USER MANUAL

OPHTHALMIC and LARYNGOLOGICAL CHAIR FL-02

iMS™

iNSPIRIT MEDICAL SOLUTIONS™

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This manual is approved, in English, by FAMED ŻYWIEC Sp. z o.o., the Manufacturer.

Table of Contents

1.0 Intended Use

The FL-02 Ophthalmic and Laryngological chair is intended to establish and hold a sitting position of a patient and to hold position of the head during laryngological or ophthalmologic examination.

2.0 Contraindications

There are no known contraindications to the use of this equipment.

3.0 Warnings and Precautions

Please read this user manual carefully and completely prior to operating the FL-02 Ophthalmic and Laryngological Chair.

The user must ensure that the product is used in conformity with its intended use, 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 authorized 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.

- ***Every repair of the product must be done by an <u>Oakworks authorized Service Provider</u> with <u>records maintained</u>. Disregarding this requirement will cause the warranty for the product to be invalid.***

- ***Operating, maintaining and/or servicing of this device in any way other than what is instructed within this manual is not permitted. By doing so, there is a potential for damage(s) to the device. Should damages occur under such circumstances, the manufacturer will not be responsible for the damage(s) nor will the damage(s) be covered under the established warranty at the time of purchase.***

- ***The use of this device is prohibited if any mechanical defects are found during the initial installation and/or initial operation of the product. Please use the contact information provided within this User Manual to report all mechanical and physical defects that are found upon initial installation and/or initial operation.***

- ***Before any repair the power supply must be switched off.***

Notes concerned with safety

- To avoid the risk of electric shock, this equipment must only be connected to an outlet that is properly grounded. See installations instructions in this manual for proper grounding.

- Grounding reliability can only be achieved when this equipment is connected to an equivalent 3 prong receptacle marked “Hospital Only” or “Hospital Grade”.
- The chair has to be connected to the main power outlet that is consistent with its name plate.
- The chair should not be in a place which obstructs its disconnection from the main power outlet.
- Do not use the power cable when it is damaged or its insulation is worn out.
- Do not connect the chair to main power outlet in places where there is a danger of an explosion.
- Use of accessories, additional equipment, cables or spare parts other than those offered and/ or advised by the Manufacturer may cause an increase of emission and/ or decrease of chair resistance to all electromagnetic phenomena.
- Avoid danger to safety caused by improper operation of cables connected to main power outlet, e.g. stretching of cables, or squashing between moving parts, driving through them.
- The structure of the product assures its safe operation and use if the rules provided in this manual are followed. The weight of a patient and additional accessories fixed on the chair should not exceed **160 kg (353 lbs**).

Notes concerning: start-up, operation and use

- When carrying the chair, do not hold plastic casing because the casing may be damaged.
- The chair should be positioned at such a distance from the wall and other objects that the backrest could move within the whole range of its movements without colliding with anything. A collision may cause a breakdown of a servo-motor and damage the chair.
- When using the chair close to medical equipment which is operating using high frequencies and defibrillators, one should closely follow operating instructions for that equipment. Improper operation may become a source of dangerous accidents such as serious burning of the patient through the contact with metal parts of the chair or its equipment.

Notes concerning cleaning and 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.
- Before disinfecting disconnect from main power outlet.

4.0 Product Description

This chair has adjustable back rest segment angular positioning thanks to electric servomotors which are activated by foot operated controller. The chair is equipped with height regulation and back rest inclination angle regulation. Both of these are

operated with also operated using the foot controller. The chair is capable of rotation. The chair is equipped with manually adjusted head rest lock and two handrests (left and right) which are detachable.

4.1 Components

Components

Position on the Fig. 1 & 2	Description
1	Base set
2	Carrying column
3	Seat segment
4	Rotation interlocking mechanism
5	Arm rest
6	Back rest segment
7	Headrest interlocking mechanism
8	Headrest
9	Headrest outrigger interlocking handwheel
10	Pedal control (up-down)
11	Pedal control (back rest segment)

4.2 Product Drawing

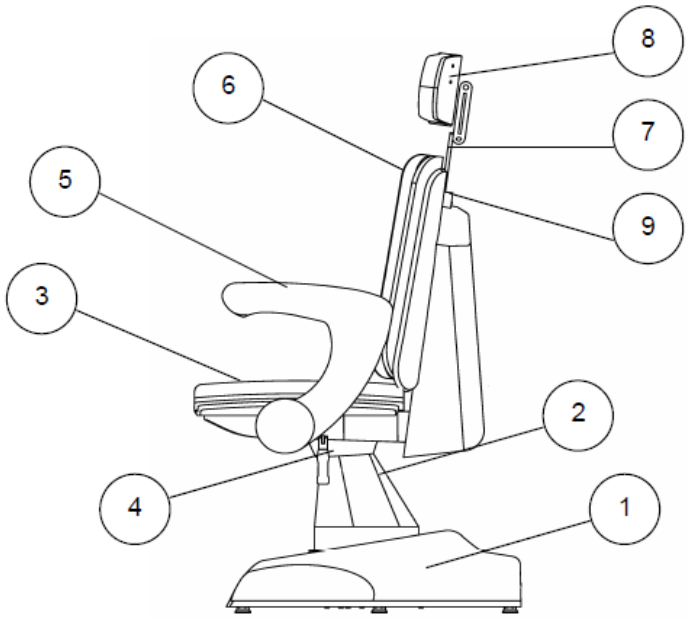


Fig.1 Side View

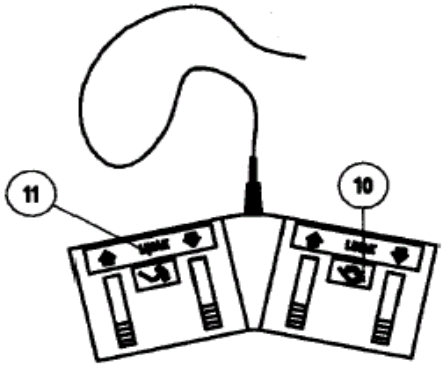


Fig. 2 Pedal control view

5.0 Unpacking

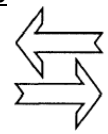
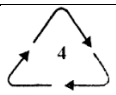
The chair is shipped assembled by the manufacturer in a cardboard box or in a wood chest. To prepare the chair for operation after its transport or delivery one should:

- set the pallet,
- take off the fastening tapes,
- remove the cardboard casing,
- remove the materials protecting the chair during its transportation
- take out equipment and put it aside,
- take the chair slowly from the palette and place in its destination,

⚠ **When carrying the chair, do not hold plastic casing because the casing may be damaged. When the chair is taken down, hold it on the inner side of the basis on the side of the floor, do not hold by the edge of the cover of the basis.**

- read the user manual carefully.
- start up the product as described in *Installation.*

The packaging may be marked with the following symbols:

	Multiuse Package
	Package for Recycling
 LDPE	Low-Density Polyethylene Packaging

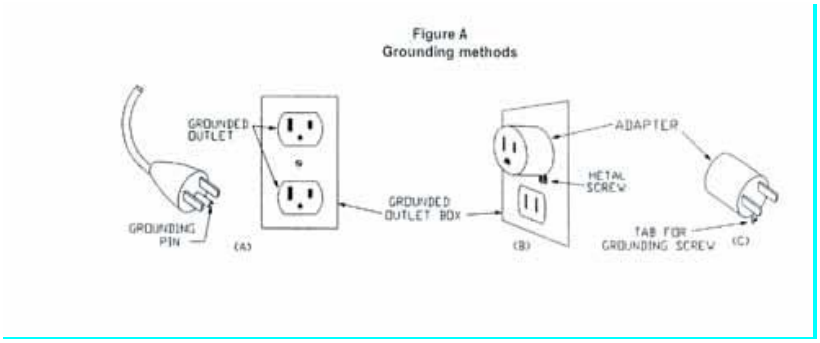
⚠ Disposal of the packaging must be compliant with the applicable regulations and requirements.

6.0 Installation

1. Place the chair on flat, hard floor in the required working place which meets the requirements determined in this Operating Manual. If the chair is not stable, the base should be levelled using adjustable feet.
2. Connect foot actuators and change of angular position of the backrest to the socket at in the base of the chair.
3. Connect the chair to the power supply by connection of the cable to the power network socket.

⚠ **Risk of Electric Shock - Connect this furnishing to a properly grounded outlet only.**

This product must be grounded. If it should malfunction or break down, grounding provides a path of least resistance for electrical current to reduce the risk of electric
shock. This product is equipped with a cord having an equipment-grounding conductor and a grounding pin. The pin must be plugged into an appropriate outlet that is properly installed and grounded in accordance with all local codes and ordinances. See U.S. sample below.



Improper connection of the equipment-grounding conductor can result in a risk of electric shock. Check with a qualified electrician or service person if you are in doubt as to whether the product is properly grounded. Do not modify the plug provided with the product - if it will not fit the outlet; have a proper outlet installed by a qualified electrician.

4. Check whether the electronic table control system works performing all table functional movements. Check the headrest and rotation mechanism by means of interlocking and unlocking them. All activities should be performed as described in section 8, Operation and section 9, Daily Inspections. Chair mechanisms should work silently, smoothly, without any jamming or creaking, etc.
5. Documented evidence of proper installation and training of the user is required for the Manufacture to approve any warranty claims. Use the "Protocol of Installation" as this record.

⚠ **If the product is not fully functional, i.e. the output parameters differ from the description contained in this manual, the Device must not be used. This situation should be reported to OAKWORKS®, Inc. The use of an improperly functioning product**

may result in damages *that will not be covered under the assigned warranty.*

6.1 Installation Checklist

☐ Check the locking and unlocking of the wheels – leave wheels locked

☐ Check all electric functions
- Backrest Adjustment
- Seat Section Adjustment
- Legrest Adjustment
- Trendlenburg
- Height Adjustment

☐ Check the correct functioning of the hand support

☐ Check manual regulations
- Foot support
- Headrest

☐ Check all electric functions (FL-02) – Foot Controller
- Backrest adjustment (Trendelenburg / reverse-Trendelenburg)
- Height Adjustment

☐ Check manual functions
- Headrest adjustment and stability
- Chair rotation

☐ Check foot operated functions
- Height Adjustment

☐ Check chair stability

Daily inspections should be performed in accordance to the instructions specified in Section 9.0 Daily Inspections of this user manual.

7.0 Accessories

Accessory Name	Identifier Number
Foot Rest	WF-45.0

8.0 Operation

The product is intended to be used indoors within a climate consisting of a temperature of +10° Celsius (50° Fahrenheit) to +40° Celsius (104° Fahrenheit). Acceptable change of temperature within an 8-hour period should not exceed 20° Celsius (68° Fahrenheit). The relative humidity in the surroundings of which chair will be functioning must range from 30% to 80%. The range of atmospheric pressure inside the area of operation can be 700 to 1060 hPa. The product should be used, maintained and serviced according to the indications of this manual.

8.1 Change of the seat height

The height of the seat is changed electronically by pressing the controller left button (pos. 10, fig. 2) which will raise the height of the seat in the range of ~150 mm, (5.9”), in relation to the ground. Pressing the right button will cause it descend to required height.

8.2 Change of angular position of the backrest (Trendelenburg and anti-Trendelenburg)

The angle at which the backrest segment is positioned is changed electronically using the controller. In order to adjust the backrest inclination angle in a range from 0 to 90^{O} press the controller left button (item 11, fig. 2).

⚠ **Warning: Do not lower the backrest to the 0^{O} position, if the chair is turned, with relation to the chair base, with an angle of 90 ^{O}, on the left or right.**

8.3 Headrest position adjusting

In order to adjust the headrest height (item 8, fig. 1) it is necessary to unlock the hand wheel, move the headrest up or down manually to the required position, and then lock it in place, (item 9, fig. 1). The angular position of the headrest is locked with a lever placed in the headrest back (item 7, fig. 1). The lever locks the headrest in its top position and unlocks in the down one. The maximum height of the guide of the headrest is marked with an arrow and word ‘MAX’.

8.4 Chair rotation

The rotation locking lever (item 4, fig. 1) is placed under the seat. In order to rotate the chair up to 90^{O} to the left or right, release the lever. In order to lock the chair in the required position, relock using the lever.

⚠ **Warning: Do not turn the chair when it is in an unfolded position.**

9.0 Daily Inspections

⚠ **THE CHAIR SHOULD BE CHECKED EVERY DAY PRIOR TO USE TO ENSURE IT IS OPERATING/FUNCTIONING PROPERLY!**

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

1. Check the mechanisms of adjustment of the height of the seat, adjustment of the backrest position, the seat rotation and the headrest locking mechanisms by changing the position, locking and unlocking (as provided in section 8, Operation).

The mechanisms should work smoothly without any jamming. After locking, the segments should not change their position.

If the chair functions properly without disturbing sounds (squeaks and grinds), the chair can be used safely. If they do not pass the checks, please see Section 11.0 Maintenance and Servicing.

⚠ ***If the product is not fully functional, i.e. the output parameters differ from those described within this user manual, the Chair must not be used.***

10.0 Cleaning and Care

1. For cleaning and disinfecting use those that are recommended by the manufacturer, refer to document List of Cleaning Agents and Disinfectants for iNSPIRIT Medical Solutions Products.
2. After disinfecting, wash the product with water to remove stains.
3. After disinfecting dry thoroughly.
4. Dry with hot air (max. temp. 60°C (140°F)) or by wiping with a soft sterile cloth.

⚠ **The product/ chair must not be disinfected in disinfecting chambers.**

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

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

⚠ **Before disinfecting disconnect the product from main power supply.**

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

11.0 Maintenance and Servicing

11.1 Storage

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, (77ºF±18ºF)
- relative humidity: 50% ± 25%.

11.2 Troubleshooting

If damage(s) and/or defect(s) are found on/in the product or product accessories, the product and/or accessories should be taken out of service and not used until properly repaired.

Problem	*Possible cause*	*Action*
Lack of stability	Uneven floor	Level the chair using adjustable feet
No movements of the backrest segment	Damaged gas spring	Request Service
Lack of stability of headrest inclination angle	Incorrectly set tightening screw	Adjust the tightening screw
No up and down movement	Damaged electric actuator	Request Service

If the problem cannot be eliminated, contract OAKWORKS®, Inc. for service.

11.3 Every 6 month Inspections: Technical Condition Check

In order to ensure safe and proper technical condition of the product, the product should undergo periodical technical inspections to be carried out by authorized and trained technical staff. (Six (6) months is the maximum time allowed in-between inspections.)

⚠ **Technical inspections of the product must be performed and recorded. Proof of 6 Month inspections are required prior to approval of a Warranty claim by the Manufacturer**

Six month inspections are to the following actions being performed and documented:

Scope of Inspection	
Joining elements in the chair	- checking bolt joints and fastening them if necessary
Headrest position adjusting mechanism	- checking and, if needed, replace the headrest height adjusting mechanism
General technical condition	- checking covers (fractures, bends) - checking upholstery (fractures, rips)
Stability	- checking chair stability and leveling, if needed

An inspection should involve a visual inspection and the noticed malfunctions should be handled as provided in *section 11.5, Repairs.*

11.4 Every 12 month Inspections/Preventative Maintenance: Technical Condition Check

In order to ensure safe and proper technical condition of the product, the product should undergo periodical technical inspections and preventative maintenance to be carried out by authorized and trained technical staff or Oakworks authorized Service Provider. Twelve (12) months is the maximum time allowed in-between inspections/preventative maintenance.)

⚠ **Technical inspections of the product must be performed and recorded. Proof of 12 Month inspections are required prior to approval of a Warranty claim by the Manufacturer**

The required inspections and their frequency are shown in the table below:

Range of technical inspections	***Frequency***
- checking of functionality - checking of general technical condition - checking of compliance with the IEC 62353 standard	Not to exceed 12 months, (maximum)
- In order to ensure safe and trouble-free operation of the product during its lifetime, the user should perform tests of compliance with the IEC 62353 standard, according to the scope of inspection table below	after repairs, & periodically (not to exceed 12 months)

Scope of inspection and tests of compliance with IEC62353 standard	
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 grounding resistance • Measurement of leakage currents • Measurement of patient's leakage current • Measurement of insulation resistance
Functional test	• The functional test should be performed in the presence of a person with appropriate qualifications and training to operate the given device • The functional test and the results of specific tests and measurements should be documented

Items to be Inspected that may need to be replaced during the 10-year product life:	• Refer to table below and inspect these components for wear, cracks, noise or reduced functionality. Replace as needed per section 11.5.

Items to be Inspected that may need to be replaced during the 10-year product life			
Name	Qt.	Category[1]	Inspection
Socket without grounding	1	1	Replace if damaged
Power supply cable	1	1	Replace if damaged
Starlock 10	2	1	Replace if worn or damaged
Stopper	2	2	Replace if worn or damaged
Back rest section actuator	1	1	Replace if worn, noise, or reduced functionality
Seat section actuator	1	1	Replace if worn, noise, or reduced functionality
Control box 120V	1	1	Replace if loss of functionality
Starlock 10	2	n/a	Replace is stripped or worn
Stopper	2	n/a	Replace is stripped or worn
Little foot	1	n/a	Replace is stripped or worn

Category Legend[1]

1 - Items expected to wear out or need to be replaced during 10-year life

2 - Items that may wear out or need to be replaced during 10-year life

3 - Items that wear or need to be replaced based on usage.

11.5 Repairs

Repairs are performed by an OAKWORKS® Inc. authorized service provider. The user cannot carry out any repairs unless they have undergone special training and has been authorised to do that. The Manufacturer only allows the use of original spare parts. Worn out parts shall be removed and disposed of per local environmental protection regulations. All repairs are required to be documented and maintained for the life of the product.

12.0 Technical Specifications

Table 12: Technical Specifications

Maximum working load[1]	160 kg (353 lbs
Total width (elbow supports parallel to seat segment)	540 mm ± 15 mm (21.3” ± 0.6)
Total length in armchair position	710 mm ± 15 mm (28” ± 0.6”)

Length of the basis	670 mm ± 10 mm (26.4” ± 0.4”)
Width of the basis	490 mm ± 10 mm (19.3 ± 0.4”)
Maximal height of the seat from the floor	650 mm ± 10 mm (25.6” ± 0.4”)
Minimal height of the seat from the floor	500 mm ± 10 mm (19.7” ± 0.4”)
Maximal length of headrest guide	110 mm ± 10 mm (4.3” ± 0.4”)
Raising angle of the backrest	$90^0 \pm 5^0$
Seat rotation	±90°
Weight	80 kg ± 5 kg (776.4lbs ± 11 lbs)
Power supply	110V~
Power consumption	200VA
Class of electric shock protection	II
Type of applicable section	B
Degree of protection from the weather conditions	IP-X1
Usage time	10 years
Work type	work interrupted 2/18 min
Padding Flammability	NFPA 261, ASTM E1537, and CA TB133

[1] Critical Parameter

13.0 Electromagnetic Information

13.1 Electromagnetic Environment

The chairs below provide recommendations as well as warnings for the user to follow in order to ensure the table is being used within the appropriate electromagnetic environment.

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

Electromagnetic Immunity

Medical device the Ophthalmonology and ENT Chair FL-02 is to be used in electromagnetic environment specified below . The customer or the user of medical device the Ophthalmonology and ENT Chair FL-02 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 The Ophthalmonology and ENT Chair FL-02 use the floor should be w ooden, concrete or covered with ceramic tiles. If the floor is covered w ith 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	Main pow er outlet pow er quality should be that of a typical commercial or hospital environment
Series of quick transitory stages IEC 61000-4-4	± 2 kV for pow er supply lines ± 1 kV for input/ output lines	± 2 kV for pow er supply lines ± 1 kV for input/ output lines	Main pow er outlet pow er quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption and voltage variations on pow er 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	Main pow er outlet pow er quality should be that of a typical commercial or hospital environment. In normal use operating table The Ophthalomonology and ENT Chair FL-02 is battery operated. Connect to main pow er outlet network only for battery charging.
NOTE U_T is the a.c. main pow er outlet voltage prior to application of the test level			

Electromagnetic Immunity

MEDICAL DEVICE THE OPHTHALMONOLOGY AND ENT CHAIR FL-02 IS TO BE USED IN ELECTROMAGNETIC ENVIRONMENT SPECIFIED BELOW. THE CUSTOMER OR THE USER OF MEDICAL DEVICE THE OPHTHALMONOLOGY AND ENT CHAIR FL-02 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 w ith radio frequencies IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be not used not closer to any part of the The Ophthalmononlogy and ENT Chair FL-02 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the trasmiter. **Recommended separating distance:** $d = 1{,}2\sqrt{P}$
Electromagnetic field w ith 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 w here *P* is the maximal output pow er of the transmitter in w atts (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.[b] Interference may occur in the vicinity of equipment marked w ith follow ing 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 the medical device Ophthalmonology and ENT Chair FL-02 is used exceeds the applicable RF compliance level above medical device the Chair FL-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 Ophthalmonology and ENT Chair FL-02

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.

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.

NOTES

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

13.2 Electromagnetic Compatibility

The Ophthalmic and Laryngological Chair FL-02 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.

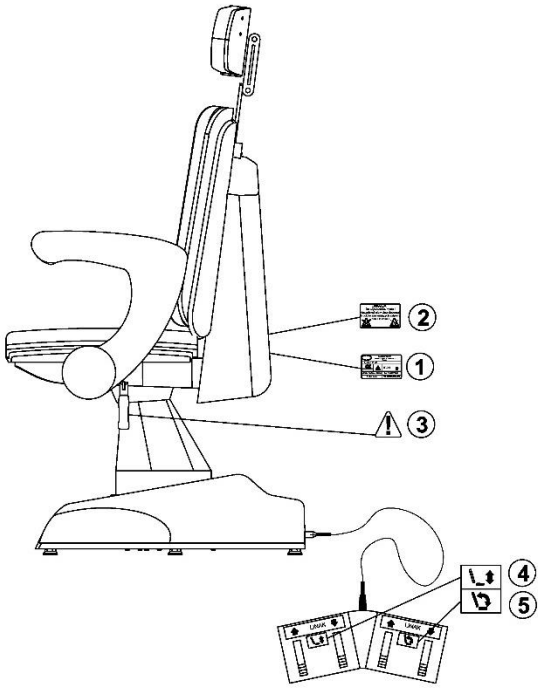
Electromagnetic Emissions

Medical device the Ophthalmonology and ENT Chair FL-02 is to be used in electromagnetic environment specified below. The customer or the user of medical device the Ophthalmonology and ENT Chair FL-02 should assure that it is used in such an environment.		
Emission type	**Classification**	**Electromagnetic environment – guidance**

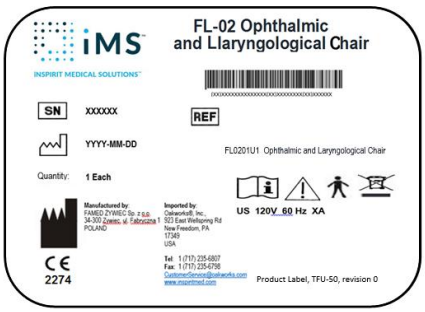
emission RF CISPR 11	Group 1	Medical device the Ophthalmonology and ENT Chair FL-02 produces energy w ith radio frequency only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interference in nearby electronic equipment.
emission RF CISPR 11	Class B	Medical device the Ophthalmonology and ENT Chair FL-02 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low - voltage pow er 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	

14.0 Symbol and Label Identification

14.1 Placement of Labels



14.2 Symbols

1		Product label

2		For cleaning and disinfection you should not use agents containing active oxygen and chlorine
3		"Warning! - Follow the instructions for safe use ".
4		Seat segment height regulation
5		Back-rest angle adjustment
6		Maximum load
7		Follow the instructions

15.0 Disposal

Disposal of the chair and/or packaging materials must be compliant with the applicable regulations and requirements of the local state environmental protection agency, state health agency, Centers for Disease Control (CDC), Occupational Safety and Health Administration (OSHA), U.S. Food and Drug Administration (FDA) as well as any other local authorities that apply to this medical device.

As provided in the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, this device is a Class I medical device per Rule 12.The manufacturer declares that the product meets the essential requirements of the directive contained in Annex I. The compliance procedure was carried out in accordance with Annex VII of the directive.

CE
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Manufactured by:
FAMED ŻYWIEC Sp. z o.o.
34-300 Żywiec, ul. Fabryczna 1
POLAND

Imported by:
Oakworks® Inc.,
923 East Wellspring Rd
New Freedom, PA 17349, USA