USER MANUAL

Operating table
SU-14

Factory number: .....
.....
.....

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FAMED
Medical Solutions

FAMED ŻYWIEC Spółka z o.o.

Appendixes: 2, 3, List of Spare Parts.

As provided in the Directive on Medical Equipment 93/42/EEC of 14 June 1993 this is first risk class product.
The producer declares that the product meets basic requirements of the directive contained in Appendix 1.
The compliance procedure was carried out in accordance with appendix VII of the directive.

CE

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Dear Clients,
Congratulations on choosing the right product, we wish you would find a lot of satisfaction while operating it.
Please read this manual very carefully as it includes all the vital information and notes from the producer concerning proper installation and maintenance of the product as well as its service.

FAMED ŻYWIEC Spółka z o.o.

General notes

- ***The use, maintenance as well as servicing of this product performed in other ways than those, which have been stated in this manual is forbidden and may result in damages, which will encumber the user and which will not be a matter of producer's responsibility.***
- ***When the operation and parameters of the product do not match the description in item 'Operation' in this manual, the use of the product is not allowed and any defects have to be reported to the producer or the supplier.***
- ***Every repair of the product must be done by a factory or an authorized service and recorded on the list of repairs, which is supplied with the guarantee certificate. Disregarding this requirement will cause the guarantee for the product to be invalid.***
- ***Before starting any repairs the table must be disconnected from mains.***
- ***Operation table has been designed for a patient of 200kg of weight.***

Notes concerned with safety

The sign shown below says: : *"Warning! - Follow the instructions for safe use ".*

A label showing this sign is placed on any parts or mechanisms, which may prove to be harmful to the patient or the personnel if their operation does not comply with the descriptions found in this Operating Manual.

- ***Do not move the table when it is connected to the main power supply. Before moving the table, remove the power cord from the mains.***
- ***The table should not be in the place which obstructs its disconnection from the mains!***
- ***Throughout surgical procedures table wheels should be blocked.***
- ***Do not lay patient's torso on the footrest segment.***
- ***During carrying out angle adjustments or lowering operation table's height, anyobstacles must be removed from below the table's surface.***
- ***During changing the position of the table top segment should not extend belowor between elements of tabletop.***
- ***Do not shift operation table's position with installed orthopedic attachment,proctology attachment, installed gynecological segment or installed shoulder operation attachment due to danger of capsizing the table.***

- ***Lock operation table in given position before transporting a patient.***
- ***When using the table close to medical equipment working on high frequencies and defibrillators one should closely follow operating instruction for that equipment. Improper operation may become a source of dangerous accidents. There is a danger of serious burning of the patient through the contact with metal parts of the table or its equipment.***
- ***Throughout surgical procedures the table must be connected to the installation of potential equalization in the operations room.***
- ***You must make sure, that accessories are properly fixed to the tabletop.***
- ***When changing operation table's position you must avoid any collisions between the table and accessories.***
- ***Not original accessories may be applied only after consulting with Famed Żywiec company about their use.***
- ***Operation table's electrical conductivity must be checked once a year. The check should be carried out by trained service personnel.***
- ***Avoid endangering patient's respiratory system, neural pathways and circulatory system by ensuring the patient is in proper position and by observing his/her condition.***
- ***When performing longitudinal (Trendelenburg or reverse Trendelenburg) and lateral tilt, patient should be secured against uncontrolled sliding down from the operating table. Use shoulder supports, supporting rollers, side supports, belts and grips as securing elements.***

Notes concerning: start-up, operation and use

- ***The table, during use, should not be in the place which obstructs its disconnection from the mains!***
- ***When performing longitudinal (Trendelenburg or reverse Trendelenburg), backrest should be in zero position or above the horizontal level.***
- ***When anti-trendelenburg function is performed, footrests may collide with the basis.***
- ***When performing Trendelenburg function or functions downward movement may take place collision with the base of the backrest (backrest tilted down).***
- ***Adjusting angle position of a back rest requires manual operation.***
- ***The table should be moved by 2 people at least.***
- ***Do not move table with workload (patient).***
- ***The table should be moved in minimal height.***
- ***The floor under the table should be free from any obstacles.***
- ***When rolling the table avoid collisions.***
- ***Do not roll the table over electric cables.***
- ***The table has to be connected to mains in consistence with its name plate.***
- ***Do not use the cable when it is damaged or its insulation is worn out.***
- ***Do not connect the table to mains in places where there is a danger of an explosion.***
- ***Do not store a table with flat batteries (a red diode is illuminated on a controlling device during any movement).***

- ***When batteries need to be exchanged, do always exchange a set of two batteries, exchange of a single battery causes limitation to operating time of a table and quick wear of a new battery.***
- ***Hand support should be fixed on table strip with a multi-position grip which makes angular movement of the support possible.***
- ***If it is necessary to replace oil or a battery (dangerous waste), one should follow existing environmental protection regulations.***
- ***Hand controller is the obligatory accessories for surgical tables.***
- ***Hand controller must be within reach of the medical staff.***

Notes concerning disinfecting

- ***The product must not be disinfected in disinfecting chambers!***
- ***No bleaching agents (containing active chlorine or oxygen), caustic or corrosive chemicals are allowed!***
- ***No agents destroying the structure of plastic (organic solvents) can be applied to the plastic elements!***
- ***No disinfecting agents containing alcohol are allowed for cleaning of polyurethane elements (mattresses).***
- ***Before disinfecting disconnect the table from mains pulling out the cable!***

Disregarding the above requirements concerning cleaning and disinfecting shall result in losing the guarantee for the product!

Contents

1. Proper use and application

1.1 Use

Operating table SU-14 is designed for supporting the patient during carrying out treatments and operations. The table with the proper accessories can be used for treatments and operations in the range of general surgery, vascular surgery, cardio surgery, neurosurgery, urology, proctology, gynecology, laryngological, ophthalmology, endoscopies, laparoscopy, traumatic, oncology, dental, plastic surgery and others. Table top segments are X-ray permeable.

1.2 General requirements

The product is intended to be used indoors. Required climatic conditions: temperature from +10 to +45ºC, acceptable change of surrounding temperature during 8 hours should not exceed 20°C, relative humidity of the air should range from 30 to 80%, atmospheric pressure from 700 to 1060 hPa. The product should be used, maintained and serviced according to the instructions contained in this manual.

Caution!

Using, maintaining and servicing the product in other way than indicated in this manual is not permitted and may lead to damages for which the user is to blame and for which the producer is not responsible.

Installation of other accessories than those offered by the producer for the product is allowed only on the basis of a written acceptance of the producer.

1.3 Duties of the user

User: any individual or corporate body who uses the product as its owner, lessee, pledge or who has a different right to the product as well as an entity who uses the product on its own or on whose behalf it is used.

The user must ensure that the product shall be used exclusively in conformity with its destination and that it is used in appropriate conditions and in consistence with this manual. The user is also obliged to take all necessary precautions in order to prevent all life and health hazards concerning the user, patients and any third party. Only authorised persons who underwent special training and are acquainted with this manual may operate the product. The user must also ensure that all persons who operate the product have read, understood and apply instructions contained in this manual.

1.4 Description of product

The operating table consist of table base and table top that are permanently connection.
In standard version the table has a mobile base , equipped with central blockade, which is released with a foot lever.
The table-top consists of segments, which number and configuration has constants number and configuration (according to a customer special order this number will be change). Segments of table top are X-ray permeable. The table top is provided with polyurethane mattresses. On both sides of the top there are side strips which allow installing accessories.
Change of the angle of table top segments as well as movement of the column are adjusted by mechanic electro-mechanics systems. In standard version the electric and electromagnetic movements of table can be controlled by wire-connected controller.
Thanks to the wide range of offered accessories the table can be used for different types of operations according to client wish. List of accessories you can find in Paragraph 4 - *Installation and operation of accessories*.
The main power outlet is connected to the table by the power cord. In order to disconnect, the user must unplug the power cord from the main power outlet.

The producer reserves the right to introduce in the product structural modifications resulting from technical progress which are not covered in this user manual.

The producer reserves that all parameters and accessories can be modified or change, especially construction, technology and materials, not lowering accepted parameter technically - user and safeties of products.

1.5 Components and Functions description

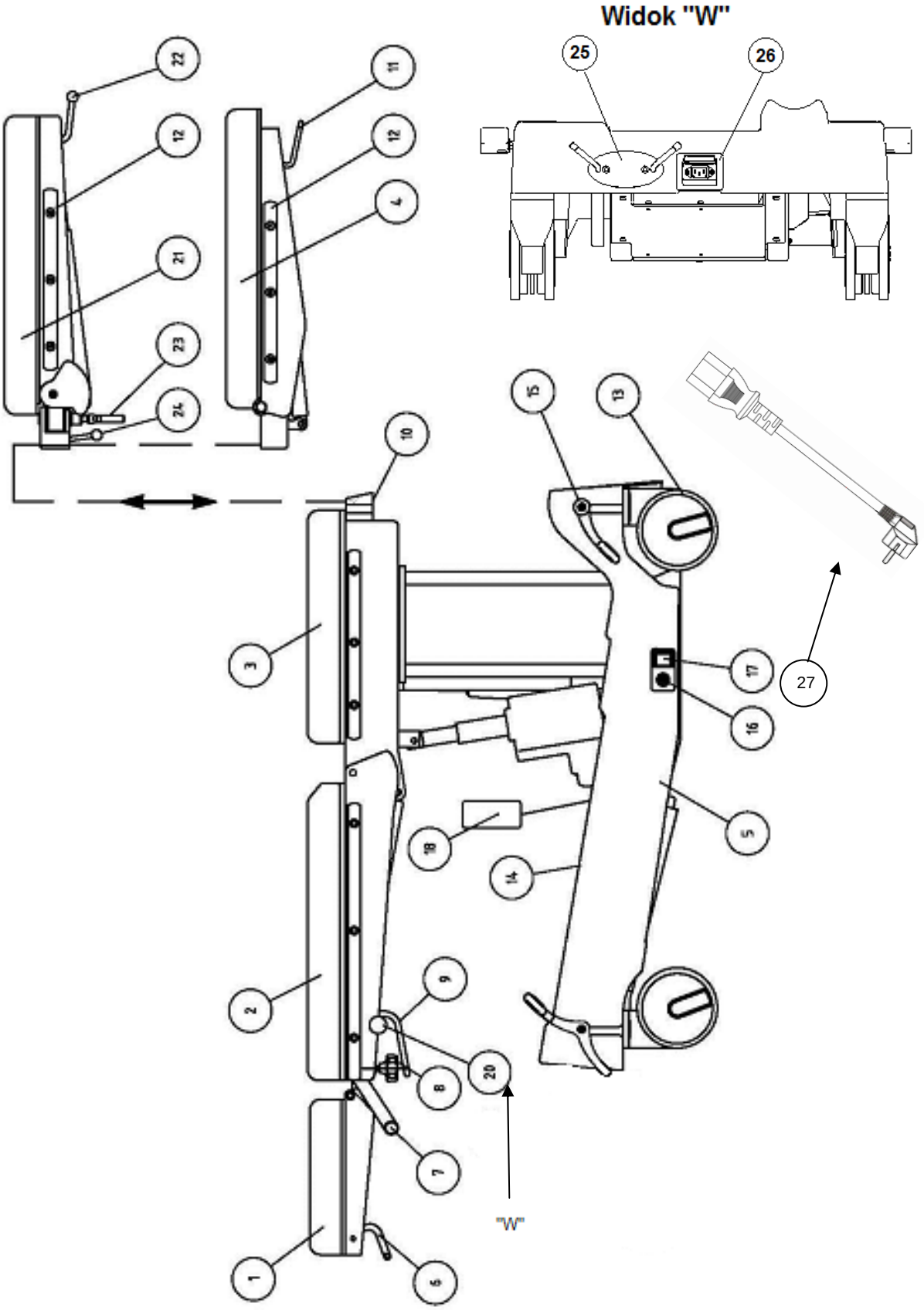


Fig.1 Operating table SU-14

Nr on fig.1	Description
1	headrest
2	backrest segment
3	seat segment
4	footrest segment
5	basis
6	headrest angle change lever
7	table top handle
8	blocking control of headrest
9	backrest position angle change lever
10	footrest blockade control
11	footrest angle change lever
12	side stripes
13	wheels
14	bottle assembling belts (option)
15	wheels central blockade lever
16	Potential equalizing clamps
17	central switch(off) table supplying
18	wire-connected controller
19	basket for accessories (option)
20	Blockades of lowering of backrest lever
21	Footrest segment two-piece (option)
22	Footrest angle change lever
23	Footrest abduction bolt
24	Footrest blockade lever
25	Alimentation cable holder
26	Power socket
27	Power cable

1.6 Technical data

- total table top length 2030mm ± 15 mm
- mattress width 605 mm ± 5 mm
- total width of the table top (with terminal) 650 mm ± 5 mm
- min table top height from floor (the table stands on wheels) 750 mm ± 15 mm
- max table top height from floor (the table stands on wheels) 1050mm ± 15 mm
- lifting angle of seat segment 85°
- lowering angle of seat segment 40°
- lifting angle of leg segment 20°(25)*
- lowering angle of foot-support 90°
- Footrests widening angle 180° (for two-piece footrests)
- angle of lateral tilt ± 20°
- head section lifting angle up 35°
- head section lifting angle down 65°
- Trendelenburg 20°
- Anti-Trendelenburg 20°
- table mass 160 kg
- maximum workload 200 kg
- power supply 24V –
- work time without external alimentation ok. 10 operations
- power supply from main charge the batterie ~230 V 50/60 Hz
- integrated driver with charger and batteries
- Power consumption 240VA
- Class of protection before electric paralysis I
- Type of the part application B
- Degree of protection before influence of environment IP-X4
- type of work missing 2 / 18 min
- usage time 10 years

For special requests of the client it is possible to make a product of changed technical parameters, not lowering its safety.

1.7 *Use parameters*

The drawing below presents the main use parameter

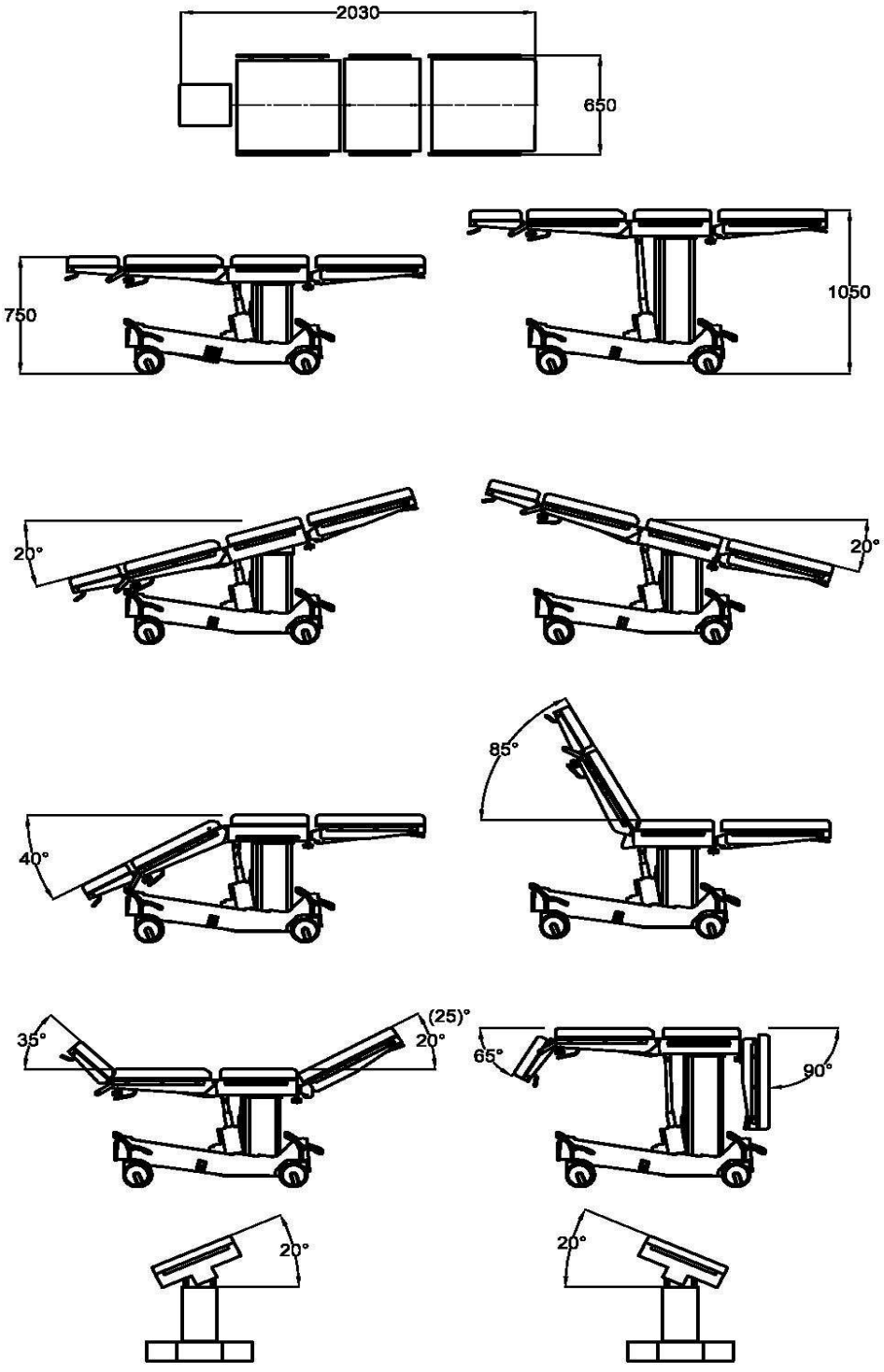


fig.2

1.8 Safety

The structure of the table assures its safe operation and use if the rules provided in this manual are followed.

The sign shown below says: "Warning! - Follow the instructions for safe use ".

A label showing this sign is placed on any parts or mechanisms, which may prove to be harmful to the patient or the personnel if their operation does not comply with the descriptions found in this Operating Manual.
When operating the table one should pay attention to elements and mechanisms with this label.

- ***Throughout surgical procedures table wheels should be blocked.***
- ***When using the table close to medical equipment working on high frequencies and defibrillators one should closely follow operating instruction for that equipment. Improper operation may become a source of dangerous accidents. There is a danger of serious burning of the patient through the contact with metal parts of the table or its equipment.***
- ***Throughout surgical procedures the table must be connected to the installation of potential equalization in the operations room.***
- ***When performing longitudinal (Trendelenburg or reverse Trendelenburg) and lateral tilting, patient should be secured against uncontrolled sliding down from the operating table. Use shoulder supports, supporting rollers, side supports, belts and grips as securing elements.***
- ***Pay special attention when performing sliding down from the operating table ,Trandelenburg or anti- Trandelenburg while the backrest or fotrest are inclination to the bottom.***

1.9 Critical parameters

Maximum work load	- 200 kg
Maximum authorized segment load:	
- head rest	15 kg
- backrest segment	75 kg
- seat segment	70 kg
- footrest (single)	20 kg
- footrests (simultaneusly loaded)	40 kg

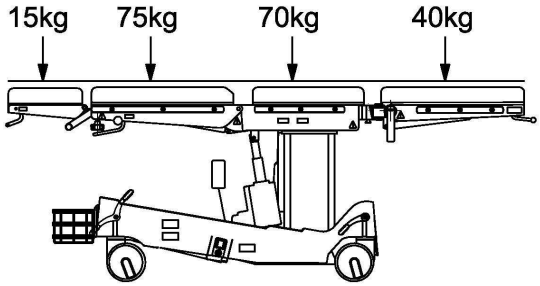


Fig. 3

1.10 Electromagnetic compatibility

Medical device the **operating table *SU-14*** is an electric appliance. Electric appliances are a source of electromagnetic radiation and themselves are under its influence Therefore, use of an electric appliance requires some safety precautions connected with electromagnetic compatibility.

In tables: *item 7 Characteristics of electromagnetic environment* – electromagnetic environment in which medical device **the table SU-14** should be used. Recommendations and warnings which should be followed by the users were also presented.

Caution!

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-transmitters and the product

Rated maximum output power of transmitter W	**150 kHz to 80 MHz** $d = 1{,}2\sqrt{P}$ **distance in meters**	**150 kHz to 800 MHz** $d = 1{,}2\sqrt{P}$ **distance in meters**	**800 MHz to 2.5 GHz** $d = 2{,}3\sqrt{P}$ **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, 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 first use

2.1 Transport

There is a possibility to transport the product by any covered transport means.

The transport conditions are as follows:
- temperature: from –10^{O}C to 60^{O}C,
- relative humidity: from 25% to 75%.

Operating table must be set in transportation position during carrying table by locomotion means without using table movable system (truck, trolley). Table base and tabletop should be transported in separate package. Transportation position means that table base is on minimum height and tabletop in horizontal position with leg segments and head rest. Transportation position is shown on the label situated on table base and table top. Product should be secured against humidity and stable. In case of lack of original packaging, the product should be properly secured in order to prevent its damage, preferably by experienced transport company.

While product transporting, storage and unpacking, the temperature gradient should be less than 10^{O}C per hour. It is strongly recommended to unpack the product after reaching room temperature.

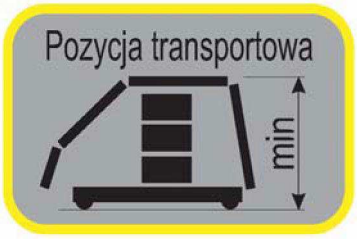
After transporting a product into a building where it is to be installed, a product should be left for at least 12 hours. Only after this time you can set a product in operation.

Laminar storage is permissible in accordance with the packaging marking. In the absence of the marking, storied storage is prohibited.

In case of the specific transport conditions (particularly: low temperature transport), it is necessary to negotiate the way of transport and product packaging with the product manufacturer in order to ensure safe transport.

A label which indicates product position during transport

A label for the Polish market.



A label for foreign countries

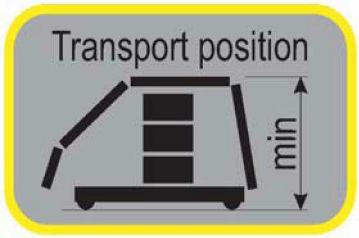


Fig. 3 Label “Transport position”

2.2 Unpacking and first use

If the Product is installed by service point of FAMED ŻYWIEC company, User is released from the responsibility to carry out procedures described in this section.

Caution!

The table is shipped by the producer in an assembled form in a wooden, open-work chest or in a cardboard box with the following dimensions L: 1340 x W:700 x H:890 mm and weight 160 kg. The table should be unpacked indoors in order to be protected from damages.

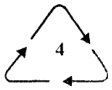
To prepare the table for operation after its transport or delivery one should:
- read product operating manual carefully
- take off the fastening tapes
- remove the package
- remove the materials protecting the table during its transportation

Caution!

Package may be marked with following signs:

 **-** multiuse package

 **-** package for recycling



- low-density polyethylene packaging

Packaging waste disposal should be carried out in accordance to environmental regulations, that are in force where the packaging containing the Product was delivered.
Packaging waste are the materials subject to recycling, they should be properly segregated and passed to selective waste collection point in accordance with local law regulations.
Returnable packaging must be returned the medical product's supplier.

- take out accessories
- remove elements which block the table base
- place the footrests horizontally (*items 3.7 Change of angular position of the footrests and 3.11 Change of angular position of separated footrests*)
- release the central blockade (*item 3.12 Table mobility*)
- with a help of another person carefully take the table from the palette and stop it
- add the headrest *(item 3.10 Installation and operation of the headrest)*
- place the product in its destination which meets the requirements described in this manual (*item 1.2 General requirements*),

- Connect the table to the mains voltage of 230V, 50/60 Hz, by connecting the power cord (fig. 1, Item 27) into the power socket at the base of the table, and then to a wall outlet

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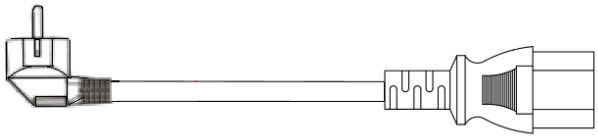


Fig. 4 Power cord – european version

- connect to the electric mains by connecting of the wire to the socket and charge the batteries,
- on the basis of information given in item *3 Operation* check whether the table works as described in item *5 Criteria on whose basis it is assessed whether product operation is correct or not.*

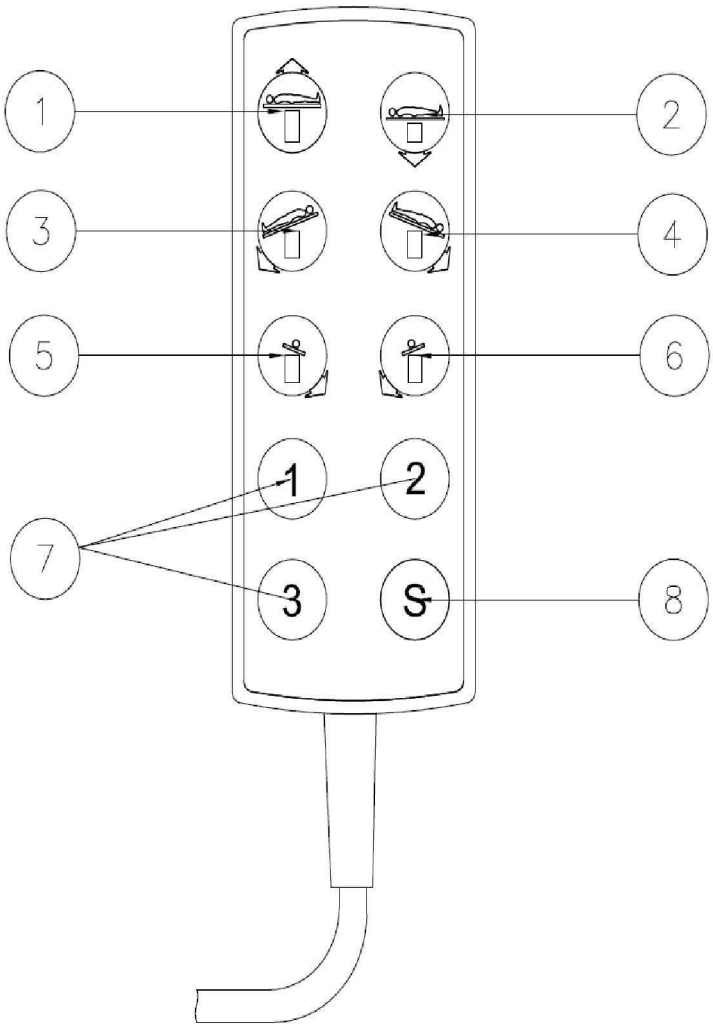
Caution!

If the product is not fully functional, i.e. the output parameters differ from the description contained in this manual, the bed must not be used. This situation should be reported to the producer or supplier. The use of an improperly functioning product may result in damages, which will encumber the user and which will not be a matter of producer's responsibility.

3 Operation and use

3.1 Controlling elements

3.1.1 Wire- connected control



1,2 – Height adjusting
3,4 – Longitudinal movement
5,6 – Side inclination
7 – Memory buttons
8 – Record for memory button

Fig.5 wire-connected control

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The wire-connected control is permanently connected to the controlling box at the table basis. The table is switch on through place the switching in “I „position (Fig. 1, pos. 17). At this moment the table is activated and carrying out the movements through pushing the functioning control button is possible. The buttons [1] to [7] are functioning buttons. When the functioning button is pressed, the movement represented by button’ symbol is operated so long as the button is pressed.

Caution!

The wire-connected controller is obligatory accessories for surgical tables.
The wire-connected controller must be on the hand of operating personnel.
To recommended use the operating table connected to net.

3.2 Raising and levering of table top

The height of table top is changed within the range defined in technical data by pressing the button [1] or [2] of controller (wire-connected controller, wireless controller or side control panel). When the extreme position is reached, table top stops automatically.

3.3 Table top longitudinal inclination

In order to change longitudinal inclination of table top (trendelenburg and anti-trendelenburg) within the range indicated in technical data, one should press button [5] or [6] of controller (wire-connected controller, wireless controller or side control panel). The movement lasts as long as the button is being pressed. When an extreme position is reached, table top stops automatically.

Caution!

Angular couch position can be changed only by medical personnel. The Trendelenburg position is a rescue position.

When performing longitudinal and side tilting functions, patient should be secured against uncontrolled sliding down from the operating table. Use shoulder supports, supporting rollers, side supports, belts and grips as securing elements.

When trendelenburg function is performed, the backrest should be in zero position or above the horizontal level so that no collisions take place!

3.4 Table top side inclination

In order to change side inclination of table top within the range indicated in technical data, one should press button [5] or [6] of controller (wire-connected controller, wireless controller or side control panel). The movement lasts as long as the button is being pressed. When an extreme position is reached, table top stops automatically.

Caution!

When performing longitudinal and side tilting functions, patient should be secured against uncontrolled sliding down from the operating table. Use shoulder supports, supporting rollers, side supports, belts and grips as securing elements.

3.5 Memory of table top position (zero position)

The table controller enable writing 3 any table top position in this memory. Every table top position may have free height, longitudinal and side inclination. One of this changed position can be the zero position of table top.

In order to write the position in memory, first should place the required position by means of function buttons 1-6 on the controller (fig. 4). Press (just a while) the 8 function button of controller (fig. 4). Next press one of the changed memory buttons-7 (fig. 4), which writes the preset table top position. The proper writing of position is signalizing by meant of sound signal.

In order to receive the preset position should press one of the function buttons of controller- 7and keep until receiving the changed position, which is until moment when the table op has been stopped.

Caution!

In the case of finding the discrepancy between preset and receive position, one should again carry out the position preset procedure.

3.6 Change of angular position of the backrest segment

The angle of the backrest segment (fig. 1, item 2) is changed by the use of the force of muscles with support of gas spring. In order to adjust a segment position, press blockade (fig.1, pos.20), deviate the lever (fig. 1, pos.9) to up and then place a segment in a desired position and release a lever (fig.1, item 9). After releasing a lever, a backrest segment mechanism is blocked and further movement is prevented. **Remember to hold a segment with both hands while adjusting position**. Thanks to the

central position of the lever the backrest segment can be operated from the right, from the left and from behind the backrest segment.

Caution!

If a patient is very heavy, over 90 kg, the angle of backrest segment should be changed with particular care; one should be prepared that it would be necessary to use considerable force to move it up and to cushion lowering at the moment of lever release (drawing 1 and 2, item 9).

3.7 Change of angular position of the footrests

Angular position of the footrest inclination is changed within the range defined in technical data by rising of the lever (drawing 1, item 11) or pressing the lever (fig.1, item 22) (on the side removable footrests) or rising or lowering of the footrest segment to the required level. When the pressure is removed from the lever, the mechanism is locked and the position of the footrest determined.

Change of the angle between the divided footrests, in the range included in technical data, is obtained by turning of footrest abduction bolt 3-4 turns (fig.1, item.23) and turning the footrest of the desired angle to the side.

Caution!

When the function is performed, the footrests may collide with the base!

Check the proper clamp of the handle that locked the footrest turning.

3.8 Insert and take out of footrest

Footrest plate (fig. 5, item 1) is fixed by wedges (fig. 1, item 10) placed on the bottom of the seat segment by the blockages placed on both sides of the footrest (fig.5, item 2). Before assembling the footrest to the seat segment it is necessary to pull out and turn both blockades of the footrest about 90º. After that put on wedge sockets of the footrest on wedge plugs of the seat segment and establish its position by turning blockades of the footrest up back to the starting position. Disassembly of the footrest relies on pulling out and turning both blockades of the footrest about 90º and pulling out the footrests of the wedge plugs of the seat segment. Footrest angle change is obtained by a lever (fig.5, item 3) activating the gas spring mechanism. Pressing of the lever makes possible the change of angular position of the footrest. Releasing of the lever provokes blocking of the footrest in chosen position.

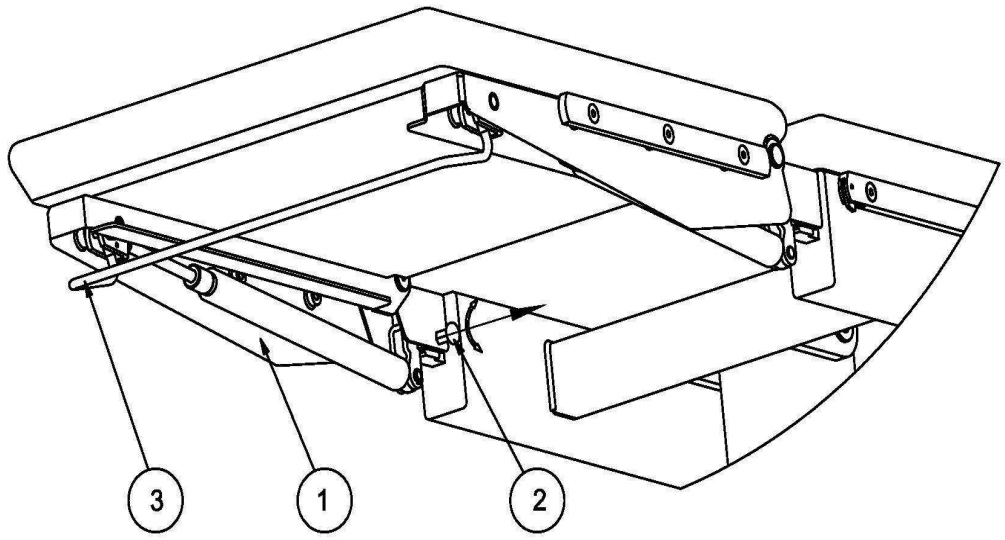


Fig. 6

Caution!

Make sure that the footrest is correctly fixed!

3.9 Inserting and Removing Footrest

Footrest segments (Fig. 1, Pos. 4) can be attached and removed from the seat segment thanks to the mechanism activated by the lever (Fig. 1, Pos. 24). In order to remove the footrest segment, it should be grasped from underneath, the lever (Fig.1, Pos. 10) should be pulled till its level, and the footrest segment should be lifted till it comes off the wedge pin located on the seat segment (Fig. 1, Pos.2 4). Attaching footrest segment consists of raising the lever to its horizontal position (Fig. 1, Pos. 10) and mounting wedge socket of the footrest on the wedge pin of the seat segment till their levels are even. After mounting the segment the lever must be lowered (Fig. 1, Pos. 24) back to the starting position and pressed down.

Caution!

Make sure that the footrest is correctly fixed!

3.10 Installation and operation of the headrest

The headrest is fastened on installation wedges which are situated at the end of the backrest segment using a knob. When the headrest is put on the stripe, one should determine its position by screwing down the screw (fig.1, item 8). The headrest is dismounted by unscrewing of the screw and removal of the headrest from the stripe. The angle of the headrest is changed similarly to the backrest segment, that is, by the handle which moves the mechanism of the gas spring. When the lever is pressed (fig.1, item 6), the required angle of the headrest may be chosen. Its release locks the headrest in the chosen position.

Caution!

Make sure that the headrest is correctly locked!

3.11 Installation and disassembly of mattresses

All mattresses can be removed without any tools. They are fixed on fixing pegs

3.12 Table mobility

Wheels installed in the base of table make it possible to move it in every direction. The table is equipped with movement lock used during operations and treatments performed on the table.

The table is equiped with central blockades of wheels. The central blocking pedal has three position:
- Upper - direction blockade (fig.7, pos.3),
- Middle (horizontal) - blockade released (fig. 7, pos.1),
- Lower - all castors blocked (fig.7, pos.2).

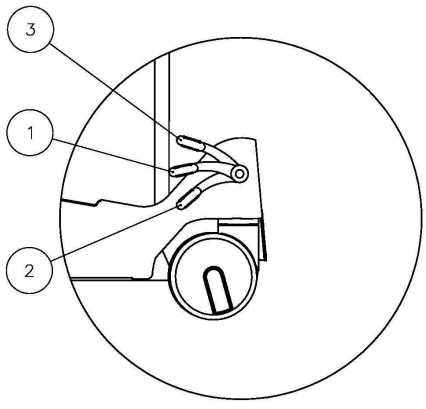


Fig.7

The direction blockade is used during the table movement on long, straight sections and makes it easy

to turn the table. All castors brake causes a total bed immobilization.

Caution!

Throughout surgical procedures table wheels should be blocked.

Table should be move by 2 people at least.

Do not move table with workload (patient) through inclines and outside of buildings).

Table should be move in minimal height.

The floor under the table must be free from any obstacles!

When rolling the table avoid collisions!

Do not roll the table over electric cables!

3.13 Antistatic properties

A table structure allows for drainage of electrostatic charge through the following channels:

- By antistatic wheels to conducting floor,
- By potential equalisation clamp.

Operating table SU-14 should be used on antistatic floor. In case of lack of such floor, an electrostatic charge is drained through a potential equalization line. The potential equalising conductor is a standard table accessory.
Antistatic properties of the table shall be maintained if mattresses produced by FAMED Sp. z o.o. are used.

3.14 Potential equalising clamp

Operating table have inside system of potential equalization leading to the clamp (fig. 1, item pos. 16) marked by symbol  .

Caution!

Throughout surgical procedures the table must be connected to the installation of potential equalization in the operations room.

The cable is provided in standard table accessories

3.15 Collisions

In some extreme positions of the table, in particular, when accessories installed on side stripes are used, mechanical collisions may take place. Because of that, one should protect the table and accessories from damages.

3.16 Battery charging

A charger built-in in the table makes it possible to charge the batteries in the table.

In order to charge batteries, connect a power supply cord to a socket in a table and set a switch (fig.1, item 17) in position „I". The batteries are charge automatically.

Caution!

If after 12 hours of charging and after disconnecting a power supply cord, it is impossible to activate any electrical movements, this means that the table is damaged. This fact should be notified to an authorized service centre.

Table work time is about 10 surgeries from full batteries.
It is required to charge batteries when there is a lack of possibility of carrying out movements or in the case of noticeable slowdawn of movements.
Battery life time is 3 years.

Caution!

The table may not be stored with batteries low.

If batteries need to be exchanged, do always exchange a set of two batteries. Exchanging a single battery limits an operating time of a table and causes quick wear of a new battery.

4 Installation and operation of accessories

The following extra accessories may be provided with the operating table SU-14:

	Elements of accessories	***Symbol***	
1	Screen frame	WS-01.5	14 kg
2	Screen frame with width regulation	WS-01.6	14 kg
3	Hand grip	WS-02.5	17 kg
4	Thigh grip	WS-03.5	23 kg
5	Shank grip	WS-04.5	23 kg
6	Knee support	WS-05.5	17 kg
7	Left and right arm support	WS-06.5	14 kg
8	Hand angular support	WS-07.5	14 kg
9	Big supporting bolster	WS-08.5	50 kg
10	Trolley for accessories	WS-13.5	50 kg
11	Grip for anaesthesiologist pipes	WS-14.5	14 kg
12	Table for tools	WS-15.5	14 kg
13	Single position stripe	WS-16.5	100Nm
14	Multi position clamp mechanism	WS-17.6	100Nm
15	Multi position clamp mechanism	WS-17.7	100Nm
16	Hand support	WS-22.5	20 kg
17	Complete handrails	WS-32.5	23 kg
18	Side x-ray handle	WS-33.0	14 kg
19	Wrist grip	WS-34.5	14 kg
20	Attachment do arthroscopy	WS-39.5	17 kg
21	Attachment for meniscus operation	WS-40.5	17 kg
22	Belly belts	WS-41.0	125 kg
23	Footrest belts	WS-42.0	23 kg
24	Hand belt	WS-43.0	17 kg
25	Thigh belt	WS-44.0	23 kg
26	Support for hand surgery	WS-48.5	17 kg
27	Womb support	WS-49.5	40 kg
28	Side support	WS-50.5	40 kg
29	Side rest with lever	WS-50.6	40 kg
30	Chest rest	WS-52.5	40 kg
31	Partial denture of sides shelves	WS-53.0	14 kg
32	Shoulder-sides rest	WS-59.5	14 kg
33	lithotomic stirrups	WS-64.5	25 kg
34	Mattress for spine	WS-65.0	80 kg
35	collar	WS-66.0	20 kg
36	Collar under neck	WS-68.0	10 kg
37	headrest	WS-69.0	10 kg
38	Support for shoulder surgery	WS-87.5	14 kg
39	hand rest	PR-01.5	20 kg
40	Drip hander	WK-01.5	10 kg

When ordering table accessories, please give table's name and symbol.

The producer reserves the right to modify accessories according to client requirements and produce new accessories complains with norm of safety.

5 Criteria on whose basis it is assessed whether product operation is correct or not

Correctness of table operation shall be checked every day before the beginning of its operation.

Caution!

The method of checking whether operation of the table is correct:

1. Check stability of the table when its feet are down by trying to move the table manually (when the wheels are blocking): pushing of the table in any direction should not cause tilting or moving.
2. Check mechanisms of adjustment of positions of the segments controlled by gas springs by a change of position and locking (see item *3 Operation*). The mechanism should work without jamming, after locking the segment should not change its position (check by manual pressing of the segment).
3. Check if there are no mechanical plays by manually moving the top of the table.
4. Check the work of the electro-mechanics system by performance of all movements controlled by wire-connected control.

If the table underwent the above described tests with positive results and there were no disturbing sounds (squeaks and grinds), the table can be used safety.
Otherwise see item 6.6 *'Location and removal of defects'*.

Caution!

If the product is not fully functional, i.e. the output parameters differ from the description contained in this manual, the bed must not be used. This situation should be reported to the producer or supplier (dealer). The use of an improperly functioning product may result in damages, which will encumber the user and which will not be a matter of producer's responsibility.

6 Technical operations

6.1 Storing

If the product is not to be used for a longer period of time, it should be stored in the below mentioned climatic conditions:

- temperature: 25º ±10ºC,
- relative humidity: 50% ± 25%.

Caution!

During storing, the operating table must be turned off. The switch (position 17, figure 1) must be in the "0" position.

If the table is stored for a longer period of time, it must be connected to the power supply for 24 hours each 6 months to charge the batteries.

The table may not be stored with batteries low

6.2 *Cleaning and disinfecting*

For cleaning and disinfecting use cleaners, disinfectants recommended by Famed Żywiec Sp. z o.o. in Annex 2 to this manual (allowed to turnover and use on the territory of the country, where they are used).
After disinfection the Product should be washed with water to eliminate any stains.
After disinfecting dry thoroughly.
Dry with hot air (maximal temperature 60°C) or by wiping with a soft sterile cloth.

Caution!

Before disinfecting disconnect the product from mains!

The product/ table must not be disinfected in disinfecting chambers.

Bleaching (containing active chlorine or oxygen), caustic and corrosive agents must not be used.

No disinfecting agents containing alcohol may be applied to elements made of polyurethane (mattresses)!

No agents destroying the structure of plastic (organic solvents) may be applied to the plastic elements.

Disregarding the above requirements concerning cleaning and disinfecting shall result in losing the guarantee for the product.

6.3 Damages and defects

Damages and defects found in the product or product accessories should be reported immediately to a person in charge of such issues. The bed which can not be safely operated (e.g. damaged electric or mechanical elements) must not be used till it is repaired.

6.4 *Repairs and conservation*

Repairs are done by the producer. The user can not carry out any repairs on his own unless he has undergone special training or has been authorised to do that. When the producer has given his written permission for repair of the product by client's technical staff, the producer shall provide the client with necessary charts, lists of spare parts, descriptions and information on repairs.
The producer allows only using original spare parts. In order to provide safe and reliable operation of the product one should use only spare parts provided by the producer. Worn out parts shall be removed as provided in environmental protection regulations

Caution!

The product contains products which may be dangerous to the environment:

- **a battery integrated with controller – type BA 1812V 1,2Ah (2pieces).**

The rules of proceeding with used products which may be dangerous to the environment are defined in environmental regulations.
If there is a need to replace the batteries, used batteries are collected by the medical device's producer or an authorised service point indicated by the producer.

Used batteries receives a medical device manufacturer or indicated by the authorized repairer or Third Party having required by environmental law decisions to conduct.

Repairs and maintenance must be performed only by qualified personnel. If a product is operated outside Poland, one should inform about a necessity of a repair a producer or the dealer from whom the product was purchased.

Every repair of the product should be recorded on the list of repairs enclosed to the guarantee card on pain guarantee loss!

6.5 Control of technical condition

To ensure safety and proper technical condition of the product, User is required to have it undergone periodic technical inspections. These inspections are carried out at the user's expense, by the Producer or customer's qualified technical staff.

Caution!

Periodic inspections of the table must be recorded in the Device Passport or the product's warranty card.
Technical inspections of the product must be recorded on the list of repairs enclosed with the guarantee certificate.

After the product's period of use expires, permission for further use is granted after positive result from technical inspection carried out in authorised service point. Each time a permission is granted for 12 months.

Subject of inspection	*frequency*
• IEC 62353 (Table 1) compliance check • General technical condition check (Table 2) • Checking safety and functions – check of functioning of remote operated functionalities – check of reset function — calibration of inclinometers – checking collision limits – checking antistatic parameters of mattresses. Resistance value shall be within the range from 10^4 to 10^6Q – Check of electric connections. – Check of base and column condition. – Check of mechanical connections. – Check of longitudinal movement function. – Check of battery capacity. – Check of play on the column.	Every 12 months

Scope of inspection in line with IEC 62353	
Visual inspection	• Checking all fuses accessible from the outside, and their conformity with documentation (fuse capacity, characteristics), • Checking if all markings and labels are in place and legible, • Checking if all mechanical parts are in place, • Checking for damages and checking the cleanliness of the device, • Checking accessories, • Checking product documentation and documentation of previous inspections.
Measurements	• Measurement of protective earthing resistance, • Measurement of leakage currents, • Measurement of patient's leakage current, • Measurement of insulation resistance.
Functional test	• The functional test must be carried out by a suitably experienced person and trained in operation of the device. • The functional test and the results of specific tests and measurements should be documented

When to do the inspection:
– the device has been repaired;
– periodically (every 12 months) during technical inspection.

To ensure safe and correct operation of the device during the service life, the user must perform technical checks listed below every 6 months.

Scope of technical condition check
- Check of all mechanical functions by executing all movements in line with the technical specification parameters: – Checking the table movement capabilities. – Checking central wheel lock. – Checking the removal and installation of removable segments. – Checking the load bearing plates under mattresses. – Check all visible bolted connections without removing housing. – Check for mechanical play and if all locks work. – Check the condition of the power supply cable. – Check the insulation of wired controller cable. – Check the condition of columns cover. – Check condition of mattresses. – Check efficiency of the central wheel lock.

An inspection should involve a visual inspection and the noticed malfunctions should be handled as provided in item *6.6 Location of defects and their removal*.

6.6 Location of defects and their removal

damage	*Possible cause*	*removal*
The table cannot be moved	locked wheels	Unlock blockade pedal
	Batteries discharged	Charge the batteries
	Control plug incorrectly plugged to the socket in the table	Plug in the plug correctly
	Damaged pilot	Contact your service
	Blockage of the driver	Disconnect the table of the alimentation, wait few seconds and reconnect.
Plays in screw joints	Plays appeared during product operation	Screw down with generally available wrenches
Lack of possibility of using the preset position	Change of position setting	Insertion again the position to memory according to point 3.5

If a fault can't be eliminated, abstain from using the product and report the matter in the Service Department, or service of FAMED ŻYWIEC company.

6.7 Product liquidation

If the customer resigns from further product exploitation, he is obliged to product liquidation according to rules of environment protection; detailed information is situated in annex no. 3.

7 Characteristics of electromagnetic environment

Electromagnetic emissions

Medical device ***operating table SU-14*** is to be used in electromagnetic environment specified below. The customer or the user of medical device the ***SU-14*** should assure that it is used in such an environment		
Type of emission	**Classification**	**Explanations and instructions**
Emission RF CISPR 11	Group 1	Medical device operating table SU-14 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	Class B	Medical device operating table SU-14 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuation, flickering IEC 61000-3-3	Complies	

Electromagnetic immunity

Medical device ***operating table SU-14*** is to be used in electromagnetic environment specified below. The customer or the users of medical device the ***SU-14*** 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) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	In the location of SU-14 use the floor should be wooden, concrete or covered with ceramic tiles. If the floor is covered with a synthetic material, the relative humidity should be at least 30%.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Series of quick transitory stages IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip U_T) for 0.5 cycle 40% U_T (60% dip U_T) for 5 cycles 70% U_T (30% dip U_T) for 25 cycles < 5% U_T (>95% dip U_T) for 5 seconds	< 5% U_T (>95% dip U_T) for 0.5 cycle 40% U_T (60% dip U_T) for 5 cycles 70% U_T (30% dip U_T) for 25 cycles < 5% U_T (>95% dip U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. In normal use operating table SU-14 is battery operated. Connect to mains network only for battery charging.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Electromagnetic immunity

Medical device ***operating table SU-14*** is to be used in electromagnetic environment specified below. The customer or the user of medical device the ***SU-14*** should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment – guidance
Transmitted disturbances induced by fields with radio frequencies IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should not be used closer to any part of the operating tables SU-12, including cables, than the srecommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separating distance:** $d = 1{,}2\sqrt{P}$
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 the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance in each frequency range Interference may occur in the vicinity of equipment marked with following 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 SU-12 is used exceeds the applicable RF compliance level above, the operating table SU-12 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 SU-12.

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

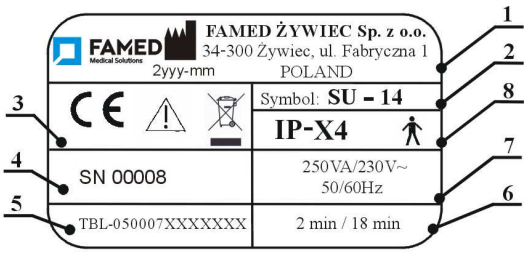
NOTES

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

8 Table identification

When sending/ asking any questions concerning the table and when ordering spare parts, please give the serial number of the table placed on the nameplate and the guarantee certificate.

8.1 Nameplate



Description of meanings of particular boxes of a name plate

1 – Name, logo and address of the Manufacturer,

2 – Product symbol,

3 – General markers,

CE – CE mark,

⚠ – "Warning! - Follow the instructions for safe use ".

Caution! – During disposal of the product, one should act according to the Act concerning electrical and electronic equipment waste.

4 – Product trade number with untypical order number (if applicable)

5 – Index of the product,

6 – Class of duty,

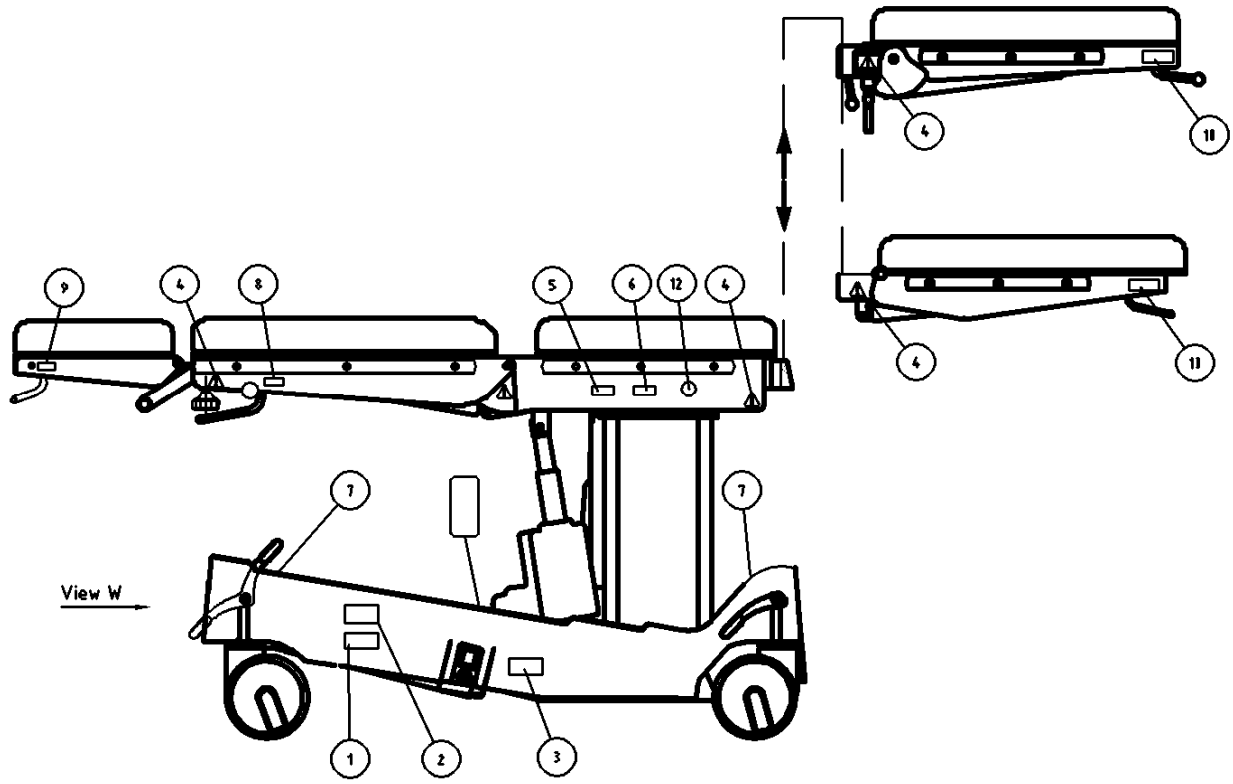
7 – Power supply specification

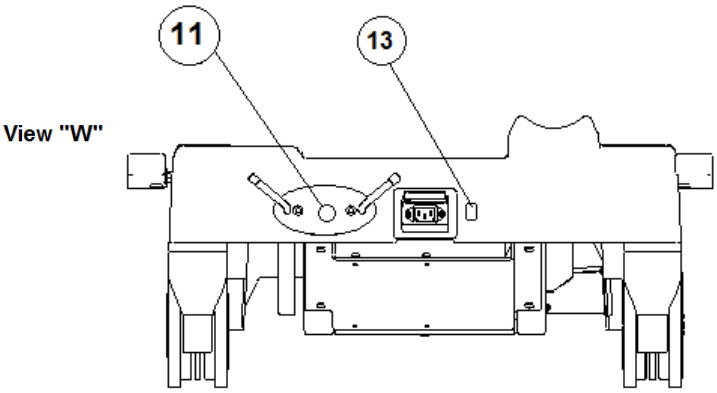
8 – Additional markings

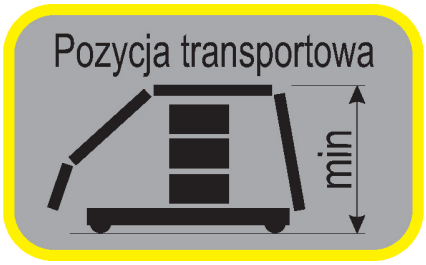
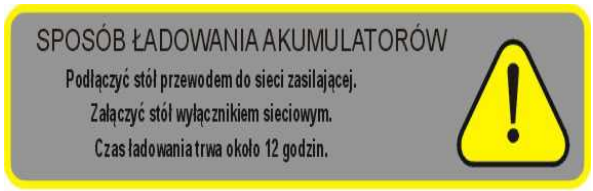
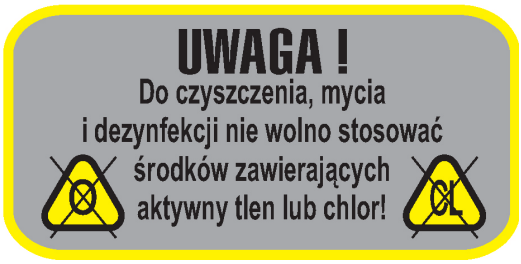
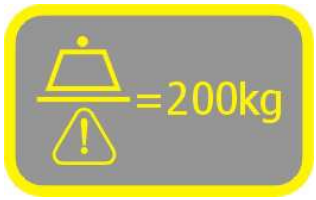
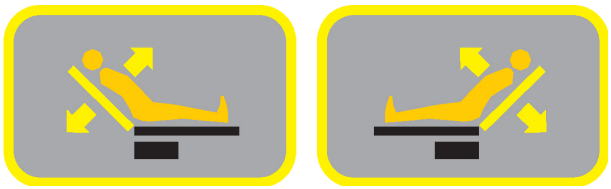
IP-X4 – Degree of protection

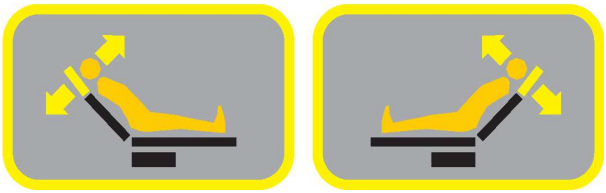
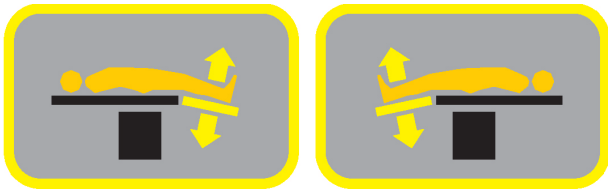
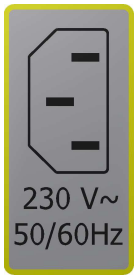
Application part B

8.2 Labels





1	Watch point 8.1	Name plate
2		Transport position of the table (see point (see point 2.1)
3		The method of battery charging
4		Warning! - Follow the instructions for safe use.
5		For clearing and disinfection you should not use agents containing active oxygen and chlorine
6		Maximal workload 200 kg
7		Central wheels blockade
8		Back rest adjustment

9		Head rest adjustment
10		Foot rest adjustment
11		Hook for alimentation cable
12		Follow the instructions
13		Power socket

Notice! The producer reserves the right to introduce in the product structural modifications resulting from technical progress which are not covered in this operating manual.

FAMED Medical Solutions

Item: **SU-14**

Edition: **August 2014**

Spare Parts List

SJW-4-01-02

Basic spare parts

No.	Name	Qt.	Code number	Category	Remarks
1	Column	1	S09164004010310	3	Famed Żywiec Sp. z o.o.
2	Control box	1	S09164004020710	1	Famed Żywiec Sp. z o.o.
3	Brake lever	1	C043306000501/-02/	2	Famed Żywiec Sp. z o.o.
4	Caster	1	S06549041501031	3	Famed Żywiec Sp. z o.o.
5	Caster	1	S06549041501030	3	Famed Żywiec Sp. z o.o.
6	Caster	2	S06549041502014	3	Famed Żywiec Sp. z o.o.
7	Pilot sleeve I	2	C073600000014/-01/	2	Famed Żywiec Sp. z o.o.
8	Sliding sleeve	4	S30250100000200	2	Famed Żywiec Sp. z o.o.
9	Pin I	3	C183600000005	2	Famed Żywiec Sp. z o.o.
10	Pin II	1	C183600000006	2	Famed Żywiec Sp. z o.o.
11	Motive system of head rest section	1	C183701020000	2	Famed Żywiec Sp. z o.o.
12	Driving unit of backrest	2	C183702050000	2	Famed Żywiec Sp. z o.o.
13	Head rest matress	1	C183701000005	2	Famed Żywiec Sp. z o.o.
14	Earthing screw	1	C028001010088000	2	Famed Żywiec Sp. z o.o.
15	Base cover	1	C183600000016	2	Famed Żywiec Sp. z o.o.
16	Lock pedal left	2	S06549065006020	2	Famed Żywiec Sp. z o.o.
17	Lock pedal right	2	S06549065006021	2	Famed Żywiec Sp. z o.o.
18	Back rest mattress	1	C183702000003	2	Famed Żywiec Sp. z o.o.
19	Servo-motor for Trendelenburg	1	S09164004005711	2	Famed Żywiec Sp. z o.o.
20	Servo-motor of heel side	1	S09164004003111	2	Famed Żywiec Sp. z o.o.
21	Backrest rail	2	C183702000004	2	Famed Żywiec Sp. z o.o.
22	Seat mattress	1	C183703000003	1	Famed Żywiec Sp. z o.o.
23	Seat pin	2	C183703000004	1	Famed Żywiec Sp. z o.o.
24	Manual control device (pilot)	1	S09164004025510	1	Famed Żywiec Sp. z o.o.
25	Side strip	2	C047311000019	1	Famed Żywiec Sp. z o.o.
26	Mattress of footrest	1	C183704030005	3	Famed Żywiec Sp. z o.o.
27	Driving unit of foot stool L+P	2	C183704080000	3	Famed Żywiec Sp. z o.o.
28	Handwheel	2	S13622900000867	3	Famed Żywiec Sp. z o.o.
29	Stopper	2	S13622900010250	2	Famed Żywiec Sp. z o.o.

Repair kit

No.	Name	Qt.	Code number	Remarks
1				
2				

Legend:

Markers in column „Category"

1 - The elements endanger fast wear out

2 - The elements not endanger fast wear out

3 - The elements wear out depended of condition of exploitation