

# USER MANUAL



## FG-06 Gynecological Chair



INSPIRIT MEDICAL SOLUTIONS™



**INSPIRIT MEDICAL SOLUTIONS™**

A Collaboration of OAKWORKS MEDICAL  
and FAMED Medical Solutions

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This manual is approved, in English, by FAMED ŻYWIEC Sp. z o.o., the  
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## 1.0 Intended Use

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The FG-06 Gynecological Chair is intended to be used to support a patient during gynecological examinations and procedures. It may be also used for urological examinations and procedures.

## 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 FG-06 Gynecological Chair.***

***Operating, maintaining and/or servicing of the FG-06 Gynecological Chair 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 FG-06 Gynecological Chair. 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 the FG-06 Gynecological Chair 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.***

- When Trendelenburg and reverse-Trendelenburg functions are being performed and the angular position of the backrest is being adjusted one shall safeguard the patient, that is, use a little force to prevent a sudden fall of the adjusted segment.
- When carrying the chair, do not hold plastic casings of the basis and the column because that may cause their damage.
- One may neither stamp on the casing of the basis nor put any heavy objects there because that may cause a damage (cracking) of the casing.
- A patient may sit on the chair only when the shank segment is removed.
- In order to avoid permanent iodine or blood stains, one shall remove them directly after a procedure and use disposable towels.
- Move the chair without the patient
- While the chair is being moved the floor must be free from obstacles!
- When moving the chair, avoid collisions!

- Do not roll the chair over electric cables!
- The weight of the patient cannot exceed 135 kg (298 lbs)!

## 4.0 Description of FG-06 Gynecological Chair

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The FG-06 Gynecological Chair is equipped with the possibility to change the gynecological chair's backrest and seat segment angular position due to pneumatic springs which are activated by movement of levers located in places convenient for the operator. On both sides of the chair there are side rails for mounting the accessories e.g. arm support, knee rests etc.

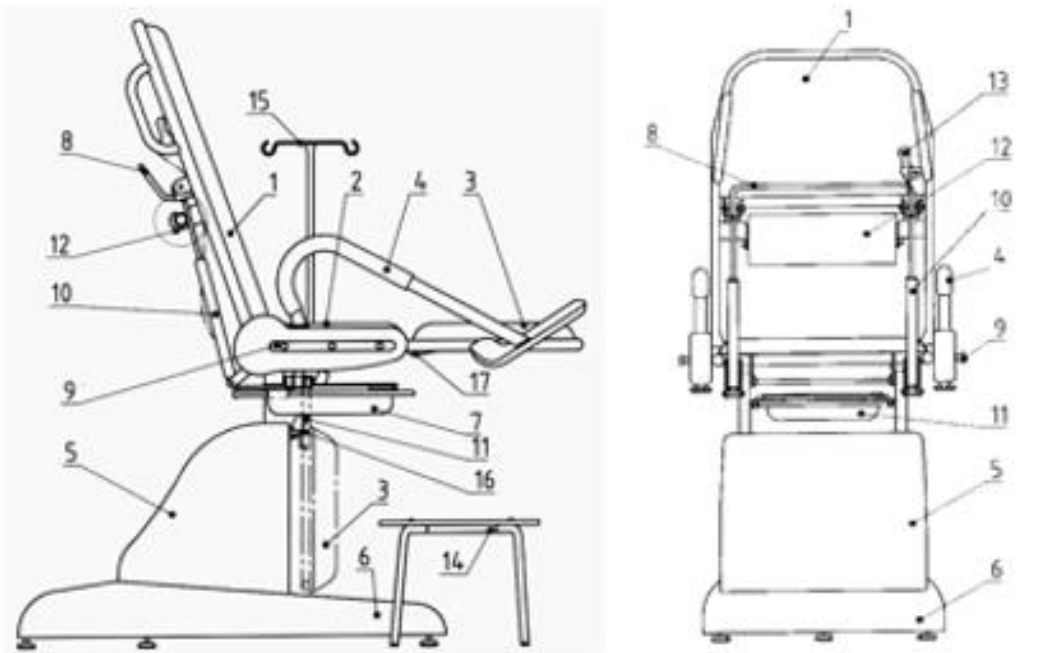
Optionally the seat segment can be extended with leg support. The pull out bowl is placed under the seat segment. Inside the backrest there is a paper roll which protects the patient against the direct contact with the chair covers. In the standard version, the base of the chair is equipped with regulated feet (to place the base in horizontal position), optionally the base can be equipped with wheels that have individual brakes.

### 4.1 Components of the FG-06 Gynecological Chair

**Table 1: Components of FG-06 Gynecological Chair**

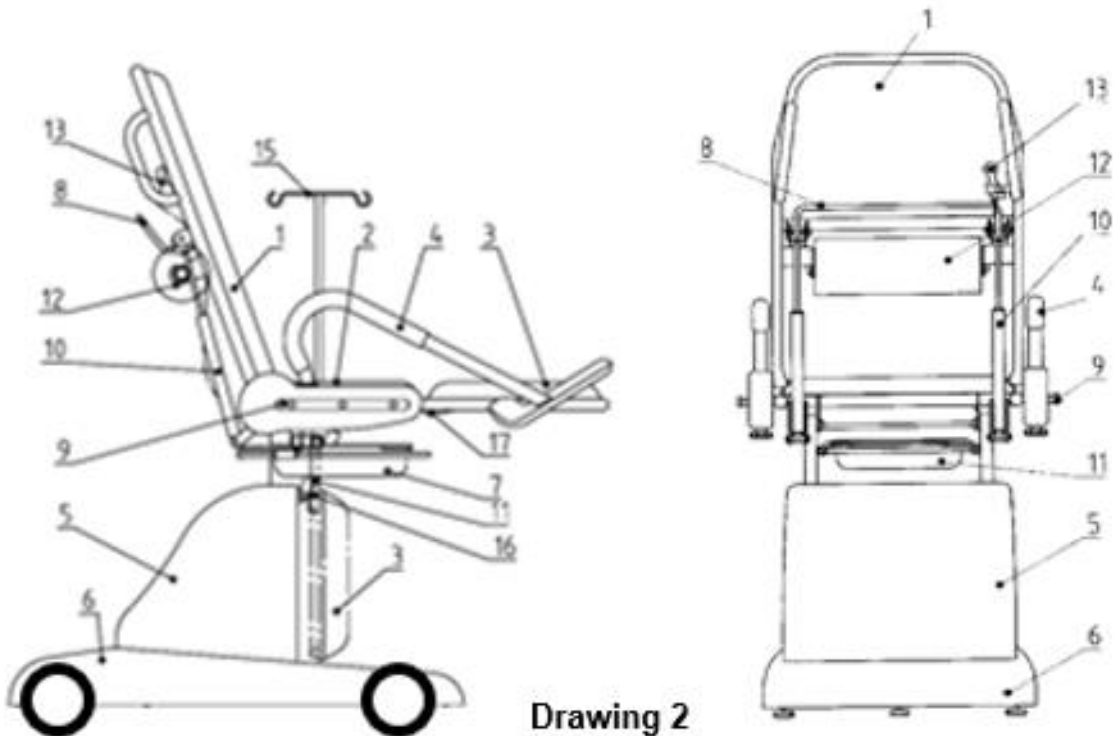
Item Number Listed on the Drawings in Section 4.2	QTY	Equipment Type S-Standard O-Optional	Description
1	1	S	Back rest segment
2	1	S	Seat segment
3	1	O	Thigh segment WF-22.1
4	2	O	Hand rest with leg support WF-35.0, WF-36.0, WF-37.0
5	1	S	Column
6	1	S	Base
7	1	S	Bowl
8	1	S	Lever
9	2	S	Side rails
10	1	S	Gas springs of backrest
11	1	S	Gas springs of seat segment
12	1	S	Sheet paper – foil
13	1	S	Grip
14	1	O	Knee rests WF-03.5
15	1	O	Drip bottle holder
16	2	S	Hangers
17	1	S	Lever

## 4.2 FG-06 Gynecological Chair Drawings – Standard Model and Mobile Model



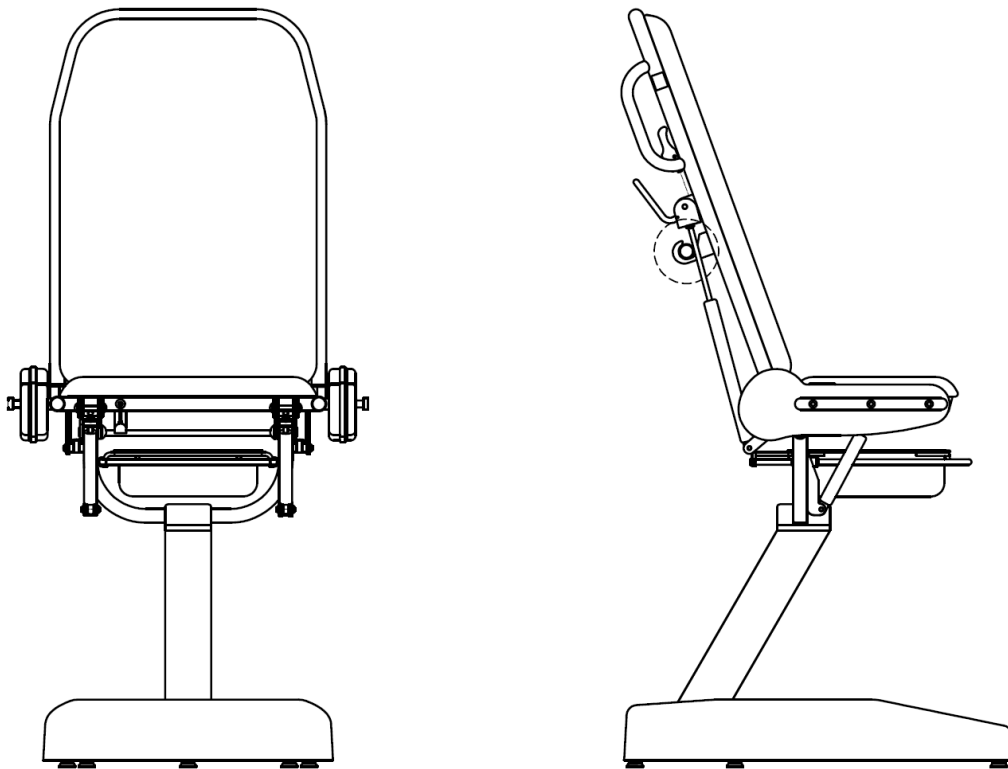
**Drawing 1**

**Stationary chair – standard version FG-06.0**



**Drawing 2**

**Mobile chair- optional version FG-06.0**



**Drawing 3**

Chair without column housing, with modified base– optional version FG-06.1 (subassemblies marking as above).

## 5.0 Unpacking the FG-06 Gynecological Chair

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The FG-06 Gynecological Chair is shipped by the manufacturer in an assembled form within a wooden crate or a cardboard box.

To prepare the chair for its 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,

**⚠ Proceeding with the package waste should comply with the law requirements from the area of environment protection obligatory in place of introducing the product in package. Package waste is recyclable and should be properly segregated and deliver according to local law requirements to the disposal point of waste separately collected.**




To unpack the FG-06 Gynecological Chair, the following actions must be completed:

- Read the FG-06 Gynecological Chair User Manual completely and entirely



- Remove the fastening tape
- Remove the package
- Remove the materials used for protecting the table during transit
- Remove the equipment from the shipping container
- Take the equipment out of the package
- Remove the chair from the pallet slowly and move it to its destination

The FG-06 Gynecological Chair 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 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 each type of packaging.**

**⚠ When moving the chair, do not hold the plastic casings of the base and frame as that may result in damage. When removing elements, select support points on base surface from ground side. Do not grip by base cover edge.**

## 6.0 Installation of FG-06 Gynecological Chair

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After unpacking the FG-06 Gynecological Chair, the below steps must be followed in order to prepare the table for operation:

Step 1: Read the user many extremely carefully

Step 2: Start up the FG-06 Gynecological Chair as described in Section 6.1 Installation and First Use

**⚠ If the product is not fully functional, i.e. the output parameters differ from those described within this user manual, the FG-06 Gynecological Chair 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 for the table.**

## 6.1 Installation and Start-Up

Step 1: Install additional accessories

Step 2: level the chair using adjustable feet (with a flat wrench with span 16),

Step 3: paper sheet roll (Drawing 1, Item 22) should be fixed on grips behind the backrest. The band of the sheet should be wrapped behind the upholstery of the backrest to the seat,

Step 4: place the product at its destination which meets the requirements defined in this manual

Step 5: based on the information provided in the Operation section of this manual.

**⚠ If the product is not fully functional, i.e. the output parameters differ from those described within this user manual, the FG-06 Gynecological Chair 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 for the table.**

## 6.2 Installation Checklist

- Check Manual Regulations
  - Backrest Adjustment
  - Trendelenburg / reverse-Trendelenburg – seat section and backrest section
- Install and adjust footrests
- Replacement of paper rolls
- Install leg plate (Option)

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

## 7.0 Installation and Operation of Accessories

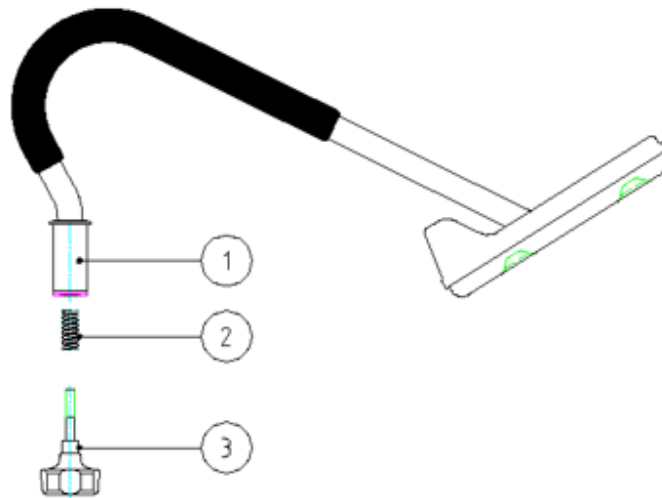
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The FG-06 Gynecological Chair is equipped with a variety of accessories, which are specified in the table under Drawing 1. The accessories are mounted in suitable seats fitted for this purpose, or in special rails used to fasten equipment.

**Table 2: Extra Accessories That May Be Provided With the FG-06 Gynecological Chair**

<b>Accessory</b>	<b>Part Number</b>
Thigh segment	WF-22.0
Knee rest together with hand rest (2 pcs)	WF-42.0
Foot stool with laminated board /varnished steel/	WF-03.5
Foot stool with upholstered board /chromium plated steel/	WF-03.3
Foot stirrups (2 pcs) only with WF-42.0	WF-23.0
Drip bottle holder	WK-01.5

## 7.1 Footrest



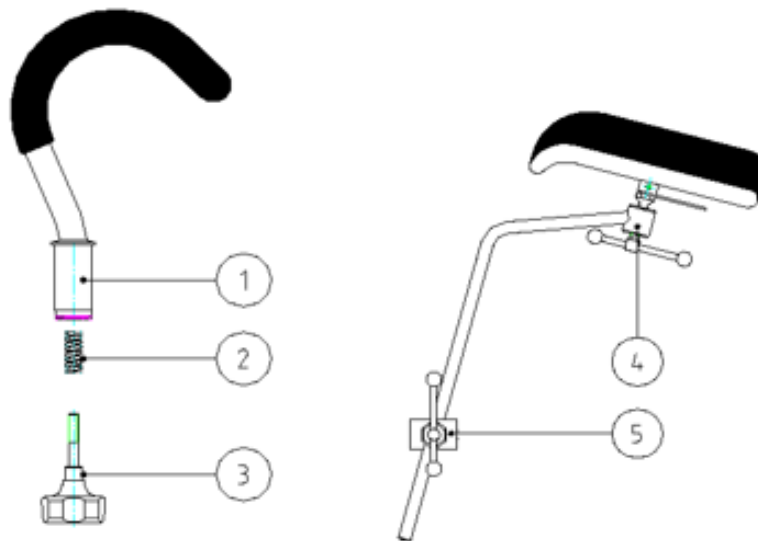
**Drawing 4**

The Footrest (Drawing 4) is offered in three versions:

- Footrest with shank grip without the arm's length regulation (WF-35.0)
- Footrest in standard version without the arm's length regulation (WF- 36.0)
- Footrest with arm's length regulation (WF-37.0)

In order to install the footrest one should put the spring (Drawing 4, Item 2) in the seat of the arm support (Drawing 4, Item 1) put the whole footrest towards the inside of the chair in the seat. Do not remove the lubricant from the sleeve of the arm support. Then screw the knob from below (Drawing 4, Item 3) and screw it down till the footrest is fixed.

## 7.2 Knee Rest Together with Handrest



**Drawing 5**

The Knee rest and hand rest (WF-42.0) are offered instead of footrests. The hand rest should be mounted like the footrest. They should be put on the socket inside of the chair then screw the knob from below (Drawing 5, Item 3) and screw it down until the footrest is fixed.

The knee rest should be installed on the side strips of the chair using multi-position grips (Drawing 5, Item 5).

**⚠ *Simultaneously applying the footrest and knee rest is prohibited and could result in damages of the polyurethane cover of the footrest.***

### **7.3 Shank Segment**

The shank segment WF-22.0 is fastened to the seat by its installation on the guides located in the seat. After the installation the segment is blocked automatically which makes slipping out impossible. In order to remove the segment, release the lock by pressing the levers placed inside of the pipes of the framework of the shank segment.

### **7.4 Drip Hanger**

The drip hanger (Drawing 1, item 15) shall be installed with a multi-position grip on the side strip of the chair (Drawing 1, Item 9)

**⚠ *Drip hanger hook (basket) maximum load should not exceed 2 kg (4 lbs).***

## **8.0 Operation**

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The FG-06 Gynecological Chair is designed 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 the FG-06 Gynecological 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.

### **8.1 Backrest Position Adjustment**

The position of the backrest is adjusted manually (with the power of one's muscles) using pneumatic springs. The mechanism of adjustment of the angle of the backrest allows to set any angle of inclination within the range indicated within Section 12.0 Technical Specifications. In order to change the angle of the backrest, press the lever (Drawing 1, Item 8), adjust the backrest in the required position and release the lever.

**⚠ *During the above activity protect the patient, i.e. use some force to prevent sudden dropping of the backrest.***

## 8.2 Adjustment of the Trendelenburg and reverse-Trendelenburg Positions

The Trendelenburg and reverse-Trendelenburg positions are adjusted manually (with the power of one's muscles) using pneumatic springs. In order to set the required Trendelenburg or reverse-Trendelenburg position, hold the backrest with both hands from behind (Drawing 1, Item 13), and by pressing the lever with your right thumb set the pallet in a required position and finally release the lever.

**⚠ During the above activity protect the patient, i.e. use some force to prevent sudden dropping of the body of the chair in the Trendelenburg direction.**

## 8.3 Changing the Angle of Rotation of the Armrest with Footrest

The angle of rotation in the horizontal plane is changed by turning the knob (Drawing 1, Item 4) to the left till the lock is unlocked, then the position of the armrest with footrest should be adjusted and locked again by turning of the knob to the right till resistance is felt.

## 8.4 Adjustment of the Positions of the Armrest, Knee Rest, and Stirrup

After installation of the armrest on the side strip, set it in the required position and lock with a knob with a butterfly screw.

Depending on the needs and the size of the legs of a patient, the knee supports may be put in the following positions:

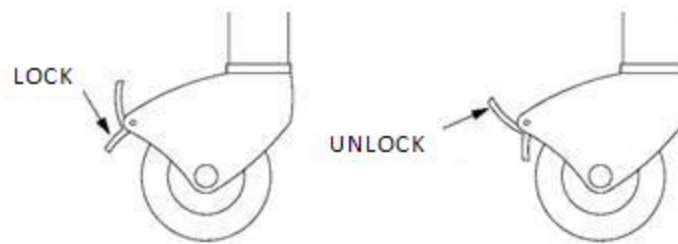
1. spreading to the sides,
2. raised or lowered in relation to the seat,
3. the required inclination which changes the position of the part of the leg of a patient under the knee.

Knob of multiposition clamp (Drawing 5, Item 5). is used to set the position described in item 1 and 2. If the knob is turned to the left and the extension arm is turned around the axis of its fixing in the grip, the position described in item 1 will be set. If the extension arm is raised or lowered in relation to the grip, the position described in item 2 will be set. The knee support is locked in the chosen position with identical knob turning it to the right. After the knob is unlocked by its turning to the left, set the knee support in the required inclination position (Drawing 5, Item 4 or 5) – the knee support is set in the position described in item 3; then lock the knob turning it to the right.

The stirrup is fixed on the rod of the extension arm. The height of the stirrup is adjusted by turning of the knob, raising or lowering of the stirrup and then turning it down lightly. The length of the stirrup is adjusted by inserting one element into another or pulling it out of the other, and the position is locked and unlocked by turning of the knob.

## 8.5 Mobile Base With Wheels Blockade (Option)

The optional version the base of the chair is equipped with four wheels with individual brakes. When the brakes are released it is possible to move the chair in all directions, when brakes are fixed the chair stands stable. To move the chair again brakes should be released again. See below drawing.



**Drawing 6**

The mobile base makes it possible to disinfect the floor under the chair.

- ⚠ ***Move the chair without the patient***
- ⚠ ***While the chair is being moved the floor must be free from obstacles!***
- ⚠ ***When moving the bed, avoid collisions!***
- ⚠ ***Do not roll the bed over electric cables!***

## **9.0 Daily Inspection**

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- ⚠ ***The FG-06 Gynecological 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:

- Check the mechanisms of adjustment of the height of the couch, adjustment of the backrest position, the Trendelenburg and reverse-Trendelenburg position and the locking mechanism of the shank segment by changing the position, locking and unlocking. The mechanisms should work smoothly without any jamming. After locking the segments should not change their position.
- Check if additional accessories are fixed firmly and reliably.

If the chair underwent the above-described tests with positive results, it can be used safely.

Otherwise see the 'Location of defects and their removal' section of this manual.

- ⚠ ***If the product is not fully functional, i.e. the output parameters differ from those described within this user manual, the FG-06 Gynecological Chair must not be use***

## **10.0 Cleaning and Care**

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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.

After disinfecting, wash the product with water to remove stains.

After disinfecting dry thoroughly.

Dry with hot air (max. temp. 60°C or 140°F) or by wiping with a soft sterile cloth.

⚠ Elements made of plastic cannot be treated with any cleaning or disinfecting agents that contain ingredients which would destroy the linkage structure. An example of such ingredients would be organic solvents.

⚠ No bleaching agents (containing active chlorine or oxygen), caustic or corrosive chemicals are allowed to be used on the FG-06 Gynecological Chair.

⚠ The product must not be disinfected in disinfecting chambers.

**Disregarding the above requirements for cleaning and disinfecting shall result in loss of the warranty for the FG-06 Gynecological Chair.**

## 11.0 Maintenance and Servicing

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- Hand supports should be fixed on the table strip with a multi-position grip. This enables the support of angular movements.
- If it is necessary to replace oil, the user should follow the appropriate environmental protection regulations.

### 11.1 Storage

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

- temperature: 25° (77°F) ±10°C (18°F)
- relative humidity: 50% ± 25%.

### 11.2 Damages and Defects

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.

### 11.3 Repairs and Inspections

Prior to starting any repairs the chair must be disconnected from the main power outlet.

Repairs are done by an Oakworks® Inc., authorized service provider and recorded. The user cannot carry out any repairs on their own unless they have undergone special training or has been authorized to do so by Oakworks® Inc.

In order to provide safe and reliable operation of the product, spare parts recommended by the manufacturer should be used.

Records of repairs and inspections must be retained to maintain warranty.

## 11.4 Control of Technical Condition

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.

 **Only a positive result of product inspection can be the basis for its further operation.**

Required inspections and the scope of the review	frequency
<ul style="list-style-type: none"> <li>- checking of functionality</li> <li>- checking of general technical condition</li> </ul>	every 12 months

In order to ensure safe and proper technical condition of the chair during its whole lifetime, every six months the user should carry out inspections and perform maintenance activities as provided on the list below:

Basis	- Check pins of the main brackets (between the basis and the couch)
Seat	<ul style="list-style-type: none"> <li>- check pins in the brackets between the seat and the backrest</li> <li>- check whether pneumatic springs seat work correctly</li> <li>- check whether pneumatic springs backrest work correctly</li> <li>- check the blockade of the foot support</li> </ul>
Accessories	<ul style="list-style-type: none"> <li>- check functionality</li> <li>- check whether locks work correctly</li> </ul>

## 11.5 Location and Removal of Defects

defect	possible cause	removal
Lack of stability	Uneven floor	Level the chair using adjustable feet
No movements of the backrest segment	Damaged gas spring	Inform the service
No up and down movement	Damaged hydraulic actuator	Inform the service
No inclination movement of the seat.	Damaged gas spring or locking cord	Inform the service

## 11.6 Spare Parts List for the FG-06 Gynecological Chair

### Basic spare parts

No	Name	Qt.	Category	Inspection
1	Mandrel of seat hinge	1	2	Replace if worn or cracked
2	Mandrel of back rest hinge	2	2	Replace if worn or cracked
3	Pin I	2	2	Replace if worn or cracked
4	Pin II	2	2	Replace if worn or cracked
5	Pin III	2	2	Replace if worn or cracked
6	Rope	1	1	Replace if worn or cracked
7	Sleeve	8	3	Replace if worn or cracked



8	Gas spring	2	1	Replace if worn or cracked
9	Gas spring	2	1	Replace if worn or cracked

### Category Legend

- 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.

## 12.0 Technical Specifications

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**Table 12: Technical Specifications**

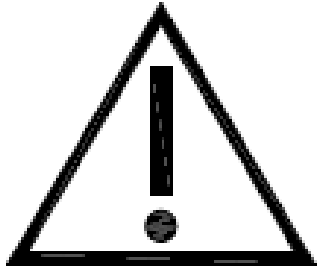
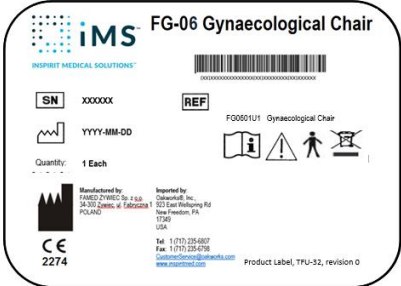

Total length with the thigh segment	1740 mm ± 15 mm 69 in ± 0.2 in
Total length without the thigh segment	1280 mm ± 15 mm 50 in ± <b>0.2 in</b>
Seat Width	600 mm ± 10 mm 29 in ± 0.4 in
Total Width	775 mm ± 10 mm 31 in ± 0.4 in
Height– standard model	860 mm ± 20 mm 34 in ± 0.8 in
Height – mobile model	880 mm ± 10 mm 35 in ± 0.4 in
Backrest angel	0° ÷ 70° ± 5°
Trendelenburg position	0° ÷ 20° ± 3°
reverse-Trendelenburg position	0° ÷ 10° ± 3°
Seat dimensions with thigh segment	1740 x 600 mm ± 15 mm 69 x 24 in ± 0.2 in
Seat dimensions without thigh segment	1280 x 600 mm ± 15 mm 50 x 24 in ± 0.2 in
Weight	about 125 kg about 276 lbs
Maximal working load of the chair	135 kg 298 lbs
Usage period	10 Years





### 12.1 Critical Parameters

**Maximal Workload: 135 kg (298 lbs).**

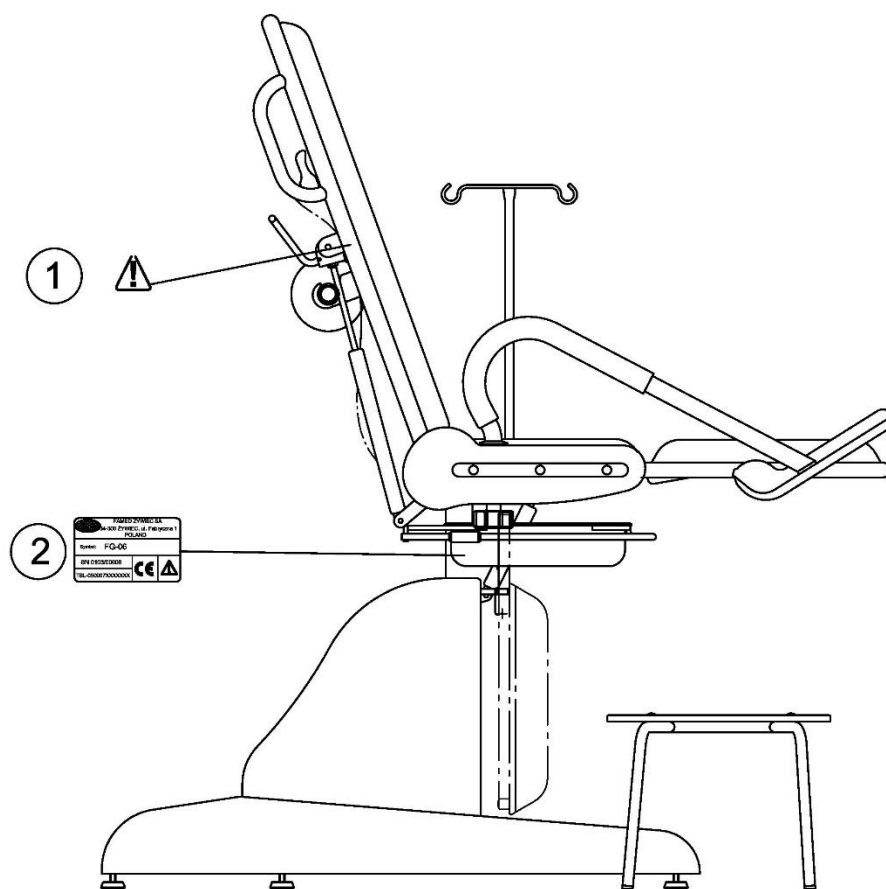
**Drip Hanger Maximum Load: 2 kg (4 lbs ) per one hook / basket**

## 13.0 Symbol and Label Identification

<p>1</p>		<p>“Caution”</p>	<p>Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.</p> <p>This label will be placed on any part(s) or mechanism(s) which may prove to be harmful to the patient or user if the directions within this manual are not followed appropriately.</p> <p>Section 13.1 Placement of Labels on the FG-06 Gynecological Chair – Drawing 7, Item 1.</p>
<p>2</p>		<p>Product label</p>	<p>Drawing 7, Item 2</p>
<p>3</p>		<p>Maximum Weight</p>	<p>This label is a visual indicator for the maximum weight of the FG-06 Gynecological Chair.</p> <p>For the location of this label, see Section 13.1 Placement of Labels on the FG-06 Gynecological Chair – Drawing 7, Item .</p>

4		Follow the Instructions Label	<p>This label is a visual indicator for the user to follow the instructions provided within this manual.</p> <p>For the location of this label, see Section 13.1 Placement of Labels on the FG-06 Gynecological Chair – Drawing 7, Item .</p>
-		“Multiuse Package”	This symbol may be located on the packaging of the FG-06 Gynecological Chair when being transported.
-		“Package for Recycling”	This symbol may be located on the packaging of the FG-06 Gynecological Chair when being transported.
-		“Low-density Polyethylene Packaging”	This symbol may be located on the packaging of the FG-06 Gynecological Chair when being transported.

## 13.1 Placement of Labels on the FG-06 Gynecological Chair



Drawing 7

## 14.0 Disposal

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Disposal of the FG-06 Gynecological Chair 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.

This product contains products which may be dangerous to the environment such as oil (pneumatic spring oil). Please dispose of properly per the above instructions.

*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:  
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POLAND

Imported by:  
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923 East Wellspring Rd  
New Freedom, PA 17349, USA