

# Raphael 707-PR

***Orthopedic Adjustment Equipment (R707-K)***

***Issued Date : August 02, 2023 (Rev.1.00)***

***Document number : R707\_UM***

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## General Information

This User Manual provides a description of the system component, its controls and display, instructions for how to use, safety information and labeling to user.

Please be aware of all these precautionary before operating the system and keep informed on appropriate indications and contraindication for the uses of R707

This User Manual is not a substitute for clinical treatment guidelines and training provided by the company

# CHAPTER 1. System Description

## 1.1 Introduction

R707-K stands for Raphael 707 Prestige, and R707-K is a non-surgical spine treatment table. It is a Chiropractic Table that can be treated using drop, flexion, automatic flexion, traction, decompression and ascent of various angles and heights.

## 1.2 Product Raphael 707-PR

<i>Product or trade name</i>	Raphael 707-PR
<i>Model number</i>	R707-K
<i>EMDN code</i>	V080699, Medical beds - other
<i>MDN/MDA and MDS/MDT scope</i>	MDA 0313, in accordance with the Medical Device Coordination Group (MDCG 2019-14) established by Article 103 of Regulation (EU) 2017/745.
<i>Basic unique device identification device identifier (UDI-DI)</i>	{88001606RaphaelQS}

## 1.2 Specification

Model name		R707-K
Product name		Orthopedic Adjustment Equipment
Power		AC 220/230V, 50/60Hz, 400VA
Width		670 mm
Height		1,760~2,280 mm
Elevation height		830~1,130 mm
Weight		130 kg
Mattress angle	Cervical	-23.5°(bottom) ~ 17.8°(top)
		14°(left) ~ 14° (right)
	Pelvic	Flexion : 0°(top)~ -22.4° (bottom)
		22°(left) ~ 22° (right)
Size(mm)	Traction	0 ~ 100mm
	Cervical handle	0 ~ 240mm

	<b>Ankle mattress</b>	0 ~ 280mm
	<b>Safe working load</b>	150kg
	<b>Operating condition (Traction, Flexion, Elevation)</b>	On time : 2min , Off time : 18min
	<b>Environmental condition</b>	<p style="color: red;">&lt;Operating condition&gt;            Temperature: 10-40℃             Relative Humidity: 20-75 % R.H.            Atmospheric pressure: 700-106 KPa            Hospital environment, Indoor</p> <p style="color: red;">&lt;Transport &amp; Storage condition&gt;            Temperature: 0 ~ 40℃             Relative Humidity: 25-80 % R.H.            Atmospheric pressure: 70-106 KPa</p>

### 1.3 Device Description

R707-K is to correct human body into a normal position and has 5 different mattresses(cervical, lumbar, pelvic, ankle, armrest) with touch screen to control operation, switches, levers, etc. Main functions like elevation, drops, traction, flexion can be controlled by touch screen. With foot switch (\*option), elevation and cocking can be controlled. Also, safety function like emergency stop and 'back to the original position' are adopted for patient's protection.

### 1.4 Intended purpose of the device:

This Orthopedic adjustment equipment is to correct human body into a normal position. spine treatment device made by grafting the treatment techniques of various spine treatment devices into one device.

### 1.5 Intended users of the device:

- 1) Education: At least fourteen years of education and have a doctor/nurse license and no maximum limitation.
- 2) Knowledge: Minimum they can read and understand Arabic numerals and distinguish mouth, nose, ear, torso, head, arms and legs. And also they have the knowledge of physiotherapy, there is no maximum limitation
- 3) Language understanding: They should be able to understand the numeric values and general technical information presented in the user manual written in Korean or English
- 4) Experience: No special experience needed and no maximum
- 5) Permissible impairment:
  - Mild reading vision impairment or vision corrected to log MAR 0.2(6/10 or 20/32)
  - Impaired by 40% resulting in 60% of normal hearing at 50Hz to 2kHz

## 1.6 Intended patient population

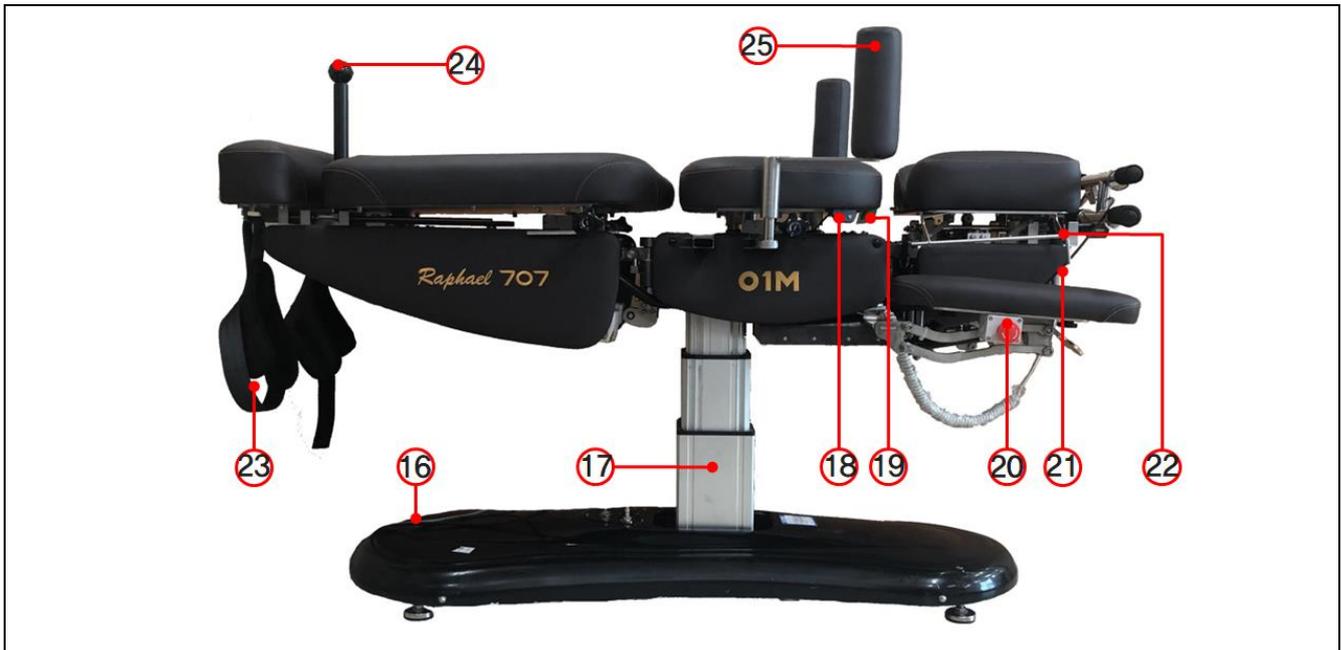
- 1) Age : No limitation
- 2) Health : No limitation
- 3) Nationality : No limitation
- 4) Patient state : No limitation

1.3.1 System Overview / Functionality of each part.

Model no.	Photos
R707-K	



	<b>Parts</b>	<b>Functions</b>
1	Cervical mattress	Supports patient's head
2	Lumbar mattress	Supports patient's lumbar
3	Pelvic mattress	Supports patient's pelvic
4	Ankle mattress	Supports patient's ankle
5	Armrest mattress	Supports patient's arm
6	Cervical handle	Patient or doctor can grab on
7	Length adjustable lever (Cervical handle)	Adjusts length or cervical handle
8	Tension adjustable knob (Cervical)	A knob which can adjust drop strength of cervical mattress
9	Tension adjustable knob (Lumbar)	A knob which can adjust drop strength of lumbar mattress
10	Tension adjustable knob (pelvic)	A knob which can adjust drop strength of pelvic mattress
11	Angle adjustable lever (Cervical)	A lever which can adjust left-right angle and can fix of cervical mattress
12	Angle adjustable lever (Pelvic)	A lever which can adjust left-right angle and can fix of pelvic mattress
13	Length adjustable lever (Ankle)	A lever which can adjust length of ankle mattress
14	Height adjustable lever (Armrest)	A lever which can adjust height of armrest mattress
15	Height adjustable lever (Cervical)	A lever which can adjust height of cervical mattress



	Parts	Functions
16	Protection case	A case which protects frame and interior
17	Column	A motor which adjust table height
18	DP switch	A switch which can adjust elevation of the table
19	Drop on / off Switch	A switch to lum the drop on and off
20	Emergency button	A button which patient can cut the power of the table for himself
21	Hand switch	A switch which patient can make table into the original position
22	Paper roll holder	A paper holder that covers the cervical mattress
23	Ankle belt	A belt which fixes patient's ankle
24	Flexion rod	A rod which adjusts left and right angle of pelvic mattress
25	Traction fix rod (option)	A rod which fixes patient's body when traction

	Touch screen
	Device control
	Emergency button
	Device power block and stop

	Hand switch
	Original positioning of device
	DP Switch
	Device height control

	Foot switch1
	Device height Control
	Foot switch2
	Semi-auto Cocking control

## 1.4 Intended Use

This Orthopedic adjustment equipment is to correct human body into a normal position. spine treatment device made by grafting the treatment techniques of various spine treatment devices into one device.

## CHAPTER 2. Safety and Precautions

### 2.1 General

The precautionary instructions are can be found in this section throughout this manual are indicated by specific symbols itself.

Understanding the following symbols and definitions before actual operating devices.

The definitions of the symbols are following;



Prohibition = Warning of risk of injury or health hazards



Warning = Safety information about possible damage



Caution = Important information

### 2.2 For Operating the device

	If the patient's height or weight is excessive or if the patient is a child, special care is required
	For operating, one operator holds the patient and the other operator adjust the table height and angle
	When an abnormality is found in the patient and the table, stop operation of the table immediately and take appropriate measures
	When the table is raised or lowered, user should maintain physical contact with the patient so that the patient does not fall off the table
	Makes sure that the patient and table do not collide with during medical treatment
	Before the patient goes up or down the table, make sure that the table is locked and assist the patient
	Be sure to read the manual of the safety instructions of the technician and the manufacturer before use
	Children should not be allowed near the table. A child may get injured by putting his or her hands or other parts of the body on the table
	When the table is lowered, make sure that obstacles or parts of the body are not positioned between the table and the ground
	The patient should not sit on the table's head cushion. It may damage the table

	Device should be operated by an expert
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### 2.3 For Electrical Safety

	Check the connection between the power cable and the switch and confirm that the table operates correctly
	Do not modify the table
	After using, turn off the power switch normally and disconnect the power cord when not in use for a long time
	Pay attention to the frequency of the power source and the rated voltage
	Do not touch the power cord with wet hands, and do not allow water to ingress the control box and actuator
	To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth)

### 2.4 General precaution

	Before using the table, the user should be fully familiar with the table
	If there is any foreign material on the device, wipe it off with a cloth
	Unintended users should not get on the table
	Check if the ground is flat and whether there is no movement or fluctuation by using the control knob of the table
	Ensure that there are no obstructions around the operation of the table
	Check whether the table is damaged
	In case of other faults, make proper inspection and refer to repair specialist (manufacturer)
	During treatment, the patient is treated while wearing patient clothes (long top and bottom). This is to prevent the patient's skin from directly touching the device.

## CHAPTER 3. Installation

### 3.1 Unpacking and Inspection

R707-K has passed full quality assurance testing before shipment.

Thus, the unit should be operational upon delivery. The unit should be unpacked, installed and tested only by an authorized YOUNG IL M representative. Do not attempt to unpack or assemble the unit.

If there has a problem for installation, please contact to manufacturer (refer to Chapter 7)

### 3.2 Space Requirements

	Do not install in a place with high humidity
	Install in a place where the humidity and temperature doesn't rise, and where there is no adverse effect due to direct sunlight or dust
	Note safety conditions such as inclination, vibration, shock (including during transportation)
	Not to be installed at the storage place of the chemical or gas generating place
	Check if the ground is flat
	Check that there is no obstacle around the device
	There must be enough space for the user to connect the power cord

#### Installation space

R707-K should be installed 2600\*3070\*1070mm (WxDxH).

### 3.3 Environmental Requirements

#### Air quality

R707-K should operate in a non-corrosive atmosphere. Corrosive materials such as acids can damage electrical wiring, electronic components and the surfaces of optical components

#### Temperature and Humidity

To ensure that R707-K can perform optimally, it is recommended to maintain room temperature between 0°C and 40°C and relative humidity between 25 and 80%. It is recommended to install 70~106 kPa

#### Condition in delivering and storing

Temperature 10~30°C, humidity 20~65%, pressure 70~106 kPa

### 3.4 Electrical Requirements

- Power supply: 220/230V~, 50Hz/60Hz, 400VA

#### Fuse information

Type	Voltage rating AC	Interrupting rating (amps)	High breaking capacity	Max temperature
Time delay	250 V	63 A	<b>63A</b>	125 °C

## CHAPTER 4.Operation

### 4.1 General

This chapter contains detailed operating instructions for R707-K. For easy reference, a checklist-type summary of procedures for the entire operation is also included

#### Intended User Profile:

Intended user of R707-K should be a person satisfied with below user profile.

- 1) Education: At least fourteen years of education and have a doctor/nurse license and no maximum limitation.
- 2) Knowledge: Minimum they can read and understand Arabic numerals and distinguish mouth, nose, ear, torso, head, arms and legs. And also they have the knowledge of physiotherapy, there is no maximum limitation
- 3) Language understanding: They should be able to understand the numeric values and general technical information presented in the user manual written in Korean or English
- 4) Experience: No special experience needed and no maximum
- 5) Permissible impairment:
  - Mild reading vision impairment or vision corrected to log MAR 0.2(6/10 or 20/32)
  - Impaired by 40% resulting in 60% of normal hearing at 50Hz to 2kHz

#### Intended Patient Population:

Intended patient population of R707-K should be considered as following;

- 1) Age: No limitation
- 2) Health: No limitation
- 3) Nationality: No limitation
- 4) Patient state: No limitation

#### Intended part of the body or type of tissue applied to or interacted with:

Patient's body skin interacted with head cushion, back cushion and leg cushion (type B applied parts)

#### Frequently Used function

- 1) Cocking the cushion.
- 2) Press the switch on actuator
- 3) Adjustment angle adjustment lever

### Start-up procedure

- 1) Check the connection between the power cable and the switch and confirm that the table operates correctly
- 2) Check if the ground is flat and whether there is no movement or fluctuation by using the control knob of the table
- 3) Before using the product for patient treatment, perform a simple inspection according to 5.2
- 4) Before adjusting the angle and height, the patient is laid down on the table and one person maintain physical contact with the patient

### Cleaning

If there are some foreign substance or stain on the device, clean it before operate using the dry cloth

### Disposal

Not specific disposal regulation, follow the hospital's policy

## 4.2 Procedure

- 1) Check if the ground is flat and make sure there is no movement and shake through using levelingmount



**!** If devices were not fixed on the flat ground, patient could be damaged

- 2) Connect the power cord of the main unit (Noise pilter) to the 220V power outlet
- 3) Check if there are operational problems through foot switch or DP Switch before patient use

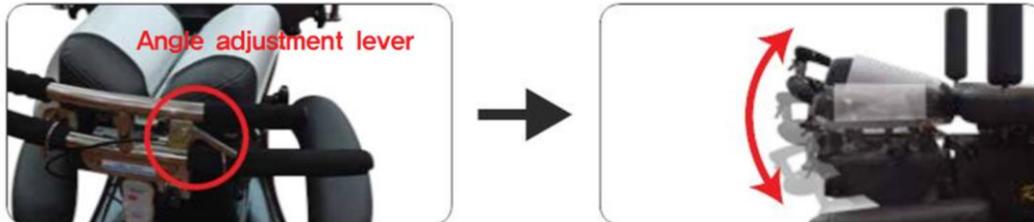


DP switch	Foot switch1
▲ Ascending	⬆ Ascending
▼ Descending	⬇ Descending

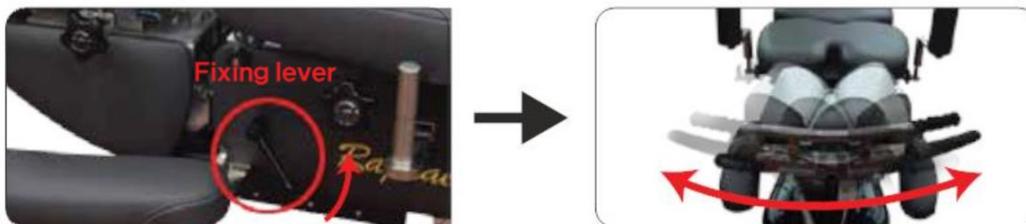
- 4) Board the patient safely on the center of the table
- 5) Press the switch on culumn to adjust the table height and move the table to a convenient position for treatment

6) If necessary, adjust the angle of the cervical mattress, lumbar mattress, pelvic mattress or ankle mattress.

1. Pulling angle adjustment lever for cervical mattress, adjust up and down angle and then release lever.



2. Release a lever under cervical mattress, adjust left and right angle and then rotate lever towards the head side to fix.



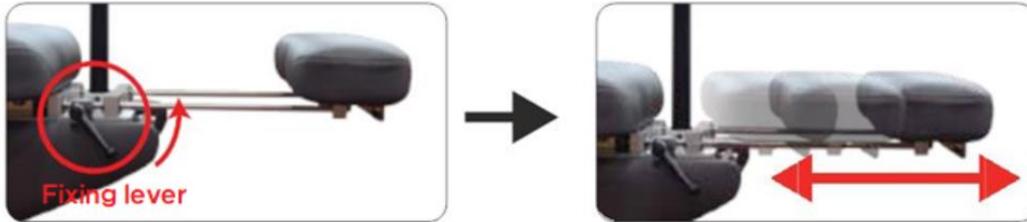
3. Turn lever towards the foot side to release, adjust left and right angle and then rotate lever towards to head.



4. Turn the lever under cervical mattress towards the foot side to release, adjust handle length and then turn the lever towards the head side.



5. Turn the lever between pelvic mattress and ankle mattress towards the foot side to release, adjust ankle mattress and then turn the lever towards the head to fix.



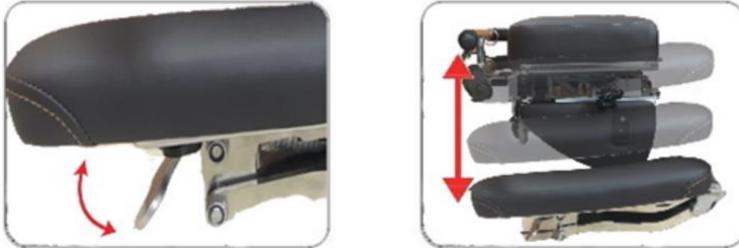
6. Adjust drop tension with knobs.



7. Up height lever for cervical mattress, adjust up and down height and then down lever.



8. Pulling height adjustment lever for armrest mattress, adjust up and down height and then release lever.



9. When the button is pressed, the drop function is turned on, Press the button again to turn off the drop function.



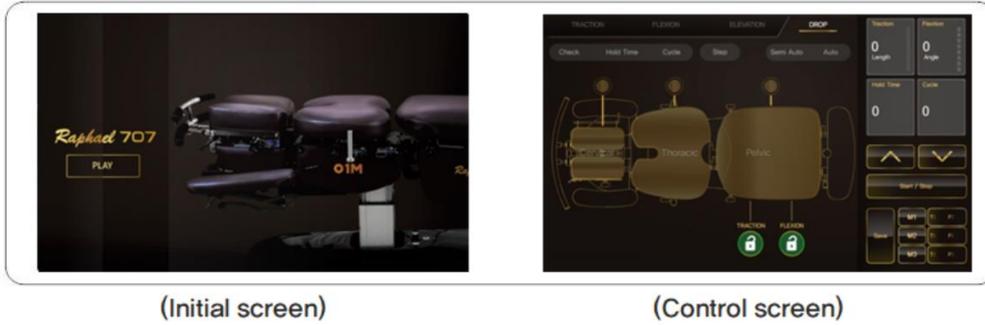
10. Push the emergency button to block power and to stop device operation. After using, turn the button to the arrow direction to clear power block.

When you push the emergency hand switch, the traction and flexion operation becomes to the original position.

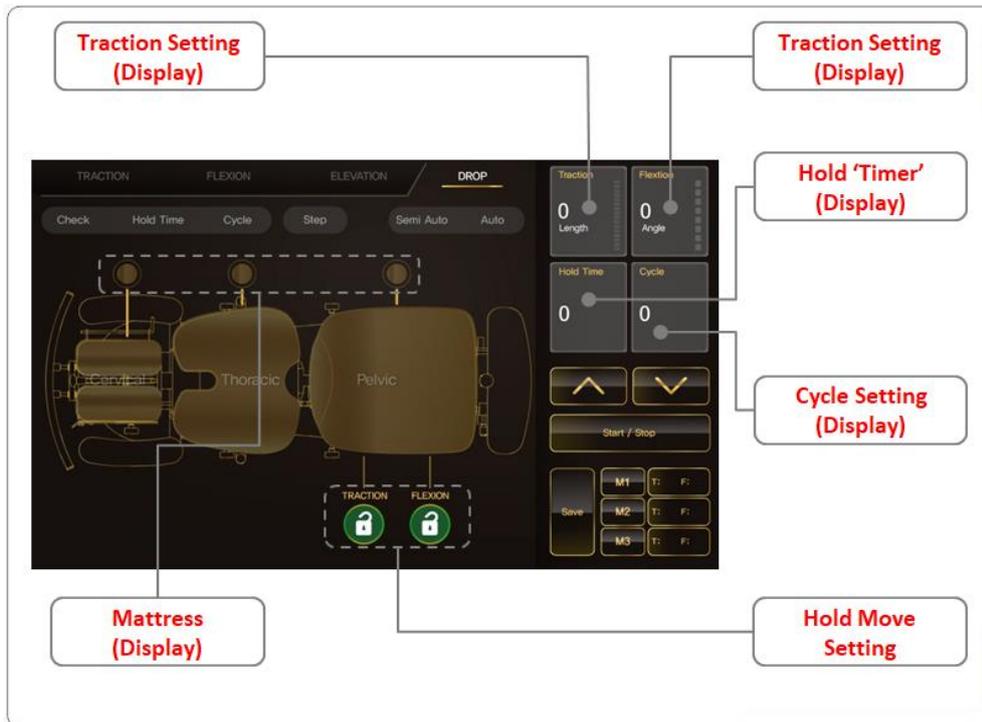


7) Touch Screen operation

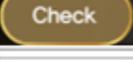
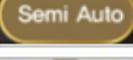
1. When you touch the 'PLAY' icon in the initial screen, it turns to control screen.



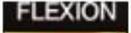
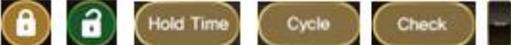
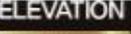
2. Touch screen function explanation



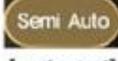
### 3. Touch Screen Function explanation

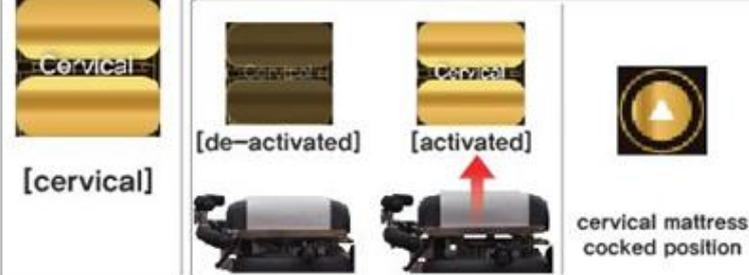
No	Button	Function	Explanation
01		TRACTION	a pelvic mattress moves to pull patient's body in a certain interval
02		FLEXION	a pelvic mattress moves up and down
03		HOLD MODE	hold either traction or flexion function
04		HOLD	maintain set-up time when traction and flexion operated
05		COUNTER	set the operation cycle
06		ELEVATION	adjust device height
07		CHECK	check traction and flexion step to set up adequate length and angle of mattress
08		Semi Auto	set up dropped mattress with semi-auto cocking (operated with extra foot switch)
09		SAVE	memorizes steps and cycles of device operation
10		STEP	length extension from minimum stage to maximum stage one by one
11		cervical mattress cocking	activates cervical mattress cocking
12		thoracic mattress cocking	activates lumbar mattress cocking
13		pelvic mattress cocking	activates pelvic mattress cocking
14		start/stop	control device operation
15		UP/DOWN	controls operation cycles, fixation mode select, height adjustment and set steps
16		save & import	save and import of set-up function button when you're using memory function

4. How to operate the touch screen

No	Function	Explanation	
1	TRACTION	 [selected button]	activates traction
		 [step setting]	adjusts traction length using UP/DOWN button  [minimum] [maximum=16 steps]
		 [start/stop]	operates device using start/stop button. 
		※Refer to following set-up methods for traction's additional functions. 	
2	FLEXION	 [selected button]	activates flexion
		 [step setting]	adjusts flexion angle using UP/DOWN button  [minimum] [maximum=8 steps]
		 [start/stop]	operates device using start/stop button 
		※Refer to following set-up methods for flexion's additional functions. 	
3	ELEVATION	 [selected button]	activates elevation
		 [height adjustment]	 [DP Switch] Adjusts height using UP/DOWN button
		※Operating stops when you touch UP/DOWN button ※Additional height adjustment can be controlled with DP Switch embedded with lumbar mattress	

No	Function	Explanation
4	start stop	 [start/stop] start/stop button to operate device. When you push button, functions will be started. When you push one more, then device stops.
5	Hold mode	 [selected button] activates hold function
		 [function setting] using UP/DOWN button, you can select either traction of flexion hold.  [traction hold]      [flexion hold]
		※traction fix setting : only flexion operates ※flexion fix setting : only traction operates
6	Hold Time	 [selected button] activates hold
		maintain holding time using UP/DOWN button (unit : sec)  [time setting] 
		※device function moves to the set stage, stops for a certain time of setting and then operates again
7	operation cycle	 [selected button] activates cycle
		sets cycles using UP/DOWN button (unit : cycle)  [cycle setting] 
8	check	 [selected button] activates check function ※move to traction, flexion setting steps and stops

No	Function	Explanation	
9	memory	 [selected button]	activates memory function
		 [save]	After setting by functions, save setting value among M1, M2, M3 button 
		 [Display]	The saved settings are displayed. *It is displayed in steps.
10	step	 [selected button]	activates step function
		 [selected button]	activates counter button, uses UP/DOWN button to adjust traction steps and cycles  [setting]
		only for traction function, length extends by one step from minimum to maximum steps	
11	cocking method select	 [selected button]	touch 'Semi Auto' button to select cocking method (auto/semi-auto)  [activated]  [de-activated]
		※activated : can cock dropped mattress by semi-auto using foot switch for cocking ※de-activated : can cock automatically the dropped mattress	

No	Function	Explanation
12	cocking	<p>when button is activated, then you can cock mattress by auto/semi-auto, you can also check mattress position with displayed icon</p>  <p>The diagram for the cervical function shows a yellow icon labeled 'Cervical' with '[cervical]' below it. To the right, two smaller icons show the state '[de-activated]' (dark) and '[activated]' (yellow), with a red arrow pointing up from the activated state. Below these are two photographs of the table's head section: the left one is flat, and the right one is tilted upwards, with a red arrow pointing up from the tilted position. To the right of the photographs is a circular icon with a yellow triangle pointing up, labeled 'cervical mattress cocked position'.</p>
		<p>when button is activated, then you can cock mattress by auto/semi-auto, you can also check mattress position with displayed icon</p>  <p>The diagram for the thoracic function shows a yellow icon labeled 'Thoracic' with '[Thoracic]' below it. To the right, two smaller icons show the state '[de-activated]' (dark) and '[activated]' (yellow), with a red arrow pointing up from the activated state. Below these are two photographs of the table's middle section: the left one is flat, and the right one is tilted upwards, with a red arrow pointing up from the tilted position. To the right of the photographs is a circular icon with a yellow triangle pointing up, labeled 'Thoracic mattress cocked position'.</p>
		<p>when button is activated, then you can cock mattress by auto/semi-auto, you can also check mattress position with displayed icon</p>  <p>The diagram for the pelvic function shows a yellow icon labeled 'Pelvic' with '[pelvic]' below it. To the right, two smaller icons show the state '[de-activated]' (dark) and '[activated]' (yellow), with a red arrow pointing up from the activated state. Below these are two photographs of the table's base section: the left one is flat, and the right one is tilted upwards, with a red arrow pointing up from the tilted position. To the right of the photographs is a circular icon with a yellow triangle pointing up, labeled 'pelvic mattress cocked position'.</p>

8) After finishing the treatment, make the table position to the lowest height through using switch on column and let the patient descend safely from the table

1. Adjust the angle of the cushion to the original level
2. Adjust the table height to the lowest
3. The patient gets off the table
4. Turn off the power switch normally and disconnect the power cord when not in use for a long time

## CHAPTER 5.Maintenance

### 5.1 Introduction

This chapter is for maintenance instructions of R707-K included routine inspection.

Repair, maintenance, and regular technical inspections are performed by service representatives authorized by YOUNG IL M\*.

Some simple inspections can be performed by the user

\* Service representatives can be referred "Service Manual" when they need to repair, maintenance etc.

	DO NOT modify this equipment without authorization of the YOUNG IL M. Any repair or maintenance service performed by non-authorized personnel immediately voids all warranty and liability claims. Maintenance services performed improperly can cause system malfunctions that may put the operator and patients at risk.
	If this equipment is modified appropriate inspection and testing must be conducted to ensure continued safe use of the equipment

### 5.2 Routine Maintenance

The unit should be periodically inspected and serviced to maintain it in optimum condition. A recommended routine inspection and maintenance schedule are in the table below;

#### ***Recommended Routine Inspection and Maintenance Schedule***

Inspection/Service	Frequency	Performed By
Check the table power ON / OFF before use	Before every operation	User or Staff
Adjust the angle of the table and check whether it supports	Before every operation	User or Staff
Check maximum angle range	At least every 2 year	Confirmed by YOUNG IL M's authorized specialist
Check actuator status	At least every 2 year	Confirmed by YOUNG IL M's authorized specialist

### 5.3 Cleaning

- Remove the power cord from the AC outlet before cleaning the product.
- When the product is first received, the external surface of the product should be cleaned with a clean cloth or cotton.



- Do not use solvents, polish or cleaning agents when cleaning the product. The surface of the product may be damaged.
- Do not cleaning and disinfection with flammable or explosive liquids. In unavoidable circumstances, these liquids must be evaporated before the unit is turned on.

## 5.4 Disposal

	<p><b>Disposal of old Electrical &amp; Electronic Equipment</b> (Application in the European Union and other European countries with separate collection system.)</p> <p>This marking shown on the product or its literature, indicates that it should not be disposed with other household wastes at the end of its working life. To prevent possible harm to the environment or harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.</p> <p>Should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take this item for environmentally safe recycling. This product should not be mixed with other commercial wastes for disposal.</p>
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## CHAPTER 6. Troubleshooting

### 6.1 General

Should the YOUNG IL M Co., Ltd. Raphael 707-PR malfunction, refer to troubleshooting guide in this chapter to identify the possible cause.

Clinic / hospital staff may perform the troubleshooting procedures in this chapter, except where specifically stated that troubleshooting must be carried out by YOUNG IL M Co., Ltd. – authorized technical personnel only.

	Pay attention to the frequency of the power source and the rated voltage
	Improper use or adjustment of this device may invalidate the YOUNG IL M Co., Ltd. service warranty agreement. Contact your YOUNG IL M Co., Ltd. representative before any attempt to troubleshoot this unit in any manner other than as specified in this manual.

### 6.2 Troubleshooting Guide

If corrective action, listed in both tables, does not solve the problem, contact your authorized YOUNG IL M Co., Ltd. service representative. The troubleshooting tables do not attempt to anticipate all possible failures.

Any fault not listed in the table must be referred to YOUNG IL M Co., Ltd. –authorized technical personnel.

PROBLEM	ADVISED ACTION
Main power doesn't work.	Step 1 :Check that the power outlet and power plug are properly connected and that electricity is being supplied correctly. Step 2 :Check the control box lamp and if the lamp won't turn on, replace the control box.
Elevation doesn't work	Step 1 :If the elevation doesn't work while the control box light turns on, check the sensor of actuator and total switch and adjust or replace.
Noise generation	Step 1 :Apply grease to the bolt, shaft, acetal and drive. Step 2 :Reassemble the noise area when noise is generated even after applying grease.
Control lever doesn't operate	Step 1 : Check the shock absorber quality - If the button of shock absorber is pressed, return its position to the original position. - Replace if the oil in the shock absorber leaks. Step 2 : Check if the lever pin or angle is normal and if not, adjust it
Total lock doesn't operate	Step 1 :Make sure wheels are working properly. Step 2 :Check the assembly of the fastening part. Step 3 :Check if the total lock bar gets bent and if it gets bent, make it straighten.

## CHAPTER 7. Manufacturer Information

Manufacturer : YOUNG IL M Co., Ltd.  
Address : 7F Starwoodplaza, 400, Dunchon-daeroJungwon-gu, Seongnam-Si, Gyeonggi-Do,  
Republic of Korea  
TEL : +82 70-4630-8808, +82 70-4630-8888  
FAX : +82 31-737-0801  
e-mail : 01md@01m.co.kr  
Web : www.01m.co.kr

## CHAPTER 8. Authorised Representative in the EC

Company name : ADVENA LIMITED  
Address : Tower Business Centre 2nd Flr. Tower Street Swatar, BKR 4013 Malta

## CHAPTER 9. Label Information

### 9.1 Device Label\_English



- Description of the symbol used in device label

Symbol	Description	Symbol	Description
	Symbol for 'Manufacturer'		Symbol for 'CE marking approved by'
	Symbol for 'Authorised Representative in the EC'		Follow the instruction for use
	Symbol for 'Manufacture Date'		No pushing
	Serial number		No sitting

	Type B Applied		No stepping on surface
	Consult instructions for use		Caution
	This symbol indicated that the device is a medical device.		

## 8.2 Device Label\_Korea



제조업 허가번호 : 제839호  
 품목명(모델명) : 정형용교정장치 (R707-P)  
 제조품목 허가(인증)번호 : 제인 18-4785 호  
 사용목적 : 인체를 정위로 교정하는 데에 사용하는 기구  
 제조번호 : R707-P  
 제조일자 :     년   월   일  
 정격 : 220V~, 60Hz, 260VA  
 기기분류 : 1급기기  
 상호 : 영일엠(주)  
 주소 : 경기도 성남시 중원구 둔촌대로 400, 7층  
 (상대원동, 스타우드아파트형공장)(제조소1)  
 경기도 성남시 중원구 둔촌대로541번길 20  
 1층 일부 (상대원동)(제조소2)  
 대표전화 : 1544-8501  
 Website : www.01m.co.kr

■ 본 제품은 "의료기기"임 ■



(01) 0 8800160 60002 5

(11)

(21) R707-P







# CHAPTER 10. Declaration of Conformity

## – Electromagnetic Compatibility

It has been independently tested and it manufactured in compliance with the following EMC standard IEC 60601-1-2:2007

<b>Guidance and manufacturer' declaration –electromagnetic emissions</b>		
The Raphael 707-PR is intended for use in the electromagnetic environment specified below. The customer or the user of the Raphael 707-PR should assure that it is used in such an environment		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment-guidance</b>
RF emissions  CISPR 11	Group 1	The Raphael 707-PR use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions  CISPR 11	Class A	The Raphael 707-PR are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supplies buildings used for domestic purposes
Harmonic emissions  IEC 61000-3-2	A	
Voltage fluctuations/ flicker emissions  IEC 61000-3-3	COMPLIES	

<b>Guidance and manufacturer' declaration –electromagnetic immunity</b>			
<b>Raphael 707-PR are intended for use in the electromagnetic environment specified below. The customer or the user of the Raphael 707-PR should assure that it is used in such an environment</b>			
<b>Immunity test</b>	<b>IEC60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment-guidance</b>
Electrostatic discharge (Raphael 707-PR) IEC 61000-4-2	±6 kV contact  ±8 kV air	±6 kV contact  ±8 kV air	Floors should be wood, concrete or ceramic tile.  If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	2kV for powersupply lines 1kV for input/output lines	2kV for powersupply lines  1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	1 kV differential mode  2kV commonmode	1kV differentialmode  2kV commonmode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC6100-4-11	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycle 70% $U_T$ (30% dip in $U_T$ ) for 25 cycle  <5% $U_T$ (<95% dip in $U_T$ ) for 5 s	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycle 70% $U_T$ (30% dip in $U_T$ ) for 25 cycle  <5% $U_T$ (<95% dip in $U_T$ ) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Raphael 707-PR requires continued operation during power mains interruptions, it is recommended that the Raphael 707-PR be powered from an uninterruptible power supply or a battery
Power frequency	3 A/M	3 A/M	Power frequency

<p>(50/60Hz)</p> <p>Magnetic field</p> <p>IEC61000-4-8</p>			<p>magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment</p>
<p>Note UT is the a.c. mains voltage prior to the application of the test level</p>			

<b>Guidance and manufacturer' declaration –electromagnetic immunity</b>			
<b>Raphael 707-PR are intended for use in the electromagnetic environment specified below. The customer or the user of Raphael 707-PR should assure that it is used in such an environment</b>			
<b>Immunity test</b>	<b>IEC60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment-guidance</b>
			Portable and mobile RF communications equipment should be no closer to any part of the Raphael 707-PR Including cables, than the recommended distances calculated from the equation applicable to the frequency of the transmitter Recommended separation distance
Conductive RF IEC61000-4-6	3Vrms 150kHz to 80MHz	3Vrms	$d=1.2\sqrt{P}$
Radiated RF IEC61000-4-3	3V/m 80MHz to 2,5GHz	3V/m	$d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic survey, a should be less than the compliance level in each frequency range.  B Interference may occur in the vicinity of equipment marked with the following  symbol:
Note 1 At 80MHz and 800MHz the higher frequency range applies.			
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitted, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy.  To assess the electromagnetic environment in the location due to fixed RF transmitters, an electromagnetic site survey should be considered.			

If the measured field strength in the location in which the Raphael 707-PR are used exceeds the applicable RF compliance level above, Raphael 707-PR should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Raphael 707-PR.

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

**Recommended separation distances between portable and mobile communication equipment and the Raphael 707-PR**

Raphael 707-PR are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the Raphael 707-PR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Raphael 707-PR as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitter rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1. At 80MHz and 800MHz the higher frequency range applies.

Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.