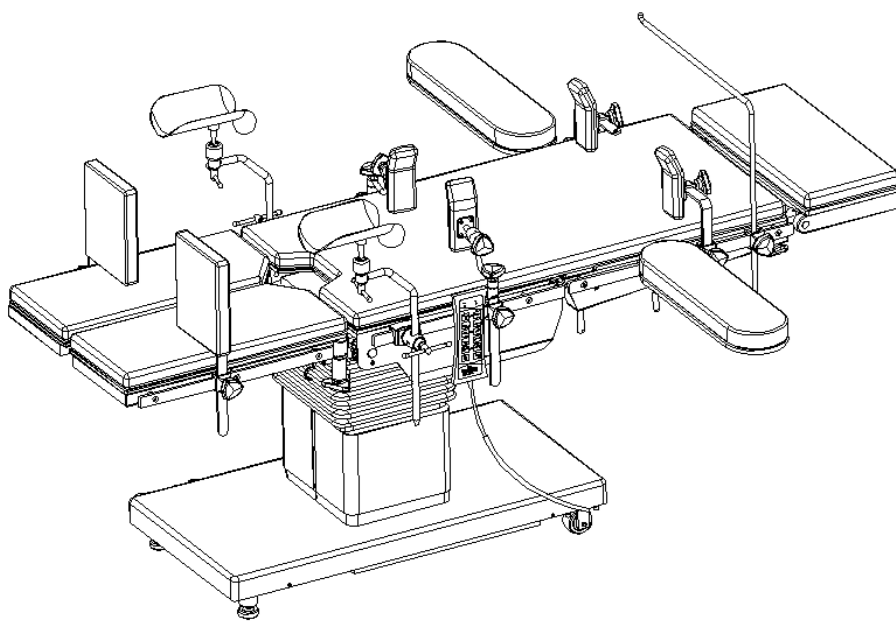




GIMA

PROFESSIONAL MEDICAL PRODUCTS

TAVOLO OPERATORIO ELETTRICO CON TR E RTR ELECTRIC OPERATING TABLE WITH TR AND RTR TABLE OPÉRATOIRE ÉLECTRIQUE AVEC TR ET RTR MESA DE OPERACIONES ELÉCTRICA CON TR Y RTR



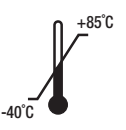
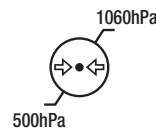
MANUALE D'USO – USER MANUAL – MODE D'EMPLOI – MANUAL DE USO

- È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.
- All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.
- Il est nécessaire de signaler tout accident grave survenu et lié au dispositif médical que nous avons livré au fabricant et à l'autorité compétente de l'état membre où on a le siège social.
- Es necesario informar al fabricante y a la autoridad competente del Estado miembro en el que se encuentra la sede sobre cualquier incidente grave que haya ocurrido en relación con el producto sanitario que le hemos suministrado.

REF A100-4 (Gima 44775)



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INTRODUCTION

ABOUT THIS OPERATING MANUAL

This operating manual includes introduction about the symbols and safety instructions. You can see the description, instruction and maintenance about our product in the followed pages. And some technical data and information about the product.

In case of any question, we therefore kindly ask you to contact after-sales service personnel or distributor.


This operating manual is to be read and observed by any person using or handle this operating table.


In addition to some accident, we obtest users to be familiar with the usage and the points of attention.


Intended Purpose


The electric operating table is used for maternity, childbirth and diagnosis, and for carrying patients during surgery.

SYMBOLS USED IN THE TEXT

Danger!
 This symbol will appear whenever safety instruction are designed to protect people from physical harm. The symbol stands for imminent danger of death or of serious injury.


Caution!
 This symbol will appear where situations are described which might be dangerous ,and which might inflict slight injuries.


Attention!
 This symbol will appear in front of such hints which shall prevent the table or other equipment from being damaged


Advice !
 This symbol will appear in front of additional helpful pieces of advice.


- A dot in front of the text means:
Please pay attention and you have to do.


SUMMARY OF THE INSTRUCTIONS


Danger!
 Patients may be exposed to danger by electrostatic tension.By means of the potential equalization device electrostatic tension are conducted to earth. Always connect the potential equalization device of the operating table to earth before use.


Danger !
 The patient may get hurt if the operating table is displaced while he or she is lying on the top in the knee-elbow-position. Do not displace the table with the patient in knee-elbow-position.


Danger !
 The patient may get hurt if the operating table is displaced with an attached extension device, due to its reduced stability against tilting.Do not displace the operating table with an attached extension device when a patient is lying on the top.


Danger !
 Do not press two buttons at the same time !

Attention!
 never press one button over 2min!

Attention!
 The cushion will deform if exposed to heat. The operating table, including its cushion ,must not be sterilized bu super heated steam.

Attention!
 Agents for disinfection of the patient’s skin may cause discolorations on the cushions.Remove such disinfecting agents from the cushion in order to avoid such discolorations.

Attention!
 Disinfecting sprays may cause corrosion on mechanical parts,or create explosive mixtures inside the table components.For this reason,do not use disinfecting sprays!

advice:
 The position of the castors will influence the stability of the operating table.

DESCRIPTION

USE AND BRIEF INTRODUCTION

The product belongs to class I, type B. Non AP or APG device, continuous device. And possesses application part.

A100-4 is designed specially to meet the different demands of the market and according to the common advice of users.

Operating table is used for general Ophthalmology operations, it uses electric hydraulic pressure, with a switch to control its elevation (up/down), easy to operating and it is reliable. The operating table is widely used, easy to operate and adjust with reliable performance, which is a ideal table for different hospital.

GENERAL CONTENT

BASIC DATA

The technical data should look at Form 1
Form 1: basic data unit:mm

basic data Model	length	Width	lowest height of tabletop	Distance of elevation
	L	B	h min	S
A100-4	≥2070	550	700±10	≥300

Gross weight、net weight、volume

Gross weight:270kg, net weight:220kg, Volume (long×width×height) 1360mm×860mm×880mm.

Safe working load of A100-4

The static safety load of the table is 200kg.

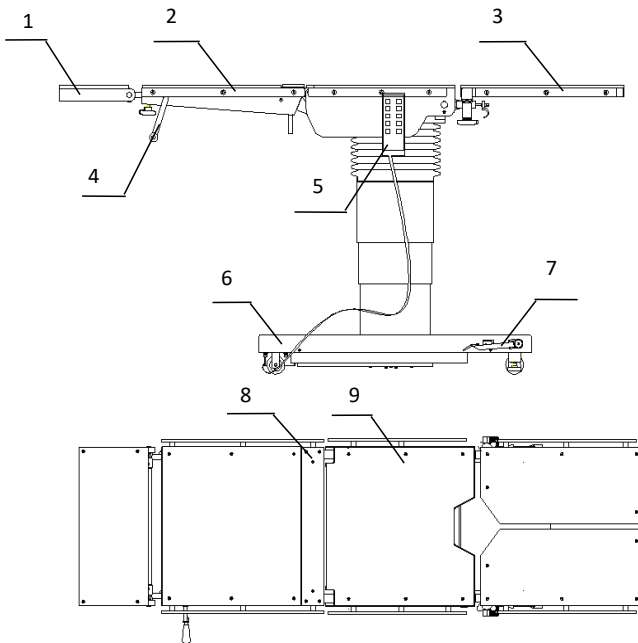
The dynamic safety load of the table is 135kg.

PRODUCT INFORMATION AND FEATURE

Product information

The operating is formed by head plate and back plate, waist plate, buttocks plate and leg plate

Please look at the Picture 2



1-Headrest; 2-back rest; 3-leg rest; 4-Handle for kidney bridge; 5-remote control; 6-base; 8-kidney bridge; 7-pedal; 9- buttocks plate;

Picture 2 Diagram of structure A100-4 Electric operating table
Feature

- You can adjust the height of the table as you wish (look at picture 2), convenient for doctors.

- you can take the cushion apart from the table for clean up.

COMMISSIONING

KEEPING

Inside its original packing the operating table may be exposed for a period of 15 weeks to environmental conditions within the limits of:

Ambient temperature	-40°C~85°C
atmospheric humidify	≤20-90%
Atmospheric pressure	500 hPa~1060 hPa

- The table should be kept in a clean place, never put in the places where influenced by atmospheric pressure, temperature, humidity, aeration, sunshine, or dust and sulfur.

- Please pay attention to the supply frequency、electric tension and normal impedance.

- The table should be kept separately from chemicals.

- stock in a ventilated place.

TRANSPORTATION

Upon leaving the factory, the operating table are positioned fit for transportation. In case of further transportation at a later date, we recommend to adjust the operating table into the same position.

- In order to transport the operating table, adjust seat and back section in to horizontal position.

- Remove the head and leg plates, and detach other accessories.

- Adjust the table-top into minimum height.

UNPACKING

Carry the operating table, if possible, inside its original packing to its final site of use. Check the condition of the operating table.

Any possible damage occurred during transportation should be reported immediately to Karen Wu . You will find their address and telephone no. On the last page of this operating manual.

POWER REQUIREMENTS

supply voltage	~220V±10%
supply frequency	60Hz±2%
Power capacity	≥1kw

USING

Ambient temperature	10°C~40°C
atmospheric humidify	≤80%
Atmospheric pressure	760 hPa~1060 hPa

- Please pay attention to supply frequency、electric tension and normal impedance.
- Should choose anti-static cushion.
- Please check the operating table all the times.
- Once found it out of work ,please stop using.
- Make sure that the patient won't touch the table.
- Please don't take them down when they are out of work, contact the serviceman in time.
- When change the fuse, you should turn off the power.
- It should be separated from the magnetic field when using.

ATTENTION BEFORE USING

- Please read the instruction before using, people who doesn't know the operating method is forbidden to use.
- Please Check the switch, and be sure they can work.
- Please confirm all the power line are connected right and safely.
- When it work with high frequency surgical equipment, the equipment should comply with GB9706.1.

ATTENTION AFTER USING

- To return to the former condition, and turn it off, cut off the electricity supply.
- Put the telecontroller in the right place.
- Clean the table after operations.

A100-4 requires special preliminary measures pertaining to EMC that necessitates installation and commissioning in conformity with the EMC information given in this Manual.

Electromagnetic Radiation

Test	Range	Measurement Uncertainty	Notes
Radiated Emission	30~1000MHz	4.24dB	(1)
Conducted Disturbance	0.15~30MHz	3.35dB	(1)

(1) This uncertainty represents an expanded uncertainty expressed at approximately the 95% confidence level using a coverage factor of k=2.

Electromagnetic Resistance

Resistance Test	Test Level as per EN 60601	Test Level as per EN 60601	EN 60601 Level of Compliance Electromagnetic Environment
Severity levels of electrostatic discharge IEC60601-1-2:2014	±2KV, ±4KV&±8KV for air discharge and ±2KV, ±4KV&±8KV for contact discharge	±2KV, ±4KV&±8KV for air discharge and ±2KV, ±4KV&±8KV for contact discharge	*Ensure that the following requirements are met: Floors: wood, concrete or ceramic tiles Relative humidity: >30%
Electrical fast transient response/ Burst IEC60601-1-2:2014	±2K for A.C. Power line	±2K for A.C. Power line	*Ensure the mains quality is suitable for a commercial or hospital environment.

Severity levels of surge IEC60601-1-2:2014	±0.5KV& ±1KV for A.C. power lines to lines and ±0.5KV,±1KV& ±2KV for A.C. power lines to PE	±0.5KV& ±1KV for A.C. power lines to lines and ±0.5KV,±1KV&±2KV for A.C. power lines to PE	*Ensure the mains quality is suitable for commercial or hospital environment.
Severity levels of magnetic field immunity IEC60601-1-2:2014	3 A/m	3 A/m	*Ensure the magnetic fields of the network frequency conform to the normal levels of commercial or hospital environments.
Severity levels of radio-frequency, electromagnetic field IEC60601-1-2:2014	3 V/m	3 V/m	*Do not use portable and mobile HF communication equipment near the bed. *Observe the distances indicated below.
Severity levels of conducted disturbances induced by radio-frequency fields discharge IEC60601-1-2:2014	3 V/m 80 MHz	3 V/m 80 MHz	Recommended distances: d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz P is the rated maximum output power of the transmitter in Watts (W) defined by the transmitter's manufacturer. d is the recommended separating distance in metres (m).

METHOD OF USING OPERATION TABLE

PREPARATION BEFORE USING

- Electric tension: 220V、 frequency: 60Hz;
- No objects exist that affect the operations;
- Confirm if all the power lines are connected well, the switch is in "O"condition;
- Move the table to the right place you need;
- Connect the telecontroller with the table;
- Please check the power supply before turning it on;
- Lock the base of the table;
- Fix up the head plate, leg plate and accessories according to the picture.
- The table adopts short-time work, attention: never press one button over 2min.

Danger! Patients may be exposed to danger by electrostatic tension. By means of the potential equalization device electrostatic tension are conducted to earth. Always connect the potential equalization device of the operating table to earth before use.

Attention! never press one button over 2min!

DISPLACEMENT

Moving and locking the operating table

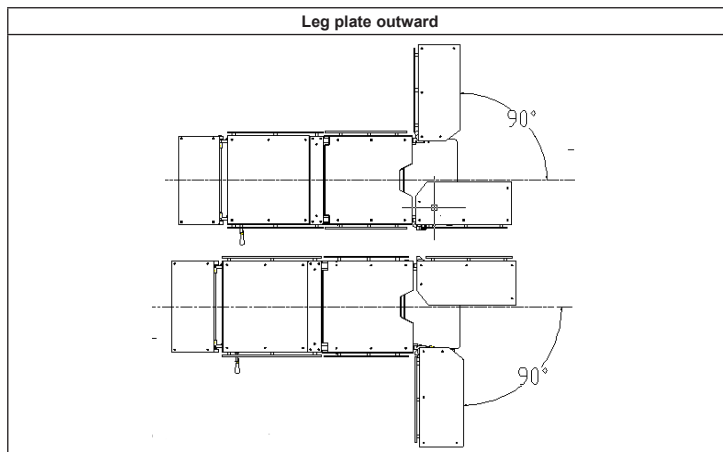
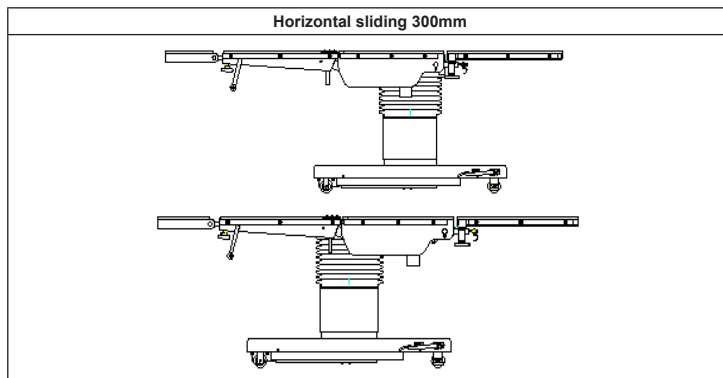
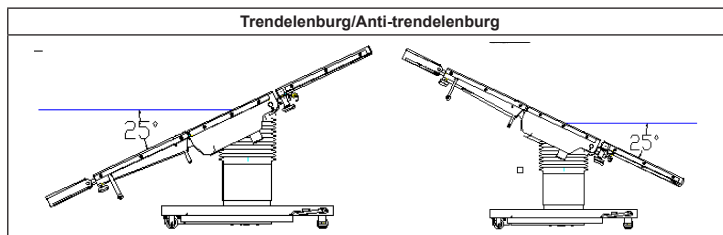
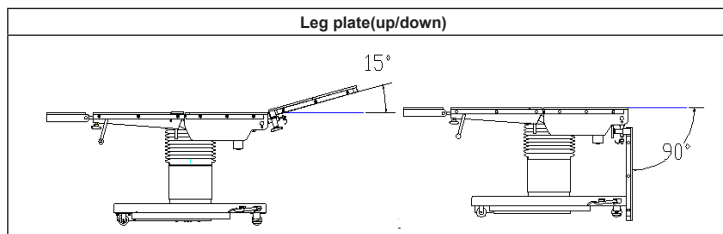
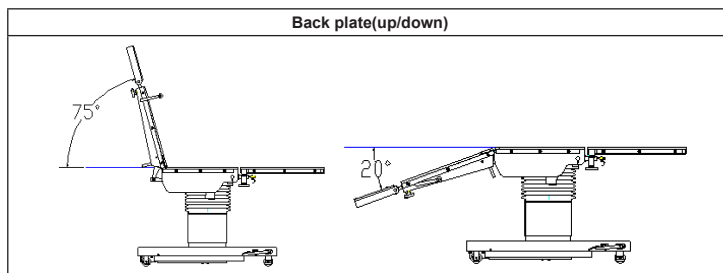
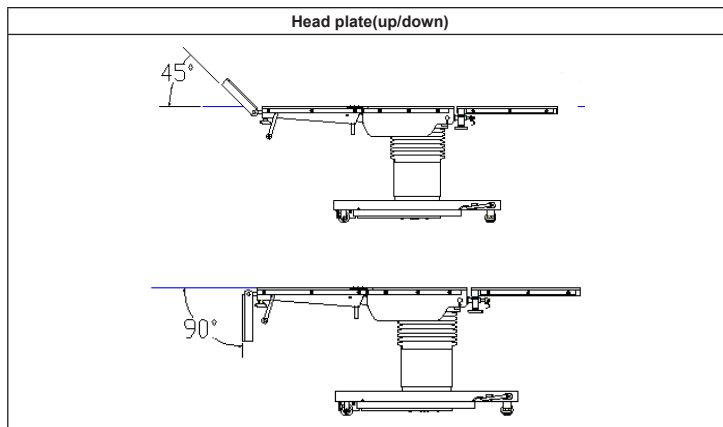
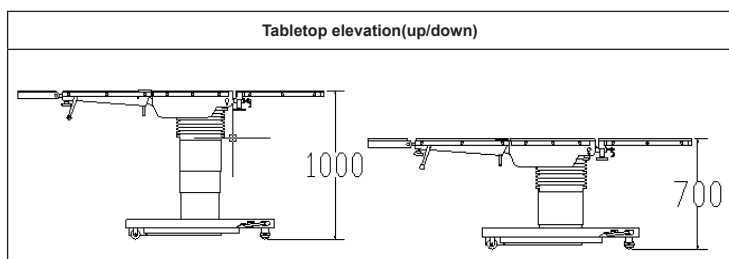
Danger! The patient may get hurt if the operating table is displaced with an attached extension device, due to its reduced stability against tilting. Do not displace the operating table with an attached extension device when a patient is lying on the top.

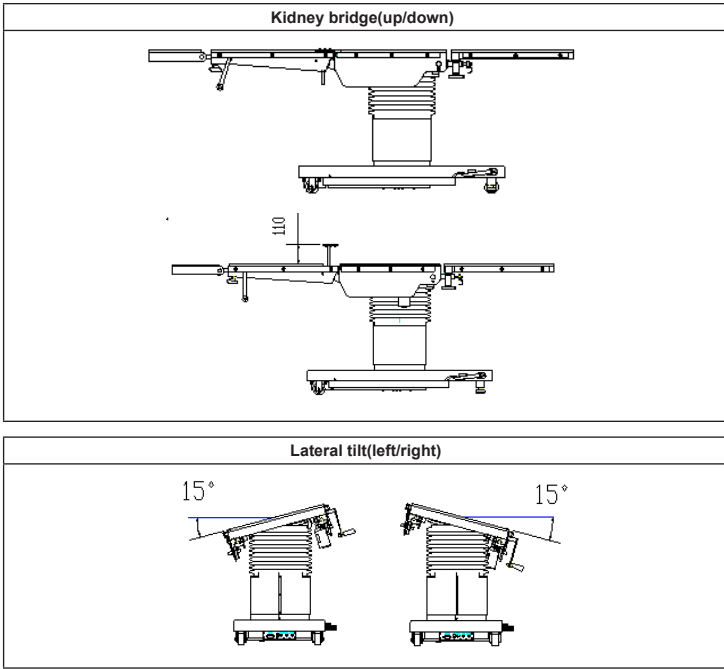
Danger! Remember lock the brake when the patient is on the operating table. The patient will be easily hurt if the operating table suddenly move by itself.

USING ADJUST

- Adjustment of leg plate
Slacken the handle between leg plate and buttocks plate, put it to a proper place and screw up the handle.
- Fixing of accessories
There is rail on the both side of the table, you can use the fixing clamp the set up all the accessories.

MOVEMENTS DIAGRAM OF A100-4





- 11 TILT R
Tilt to the right.
- 12 BACK DOWN
Lowers the back plate.
- 13 SLIDE HEAD
Move in the direction of the head plate.
- 14 BRAKE UNLOCK
Can move the operating table.

Danger!
Do not press two buttons at the same time!

CLEAN OUT AND DISINFECTION

The cushion on the operating table are all removable. Head section and leg plates can be removed completely. This way they can easily be cleaned individually. Stainless steel, sprain paint part and cushions of the operating table may only be cleaned using appropriate cleansing agents. The cushion should be cleaned twice by 75% alcohol and then use disinfectant and ultraviolet radiation for sterilization.

- Turn off the power after operations, raise the operating table to the minimum height and move seat and back section into horizontal position.
- If required, remove the cushion of the seat and back sections.

Attention!
The cushion will deform if exposed to heat. The operating table, including its cushion, must not be sterilized by super heated steam.

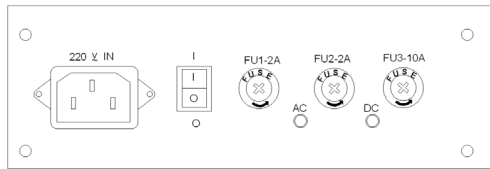
Attention!
Agents for disinfection of the patient's skin may cause discolorations on the cushions. Remove such disinfecting agents from the cushion in order to avoid such discolorations.

Attention!
Disinfecting sprays may cause corrosion on mechanical parts, or create explosive mixtures inside the table components. For this reason, do not use disinfecting sprays!

Attention!
Agents for disinfection of the patient's skin may cause discolorations on the cushion. Remove such disinfecting agents from the cushion in order to avoid discolorations.

PICTURE OF CONTROL PANEL

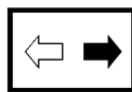
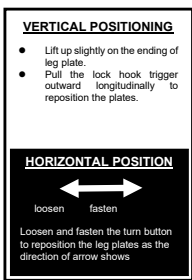
Please look at the picture 4:



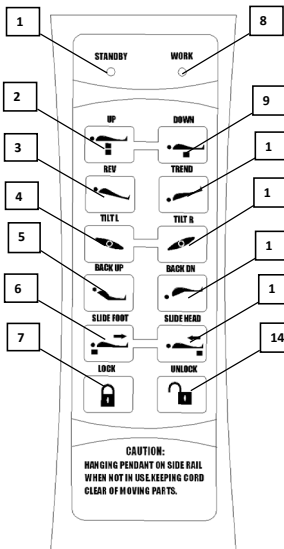
- Power supply jack:100-240V IN AC socket;
- Switch "I" means "ON"
"O" means "OFF";
- Fuse :FU1、FU2、FU3;
- "C IN" means jack;

LABEL ON THE TABLE

- 1. Normal leg plate
- 2. Gas spring leg plate



FUNCTION OF TELECONTROLLER



- 1 **STAND BY**
Operating table is in the ready mode. Green LED on.
- 2 **UP**
Raise the table top.
- 3 **REVERSE**
Reverse trendelenburg (head down).
- 4 **TILT L**
Tilt to the left.
- 5 **BACK UP**
Raise the back plate.
- 6 **SLIDE FOOT**
Move in the direction of the foot plate.
- 7 **BRAKE LOCK**
Can't move the operating table.
- 8 **WORK**
Operating table is in the work mode. White LED on.
- 9 **DOWN**
Lowers the table top.
- 10 **TREND**
Trendelenburg (foot down).
- 11 **TILT R**
Tilt to the right.
- 12 **BACK DOWN**
Lowers the back plate.
- 13 **SLIDE HEAD**
Move in the direction of the head plate.
- 14 **BRAKE UNLOCK**
Can move the operating table.

MAINTENANCE

- Users should check the table and maintain it from time to time.
- When the table hasn't been used for long time, you need to check it before using.
- In order to prolong its using life and keep it in a good condition, you need to pay attention to the daily maintenance.
- You cannot use caustic cleaner to clean the cushion after operations.
- Do not use industrial alcohol to clean the cushion, it will be react with the cushion.
- Please lower the lowest position after using.
- When it cannot work any more, the scrap of the equipment should comply with legal regulations.

COMMON PROBLEMS AND SOLUTIONS

Wrong operations

problem: when you press only one button, but over one and wrong action worked
cause: the elements of the base become damp.

Solution: use gauze to dry it, and adopt 300V blow drier.

The table cannot work:

cause1: disabled fuse

cause2: the jack of telecontroller has loosen.

solution1: replace fuse

solution 2 connect the power of telecontroller with the table again

Some buttons cannot work:

Cause 1: the button are out of work.

Cause 2: the jack didn't connect well.

Solution: you can replace the buttons or jack

MAIN TECHNICAL DATA

Form 3: Main technical data

Item		Basic Data
Trendelenburg	forward	≥25°
	backward	≥25°
Lateral tilt	Left	≥15°
	Right	≥15°
Head plate	Up	≥45°
	down	≥90°
Back plate	Up	≥75°
	Down	≥20°

CAUTION:
HANGING PENDANT ON SIDE RAIL
WHEN NOT IN USE,KEEPING GOOD
CLEAR OF MOVING PARTS.

Leg plate	Up	≥15°
	Out	≥90°
Kidney bridge		≥110mm
Translation		≥300mm

Input power: 200VA

PACKING LIST

Form 4 packing list

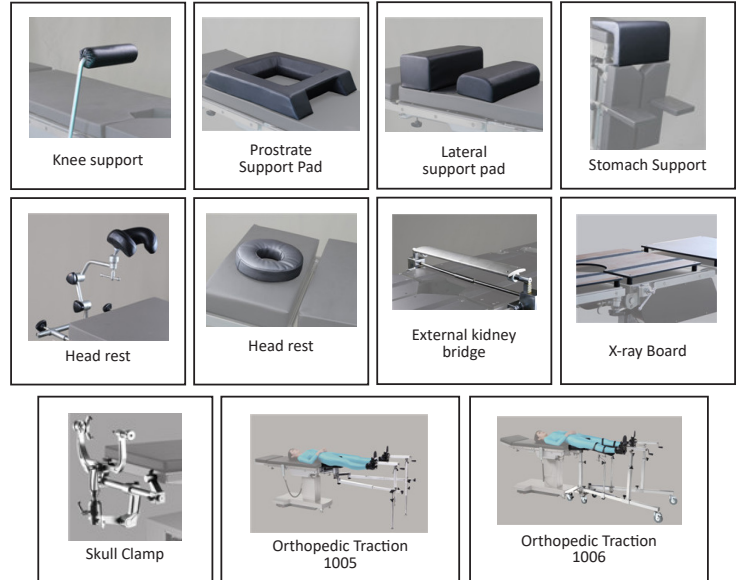
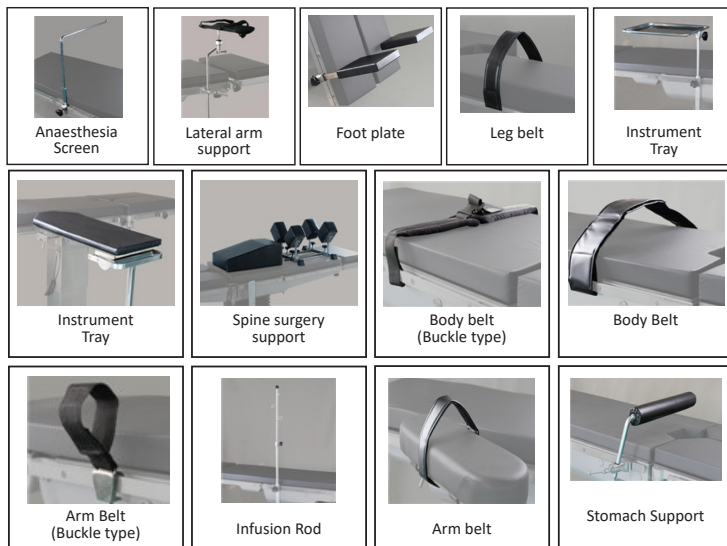
NO.	Item	quantity	NO.	Item	Quantity
1	Anaesthesia screen	1 piece	7	leg plate (cushion)	2 piece
2	Shoulder support (cushion)	2 piece	8	cushion	1 piece
3	Body support (cushion)	2 piece	9	Foot plate (cushion)	2 piece
4	Arm support (cushion)	2 piece	10	Fixing clamp	2 piece
5	Leg support (wrapper)	2 piece	11	Telecontroller	1 piece
6	Head plate (cushion)	1 piece	12	Power line	1 piece

Notice! Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established

Appendix I : Universal Accessories



Appendix II : Optional Accessories



A100-4 WITH ALL STANDARD ACCESSORIES



Picture 3 : A100-4 with all standard accessories

SYMBOL EXPLANATION:

	Keep away from sunlight		Medical Device compliant with Regulation (EU) 2017/745
	Product code		Follow instructions for use
	Date of manufacture		Lot number
	Caution: read instructions (warnings) carefully		Temperature limit
	Imported by		Serial number
	Atmospheric pressure limit		Keep in a cool, dry place
	Manufacturer		Medical Device
	Authorized representative in the European community		Humidity limit
	Type B applied part		WEEE disposal
	Covering Protection rate		

Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.