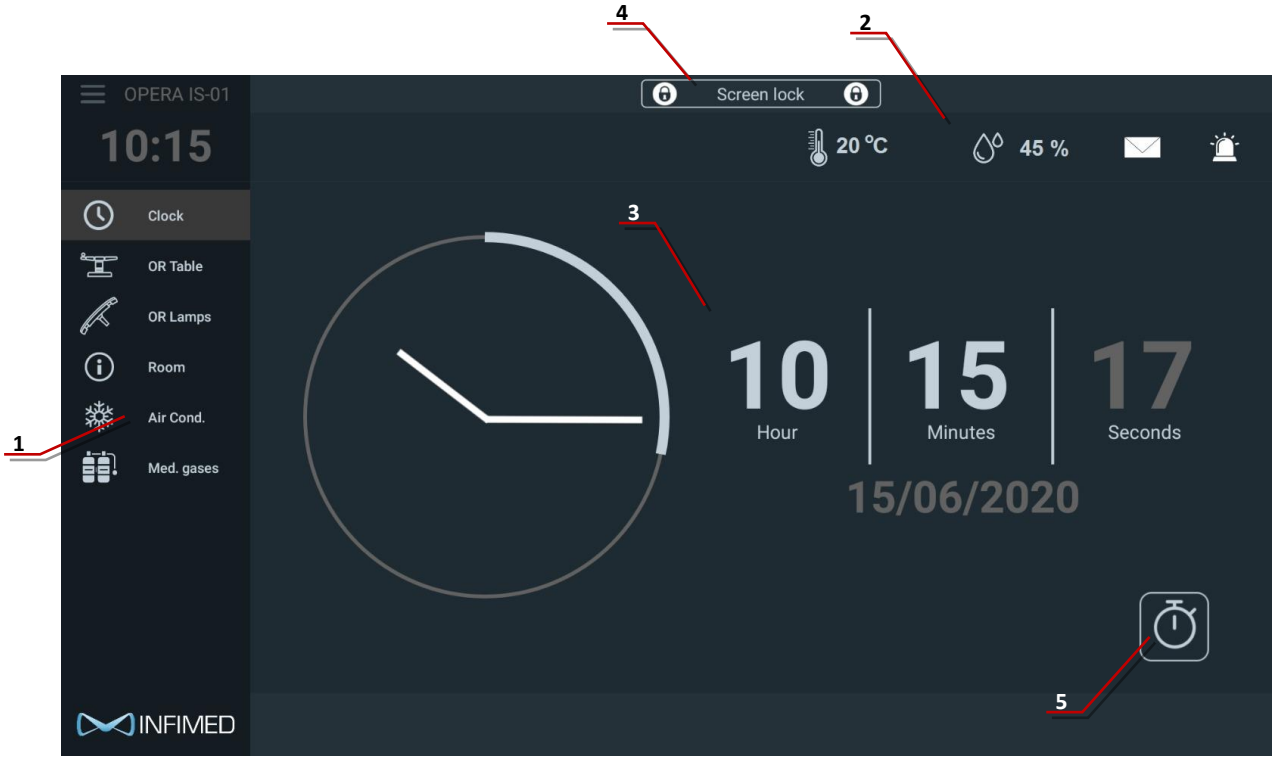
The manufacturer reserves the right to make changes to the product design in connection with the use of newer technological solutions that improve the functionality of the product.

2. INFIMED Opera system interface

To turn on the control panel, press the monostable button, which is usually located under the control panel. After loading, which may take a few seconds, the Opera application with a graphical interface will be launched.

Home screen

The screen should look similar to the one below:

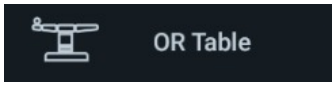


The main screen consists of the following elements:

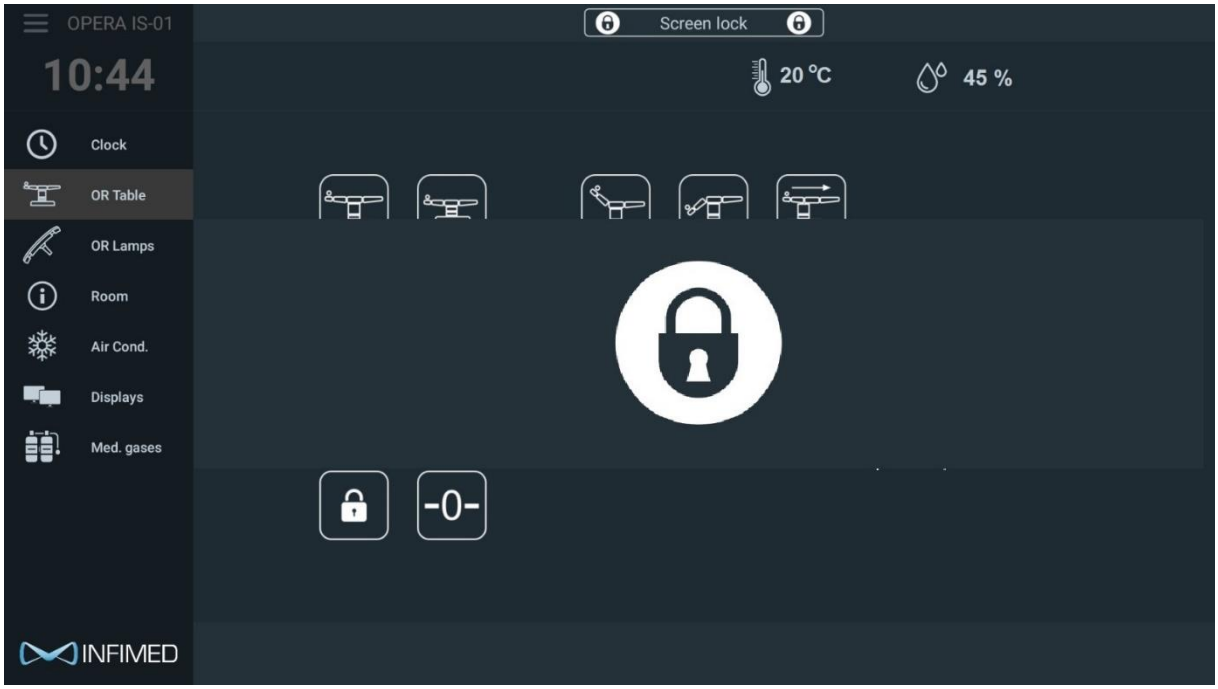
1. Menu – list of system tab buttons – in this tab you can select devices and systems that you want to control or display information about them,
2. Top information bar displaying the current status of selected peripherals. The above example displays the current temperature and humidity.
3. Main tab screen. The above example shows the main clock and date.
4. Screen lock button.
5. Timer tab switch buttons.

Operating Table Tab

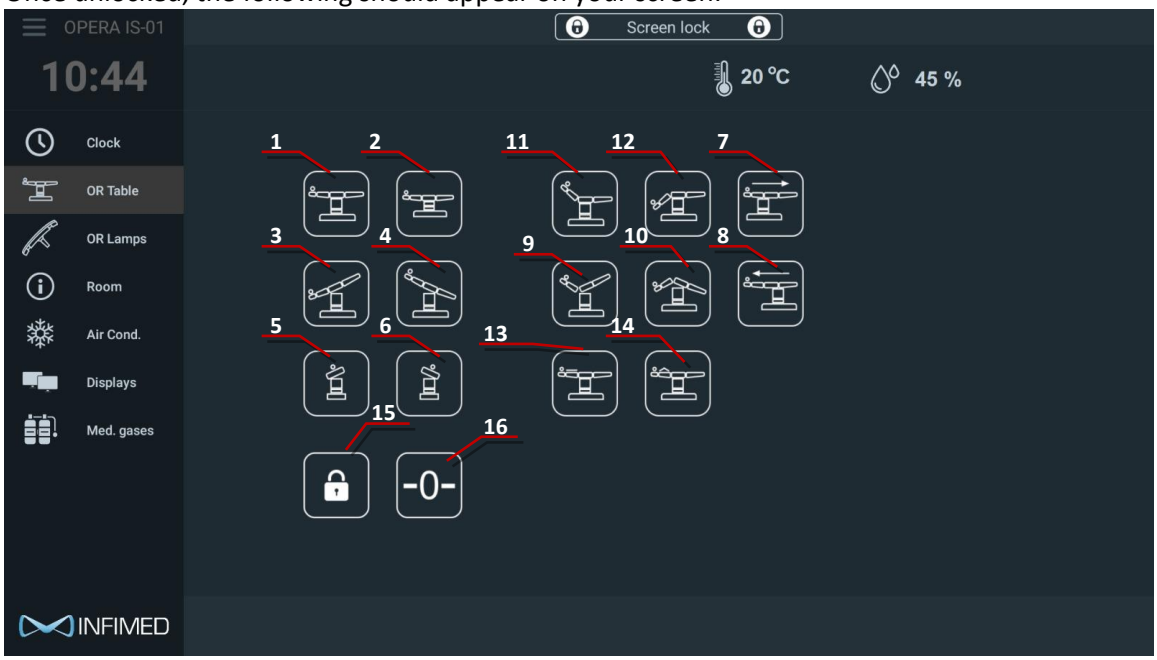
To switch to the operating table control tab, touch the button:



The buttons will be locked by default. To unlock, please hold down the button with the padlock icon.



Once unlocked, the following should appear on your screen:

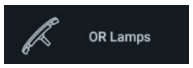


Functions and buttons:

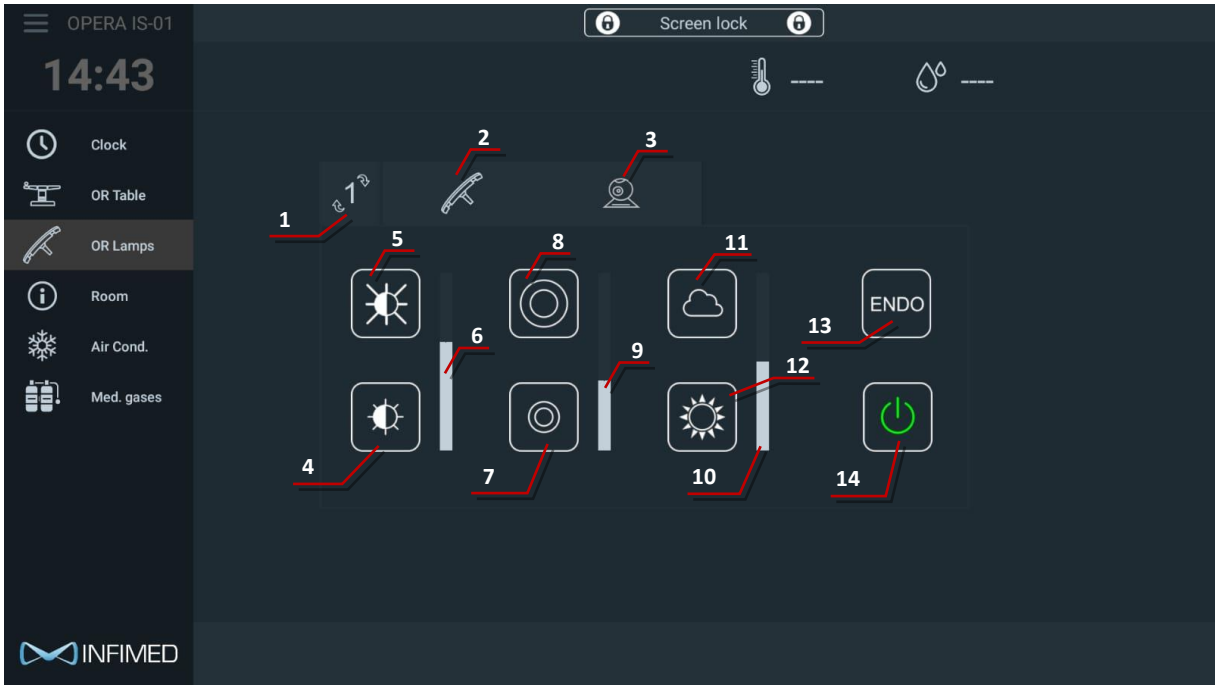
1. Up movement,
2. Down movement,
3. Trendelenburg tilt,
4. Reverse Trendelenburg tilt,
5. Tilt left,
6. Tilt right,
7. Longitudinal slide towards legs,
8. Longitudinal slide towards head,
9. Flex,
10. Reflex
11. Backrest up,
12. Backrest down,
13. Kidney bench – move down,
14. Kidney bench - move up,
15. Stop button,
16. Zero position search.

Operating Light Tab

To switch to the Operating Light control tab, touch the button:



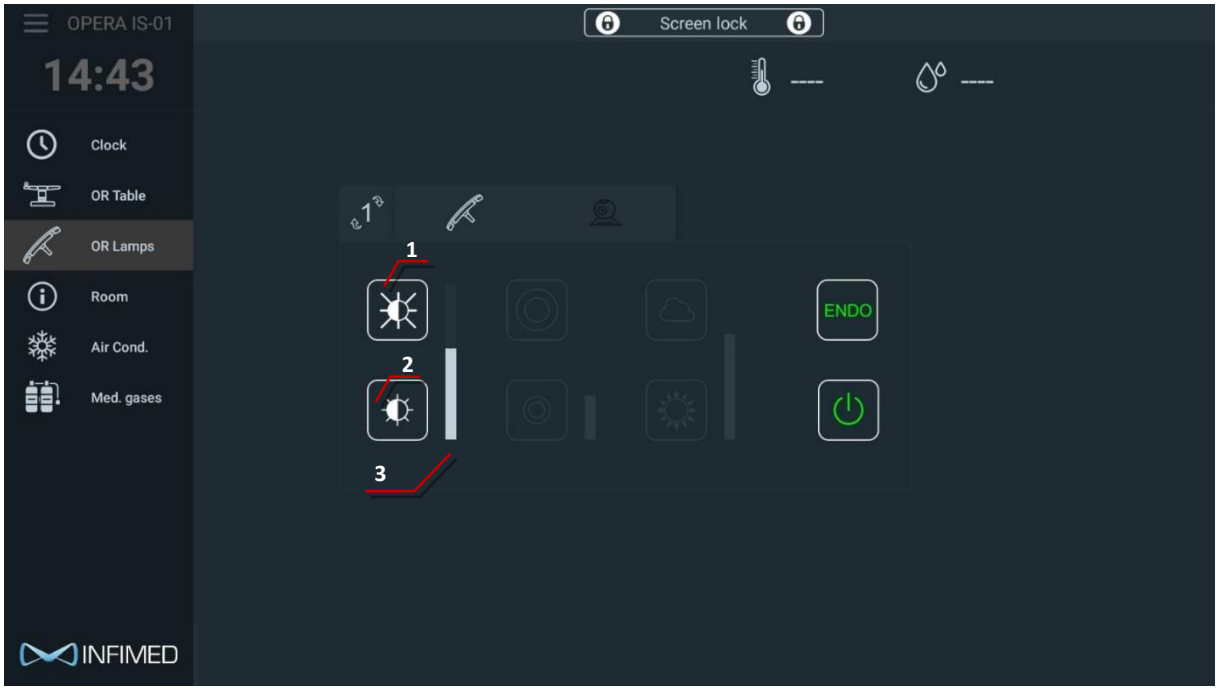
The following tab should appear on the screen.



The tab has the following functions:

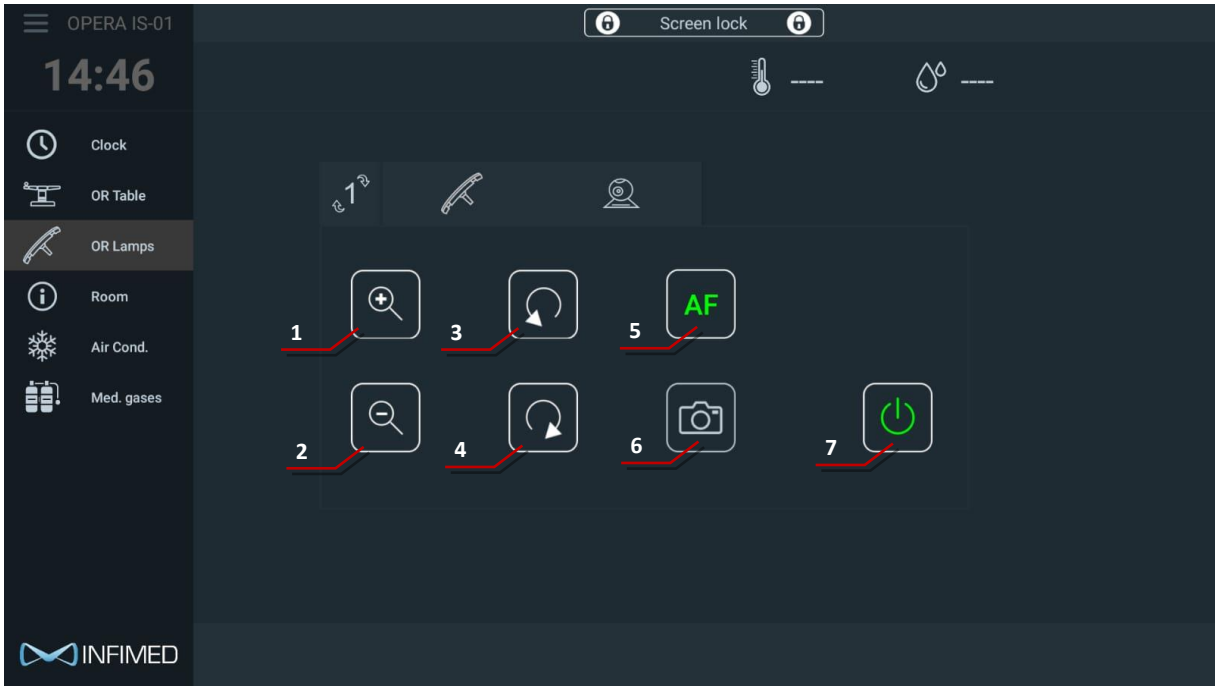
1. Button for switching to the next head (the active head number is displayed next to the pictogram - the button is not displayed if only one lamp is configured),
2. Button for controlling the lamp's lighting parameters,
3. Activation of the lamp camera control tab,
4. Bar representing the current brightness level setting (it is possible to change the parameter setting by touching the bar),
5. Increasing brightness using the button,
6. Decreasing brightness using the button,
7. Bar representing the current light spot diameter setting (it is possible to change the parameter setting by touching the bar),
8. Increasing the light spot diameter setting,
9. Decreasing the light spot diameter setting,
10. A bar representing the current lighting color temperature setting (it is possible to change the parameter setting by touching the bar),
11. Increasing the lighting color temperature setting,
12. Decreasing the lighting color temperature setting,
13. Activating Endo mode,
14. Lamp on/off button.

Lamp endo mode:



1. Increasing the brightness in endo mode using the button,
2. Decreasing the brightness in endo mode using the button,
3. A bar representing the current lighting brightness setting in endo mode (it is possible to change the parameter setting by touching the bar),

Camera

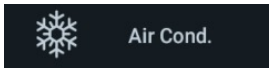


The camera tab has the following functions:

1. Zoom + cameras,
2. Zoom – cameras,
3. Rotate camera left,
4. Rotate camera right,
5. Enable Auto-focus,
6. Freeze frame mode,
7. Turn camera on/off.

Air Conditioning Tab

To switch to the air conditioning tab, touch the air conditioning button:



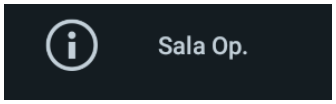
The following tab should appear on the screen.

The tab has the following functions:

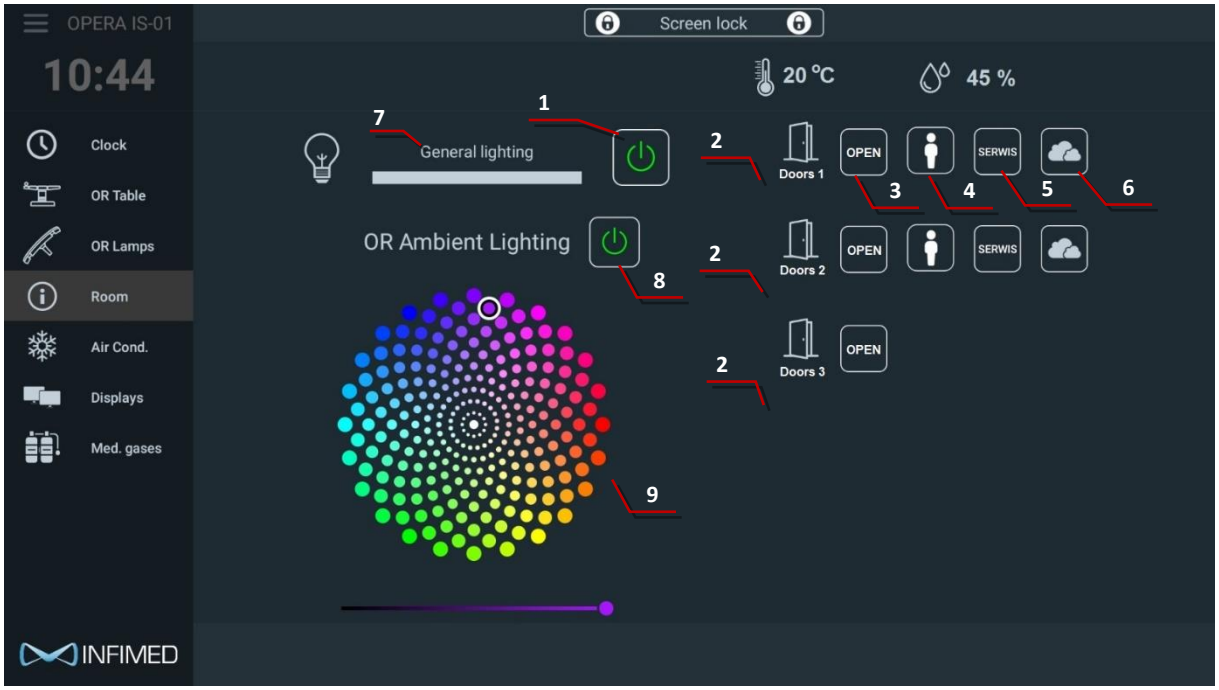
1. Setting the desired temperature using the touch slider,
2. Displaying the current temperature setting,
3. Setting the desired humidity using the touch slider,
4. Displaying the current humidity setting,
5. Current conditions in the room are displayed here,
6. Current status of the air conditioning unit is displayed,
7. Forced performance mode button – activates normal performance of the unit outside the set working hours and on weekends,
8. Connection error information is displayed,
9. Air conditioning unit failure information is displayed.

Operating Room Tab

To switch to the "Operating Room" tab, please press the button:



The following tab should appear on the screen:



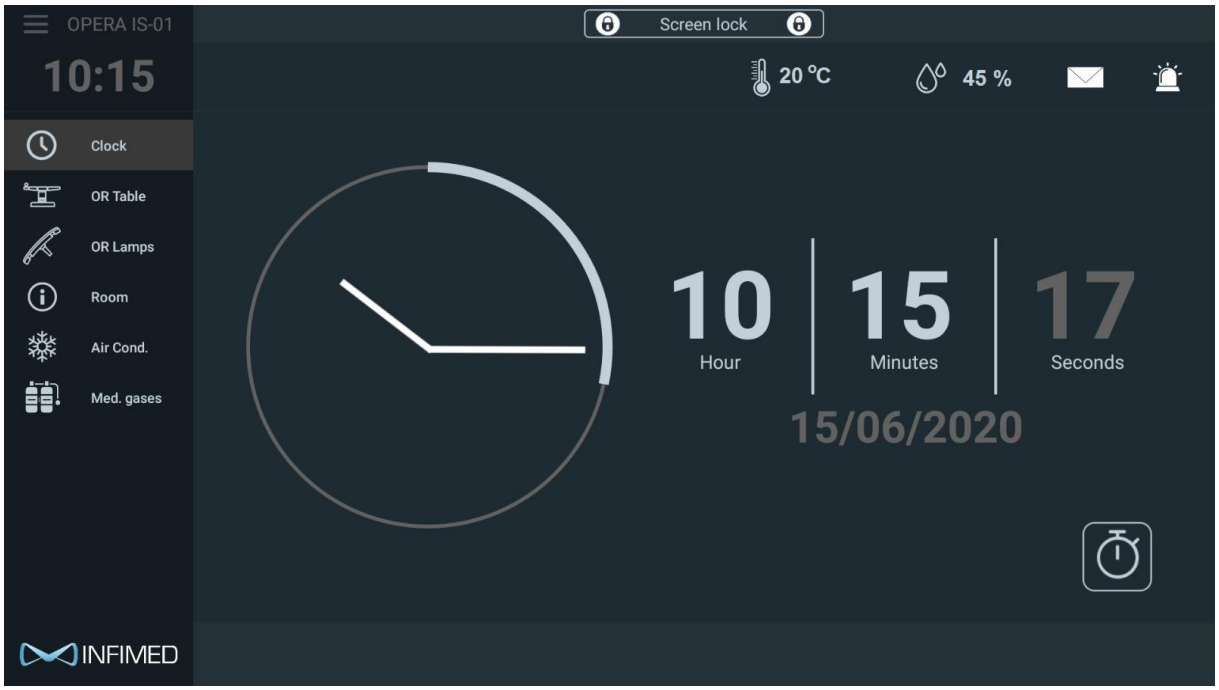
The tab has the following functions:

1. General lighting on/off button,
2. Saved name of assigned door (for example "Corridor"),
3. Full door opening button,
4. Nursing opening button,
5. "Service" button - when the button is on, the door will remain open all the time,
6. Door glass misting on/off button.
7. Illumination intensity adjustment
8. RGB on / off
9. RGB color choice

Clock Tab

To switch to the clock tab, please press the button:

The following tab should appear on the screen.

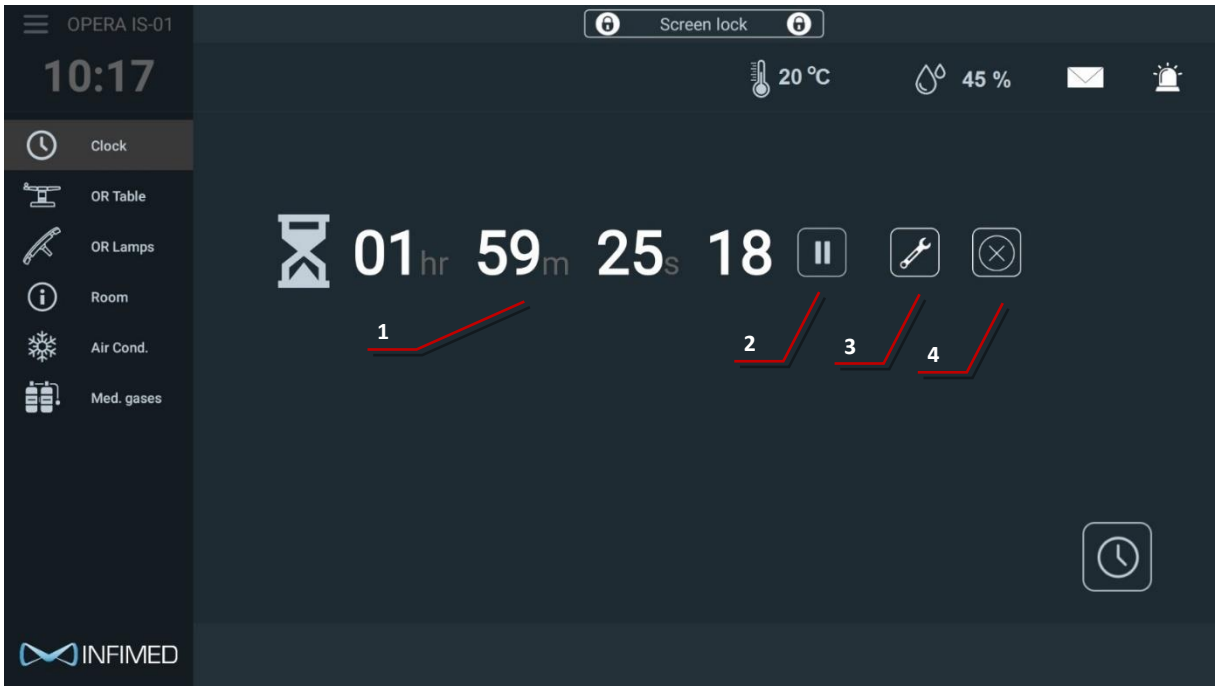


This tab displays the current time and date.

Timer

To quickly switch to the stopwatch tab, please press the button:

The following tab should appear on the screen:



The tab has the following functions:

1. Displaying the remaining time,
2. Start/pause,
3. Changing the time setting,
4. Deleting and stopping the timer.

While the timer is running, the tab can be changed to another at any time, the timer will continue to run in the background, which means that when you return to this tab, it will continue to run. After the set time has elapsed, the screen will automatically switch to the tab displaying the time.

Screen lock

To quickly switch to the stopwatch tab, please press the button located at the top of the screen:

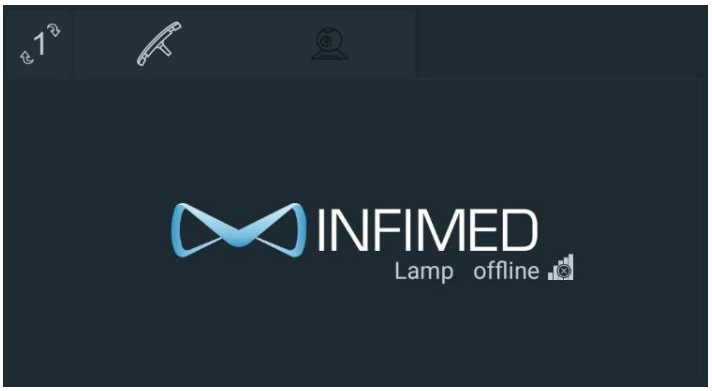
The following icon should appear on the screen:

The screen lock can be used, for example, when disinfecting the screen. To unlock the screen, please hold the padlock symbol for a moment.

3. Possible problems and displayed warnings

In the event of a lack of connection with external devices, the relevant fields are greyed out or a warning message is displayed.

In the event of a lack of connection to the lamp (for example, no power supply), the options related to it become inactive and the following message is displayed:



The Opera IO module in this project is connected to the air conditioning unit, in case of power supply/connection problems, it is not possible to change the settings or read the air conditioning parameters. Please report this fact immediately to the hospital's technical department.

In case of a failure of the air conditioning unit, a warning is displayed in the air conditioning tab:

4. Operating and storage conditions

Operating Temperature Range	**0°C ~ 35°C**
Storage Temperature	**-20°C ~ 55°C**
Humidity (Operating)	**10% to 85% (non-condensing)**
Humidity (Storage)	**5% to 93% (non-condensing)**
Control Panel IP Rating	**Front IP-X4**

5. Product life cycle

The manufacturer specifies the product lifespan as 10 years.

6. Washing and disinfection

For cleaning and disinfection, use detergents that do not contain active oxygen or chlorine. After disinfection, rinse the product with distilled water to eliminate streaks. Use a dry, soft, sterile cloth to thoroughly dry it.

It is not recommended to use a water jet when washing. It is recommended to activate the screen lock for the time of washing and disinfection.

The list of disinfectants can be found in Annex 1 to the instructions, dedicated to approved cleaning and disinfecting agents.

Failure to comply with the above requirements will void the product warranty.

7. Maintenance, inspections and repairs

The equipment does not have serviceable parts, in the event of a fault, the entire damaged or faulty module is replaced with a new one. To diagnose the fault, it is recommended to contact the manufacturer's Service Department.

All repairs to the product are performed by the appropriate service or direct representative of the manufacturer. The user is not allowed to make any modifications or repairs to the product without special training and authorization. After the customer obtains the manufacturer's written consent for any repairs to be carried out by the customer's technical staff, the manufacturer will provide all necessary information needed to perform the repair.

To ensure long and trouble-free operation, only original parts supplied by the manufacturer should be used.

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

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

8. Technical condition checks and inspections

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

Only a positive result of the inspection may constitute the basis for further use of the product.

Every 12 months, the following should be performed:

- checking the general technical condition

- checking the functionality

- checking the electrical installation

9. Liquidation of the product

When deciding to discontinue use of the product, the user is obliged to disinfect it (a product that is not disinfected in accordance with applicable environmental protection regulations is hazardous waste). There are three possible procedures:

1. Order the device manufacturer to carry out the liquidation of the product,

2. Order a company that has the required permits to receive devices for liquidation or disposal in a manner that ensures the protection of life, human health and environmental protection,

3. Carry out on your own, if you have services that can dismantle the product.

The principles of waste management are specified in the Waste Act of 27 April 2001.

10. Electromagnetic compatibility

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

In the tables - point 7 Characteristics of the electromagnetic environment - describes the electromagnetic environment in which the medical device: IS-01 should be used. The user should follow the instructions and warnings given in the tables.

Recommended distances between portable radio communication devices and the product

Rated maximum output power of transmitter in watts **W**	**150 kHz to 80 MHz** $d = 1{,}2\sqrt{P}$ **Separation distance in meters**	**150 kHz to 800 MHz** $d = 1{,}2\sqrt{P}$ **Separation distance in meters**	**800 MHz to 2.5 GHz** $d = 2{,}3\sqrt{P}$ **Separation distance in meters**
0.01	0,1	0,1	0,2
0.1	0,4	0,4	0,7
1	1,2	1,2	2,3
10	4	4	7
100	12	12	23
For transmitters whose maximum output power is not listed above, the separation distance should be calculated using the formulas given below. P is the output power in watts (W) as declared by the transmitter manufacturer. NOTE The above guidelines may not apply in all situations. Electromagnetic propagation is subject to absorption and reflection from structures, objects and people.			

11. Electromagnetic Emissions

The medical device: IS-01 is intended for use in the electromagnetic environment specified below. The user should ensure that the medical device: IS-01 is used in such an environment.		
Emission type	**Classification**	**Explanations and guidance**
RF Emissions CISPR 11	Group 1	Medical Device: IS-01 generates RF energy only for its own internal functions. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	Medical device: IS-01 is intended for use in domestic premises and in premises directly connected to the low-voltage network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations, flicker IEC 61000-3-3	Compliant	

Medical device: IS-01 is intended for use in an electromagnetic environment with the following characteristics. The user should ensure that the medical device: IS-01 is used in such an environment.			
Immunity	**IEC 60601-1-2 Test level**	**Immunity level**	**Explanations and guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	The floor where the column is used should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Surge IEC 61000-4-5	± 1 kV between power supply lines ± 2 kV between power supply lines and earth	± 1 kV between power supply lines ± 2 kV between power supply lines and earth	Mains power quality and interference characteristics should be those of a typical commercial or hospital environment
Fast transients IEC 61000-4-4	± 2 kV power supply lines ± 1 kV signal lines	± 2 kV power supply lines ± 1 kV signal lines	The mains power quality and interference characteristics should be those of a typical commercial or hospital environment.
Voltage dips, swells, voltage variations on power supply lines IEC 61000-4-11	< 5% UT (>95% dip UT) for 0.5 cycle 40% UT (60% dip UT) for 5 cycles 70% UT (30% dip UT) for 25 cycles < 5% UT (>95% dip UT) for 5 seconds		The mains power supply parameters and interference should be those of a typical commercial or hospital environment.
NOTE UT is the mains voltage prior to application of test voltages			

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

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

a The intensity of the fields from stationary transmitters, such as: radio stations, telephones (cellular, cordless), land mobile radio stations, amateur radio stations, AM FM broadcasting stations, television transmitters, cannot be estimated with sufficient accuracy. In order to assess the electromagnetic radiation from stationary radio frequency transmitters, measurements should be carried out at the place of installation of the medical device: IS-01. If the value of the electromagnetic field intensity at the place of installation of the medical device exceeds its immunity level, the correct operation of the device should be verified. If the medical device does not function properly, it may be necessary to: carry out additional measurements, change the orientation and/or location of the medical device and/or apply additional protective measures.

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

NOTE
The above explanations may not apply in all situations. Electromagnetic propagation is subject to absorption and reflection from structures, objects and people.

Appendix No. 1

Recommended agents for cleaning and disinfecting surfaces of products and elements made of glass, aluminum, powder-coated steel and plastics

PREPARATION	STEEL AND ALUMINUM	PLASTIC AND GLASS	DISTRIBUTOR/MANUFACTURER
MELISEPTOL	+	-	**Aesculap-Chifa Sp.z o.o.** ul. Tysiąclecia 14 64-300 Nowy Tomyśl tel: 061 4420100 fax: 061 4437505
DESPREJ	+	-	**Bochemie PL Sp. z o.o.** ul. Jana III Sobieskiego 11/E6 40-082 Katowice **tel:*+48694400019***
TRICHLOROL	+	+	**MEDILAB Sp. z o.o.** ul. Niedźwiedzia 60 15-531 Białystok tel./fax: (85) 7479300 tel./fax: (85) 7479301
SURFANIOS PREMIUM	+	+	
NEOFORM MED RAPID	+	-	DR WEIGERT POLSKA Sp. z o.o. ul. Wybrzeże Gdyńskie 6D 01-531 Warszawa telefon: +48 (22) 6160223, 6160231
INCIDIN ACTIVE	+	+	**Ecolab Sp. z o .o.** ul. Opolska 114 31-323 Kraków Tel.: 48-12-2616 100 Fax.: 48-12-2616 101
INCIDIN FOAM	+	+	
TERRALIN PROTECT	+	+	**Schulke Polska Sp. z o. o.** ul. Rydygiera 8 01-793 Warszawa Tel : (022) 568-22-02 (022) 568-22-03 Fax: (022) 568-22-04
PERFORM	+	-	
DESCOCID	+	-	**Antiseptica Dr. Hans-Joachim Molitor GmbH** Carl-Friedrich-Gaus-Strase 7, D-50259 Pulheim tel. +49 (0) 2234-98466-0 fax +49 (0) 2234-98466-11
ANTISEPTICA KOMBI SPRAY	+	-	
BIG SPRAY NEU	+	-	
VELOX SPRAY	+	+	**Medisept Sp. z o.o.** ul.Konopnica 193 c, 21-030 Motycz tel. +48815352222

Appendix No. 2

Card of performed repairs and product inspections

Product type..... Serial number ..... Date of purchase .....

Inspection No.	Inspection or repair date	Inspection type (annual, semi-annual)	Person performing the inspection or repair	Signature of the person performing the inspection or repair	Notes noted during the inspection or repair
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
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22					