

# USER MANUAL



## LARYNGOLOGICAL CHAIR FO-02



INSPIRIT MEDICAL SOLUTIONS™



**INSPIRIT MEDICAL SOLUTIONS**

A Collaboration of OAKWORKS MEDICAL  
and FAMED Medical Solutions

**OAKWORKS®, Inc.**

**Corporate Office:**

923 East Wellspring Rd.  
New Freedom, PA 17349 USA

**Contact Us At:**

Tel: (717) 235-6807

Fax: (717) 235-6798

[CustomerService@oakworks.com](mailto:CustomerService@oakworks.com)

[www.inspiritmed.com](http://www.inspiritmed.com)

All inquiries should be directed to **OAKWORKS®, Inc.**, the initial importer.

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

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## Table of Contents

<b>1.0 INTENDED USE</b> .....	<b>4</b>
<b>2.0 CONTRAINDICATIONS</b> .....	<b>4</b>
<b>3.0 WARNINGS AND PRECAUTIONS</b> .....	<b>4</b>
<b>5.0 UNPACKING</b> .....	<b>6</b>
<b>6.0 INSTALLATION</b> .....	<b>7</b>
6.1 Installation Checklist .....	7
<b>7.0 ACCESSORIES</b> .....	<b>8</b>
<b>8.0 OPERATION</b> .....	<b>8</b>
8.1 Change of the seat height .....	8
8.2 Adjustment of backrest segment position .....	9
8.3 Headrest position adjusting .....	9
8.4 Chair rotation .....	9
<b>9.0 DAILY INSPECTIONS</b> .....	<b>9</b>
<b>10.0 CLEANING AND CARE</b> .....	<b>10</b>
<b>11.0 MAINTENANCE AND SERVICING</b> .....	<b>10</b>
11.1 Storage .....	10
11.2 Troubleshooting .....	10
11.3 Every 6 month Inspections: Technical Condition Check .....	11
11.4 Every 12 month Inspections/Preventative Maintenance: Technical Condition Check .....	11
11.5 Repairs .....	12
<b>12.0 TECHNICAL SPECIFICATIONS</b> .....	<b>13</b>
<b>13.0 SYMBOL AND LABEL IDENTIFICATION</b> .....	<b>14</b>
13.1 Placement of Labels .....	14
13.2 Symbols .....	14
<b>14.0 DISPOSAL</b> .....	<b>15</b>

## 1.0 Intended Use

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The FO-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

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

## 3.0 Warnings and Precautions

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***Please read this user manual carefully and completely prior to operating the FO-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.



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

### Notes concerned with safety

- Do not use accessories, additional equipment, or spare parts other than those offered and/ or advised by the Manufacturer.

- 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.
- 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.

**4.0 Product Description**

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This chair has adjustable height due to a foot controlled hydraulic actuator. The back rest segment inclines/declines utilizing a gas spring and a hand operated lock. The chair is capable of rotation and is equipped with assembled, adjustable, head rest with locking mechanism. The chair is equipped with left and right hand rests that are adjustable up and down and are detachable.

**4.1 Components**

**Components**

<b>Position on Figure 1</b>	<b>Description</b>
1	Base set
2	Carrying column
3	Seat segment
4	Swivel lock
5	Arm rest
6	Back rest segment
7	Headrest interlocking mechanism
8	Headrest
9	Back rest release mechanism
10	Pedal of up-down adjustment pump
11	Head rest bar lock knob

## 4.2 Product Drawing

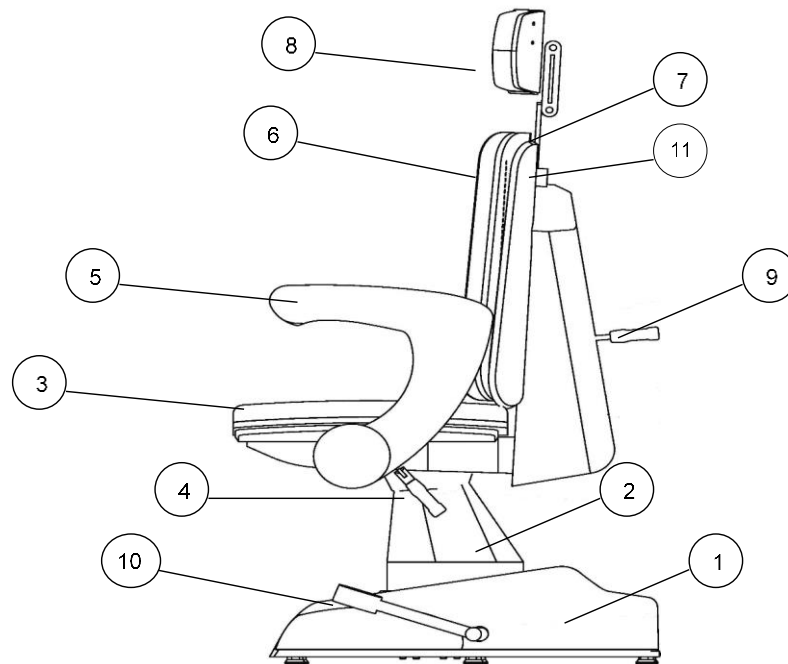


Fig.1 The Laryngological-Mechanical chair FO-02

## 5.0 Unpacking

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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:




1. set the pallet
2. take off the fastening tapes
3. remove the cardboard casing
4. remove the materials protecting the chair during its transportation
5. remove the chair from the pallet slowly and move it to its destination (during removing, places of support must be chosen on the base surface from the floor side, do not grip the edge of base support).



**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**

6. read the user manual carefully.
7. start up the product as described in Installation.

The packaging may be marked with the following symbols:

	Multiuse Package
	Package for Recycling
	Low-Density Polyethylene Packaging



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

## 6.0 Installation

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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. Check if there are any clearances in mechanical joints by manual moving seat chair segments and construction elements.
3. Check the adjustment mechanisms for seat position, backrest and headrest by locking and unlocking (acc. to point. 3 – Service). Mechanisms should work without jamming. After locking, the segments should not change their positions.
4. 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 manual functions
  - Backrest Adjustment
  - 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**

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Accessory Name	Identifier Number
Foot Rest	WF-45.0

## **8.0 Operation**

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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 hydraulically by pressing the lever located at the base of the chair, (fig. 1, pos. 10). In order to change the height of the seat in the range of ~140 mm (5.5”) from the floor level, the lever should be pressed with foot until the desired height is obtained. To lower the chair, the lever should be lifted with foot and the chair will be lower as long as the lever is lifted or until it is in the lowest position.



## 8.2 Adjustment of backrest segment position

Adjustment of backrest inclination angle is done with gas springs. Gas springs should be unlocked with lever located behind the backrest segment. (fig. 1, pos. 9). After adjusting, relock the backrest.

## 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° to the left or right, release the lever. In order to lock the chair in the required position, relock using the lever.

## 9.0 Daily Inspections

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**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

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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

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 **The product contains products which may be dangerous to the environment:**  
**- oil (hydraulic actuator, pneumatic spring)**

### 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: 25° ±10°C, (77°F±18°F)
- 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.

<i>Problem</i>	<i>Possible cause</i>	<i>Action</i>
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:

<i>Scope of Inspection</i>	
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:

<i>Range of technical inspections</i>	<i>Frequency</i>
- checking of functionality - checking of general technical condition	Not to exceed 12 months, (maximum)
- Items to be Inspected that may need to be replaced during the 10-year product life, see table below.	Not to exceed 12 months, (maximum)

Items to be Inspected that may need to be replaced during the 10-year product life			
Name	Qt.	Category <sup>1</sup>	Inspection
Foot pump	1	1	Replace if worn or damaged
Cord L-600	1	1	Replace if worn or damaged
Stopper for wood screws	2	2	Replace if damaged
Sealing ring 8,3x2,4	1	1	Replace if leaking, worn or damaged
Sealing ring 24,2x3	1	1	Replace if leaking, worn or damaged
Release lever	1	2	Replace if worn or damaged
Starlock 10	2	n/a	Replace if damaged
Starlock 8	2	n/a	Replace if damaged
Stopper for wood screws	2	n/a	Replace if damaged
Stopper M12x30	1	n/a	Replace if damaged

#### **Category Legend<sup>1</sup>**

- 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

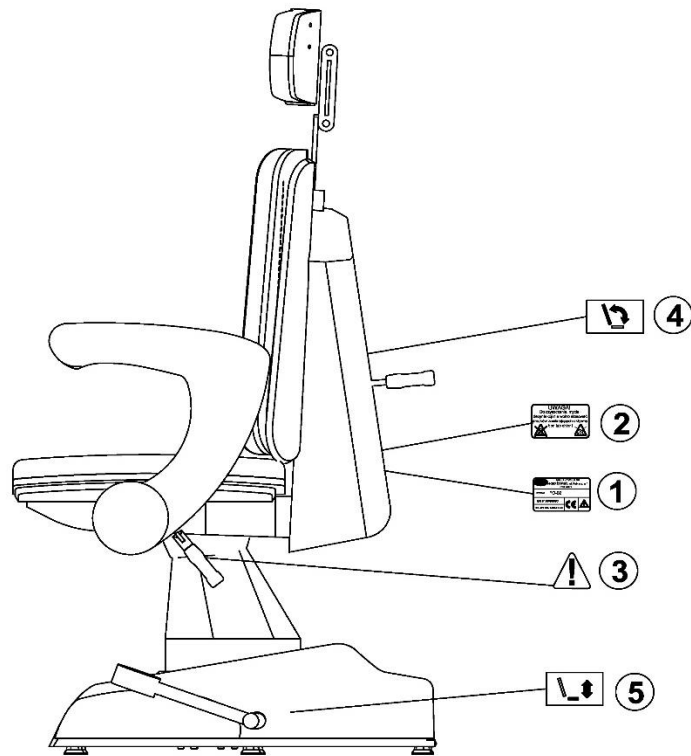
**Table 12: Technical Specifications**

Maximum working load <sup>1</sup>	160 kg (353 lbs)
Total width	540 mm ± 15 mm (21.3" ± 0.6)
Total length in armchair position	710 mm ± 15 mm (28" ± 0.6")
Length of the base	670 mm ± 10 mm (26.4" ± 0.4")
Width of the base	490 mm ± 10 mm (19.3 ± 0.4")
Maximal height of the seat from the floor	640 mm ± 10 mm (25.2" ± 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	45 <sup>0</sup> ± 3 <sup>0</sup>
Rotation of back rest segment	±90°
Weight	80 kg ± 5 kg (776.4lbs ± 11 lbs)
Drive	hydraulic actuator & gas spring
Usage time	10 years
Work type	work interrupted 2/18 min
Padding Flammability	NFPA 261, ASTM E1537, and CA TB133

<sup>1</sup> Critical Parameter






# 13.0 Symbol and Label Identification

## 13.1 Placement of Labels



## 13.2 Symbols

1		Product label
2		It means that there should be no contact between product and agents containing active chlorine or oxygen.

3		Warning! - Follow the instructions for safe use.
4		Back-rest angle adjustment keys
5		Seat segment height regulation
6		Maximum load
7		Follow the instructions

## 14.0 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 1. 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.*



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