

User Manual

OPERATING TABLE VIVAX

OT-02

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Manufacturer:

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In accordance with Annex VIII to Regulation (EU) 2017/745 of the European Parliament and of the Council, the table 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.



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 table.

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.

INFIMED

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1. Safety

The product has been designed and manufactured in order to ensure the safe use and maintenance of the device. In order to use the table safely it is necessary to read, understand and follow the rules set out in this manual.



This sign was placed on parts and mechanisms, which may cause a hazard to the patient's or staff's safety when not operated in accordance with the manual's guidelines.

Consulting the instruction is absolutely necessary.

1.1. General safety remarks

- Do not use, operate or service the table in a manner inconsistent with these instruction manuals.

- If the user notices that the parameters of the table do not comply with the description contained in the user manual, the product must not be operated and this fact must be reported to the supplier, service or manufacturer.

- The user has no right to make modifications or repair the product on their own. The occurrence of such a fact will void the warranty for the product. 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 to the competent authority of the Member State where the user or patient is resident.

1.2. General remarks concerning the safe use of the product

- Before using the table, make sure that the footrests and headrest are properly fastened and locked.

- Before performing functional movements, the possibility of rolling the table must be blocked (the lock is signaled by a glowing LED at the closed padlock button).

- After changing the angle of the footrest and locking its position with the handle clamp you should make sure that it is properly locked.

- When using the Trendelenburg and reverse Trendelenburg position as well as the lateral tilting of the table top, you should always remember to secure (fasten) the patient in order to protect him or her from sliding down from the operating table.

- When using electro-hydraulic Trendelenburg/reverse Trendelenburg position, lateral tilts, segments, and longitudinal slide, you should pay attention that they do not collide with the base or floor.

- When using the Trendelenburg and reverse Trendelenburg position the footrests, back rest and head rest should be either leveled or raised above level.

- The longitudinal slide cannot be adjusted if the table-top is in angular position in relation to the floor (for example Trendelenburg and reverse Trendelenburg positions and lateral tilts)



- When using the operating table near high-frequency medical devices and defibrillators you should observe the recommendations contained in the user's manuals of the devices in question. Improper use may cause dangerous accidents. There is a danger of inflicting serious burns on the patient through contact with metal parts of the table or its equipment.

- Collisions must be avoided when rolling the table.

- The floor under the table must be flat and free of obstructions.
- Do not roll the table over electrical wires.
- The table must be connected to a power source in accordance with the rating plate.
- Do not use power cords when there is a suspicion of damage.

- Do not connect the table in potentially dangerous places, for example where there is a danger of explosion.

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

- Do not disinfect the table in a disinfecting chamber and do not use the high pressure device.

- Do not use bleaching compounds, containing active chlorine or oxygen, for the washing and disinfecting of the table.

- Do not use any compounds containing ingredients which destroy the structure of plastics for the washing of plastic elements.

- Do not use alcohol-containing agents to wash and disinfect mattresses.

- When using an alternative drive (foot pump), special attention must be paid to the movements performed, due to the possibility of damage to the table through collisions, as the electronic limits and the anti-collision system do not work, e.g. in the case of folding two movements, e.g. lateral tilt with Trendelenburg.

- In tables equipped with electrohydraulic drive of table top segments or electrohydraulic longitudinal slide there is a limitation of angular ranges of movements of individual functions by anti-collision system that prevents damage to table elements.

- Do not use longitudinal slide after installing additional equipment in place of the footrests because of possible damage to the table and accessories

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

Failure to follow the above requirements, principally the ones concerning washing and disinfecting will result in a loss of warranty for the product



1.3. Technical parameters of operating tables InfiMED VIVAX OT-02

Total length of the table with 4 and 5 sections or modular table top	2100 mm
Total length of the table with a one-piece top for X-rays	2200 mm
Total length of the table with 6 sections table top	2300 mm
The length of the table with a top equipped with a backrest for shoulder arthroscopy	Approx. 2100mm
Table top width (in brackets for one-piece top)	500 mm (600 mm)
Total table top width with side rails	560 mm
Standard height adjustment range (extended adjustment range)	730 mm – 1080 mm (700 mm – 1150 mm)
Height adjustment range of a table with a one-piece top without sliding, with longitudinal sliding, with longitudinal and transverse sliding (without mattress)	660-1010mm, 730-1080mm, 800– 1150 mm
Lateral tilts adjustment (in brackets for one-piece top)	± 30° (± 20°)
Trendelenburg/reverse Trendelenburg adjustment (in brackets for one-piece top)	± 40° (± 20°)
Backrest adjustment (pneumatic)	- 45° ; +85°
Backrest adjustment (hydraulic)	- 35° ; +85°
Footrest adjustment	- 90° ; +25°
Footrest abduction	180°
Headrest adjustment	± 45°
Optional kidney bench adjustment (mechanic)	~120 mm
Optional kidney bench adjustment (hydraulic)	~120 mm
Optional longitudinal slide	350 mm
Optional transverse movement of the one-piece top	210 mm
Table mass (in brackets for one-piece top)	280 kg (250 kg)
Power	24 V
Batteries (sealed, maintenance-free)	12V, 7Ah, 2 pieces
Battery charging time	Approx. 3 h (up to 80% capacity)
Working time between battery charging	Up to 65 operations
Type of operations	Interrupted operation 2/18 min
Battery charger	Built-in
Charger power	230V ~ 50/60Hz
Power consumption from mains	2 A / 230 V
Maximum working load (in brackets for the bariatric version)	250 kg (450 kg)
Period of use	10 years
Degree of protection	IP-X4
Class of protection against electric paralysis	1
Application part type	В
	•



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

1.4. General requirements

The product should be used, maintained and serviced in accordance with the principles contained in this manual.

The table is designed to be installed and operated indoors only. Permissible temperature change within 12 hours not greater than 20°C.



It is forbidden to use, maintain and service the table in a manner contrary to this user's manual. It may cause damage for which the user will be responsible, and for which the manufacturer is not liable.

Any interference with the table elements contrary to the instructions, the use of equipment other than those offered by the manufacturer may be allowed only on the basis of written consent from the manufacturer.

The user must ensure that all the personnel which operates and uses the product knows, understands and applies this user's manual. Also user is obliged to ensure that the table is used only as intended and in appropriate conditions. The user is obliged to guarantee all the necessary means to provide safe and proper function of the product and to prevent any threats to life and limb of himself, his patients and third parties.

1.5. Description

The INFIMED VIVAX OT-02 operating table is made of stainless, acid-resistant steel and is designed to support the patient during all procedures and surgical and specialist operations.

The table InfiMED VIVAX OT-02 is equipped with multisectional or one-sectional table top, X-Ray permeable, on mobile base with central braking system. Vertical movement of table top and its lateral and longitudinal tilts are realized by electro-hydraulic drive. The functional movements of the tabletop segments can be supported pneumatically or hydraulically, and the longitudinal movement of the tabletop can be supported mechanically or hydraulically. The table top can be one-piece, X-ray-permeable, orthopedic, with four, five or six segments and can be interchanged (except for one-piece and orthopedic table top). It is X-Ray permeable on whole length (excluding orthopedic table top) and equipped with high quality removable, antistatic mattresses made of polyurethane of foam. Table can be also equipped with different additional accessories supporting particular positioning of the patient depending on type of performed surgeries.

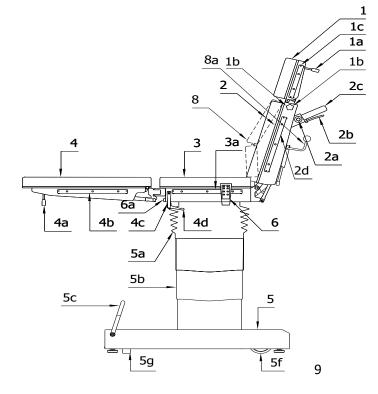
The INFIMED VIVAX OT-02 table can be optionally equipped with an alternative mechanical-hydraulic drive, a base with large wheels or a hydraulic travel lock. The alternative drive enables selected functional movements to be carried out, even in the event of a failure of the main drive or control system. The INFIMED OT-02 table is controlled using a wired remote control, and can optionally be implemented using a wireless remote control, a foot controller, a wall panel or a side control panel located on the table column.

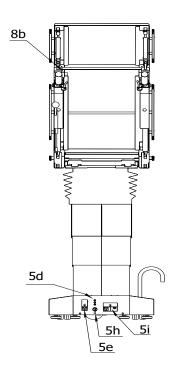


1.6. Description of table elements

Description of the components of the INFIMED VIVAX OT-02 table with a segmented top – version: OT-02-522, OT-02-422, OT-02-522OHN, OT-02-422OH, OT-02-525, OT-02-525OHN, OT-02-526OHN

No	Description	No	Description
1	Head rest segment	5	Mobile base with central lock
1a	Head rest adjustment lever	5a	Column rubber cover
1b	Fixation of head rests to back rest	5b	Column cover
1c	Side rail	5c	Central lock lever
2	Back rest segment	5d	Battery status indications
2a	Back rest adjustment	5e	Mains socket
2b	Lever of locking release	5f	Antistatic wheels
2c	Back rest handles	5g	Rotation wheel
2d	Side rail	5h	Potential equalization socket
2e	Detachable side segments	5i	Emergency power socket
3	Seat segment	5j	Foot pump drive lever
20	Cido reil	5k	Drive alternative function selection
3a	Side rail		panel
4	Foot rest segments	6	Wired remote control
4a	Foot rest adjustment	6a	Remote control socket
4b	Side rail	8	Optional kidney bench
4c	Foot rest abduction adjustment	8a	Kidney bench adjustment
4d	4d Fixation of foot rests to seat segment		Fixation socket for kidney bench adjustment lever

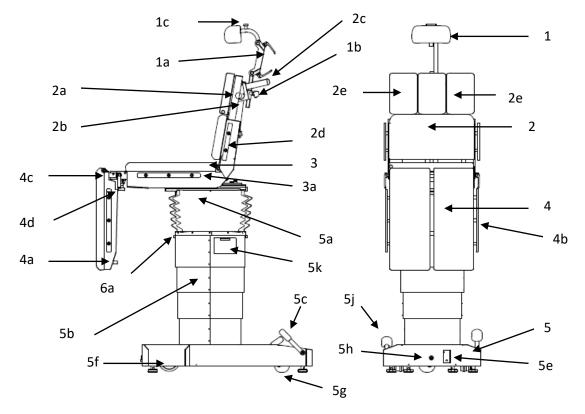






Description of the elements of the INFIMED VIVAX OT-02 table with shoulder arthroscopy backrest, version OT-02-322OH

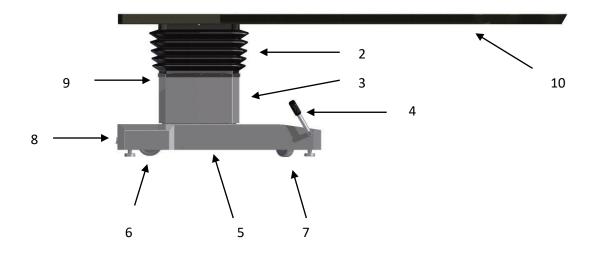
No	Description	No	Description
1	Specialistic head rest segment	4c	Foot rest abduction adjustment
1a	Head rest adjustment lever	4d	Fixation of foot rests to seat segment
1b	Attaching the headrest to the backrest	5	Mobile base with central lock
1c	Side rail	5a	Column rubber cover
2	Back rest segment for shoulder arthroscopy	5b	Column cover
2a	Back rest adjustment	5c	Central lock lever
2b	Lever of locking release	5e	Mains socket
2c	Back rest handles	5f	Antistatic wheels
2d	Side rail	5g	Rotation wheel
2e	Detachable side segments	5h	Potential equalization socket
3	Seat segment	5j	Foot pump drive lever
3a	Side rail	5k	Drive alternative function selection panel
4	Foot rest segments	6	Wired remote control
4a	Foot rest adjustment	6a	Remote control socket
4b	Side rail		





Description of the construction elements of the INFIMED VIVAX OT-02 table with a onepiece X-ray permeable table top – version OT-02-722HP

No	Description	No	Description
1	Mobile base with central lock	6	Antistatic wheels
2	Column rubber cover	7	Rotation wheel
3	Column cover	8	Potential equalization socket
4	Central lock lever	9	Remote control socket
5	Mains socket	10	One-piece table top



1.7 Electromagnetic compatibility

Medical device: **OT-02** is an electrical device. Electrical devices are a source of electromagnetic radiation and are themselves subject to its influence.

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

In the tables – point 7 *Characteristics of the electromagnetic environment* – the electromagnetic environment in which the **OT-02** medical device should be used is described. The user should follow the tips and warnings provided in the boards.

Use of different accessories, additional equipment, cables, spare parts than those offered and/ or recommended by the producer may cause an increase of emission and/ or decrease of bed's resistance to all electromagnetic phenomena.



Recommended distances between portable radio communication equipment and the product

Rated maximum			
output power of	150 kHz to 80 MHz	150 kHz to 800 MHz	800 MHz to 2.5 GHz
transmitter			
w	$d = 1, 2\sqrt{P}$	$d = 1, 2\sqrt{P}$	$d = 2, 3\sqrt{P}$
Rated maximum transmitter output power in watts In	distance in meters	distance in meters	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 trasmitters, the maximum output power of which is not specified above, the separation distance should be calculated according to the formulas provided. P is a power in watts (W) according to the declaration of the transmitter manufacturer.

NOTE The above guidelines may not be applicable to all cases. Propagated electromagnetic waves are absorbed and reflected from buildings, objects and people.

2. Transport and start-up

2.1. Transport

When transporting the table by means of transport, the table should be placed in the transport position. The transport position means a minimal lowering of the table top, lowering the segments of the backrest, headrest and footrests below the horizontal. During transport, the product must be protected against moisture and dust and immobilized. Do not move the table by grabbing it from the table top. To carry it, use straps that need to be pulled under the base of the table.

During transport, storage and unpacking of the product, the temperature change must not exceed 8-10°C per hour. Do not unpack the product before it has reached the temperature in the room intended for its installation.

In case of significant temperature differences between the transport temperature and the temperature of the room where the product will be used, the table should be left for a minimum of 12 hours in order to equalize the temperature level. After this period the table can be started.

Unless the transport packaging is clearly marked otherwise, you may not place the products in layers.

In the case of transporting the table in specific conditions (low temperature of surroundings) the method of transporting and securing the product has to be coordinated with the manufacturer.

2.2. Unpacking, storage and first start-up

The table is delivered by the manufacturer in a box with a total weight of approx. 300 kg. Do not unpack the table outside the building. Preparing the table for work should proceed in the following order:



- a) Make sure that the transport packaging has been left in the room where the table is to be used for a long time
- b) Open the shipping box and remove the table protection materials
- c) Take out and put aside all the additional equipment provided.
- d) Place the footrests, backrest, headrest in the "zero" position horizontal in relation to the ground
- e) Remove the table from the transport pallet with the help of additional people. **Do not lift the table by grabbing the elements of the tabletop.** Use the straps located under the base.
- f) Plug in the wired remote control and switch on the mains switch located under the mains socket flap.
- g) Carefully read the user's manual.
- h) Carry out the first start-up of the table according to the instructions in the next step of this manual.

If the product will not be used for an extended period of time, it should be stored under the following environmental conditions: temperature: $25^{\circ}C$ ($77^{\circ}F$) \pm $10^{\circ}C$ ($18^{\circ}F$), humidity: $50\% \pm 25\%$. The product must be turned off during storage. The switch must be in the "0" position. In case of longer storage, it should be connected to the power supply for 24 hours every 6 months to charge the batteries. The product cannot be stored when the batteries are discharged (the red LED on the panel is on).

The product is intended to be installed and operated only indoors with the following environmental conditions: temperature: $25^{\circ}C$ ($77^{\circ}F$) \pm $10^{\circ}C$ ($18^{\circ}F$), humidity: $50\% \pm 25\%$ and atmospheric pressure 700 to 1060 hPa.

2.3. Installation and first start-up

After completing all the necessary steps regarding unloading the table, the product should be placed in the desired workplace, meeting the requirements specified in these instructions. Then connect the mains cable to the socket on the table and the electrical outlet to charge the batteries. After charging the batteries (only the green LED is on after disconnecting the power cord), place the table in its working place, then press the lever blocking the passage.

After that the table must be connected to the equipotential installation by a cable via potential equalizing clamp or by antistatic floor.

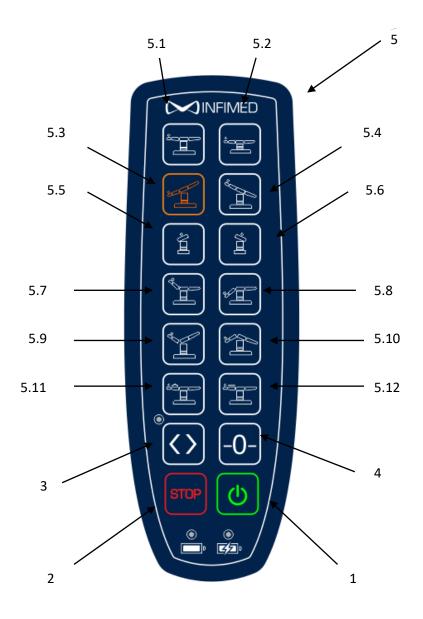
Perform the testing movements described in the manual further on, in the "Use and operation" section. During the test the elements should work silently and smoothly.

In the case the table is not fully operational, its use is not allowed. You should contact the supplier, maintenance service or the manufacturer. The use of a defective product may cause damage for which the user will be responsible, and for which the manufacturer is not responsible.



3. Use and operation

3.1. Description of remote controller and wireless remote controller



The cable remote is connected to one of two a socket located below the table top. In order to do this, place the plug in the socked (appropriate profiling of the plug prevents incorrect connection) and then tighten the mounting ring. The table (remote controller) is turned on by pressing the "1" button. To turn off the table or in emergency situation stop operation you should push again button "2". The operating buttons section is designated with the number "5". In order to use the selected function (represented by an appropriate symbol) you should turn on the remote (if it is turned off), and then press and hold the button representing the selected function. The function is activated for as long, as the given button is pressed. The button "3" is used for changing of table top orientation – after its activation the table top orientation is reversed by 180 degrees (lateral and longitudinal tilts) – that button should be used when the head and leg rest sections are exchanged. Button no "4" is



used to "zero" the table top position. Pressing and holding this button will result in the table seat and back rest taking a horizontal position in relation to the floor (optionally also backrest segment and kidney bridge, as well as longitudinal slide if the anti-collision system works).

In tables equipped with electrohydraulic table top drive or electrohydraulic longitudinal slide there is a limitation of angular ranges of movements of individual functions by anti-collision system that prevents damage to table elements.

To disconnect the remote control plug from the socket, pull back the securing ring and disconnect the connection.

3.2. Operations implemented with the remote controller

3.2.1. Raising and lowering the table top

The height of the table top is variable within the range specified in the product parameters. To set the table top to the desired height, turn on the wired remote control ("1" button), and then press and hold the appropriate "5.1" or "5.2" button. When holding the appropriate button, the tabletop

will be raised or lowered. When the end positions are reached, the table top will automatically stop.



When lowering the table top, you should pay attention so that the foot rest, backrest and headrest do not collide with the base and floor!

3.2.2. Angular change of the table top position

The change of the angular position of the table top is carried out within the range specified in the technical parameters of the table. To set the appropriate angular position, start the remote control ("1" button), and then press and hold the appropriate "5.3", "5.4" or "5.5", "5.6" button. The movement is carried out until the button is released. When the end positions are reached, the table top will stop automatically or earlier if the anti-collision system is activated.

When using the Trendelenburg and reverse Trendelenburg position as well as the lateral tilting of the table top, you should always remember to secure (fasten) the patient in order to protect him or her from sliding down from the operating table.

When changing the table top angle position, you should pay attention so that the foot rest, backrest and headrest do not collide with the base and floor!

When using the Trendelenburg and reverse Trendelenburg position the footrests, back rest and head rest should be either leveled or raised above level.

3.2.3. Table top levelling – "zero" position

To set the table top in a horizontal position in relation to the ground, turn on the remote control ("1" button), and then press and hold the "4" button. The button should be held until the table top is completely levelled (optionally also the backrest segment and kidney bench, as well as longitudinal



movement if the anti-collision system works). If the "4" button is released earlier, the table top will remain in the position it has currently reached.

3.2.4. Electro-hydraulic table top segments angle change

The change of the angular position of the backrest segment is carried out within the range specified in the technical parameters of the table. To set the appropriate angular position, start the remote control ("1" button), and then press and hold the appropriate "5.7" or "5.8" button. The movement is carried out until the button is released. When the end positions are reached, **the backrest will stop automatically**, or earlier if the anti-collision system is activated.

Optionally the table can be equipped with electro-hydraulic kidney bench adjustment. To control kidney bench adjustment there are two additional buttons 5.11 and 5.12, placed between the button for backrest segment adjustment and flex/reflex functions (replaceable with buttons for table top leveling).

Table version equipped in back rest sections operated by electro-hydraulic drive has also function "flex/reflex" activated by buttons "5.9" and "5.10". When pressing the button, the table top longitudinal angle and back rest are tilted. After reaching the extreme position the movement is automatically stopped.

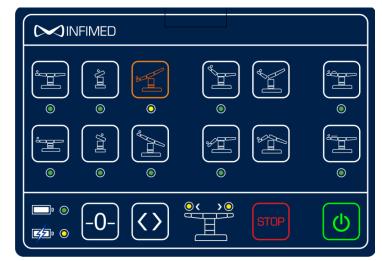


Optionally the table can be equipped with electro-hydraulic longitudinal slide adjustment. The longitudinal slide position can be changed within the range provided in the table technical parameters. The longitudinal slide will be limited by the anti-collision system if

the backrest is set below the level. The longitudinal slide can be activated by buttons "5.11 and "5.12" (interchangeably with buttons controlling kidney bench adjustment).



Do not use longitudinal slide after installing additional equipment in place of the footrests because of possible damage to the table or to additional equipment.



3.2.5. Alternative drive

Control panel for alternative hydraulic drive functions.



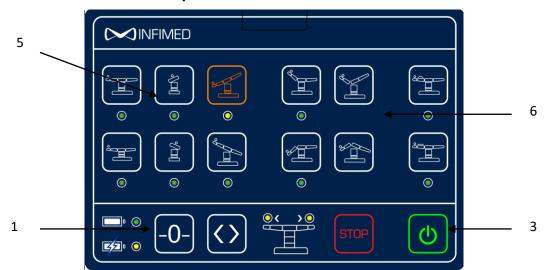
Operating table equipped with alternative drive has additional mechanic-hydraulic system controlled electrically with its own power supply. To perform any hydraulic movement of the table you should push green button "I", and then button indicating particular movement. Chosen function will be signalized with lighting diode. After choosing the function you can perform the movement pushing the foot lever placed in the basis, on alternative drive panel side. The movement is performed only during pushing the foot lever. To change the realized function, you should push the button indicating required function. Control panel after turning on will automatically turn off after 60 seconds and if necessary it should be turn on again. Pushing the button "STOP" turns off alternative drive immediately. During active operation of the table using alternative drive control panel, wire remote controller is not active. To turn the wire remote controller on, you should turn the alternative drive off using the "STOP" button or wait 60 seconds.

On the control panel there is an inactive button for leveling the table top and the Flex/reflex position.

Charging the batteries of the alternative drive takes place simultaneously with the charging of the batteries of the primary electro-hydraulic drive after connecting the mains cable to the socket and is not indicated on the panel of the alternative drive. The charge status of the batteries is indicated by a colored diode on the panel. If the LED is red, the batteries should be charged.



When using an alternative drive, special attention must be paid to the movements made, due to the possibility of damage to the table through collisions, as the electronic limits and the anti-collision system do not work, e.g. in the case of folding two movements, e.g. lateral tilt with Trendelenburg.



Additional control panel 3.2.6.

Additional control panel for electro-hydraulic drive functions.

Operating table can be equipped with additional control panel placed on the column of the table for electro-hydraulic functions. The panel is turn on with pushing the button "3". To turn the operating table off or to terminate its operation in emergency situation, push button "STOP". Functional buttons sector is indicated with no "5". To use particular function (represented with particular symbol), turn on the panel (if not active) and then push and press button representing chosen



function. The function is performed as long as you press the button. Button "1" is used for "leveling" of table top. After pushing and pressing his button seat segment will be adjusted to the level in comparison to the ground. Additional control panel after turning on, will turn off automatically after 30 seconds.

Optionally, the panel can have a hydraulically implemented longitudinal slide of the tabletop, the backrest segment, the kidney bench and the "flex/reflex" function – "6" buttons.

The panel has an indication of the battery charge level and the fact that they are charged from the mains – analogous to a wired remote control.

3.3. Operations implemented with mechanical elements

3.3.1. Adjustment of table top mechanical longitudinal slide

Before adjustment of table top mechanical longitudinal slide make sure whether the foot rests and the back rest are in a position above the table top level. If they are below the table top level it is necessary to level them or raise them above the level.

Do not perform adjustment of table top longitudinal slide when it is at an angle to the floor (e.g. In Trendelenburg and reverse Trendelenburg position or laterally tilted).

After performing the above settings in order to perform adjustment of table top longitudinal slide you should stand behind the back rest, hold the handles with both hands, press the levers on both handles at the same time and move the table top. The horizontal movement may be only performed to one of seven positions. After releasing both levers at once the movement will be locked.

It is absolutely necessary to make sure that the lock works and that you cannot (despite releasing the lever) move the tabletop.

3.3.2. Headrest angle adjustment

The headrest angle adjustment can be performed within the range provided in the technical parameters. In order to set an appropriate angle of the headrest you should stand behind the backrest, hold the lever with both hands while placing your thumbs on the headrest frame, and then pull the levers towards yourself with both hands, which will move the headrest above level. In order to lower the headrest, the same action should be repeated, but after releasing the levers they should be still held, and at the same time you should apply force to lower the headrest by pushing it downwards. In the case when the levers are released earlier the headrest will be locked in its current position.

3.3.3. Mechanical backrest segment angle adjustment

The mechanical backrest segment angle adjustment can be performed within the range provided in the technical parameters. In order to set an appropriate angle of the backrest you should stand behind the backrest, hold the handles with both hands, press the buttons (placed on the sides of the handles) with your thumbs and change the backrest angle by raising or lowering it. After releasing the levers, the backrest movement will be locked. The change of the backrest segment position is



performed by gas springs. However, they only support the user in the changes of position, and obtaining a proper angle requires the use of physical force.

The optional shoulder arthroscopy back rests additionally include two (lateral) removable segments for shoulder surgery. The removable segments are mounted and disassembled using pressure knobs. To attach the side segment, make sure that the pressure knobs are unscrewed tightly enough, then take the segment (standing behind the backrest) and slide it into the mounting socket in the frame. Once the segment is fully seated in the slot, tighten the pressure knobs. Disassembly is done in reverse order.

If the table is equipped with electrohydraulic longitudinal slide it will be blocked by the anti-collision system in the event of danger of collision or danger for the patient (slipping in the chair position) and it is necessary to change the mechanical backrest by personnel before resuming the movement.

3.3.4. Footrests angle adjustment

The footrests angle adjustment can be performed within the range provided in the technical parameters. The angle change is performed separately for each footrest. In order to set an appropriate angle, you should stand in front of the footrest, hold the footrest with one hand and the lever placed below the footrest with the other hand. Then raise or lower the footrest while pulling the lever towards yourself. It should be remembered that after pulling the lever the footrest will rise

> upwards (when not loaded down). After releasing the lever, the footrest position will be locked.



It should be noted that with a minimum lowering of the table, the footrest may collide with the base. In order to avoid it, the lower extreme position of the footrests should be set only in the position of the raised tabletop.

When performing the anti-Trendelenburg position, the footrests may collide with the base

3.3.5. Footrests rotation adjustment

The adjustment of the rotational position of the footrests is carried out within the range specified in the technical parameters of the table. The appropriate angle of the footrests is achieved by releasing (raising) the handle, then turning the footrest by a given angle and locking the handle again.

Make sure that the handle is properly clamped.

3.3.6. Mechanical kidney bench angle adjustment

The angular position of the kidney bench is adjusted within the range specified in the technical parameters of the table. To change the angle of inclination of the kidney bench, stand behind the headrest, fix the lever 8a in the socket 8b and rotate, the bench will tilt above the horizontal. In order to lower the kidney bench, repeat the above steps, but the lever should be turned in the opposite direction.



3.4. Assembly and disassembly of selected elements

3.4.1. Assembly and disassembly of headrest (or extension segments)

The headrest (or extension segments of modular table top) is mounted to the backrest segment. For this purpose, there are used dedicated headrest assembly clamps. In the backrest segment there is a yoke with the bolt placed in upper part of headrest joint (or extension segment). Locking is made with clamping knobs, which rises the locking hook in this joint.

In order to mount the headrest or extension segment, you should make sure the clamping knobs are appropriately unscrewed, then hold the headrest with both hands, and evenly place the bolts of joints on yokes. You should pay special attention to pressing the headrest uniformly, otherwise its assembly may be difficult. After placing the bolts of joints on yokes completely you should screw in the clamping knob. The disassembly of the headrest is performed in a reverse order.

3.4.2. Assembly and disassembly of footrest

The footrest is mounted to the seat segment. For this purpose, there are used dedicated footrest assembly clamps. In the seat segment there is a yoke with the bolt placed in upper part of footrest joint. Locking is made with clamping knobs, which rises the locking hook in this joint.

In order to mount the footrest, you should make sure the clamping knobs are appropriately unscrewed, then hold the footrest with both hands, and standing in front of seat segment evenly place the bolt of joint on yoke. After placing the bolt of joint on yoke completely you should screw in the clamping knob. The disassembly of the footrest is performed in a reverse order.

Before using the table, you should make sure that the footrests are properly assembled.

3.4.3. Assembly and disassembly of mattresses

Mattresses are removed without any tools. Both when the Velcro mounting and when mounting bolts are used the removal of mattresses requires the application of appropriate physical force and tearing the mattress from the surface of the given section. The installation of the mattress requires placing the mattress in the appropriate position and pressing it to the surface.

3.5. Table mobility

The table base is equipped with a set of wheels which enable moving the table in all directions. In order to prevent the table from moving the table base is equipped with a movement lock system. The best method for moving the table is placing the table top in a following position: foot rests set at an angle of approx. 45° downwards, back rest and head rest approx. 30° upwards. After setting the table in such a manner the movement lock should be released (press the "brake lever" button pending the diode near button will switch off), hold both levers in the backrest segment and by applying an appropriate physical force move the table. In order to lock the table from moving press the "brake lever" button pending the diode near button will switch on signalizing working of hydraulic drive block. Special feet will be extended, on which the table will stay immobilized. Make sure that the feet are extended.



4. Batteries charging

The table is equipped with a charger which enables the charging of the table batteries, of both main and alternative drive. The charging system is started by inserting the appropriate end of the power cord in the socket located in the table casing, and putting the plug in the electric power socket, and toggling the switch located in the table casing from position 0 to 1.

Do not operate when the table is connected to a power source

The table must be connected to a power source in accordance with the rating plate. Do not use the power cable when suspecting that it is damaged. Do not connect the table in potentially dangerous places, for example where there is a danger of explosion.

A built-in LED indicator is built into the wired remote control to indicate the charge status of the batteries. When the green LED is on, there is no need to recharge. As the energy level in the batteries decreases, the color of the LED will change. The following indications may occur:

Green LED – batteries charged

Orange LED – battery charge on a level of 60% - you may connect and charge

Red LED – battery charge below a level of 30% - charging of batteries is absolutely required

After connecting the power supply, the yellow diode will light indicating that they are charging. Charge the batteries for at least 3 hours if they have been discharged to the red indication. The process will end automatically when the batteries are charged in a shorter time. If the user finishes the charging process earlier, after disconnecting the power supply, the LEDs corresponding to the battery charge level will light up.

The nominal operating time of the batteries is approx. 65 operations. However, this period may be shortened depending on the intensity of use of its electro-hydraulic drives.



Do not store the table with discharged batteries - if the product is not used for more than a week, turn off the power switch, and after a longer period of non-use, the batteries should be charged - at least once every six months.

When replacing batteries, always replace the set.

5. Static charge prevention

The table construction enables securing the output path of the potential flux through the use of antistatic wheels and antistatic mattresses. Operating table should be used on antistatic floor. If there is no antistatic floor, the table must be connected to the equipotential installation by a cable via potential equalizing clamp. The equipotential cable is a standard table accessory.



6. Collision hazard

It is possible to set the table so that in some extreme positions, especially when using additional equipment mounted on side rails, mechanical collisions are possible. You should pay attention to avoid such a situation, as not to damage the table or additional equipment.

You should operate the table consciously, with caution and full responsibility.

7. Assessment of correct operation

Before each first use during the given day the correct operation of the table should be assessed.

How to assess the correctness of functioning:

- a) Place the table in the required position and lock it from moving. Then apply a certain force to try to move the table in any direction. In such a situation no movement should occur.
- b) Verify the action of mechanisms controlled with gas springs and appropriate releasers. After regulating the position appropriately (see the Maintenance and repairs section) there should be no possibility to change the position of various segments without pressing appropriate release mechanisms and applying appropriate force.
- c) Check for loose mechanical connections that make it difficult to use the table correctly.
- d) Verify the functioning of the electro-hydraulic drive by performing appropriate operations using the remote controller
- e) Verify the battery charge level by looking at the LED indicator in the table case.

If no inaccuracies or damage is detected during such a test and no worrying sounds were heard the table may be used. Otherwise, see the point on faults and defects.

In the case the table is not fully operational, its use is not allowed. You should contact the supplier, maintenance service or the manufacturer. The use of a defective device may cause damage for which the user will be responsible, and for which the manufacturer is not responsible.

8. Defects and faults

Defects and faults detected in the product by the operating personnel should be immediately reported to the person responsible for technical maintenance at the given station. This person, after checking the possible defect and its cause is obliged to contact the maintenance service or the manufacturer for a consultation and in order to obtain possible indications for further actions. The product which may not be safely used due to mechanical or electrical damage may not be used until repaired.



9. Cleaning and disinfecting

For the washing and disinfecting of the product you should use washing agents which do not contain active chlorine or oxygen. After disinfecting, the product should be washed with distilled water in order to remove water stains. Use a soft, sterile cloth for a thorough drying.

Do not disinfect the product in a disinfecting chamber.

Before the disinfecting the power cord should be disconnected.

Do not use a stream of water to wash the table.

Do not use any compounds containing ingredients which destroy the structure of plastics for the washing of plastic elements.

Do not use disinfecting compounds containing alcohol for the washing and disinfecting of mattresses.

The list of disinfection agents is included in the <u>Annex no. 1</u> to the user manual.

Failure to follow these requirements will cause the loss of the product warranty.

10. Emergency power supply (optional)

The table can be equipped with a connector for connecting an emergency power supply (the battery set is an additional commercial item delivered separately from the table).

11. Maintenance, service, and repairs

All repairs of the product are performed by an authorized maintenance service or a direct representative of the manufacturer. The user is not authorized to perform any modifications and repairs to the product without special training and authorization. After obtaining a written authorization from the manufacturer by the customer the manufacturer will provide all the information necessary to perform the repair. In order to ensure a long and trouble-free operation of the table only original parts provided 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 the repairs and maintenance should be registered in the Card of Repairs attached to the User Manual of the product (Annex 2).

12. Technical inspection and periodical inspection

In order to ensure the proper technical condition of the product during its use, the user is obliged to submit the product to a periodical technical inspection. The inspection is performed by an authorized maintenance service or by a direct representative of the manufacturer. The inspection is performed at the user's cost.



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

Each 12 months the following should be performed. Each 24 months the following must be performed:

- detailed technical inspection
- functionality testing
- electric and hydraulic installation testing
- lubrication of movable elements

In order to ensure the proper, safe operation of the table the user should check the technical condition of the device at least once every 6 months. This check should be performed as follows:

- a) Perform all the operational movements which are possible to command with a remote controller. Verify whether they correspond to the ones described in this manual.
- b) Perform all the operational movements which use mechanical elements.
- c) Check all screw connections that can be accessed without removing the covers

13. Removing of potential problems and diagnostic of the table

a) the table does not make movements after switching on the remote control

- verify the battery charge level
- verify whether the remote controller plug is secure in the socket
- verify the condition of the remote controller cable
- b) the table may not be moved
- verify whether the foot lock is not on
- verify whether the base has not collided with element on the floor
- c) the table is unstable
 - verify whether there are not destabilizing elements below the foot
 - verify the regulation of the foot

In case of doubts contact the manufacturer in order to obtain the necessary help and explanations.

14. Product liquidation

The user, making decision of resigning from further product exploitation, is obliged disinfect the product (the non-disinfected product according to rules concerning environmental protection is dangerous waste). There are three ways of proceedings:



- 1. Give the liquidation order to the producer.
- 2. Give the liquidation order to the company, having necessary attestation for liquidation or neutralization products in the way assuring protection of life, health of people and environmental protection.
- 3. Undertake liquidation itself, provided having the staff able to disassemble the product.

The rules for handling waste are specified in the Waste Act of December 14, 2012



15. Additional accessories

- One position clamp	EB-01
- Multi position clamp	EB-02
- Knee support	EB-03
- Angle arm support	EB-04
- Arm support	EB-05
- thigh holder	EB-06
- Side-shoulder support	EB-07
- Side support	EB-08
- Anesthetic frame	EB-09
- Anesthetic frame with adjustable width	EB-10
- Infusion holder	EB-11
- Hand/shank holder	EB-12
- Support for meniscus operation	EB-13
- Arm support, height adjustable	EB-14
- Arm support on a ball joint	EB-15
- Leg strap	ES-01
- Thigh strap	ES-02
- Abdominal strap	ES-03
- Hand/wrist strap	ES-04
- Gynecological bowl	ES-05
- Urological bowl	ES-06
- Holder for additional equipment, mobile	ES-07
- Holder for arm operations	ES-08
- Holder for tubes	ES-09
- Tray for additional accessories	ES-10
- X-ray tray	ES-11
- Chest support	ES-12
- Attachment for knee operations	ES-13
- Pubic support	ES-14
- Leg support, not-divided	ES-15
- Proctological attachment (without clamps)	ES-16
- Side rail extension	ES-17
- Table top extension	ES-18
- Strap for anesthetic frame	ES-19
- Table top bariatric, side extension	ES-20
- foot supports	ES-21
- side support to the table top	ES-22
- lithotomic stirrups	ES-23
- X-ray translucent plate	ES-30
- Orthopedic attachment with two extension devices and support roll	EO-01
-Bar support	EO-02



-Leg support	EO-03
-Support for plastering	EO-04
-Heel holder	EO-05
-Foot support	EO-06
-Clamp for orthopedic attachment supports	EO-07
- Knee operation attachment for orthopedic attachment (without extension device)	EO-08
- Hip support for side position	EO-09
- Support for orthopedic attachment arms	EO-10
- Knee support for side positions	EO-11
- Trolley for installation of orthopedic attachment	EO-12
- Mobile stand for additional equipment of orthopedic attachment	EO-13
- Leather shoes for orthopedic attachment	EO-14
- Leather shoes for orthopedic attachment - small	EO-15
- Attachment for hand operating	EO-20
- support roller for hand surgery	EO-21
- Attachment for shoulder operations	EO-30
- specialist headrest with adjustable track	EN-01
- specialist aluminum headrest	EN-02
- specialist headrest with a small flat mattress	EN-03
- specialist headrest with a large flat mattress	EN-04
- support for the doctor's hands	EN-05
- specialized horseshoe headrest	EN-06
- helmet type headrest	EN-07
- mounting adapter for specialist headrests for table backrest	EA-01
- DORO specialist mounting adapter for table backrest	EA-02
- large stainless steel clamp for the carbon tabletop	ER-01
- small stainless steel clamp for a carbon tabletop	ER-02
- large clamp transparent for X-ray radiation for a carbon tabletop	ER-03
- small clamp translucent to X-ray radiation for a carbon tabletop	ER-04
- eccentric handle	ER-05
- table top transparent for X-ray radiation	ER-06



16. Electromagnetic emissions

Medical device operating table *OT-02* is to be used in electromagnetic environment specified below. The customer or the user of medical device the *OT-02* should assure that it is used in such an environment.

Emission type	Classification	Electromagnetic environment – guidance		
emission RF CISPR 11	Group 1	Medical device operating table OT-02 produces energy with radio frequency only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interference in nearby electronic equipment.		
emission RF CISPR 11	Class B	Medical device operating table OT-02 is suitable for use in all		
Harmonic emission IEC 61000-3-2	Class A	establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies		
Voltage fluctuation, flickering IEC 61000-3-3	Complies	buildings used for domestic purposes.		

Medical device operating table <i>OT-02</i> is to be used in electromagnetic environment specified below. The customer or the user of medical device the <i>OT-02</i> should assure that it is used in such an environment.					
Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment – guidance		
Electrostatic discharge (ESD)	\pm 6 kV contact	\pm 6 kV contact	In the location of OT-02 use the floor should be wooden, concrete or covered with ceramic tiles. If the floor is covered with a particular the relative burndity about the statement of the sta		
IEC 61000-4-2	\pm 8 kV air	\pm 8 kV air	with a synthetic material, the relative humidity should be at least 30%.		
Surge	± 1 kV differential mode	± 1 kV differential mode	Mains power quality and interferences should be that of a		
IEC 61000-4-5	± 2 kV common mode	mode	typical commercial or hospital environment		
Series of quick	± 2 kV for power supply lines	± 2 kV for power supply lines			
transitory stages		supply lines	Mains power quality and interferences should be that		
IEC 61000-4-4	\pm 1 kV for input/	\pm 1 kV for input/	typical commercial or hospital environment.		
	output lines	output lines			
	< 5% U⊤ (>95% dip U⊤)	< 5% U⊤ (>95% dip U⊤)			
	for 0.5 cycle	for 0.5 cycle			
Voltage dips, short interruption and voltage variations on power supply input	40% U _T (60% dip U _T) for 5 cycles	40% U _T (60% dip U _T) for 5 cycles	Mains power quality and interferences should be that of a typical commercial or hospital environment.		
lines	70% U⊤	70% U _T			
IEC 61000-4-11	(30% dip U _T) for 25 cycles	(30% dip U_T) for 25 cycles			
	< 5% U⊤	< 5% U⊤			
	(>95% dip U _T)	(>95% dip U _T)			
	for 5 seconds	for 5 seconds			
NOTE UT is the a.c. r	mains voltage prior to a	pplication of the tes	st level		



Immunity test	IEC 60601-1-1 Test's level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used not closer to any part of the operating tables OT-02 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separating distance:
Transmitted disturbances induced by fields with radio frequencies IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1, 2\sqrt{P}$
Electromagnetic field with radio frequency IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1, 2\sqrt{P}$ 80 MHz to 800 MHz $d = 2, 3\sqrt{P}$ 800 MHz to 2.5 GHz
			where P is the maximal output power of th transmitter in watts (W) according to th transmitter manufacturer and d is th recommended distance in meters (m).
			Field strengths from fixed RF transmitters as determined by an electromagnetic sit survey, ^a should be less than th compliance in each frequency range. ^b
			Interference may occur in the vicinity of equipment marked with following symbol:
			The operating table should be observed to verify normal operation, if the table is used near to devices signed by this symbol.

a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which medical device the operating table **O7-02** is used exceeds the applicable RF compliance level above, the operating table **O7-02** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating medical device the operating table **O7-02** and/or using of additional precautionary measures.

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

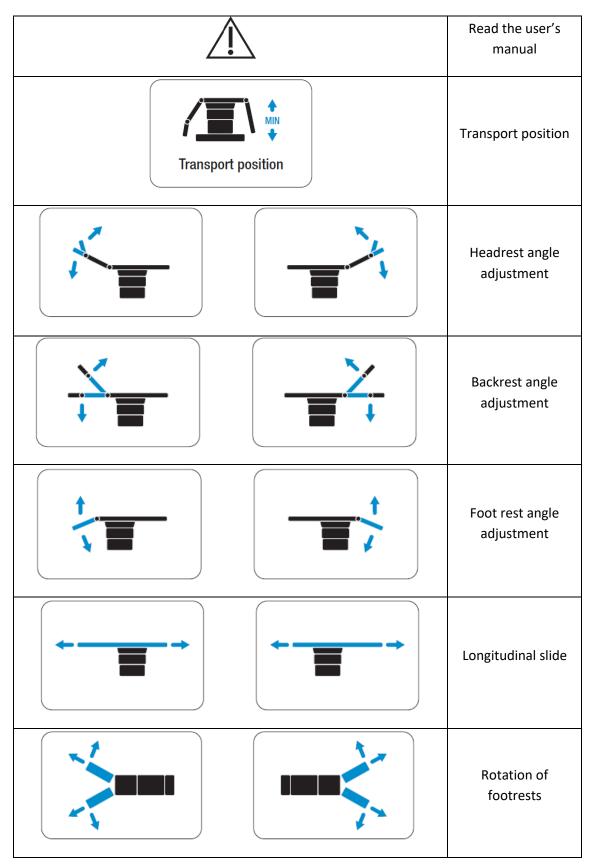
NOTES

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



17. Table labels

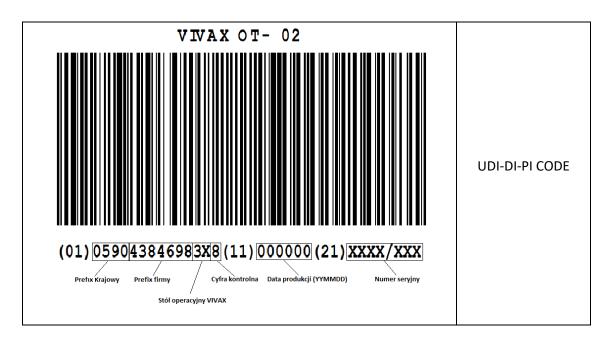
The following labels can be found on the covers and frames of the table top:



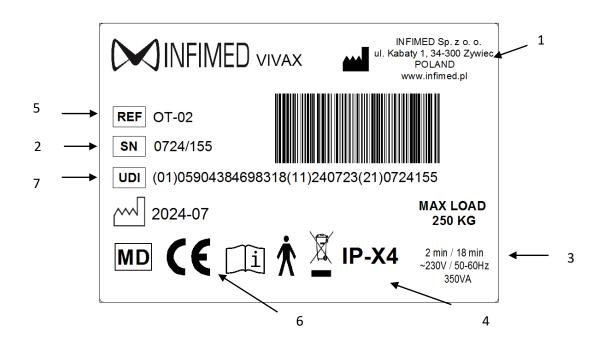


!ATTENTION! Do not use for cleaning and disinfection of operating table disinfecting means including chlorine or active oxygen.	Disinfection
	Brake lever
Method of charging the batteries LED signalization • Graen diode - batteries charged. • Orange diode - approx 50% of full charge. • Red diode - low level of batteries charging - necessity of immediate start of charging. Charging instruction Connect the mains cord to socket in the operating table. Press the switch into position 1. Time of full charge: min. 3 h. After finishing of charging the power supply cable must be disconnected. In the case of planned disuse of the table for longer period, it is necessary to fully charge the battery and then set main switch in position 0. Storage of the table with discharged battery may cause damage of the battery.	Batteries charging
$\begin{array}{c} \hline \\ \hline $	Rating label
	Potential equalization socket









Description of designations:

- 1. Manufacturer's name, logo and address
- 2. Serial number
- 3. Type of operation for elevating column 2 minutes of uninterrupted work require 18 minutes break
- 4. Designation of the application part (B type) and IP class (IPX4)
- 5. Product symbol
- 6. CE mark
- 7. UDI-DI-PI Code

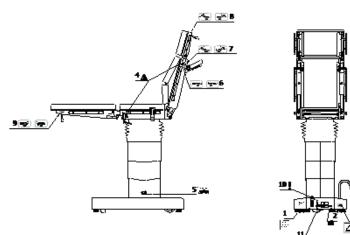


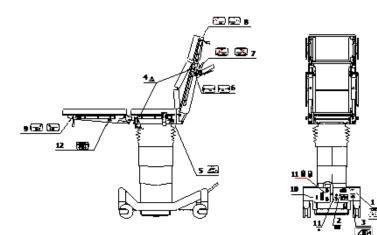
Data presented on the label:

No.	Element:	Pictogram to be used
1.	Company logo	
2.	Name and address of the manufacturer	
3.	Product name	Operating Table
4.	Catalog number	REF
5.	CE mark - product compliance with the requirements of MDR Regulation 2017/745	CE
6.	IP protection level	IP-X4
7.	Application part (type B)	Ŕ
8.	Serial number	SN
9.	Production date	
10.	Read the Instructions for Use	i
11.	Note	\triangle
12.	Medical device	MD
13.	UDI code	UDI



18. Placement of labels on the table's construction





Description:

1 – Description of the battery charging method

- 2 Rating label code UDI-DI-PI
- 3 Method for preparing the transport position
- 4 Read the user's manual (warning sign)
- 5 Description of forbidden disinfecting agents

- 6 Longitudinal movement of the table
- 7 Back rest angle adjustment
- 8 Head rest angle adjustment
- 9 Foot rest angle adjustment
- 10 LED indicator
- 11 Potential equalization socket

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



Annex no. 1

Agents recommended for cleaning and disinfection of surfaces of products and elements made of stainless steel and antistatic polyurethane.

AGENT	STAINLESS STEEL	ANTISTATIC POLYURETHANE	DISTRIBUTOR/PRODUCER
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:+ <i>48694400019</i>
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
ANTISEPTICA KOMBI SPRAY	+	-	Carl-Friedrich-Gaus-Strase 7, D-50259 Pulheim tel. +49 (0) 2234-98466-0 fax +49 (0) 2234-98466-11
BIG SPRAY NEU	+	-	
VELOX SPRAY	+	+	Medisept Sp. z o.o. ul.Konopnica 193 c, 21-030 Motycz tel. +48815352222



Annex no. 2

Card of repairs and inspections of product

Operating table type Serial no Purchase date.....

Inspection no	Inspection or repair date	Inspection type (annual, six- month)	Person performing inspection or repair	Sign of person performing inspection or repair	Comments concerning inspection or repair
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
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