

## Copyright

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Product Name: Operating Table

Product Model: WH1/WH1A/WH2/WH2A

Manufacture Date: Refer to the label

Service Life: 10 years

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- The serial number label or manufacturing mark of the product is clearly legible.
- The damage is not caused by human factors.
- All replaceable components used for maintaining the device, accessories, and consumables are originally supplied by Comen or recognized by Comen.

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## Preface

This user manual provides details on the performance, operations and safety instructions relating to the WH1/WH1A/WH2/WH2A operating table. Please read it carefully and understand the content of this manual so as to ensure the safety of patients and operators.

This manual introduces the product according to the most complete configurations. The product you purchased may not have certain configurations or functions.

Please place the user manual near the operating table so that it can be easily and timely obtained when needed.

## Intended Users

This manual is suitable for professional clinical personnel or those who are expected to have knowledge and work experience in medical procedures, practices, and terminology necessary to monitor patients.

## Illustrations

All illustrations provided in this manual are for reference only. The menus, options, values and functions in the illustrations may not exactly match what you see in product.

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# Chapter 1 Safety Information

## 1.1 Safety Warning

### **Warning**

- It indicates serious consequences, adverse events or situations that endanger safety. Failure to follow the warning will result in serious personal injury or death to the user or patient.

### **Caution**

- It indicates a potentially dangerous or unsafe operation that, if not avoided, may cause minor personal injury, product failure or damage or property, or cause more serious injury in the future.

### **Attention**

- It emphasizes important precautions and provides instructions or explanations for better use of the product.

### **Warning**

- Report any serious incident that has occurred in relation to the medical device to COMEN manufacturer and the competent authority of the Member State.
- Be sure to read and understand the entire manual before using the operating table. As with all medical devices, attempts to use this equipment without a thorough understanding of its operation can result in injury to the patient or user.
- The operating table can only be operated by trained personnel. Their training records must be archived. Any unauthorized or untrained personnel are not allowed to perform any operations.
- Be sure to keep this manual near the operating table for convenience.
- Pay attention to various warnings or prompts on the surface of the equipment to ensure the safety of operators and the normal operation of the equipment.

- This product was delivered without disinfection. It must be cleaned and disinfected before the first use.
- This equipment can only be used for the specified intended use and only allowed to be used by trained and qualified personnel.
- Before use, the user must check whether the equipment and its accessories can work normally and safely.
- This equipment can only move on flat ground and cannot be pushed to pass over steps or thresholds to avoid the risk of tipping over.
- This equipment cannot be used in the presence of flammable anesthetic gas mixed with air, oxygen or nitrous oxide.
- The equipment is not intended for use in an oxygen rich environment.
- Please carefully plug in and route the power cord and various accessory cables to avoid the patient being entangled or suffocated, cable entanglement, or electrical interference.
- Do not place the power plug that disconnects the equipment from the AC power supply in a location that is difficult for the operator to access.
- During use the operator shall always observe whether the equipment is normally connected to the power supply so as to avoid adverse events such as shutdown caused by loose power supply connection.
- Be sure to connect the protective ground terminal.
- This equipment can only be connected to a power socket with protective grounding. If the power socket is not connected to a ground conductor do not use the socket and use a rechargeable battery for power supply instead.
- If there is any doubt about the installation of the external protective ground terminal or the integrity of the wiring, the internal battery must be used to run the operating table.
- If there is an abnormality in the power supply of the equipment or during the use of the equipment, please use the emergency stop switch to terminate the current abnormal state.
- The equipment interconnected with this device should form an equipotential body (effectively connected to the protective ground).
- Do not touch the patient and hand control contact at the same time, and do not touch the fuse holder contact that can be touched during the replacement of the fuse to avoid the risk of electric shock.

- When using the operating table, be sure to cover the mattress with a sterile sheet to avoid infection. Be sure to avoid using wet sheets.
- Make sure to use this equipment on an anti-static floor.
- Please use the anti-static mattress provided by Comen. If other mattresses are used, it may cause injury to the patient or damage to the equipment.
- Do not use alcohol-containing detergents/disinfectants where high-frequency surgical equipment may be used to avoid fire.
- When using equipment such as a high-frequency electrotome, defibrillator, etc., if the patient touches the metal parts of the operating table (including accessories), or lies on wet sheets or a conductive mattress, there may be a risk of burns. During the operation, prevent the patient from touching the metal parts of the operating table (including accessories), and ensure that dry sheets and non-conductive mattresses are used.
- Electromagnetic fields can affect the performance of this equipment. Therefore, other equipment used in the vicinity of this equipment must meet the corresponding EMC requirements. For example, mobile phones, walkie-talkies, MRI and X-rays may be sources of interference as they all emit high-intensity electromagnetic radiation.
- The mass equivalent filtration of the operating table shall not exceed 1 mmAL.
- When moving the operating table please, make sure that no objects are placed on the table surface and ensure that the passage is free of obstacles to avoid damage or collision.
- When moving the operating table, please use both hands to ensure the direction of movement to avoid collisions.
- When adjusting the table surface to fall down or tilt or folding down the head/foot plate, please be careful that the table surface or head/foot plate does not collide with the base or the ground.
- When adjusting the operating table, please be mindful of hanging parts, sheets, etc. colliding or getting stuck.
- Before unlocking the operating table, be sure to grasp the operating table firmly to prevent unexpected movement of the operating table after unlocking.
- Please pay attention to the location of pinch points to avoid injury to the patient or operator.
- Please place or transfer patients under the guidance of medical personnel.
- Before placing the patient, make sure that the width of the operating table is appropriate, otherwise it may cause personal injury.

- Before placing the patient, make sure that the casters of the operating table are locked to prevent unexpected movement.
- Do not move the operating table when the patient is on the table.
- When using the operating table, be sure to confirm that it is within the maximum load-bearing range (normal position or interchange position of the head and leg plates).
- If accessories are to be used during the operation, make sure that the sum of the weight of the accessories and the patient does not exceed the maximum load-bearing range (normal position or interchange position of the head and leg plates).
- When the operating table is in some special positions, there are certain restrictions on the load bearing. Please be sure to consider the maximum load bearing and related restriction conditions when using the table. If in doubt, please consult the manufacturer or local agent before use.
- Before transferring the patient to the operating table, make sure that the operating table is locked and the entire table surface is in the best balanced position: that is, all the table surfaces are level, and the entire table surface is at the extreme position of longitudinal slide (foot). Do not transfer the patient in other positions, otherwise the table body may tip over.
- When transferring the patient please transfer from the side. Improper operation may cause the operating table to tip over.
- Improper placement of the patient will cause the operating table to tip over. When placing the patient, make sure that the direction is correct. Do not place the patient's body on the leg plate.
- When placing the patient, make sure that the patient's center of gravity is as close as possible to the center of the column, otherwise there is a danger of tipping.
- Incorrect posture may cause damage to the patient's physical functions, especially when the patient is in a lateral tilt or Trendelenburg / reverse Trendelenburg position at a large angle. When using the operating table make sure that the patient's position is correct, and pay attention to check whether the position is offset at any time.
- While ensuring the correct position, attention should be paid to the patient's condition to avoid damage to the patient's respiratory system, nervous system and circulatory system.
- When using the operating table, be sure to select the correct operation according to the patient's position, otherwise it will cause personal injury.
- The weight of different patients will affect the movement speed of the table surface, and thus please be careful during the adjustment process.

- When the patient weighs above 150 kg, the Trendelenburg / reverse Trendelenburg angle shall not exceed 10°, and the lateral tilt angle shall not exceed 5°, so as to prevent the patient from slipping and causing personal injury.
- When the table surface is tilted toward the foot, please be careful of the collision between the head plate and the patient's head when folding the back plate.
- Before using the longitudinal slide function, make sure that the surface of the operating table remains level.
- After using the longitudinal slide function, you can perform lateral tilt and Trendelenburg / reverse Trendelenburg, but not the fold up/ fold down and other movements of the back plate. Please always pay attention to the patient's position during operation to avoid collision.
- When adjusting the position of the operating table or patient, especially when the patient is in a lateral tilt or Trendelenburg / reverse Trendelenburg position at a large angle, make sure that the patient has been properly fixed, otherwise it may cause personal injury or equipment damage.
- If you use the longitudinal slide function to perform X-ray radiography on the patient before a surgical operation, after radiography, be sure to restore the table to a balanced position (translate the foot to the extreme position) before performing the operation.
- When adjusting the head plate, back plate, leg plate and other parts of the operating table, be sure to be careful of the joints to avoid pinching the patient or operators.
- When adjusting or moving the operating table, be sure to pay attention to the position of the operating table, accessories, patients and other items to avoid personal injury or equipment damage due to collisions.
- When the table surface is being adjusted to a lower position, while operating the table surface, please be careful of the collision or pinching of the table surface with the base or the ground.
- When the head/leg plate is folded down, please be careful of the collision or pinching of the head/leg plate with the base or the ground.
- When tilting the table surface or adjusting the leg plate, make sure that the table surface does not collide with the column or base.
- When adjusting the surface of the operating table, make sure that the wire controller cable is not trapped by the table surface joint.
- When adjusting the operating table, please be careful that the hanging parts (such as the leg plate, hand support, etc.) do not collide with objects in the operating room.
- When adjusting the operating table, please be careful to prevent accessories, sheets, etc. from getting stuck in the moving parts of the operating table to avoid equipment damage.

- When the operating table is not in use, the user must ensure that the equipment is locked and the entire table surface is in the optimal position: that is, all the table surfaces are level, the entire table surface is at the extreme position of longitudinal slide (foot), and the table surface is lowered to the extreme position.
- The safety and effectiveness of the operating table can only be guaranteed if it is properly maintained. Be sure to maintain the operating table according to the manufacturer's instructions.
- Do not disassemble the housing of the equipment to avoid possible electric shock. Any maintenance and upgrade of the equipment must be carried out by service personnel trained and authorized by the Comen company.
- Do not maintain the operating table when it is being used.
- Packaging materials must be disposed of in accordance with local laws and regulations or hospital waste disposal rules and regulations. Packaging materials must be placed out of the reach of children.
- The operating table can only be installed and debugged by authorized personnel of the Comen company.
- No modification of this equipment is allowed.
- The operating table must be thoroughly inspected for safety by professionals every year.
- In order to avoid environmental pollution, please dispose of discarded equipment, old batteries or accessories in accordance with relevant local regulations or hospital requirements.



### Caution

- In order to avoid equipment damage and ensure patient safety please use the accessories specified in this manual.
- Please install or move the equipment properly to prevent the equipment from falling, colliding, being damaged by strong vibration or other external mechanical forces.
- Before the equipment is powered on please confirm whether the mains power supply meets the requirements of the equipment nameplate label or the supply voltage and frequency specified in the User manual.
- In order to protect the environment, disposable accessories must be recycled or properly disposed of.

### Attention

- Please install the equipment in a place convenient for observation, operation and maintenance.
- This manual introduces the product according to the most complete configurations. The product you purchased may not have certain configurations or functions.
- Please place the user manual near the equipment so that it can be quickly and easily obtained when needed.
- This equipment cannot be used at home.
- The equipment can only be used by one patient at a time.
- In normal use, the operator's position shall be within one meter of the equipment.
- If in relation to the use of the operating table, a death or a serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.

## 1.2 Contraindications

None.

## 1.3 Symbols

- Instrument symbols

Symbol	Description	Symbol	Description
	Caution!		Refer to Instructions for Use
	Complies with Medical Device Regulation (EU) 2017/745		Authorized representative in the European Community
	Type B applied part		Protection against harmful effects of splashing water (overall unit)
	Protective grounding		Warning!
	Anti-pinch		Mains power input (national standard)
	Alternating current		Battery symbol
	Date of manufacture		Manufacturer

<b>SN</b>	Serial number		Classified collection of electrical and electronic equipment
	Environmental protection		Temperature limits
	Atmospheric pressure limitation		Humidity limitation

Description: Please refer to Chapter 2 for the button symbols and functions of the operating table's controller panel.

- **Packaging symbols**

Symbol	Description	Symbol	Description
	Do not stack		Do not roll
	This way up		Fragile, handle with care
	Keep dry		Center of gravity



### Attention

- Please refer to the actual equipment and the label on the packaging for the equipment symbols.

## Chapter 2 Product Overview

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The design of the equipment conforms to the relevant Chinese and international safety standards of medical electrical equipment.

### 2.1 Product Composition

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The operating table is mainly composed of the table (including the support component, transmission component and electric control component) and accessories (optional). Among which, the table surfaces can be divided into four segments: head plate, back plate, hip plate and leg plate.

The operating table can be equipped with general operating table accessories such as an anesthesia screen, standard circular clamp, standard quadrate clamp, hand support, leg support, foot plate, body support, shoulder support, fixing device for tubes and lines, prone position pad and body strap.

### 2.2 Applicable To

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Patients in hospital (including adults, pediatric patients and neonates).

### 2.3 Intended Use

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The operating table is intended to support and position patients for surgeries.

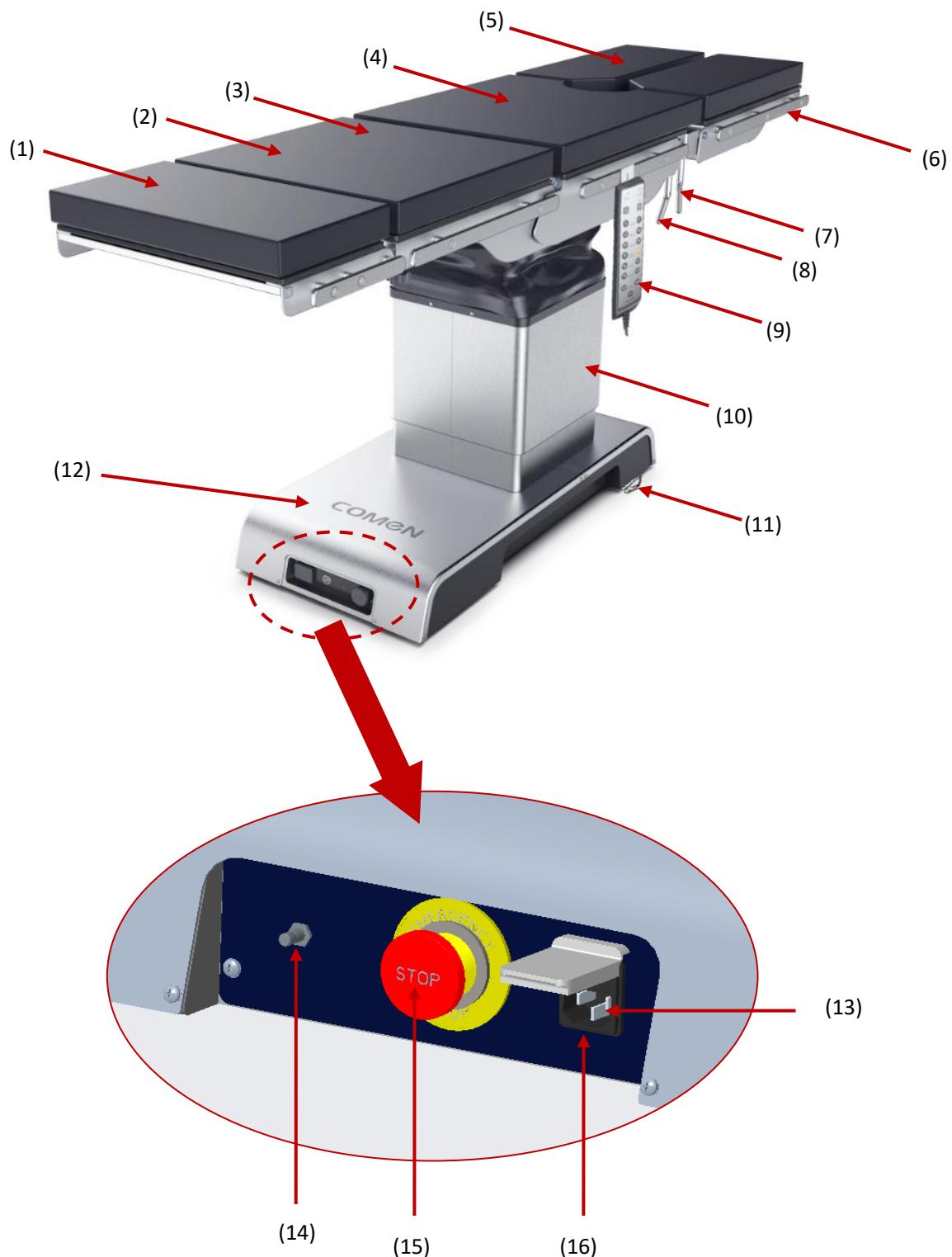
### 2.4 Applied Parts

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Applied parts of the operating table are mattress and side rail.

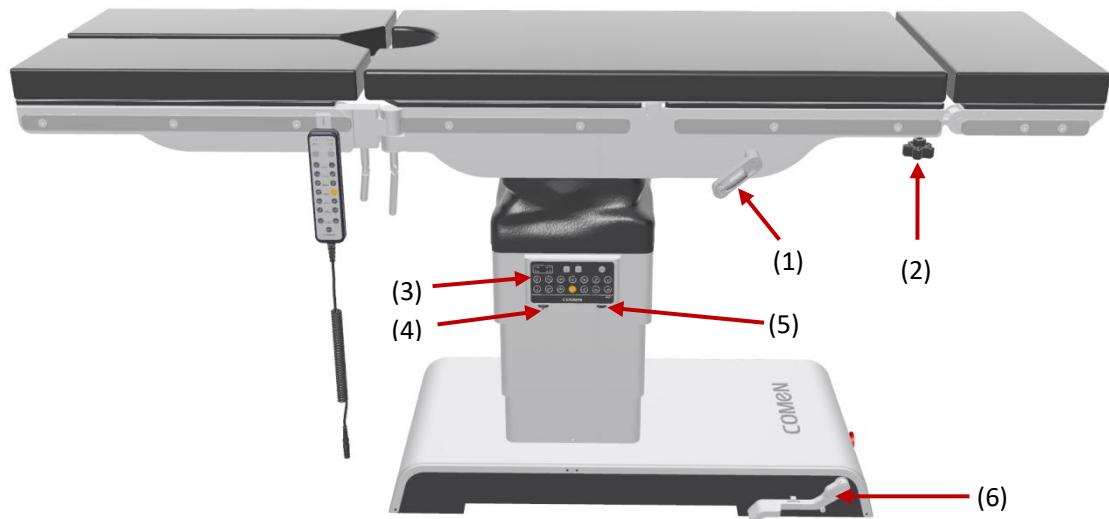
## 2.5 Product Appearance

### 2.5.1 Front and Right Hand Views



No.	Name	No.	Name
(1)	Head plate	(9)	Hand Control
(2)	Back plate	(10)	Column
(3)	Waist elevator	(11)	Caster
(4)	Hip plate	(12)	Base
(5)	Leg plate	(13)	Fuse
(6)	Side rail	(14)	Protective ground terminal
(7)	Fixed handle for leg plate	(15)	Emergency stop switch
(8)	Horizontal locking wrench for leg plate	(16)	AC power supply interface

## 2.5.2 Left Hand View



No.	Name	No.	Name
(1)	Waist elevator adjustment handle	(4)	Hand control interface
(2)	Hand knob for head plate	(5)	Foot control interface
(3)	Side control panel	(6)	brake



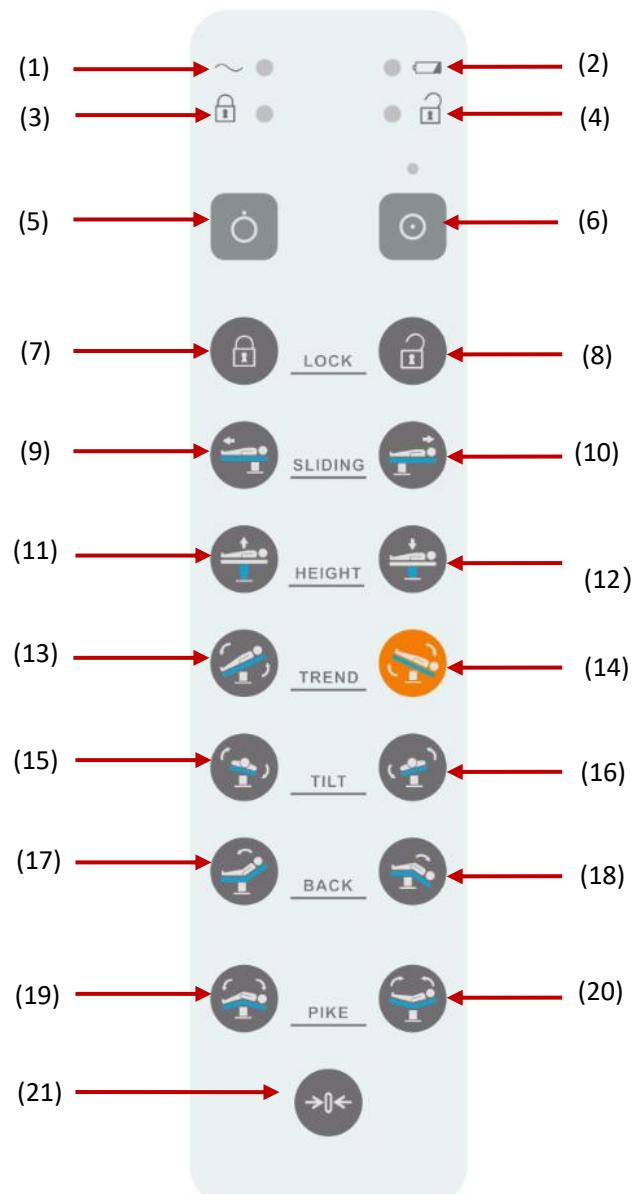
### Warning

- All analog and digital equipment connected with this device must be products certified by the specified IEC standards (such as IEC 60950 IT equipment standard and IEC 60601-1 Medical device

standard). Moreover, all configurations shall follow the valid version of the IEC 60601-1 system standard. The personnel connecting additional equipment to the input/output signal ports are responsible to ensure that they configure the entire system appropriately so that it meets the requirements of the IEC 60601-1 standard. If there are any doubts, please contact Comen.

- When signal interfaces such as the serial port are connected to multiple pieces of equipment at the same time, the total leakage current caused shall comply with IEC 60601-1.

### 2.5.3 Hand Control



No.	Name	Description
(1)	AC power indicator	<ul style="list-style-type: none"> <li>White light always on: The operating table is connected to an AC power supply.</li> <li>Light off: The operating table is not connected to an AC power supply.</li> </ul>
(2)	Battery indicator	<ul style="list-style-type: none"> <li>White light flashing: The operating table is powered by battery.</li> <li>Yellow light flashing: The battery is low.</li> <li>White light always on: The battery is being charged.</li> <li>Light off: The battery is fully charged.</li> </ul>
(3)	Locked status indicator	<ul style="list-style-type: none"> <li>White light always on: The operating table is locked and cannot be moved.</li> <li>Light off: The operating table is unlocked and can be moved.</li> </ul>
(4)	Unlocked status indicator	<ul style="list-style-type: none"> <li>Yellow light always on: The operating table is unlocked and can be moved.</li> <li>Light off: The operating table is locked and cannot be moved.</li> </ul>
(5)	Shutdown	
(6)	Startup	The white indicator light is on when the operating table is turned on, and the indicator light is off when it is turned off (the operating table will be turned off after 60 s to 70 s without operation)
(7)	Lock system	Press the button for 3 seconds to lock the equipment.
(8)	Unlock system	Press the button for 3 seconds to unlock the equipment.
(9)	Longitudinal Slide (foot)	
(10)	Longitudinal Slide (head)	
(11)	Rise	
(12)	Fall	
(13)	Reverse Trendelenburg	
(14)	Trendelenburg	
(15)	Lateral tilt (right)	
(16)	Lateral tilt (left)	
(17)	Back plate folds up	
(18)	Back plate folds down	
(19)	Forward buckling	
(20)	Backward buckling	
(21)	“0” button	Press it to return the operating table to the original position.

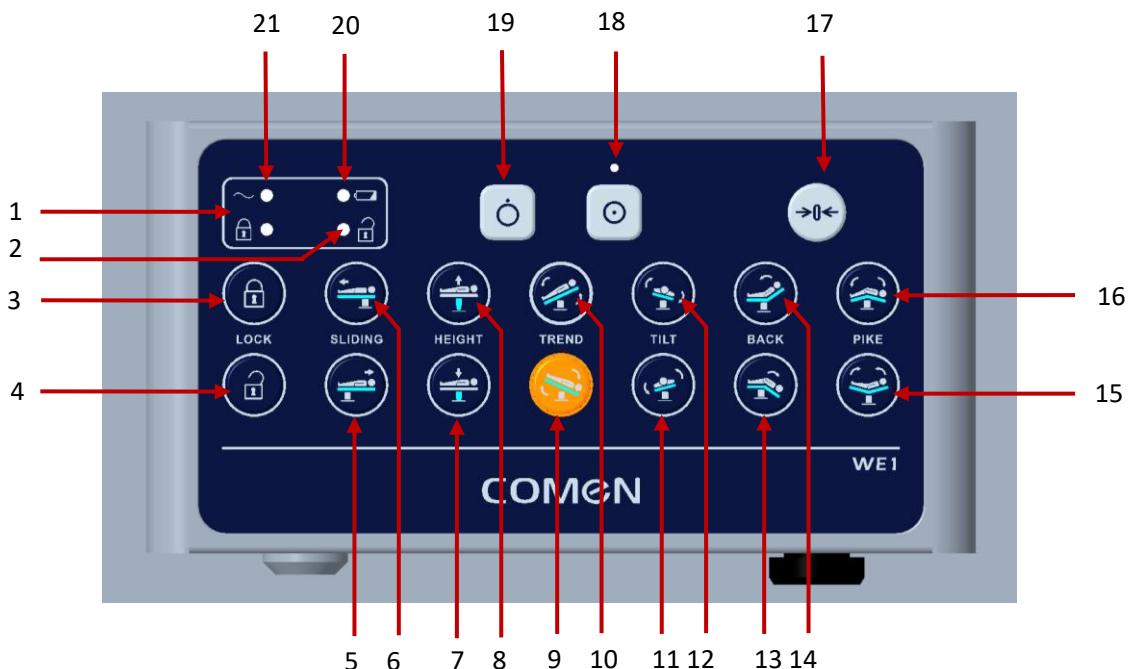
**⚠ Warning**

- When the patient's position adjustment is complete, be sure to turn off the hand control to avoid misoperation.

**⚠ Attention**

- When the hand control is idle for 60 s to 70 s, it will turn off automatically and the operating table will turn off automatically.
- Before each use of the operating table, check and confirm that all functions of the operating table can operate normally. Operate all the function buttons one by one, each operation lasting more than 3 seconds, and finally press the “0” button to adjust the table surface to the original position.

#### 2.5.4 Side Control Panel



No.	Name	Description
(1)	Locked status indicator	<ul style="list-style-type: none"> <li>● White light always on: The operating table is locked and cannot be moved.</li> <li>● Light off: The operating table is unlocked and can be moved.</li> </ul>

(2)	Unlocked status indicator	<ul style="list-style-type: none"> <li>● Yellow light always on: The operating table is unlocked and can be moved.</li> <li>● Light off: The operating table is locked and cannot be moved.</li> </ul>
(3)	Lock system	Press the button for 3 seconds to lock the equipment.
(4)	Unlock system	Press the button for 3 seconds to unlock the equipment.
(5)	Longitudinal slide (head)	
(6)	Longitudinal slide (foot)	
(7)	Fall	
(8)	Rise	
(9)	Trendelenburg	
(10)	Reverse Trendelenburg	
(11)	Lateral tilt (left)	
(12)	Lateral tilt (right)	
(13)	Back plate folds down	
(14)	Back plate folds up	
(15)	Backward buckling	
(16)	Forward buckling	
(17)	"0"button	Press to return the operating table to the original position.
(18)	Startup	The white indicator light is on when the operating table is turned on, and the indicator light is off when it is turned off (the operating table will be turned off after 60 s to 70 s without operation)
(19)	Shutdown	
(20)	Battery indicator	<ul style="list-style-type: none"> <li>● White light flashing: The operating table is powered by battery.</li> <li>● Yellow light flashing: The battery is low.</li> <li>● White light always on: The battery is being charged.</li> <li>● Light off: The battery is fully charged.</li> </ul>
(21)	AC power indicator	<ul style="list-style-type: none"> <li>● Steady white light: The operating table is connected to an AC power supply.</li> <li>● Light off: The operating table is not connected to an AC power supply.</li> </ul>

# Chapter 3 Installation and Disassembly



## Attention

- In order to ensure the normal operation of the operating table please read this chapter and the safety chapter before use, and install it as required.
- This product was delivered without disinfection. It must be cleaned and disinfected before the first use.



## Warning

- Be sure to check whether each part is in good condition, and replace it if it is damaged.
- When disassembling/installing parts of the operating table, be sure to hold the parts using both hands firmly to avoid equipment damage or personal injury caused by slipping.
- Be careful of pinching your hand when disassembling/installing each part.
- Do not install the hand support, anesthesia screen, and infusion frame on the side rail of head plate, so as to avoid unexpected movement of the head plate and thus cause equipment damage or personal injury.
- If you need to use accessories during the operation you must ensure that the sum of the weight of the accessories installed on each part and the weight of the patient's limbs does not exceed the maximum load bearing of the part.
- Be sure to use the specified mattress to avoid injury to the patient during the movement of the table surface.

## 3.1 Installation Requirements

### 3.1.1 Unpacking and Checking

Carefully take the device and its accessories out of the packing box, and save the packaging materials for future transportation or storage. Please count the accessories according to the packing list. Check for any mechanical damage. Check all external wiring and cables, and some inserted accessories. In case of any problems, please contact Comen After-sales Department or agent immediately.

**⚠ Warning**

- If any damage is found, please contact the relevant personnel of the hospital or the after-sales Service Department of Comen.

### 3.1.2 Environmental Requirements

The working environment of the operating table shall comply with the requirements specified in this manual.

The ambient temperature beyond the specified ranges may affect the accuracy of the equipment and cause damage to the components and wiring.

The operating table shall be used in an environment reasonably free from vibration, dust, corrosive or explosive gases, extreme temperatures, humidity, etc.

## 3.2 Installation of the Table

- Place the table in a suitable position;
- Press and hold the Lock System button on the side control panel to lock the table on the ground.
- If the table is unstable, please check whether the ground is flat and adjust the position of the table to ensure that the table is firmly locked to the ground.
- Insert the connecting plug of the hand control into the socket located on the column, and then hang the hand control on the side rail.

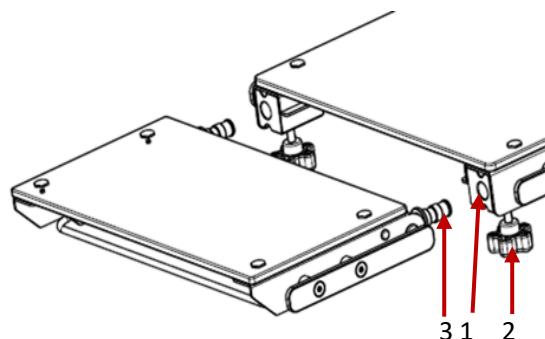


**Warning**

- Make sure to connect the protective ground terminal indicated in the figure above.
- Reserve enough space around the mains power disconnection device. The recommended space is greater than 0.5 m.

### 3.3 Installation and Disassembly of the Head Plate

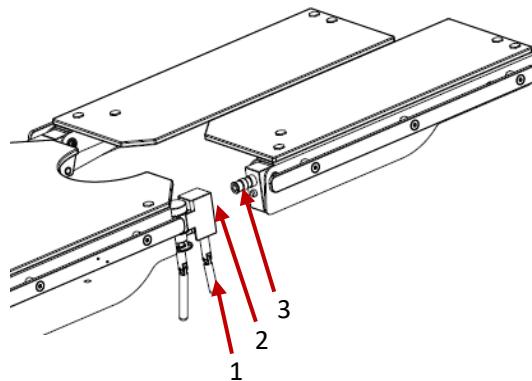
- 1) Install the head plate:
  - a) As shown in the figure below, hold the head plate firmly with both hands, and align the quick release pins (3) with the quick release slots (1) on the left and right sides of the upper back plate;
  - b) Push the head plate into the slot firmly, and tighten the hand knob (2) after a “click” sound;
  - c) Check whether the installation is safe and reliable.



- 2) Disassemble the head plate:
  - a) Hold the head plate firmly with both hands, and loosen the hand knob (2);
  - b) Pull out the head plate forcefully.

### 3.4 Installation and Disassembly of the Leg Plate

- 1) Install the leg plate:
  - a) As shown in the figure, hold the joints of the leg plate with both hands, and align the quick release pin (3) with the quick release slot (2) of the hip plate;
  - b) Push the plate forcefully into the slot, lift the fixed handle (1) for the leg plate and turn it tightly;
  - c) Check whether the installation is safe and reliable.



2) Disassemble the leg plate:

- Hold the joints of the leg plate and loosen the fixed handle (1) for the leg plate with the other hand;
- Pull out the leg plate.



**Warning**

- The leg plate is equipped with a self-locking gas spring inside, please do not disassemble it by yourself. If repair is required, please contact the authorized personnel from Comen.

### 3.5 Installation and Disassembly of the Mattress



**Warning**

- Be sure to check whether the mattress is aging or damaged before use. If there is any damage, replace it immediately.
- Do not use a mattress with a damaged surface, otherwise liquid penetration will occur, which does not meet the hygiene requirements.
- When the patient is lying on the mattress for disinfection, do not allow the disinfectant to accumulate under the patient's body.
- When installing a memory sponge mattress, make sure that the Velcro on the mattress and the one on the table surface are in complete alignment, otherwise the mattress may slip off and cause personal injury.
- When you install the mattress, damaged, loose or wet Velcro will not guarantee the safety and reliability of the mattress installation, therefore please replace it immediately.
- When using the mattress be sure to cover the mattress with a sterile sheet to avoid infection.

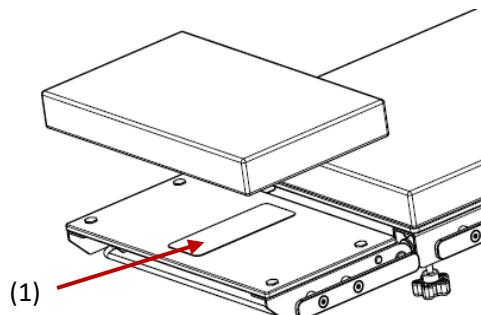
**⚠ Attention**

- The mattress shall be placed horizontally.
- Before installing the mattress, make sure that the table surface is dry.

This operating table is equipped with a memory sponge mattress, which is fixed on the surface of the operating table by Velcro. Each mattress can be disassembled.

1) Install the mattress:

- Place the mattress on the table surface and make sure that the Velcro strips under the mattress are completely attached to those on the table surface, and press them firmly together.
- Check whether the mattress installation is safe and reliable.



2) Disassemble the mattress:

Grasp one end of the mattress with both hands and pull up the mattress firmly.

### 3.6 Installation of Accessories

**⚠ Warning**

- The accessories are part of the operating table system which can only be used in conjunction with the operating table and accessories of the Comen company. Do not apply the accessories to other manufacturers' products, otherwise personal injury or equipment damage may be caused.
- Please check the condition of the accessories carefully before each use. If you find signs of aging or damage, be sure to stop using the accessories and notify the relevant personnel to check and repair the accessories, and replace them if in bad condition.

### 3.6.1 Clamp

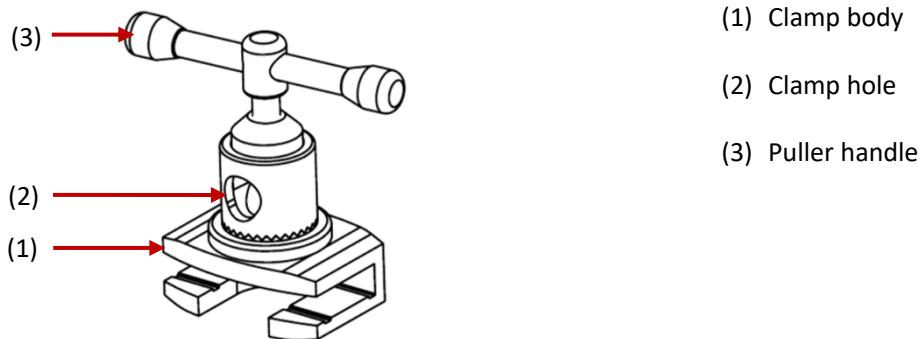
The clamp is used to fix the operating table accessories on the side rail of the operating table. The operating table can be equipped with two types of clamps: standard circular clamp and standard quadrate clamp, which are used to install accessories equipped with round and square support rods. When using a clamp, be sure to use the suitable one.



#### Warning

- Only the recommended clamp can be applied to the side rail of the table.
- When installing the clamp, make sure that the clamp body is completely fixed on the side rail of the operating table without any tilt, otherwise the accessories may slip or fall during use, which may cause personal injury or equipment damage.
- After installation or adjustment, be sure to firmly tighten the puller handle and clamp handle, otherwise the accessories may slip or fall during use, which may cause personal injury or equipment damage.

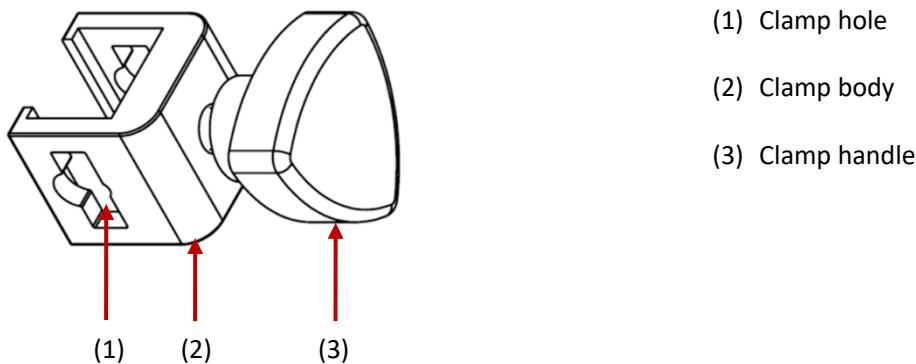
#### 3.6.1.1 Standard Circular Clamp



Installation and usage methods:

- a) First unscrew the puller handle (3), and clamp the clamp body (1) on the side rail of the operating table;
- b) Insert the accessory to be fixed into the clamp hole (2);
- c) Tighten the puller handle to fix the accessory to the clamp hole and to lock the clamp body on the side rail;
- d) Check whether the installation is safe and reliable.

### 3.6.1.2 Standard Quadratate Clamp

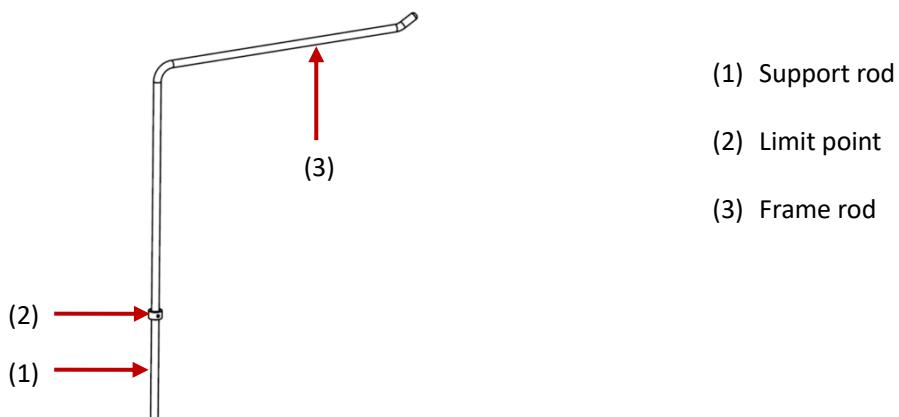


Installation and usage methods:

- Clamp the clamp body (2) on the side rail of the operating table;
- Insert the accessory to be fixed into the clamp hole (1), ensuring that the accessories are inside the side rail;
- Tighten the clamp handle (3), and lock the accessory on the clamp.
- Check whether the installation is safe and reliable.

### 3.6.2 Anesthesia Screen

The operating table can be equipped with a standard anesthesia screen for placing drape.



Installation and usage methods:

- Choose a suitable position and clamp the body of the circular clamp on the side rail of the operating table;
- Turn the tightening handle of the clamp to lock the clamp body on the side rail;

- c) Insert the support rod (1) into the clamp hole, adjust the rod up and down to adjust the anesthesia screen to a suitable height;
- d) Tighten the clamp handle to lock the anesthesia screen on the clamp;
- e) Hang the anesthesia drape on the anesthesia screen;
- f) Check whether the installation is safe and reliable.

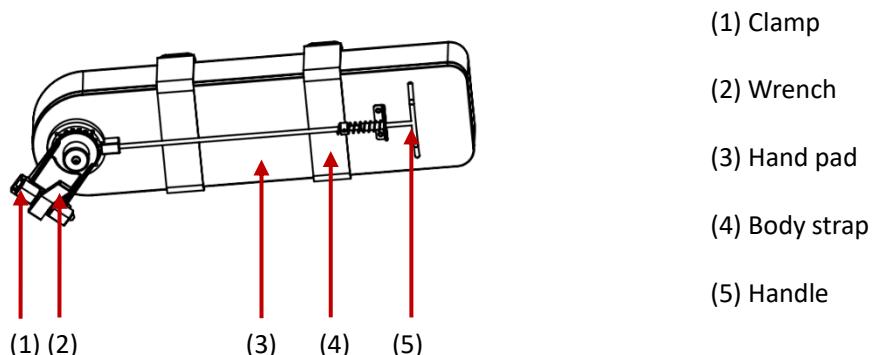
**⚠ Warning**

- The rod of this anesthesia screen is round and can only be used in conjunction with a circular clamp. Do not install this anesthesia screen with a quadrate clamp, otherwise this may cause personal injury or equipment damage.
- When installing the anesthesia screen, make sure that the anesthesia screen rod is vertically inserted into the clamp without any tilt, otherwise the anesthesia screen may slip or fall during use, which may cause personal injury or equipment damage.

### 3.6.3 Hand Support, Shoulder Support, Body Support, Foot plate, and Leg Support

The operating table can be equipped with rotatable hand support, shoulder support, body support, foot plate, and leg support, for placing and fixing the patient's body parts, one on each side.

The composition structure of the rotatable hand support is shown in the figure below:



Installation and usage methods:

- a) Choose a suitable position and clamp the clamp on the side rail of the operating table;
- b) Pull down the wrench (2) to lock the clamp on the side rail;
- c) Pull up the handle (5) to adjust the hand support to a suitable height;
- d) Fix the patient's arm on the hand support with a body strap (4);
- e) Check whether the installation is safe and reliable.

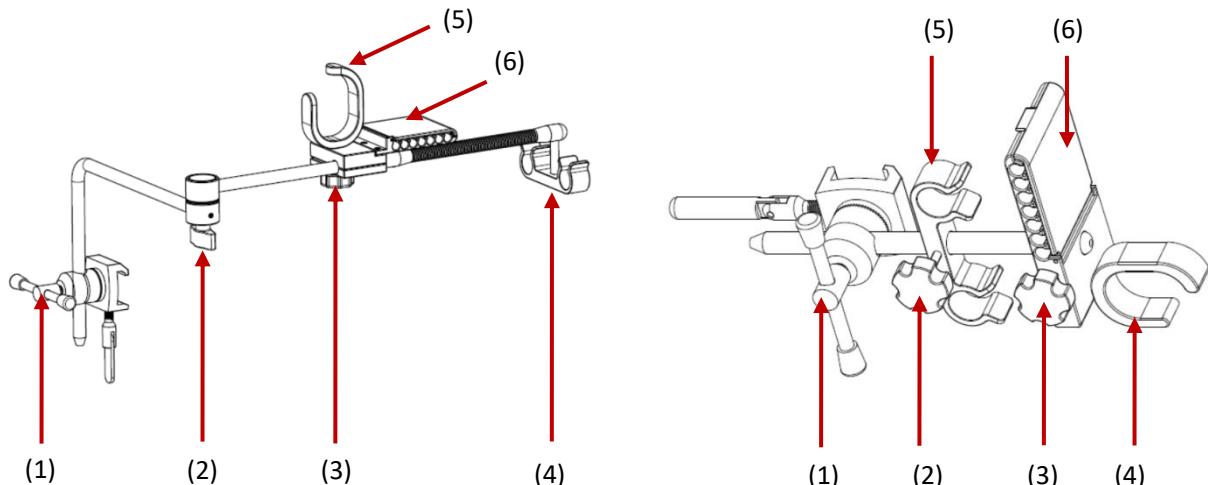
**⚠️ Warning**

- The standard leg support can only be used in conjunction with the circular clamp. The standard shoulder support, standard body support, and standard foot plate can only be used in conjunction with the quadrate clamp. Do not fit any support into an incorrect clamp, otherwise it may cause personal injury or equipment damage.
- When installing, make sure that the part is inserted vertically in the clamp without any tilt, otherwise it may slip or fall during use, which may cause personal injury or equipment damage.
- Do not rest on the parts during the operation, otherwise it will cause permanent injury to the patient's arm. During the operation, be sure to check whether the patient's body is in the correct position.
- Be sure to adjust the hand support to be parallel to the table surface to prevent the patient from being injured when moving the patient.
- When using the hand support, shoulder support, body support, leg support and foot support, be sure to cover it with sterile sheets to prevent infection.

**⚠️ Attention**

- The installation method of each accessory is similar, so you can refer to the hand support installation method when installing other accessories.

### 3.6.4 Fixing Device for Tubes and Lines



(1)	Clamp	(2)	Angle Adjustment Knob 1	(3)	Angle Adjustment Knob 2
(4)	Tube Clamp 1	(5)	Tube Clamp 2	(6)	Line Clamp

Installation and usage methods:

- a) Choose a suitable position and clamp the circular clamp on the side rail of the operating table;
- b) Turn the puller handle of the clamp to lock the clamp on the side rail;
- c) Insert the support rod of the fixing device into the clamp hole, and adjust the rod up and down to find a suitable height;
- d) Tighten the clamp handle, and lock the hand support on the clamp;
- e) Insert the cables into the line clamp;
- f) Check whether the installation is safe and reliable.

## 3.7 Equipment Preparation

### 3.7.1 Connect the AC Power Supply

Steps to connect the AC power supply:

- 1) Make sure that the AC power supply meets the specifications specified in this manual;
- 2) Use the power cord that is supplied with the operating table to connect one end of the power cord to the power outlet on the equipment and the other end to a grounded electrical socket;



#### Attention

- **Connect the power cord to the grounded socket of the hospital.**
- **When there is a battery configuration, the battery must be charged after the equipment is transported or stored. If the equipment is turned on without connecting to AC power supply, the equipment may not work normally due to insufficient battery power. After the AC power supply is connected, the battery can be charged regardless of whether the equipment is turned on or not.**

### 3.7.2 Protective Grounding

In order to protect patients and operators the metal housing of the operating table must be grounded. Therefore, the operating table is equipped with a three-wire power cord. After plugging it into a matching

three-wire socket, the equipment is grounded through the grounding wire (protective grounding) in the power cord. If there is no three-wire socket, consult the electrical management personnel of your hospital.

### **Warning**

- **Do not connect the three-wire power plug of this equipment to a two-wire socket.**
- **Be sure to connect the protective ground terminal.**
- **Make sure that the housing of the operating table is safely and reliably grounded.**

The equipment provides a protective ground terminal. Before using the equipment, be sure to connect the protective ground terminal. If it is unclear whether a particular combination of devices is dangerous (for example, danger from the accumulation of leakage current), the user shall consult the relevant manufacturer or other experts in this field to ensure that the device is used safely and will not be damaged by the recommended combination.

### **3.7.3 Condensation**

When using this device, please ensure that the equipment is free of condensation. When equipment is transferred from one room to another, condensation may form. This is because the equipment is exposed to humid air and different temperatures. In order to avoid potential risks (for example, condensed liquid can cause a short circuit on the circuit board), leave the instrument to dry before use.

Note: Condensation is the condensation of a gas or liquid when it cools. For example, steam turns to water when it cools, and water turns to ice when it cools. The lower the temperature, the faster the condensation forms.

## **3.8 Startup and Shutdown**

### **3.8.1 Startup**

This equipment can be powered by the built-in battery or an AC power supply.

- 1) Before startup, check whether all parts of the operating table are connected correctly and whether there is any mechanical damage;
- 2) Check whether the operating table can be turned on normally;

- Connect the power cord to the AC power supply, turn on the emergency stop switch (it automatically pops up when rotated), and after the power button is pressed, the white AC power indicator will light up;
- Press the startup button on the controller panel to start the equipment, and the indicators of the controller will illuminate.



#### Attention

- **Check all available functions to make sure that the operating table is functioning properly.**
- **The battery of this equipment is optional. If a battery is fitted to this equipment, please charge the battery after each use to ensure that there is sufficient power reserve.**
- **It is recommended that the time interval of startup and shutdown is greater than 1 minute to prevent shortening the service life of the equipment.**

### 3.8.2 Shutdown

If you need to turn off the operating table, please follow the steps below:

- 1) Confirm that the adjustment of the operating table is completed, and press the shutdown button on the controller panel;
- 2) The hand control or side control panel will automatically shut down after 60 s to 70 s without operation;
- 3) After confirming that you can stop using the operating table, turn off the power switch and the AC power indicator on the controller will be turned off, and disconnect the AC power cord.
- 4) When the operating table will not be used for long periods, please press the emergency stop switch.

## Chapter 4 Basic Operation

### 4.1 Activate the Functions of the Operating Table

All functions of the operating table can be activated through the hand control or the side control panel, and some parts can also be adjusted manually.

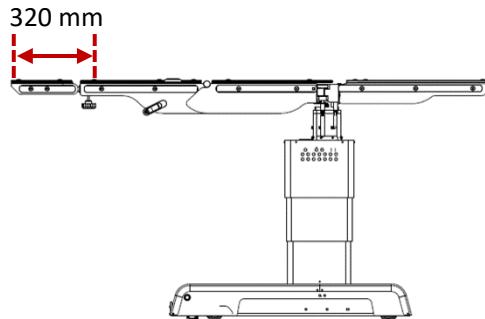
Operating steps of the hand control or the side control panel:

- 1) Turn on the emergency stop switch (automatically pops up when rotated);
- 2) Press the Startup button to start the operating table;
- 3) Press the Startup button and the corresponding function button at the same time and release it when the intended position is reached, and the table will automatically stop.

### 4.2 Longitudinal Adjustment Operation

Press the Startup button and the Longitudinal Adjustment function button at the same time to adjust the length of the operating table.

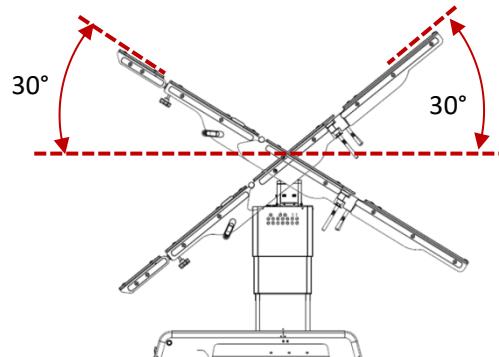
The adjustment range is shown in the following figure.



### 4.3 Trendelenburg/ Reverse Trendelenburg Operation

Press the Startup button and the Trendelenburg/ Reverse Trendelenburg function button at the same time to adjust the operating table to stay in either position.

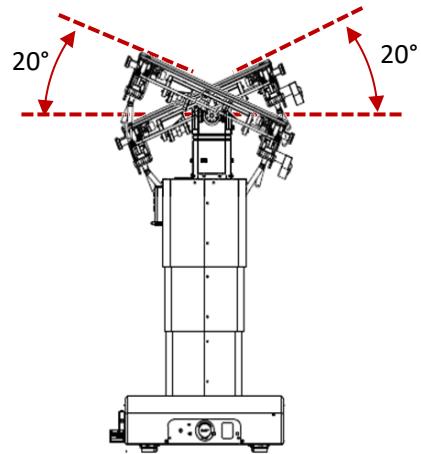
The adjustment angle range is shown in the following figure.



## 4.4 Lateral Lift Operation

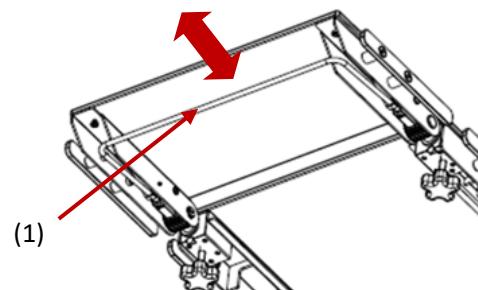
Press the Startup button and the Lateral Lift function button at the same time to make the operating table lean to the left or right.

The adjustment angle range is shown in the following figure.

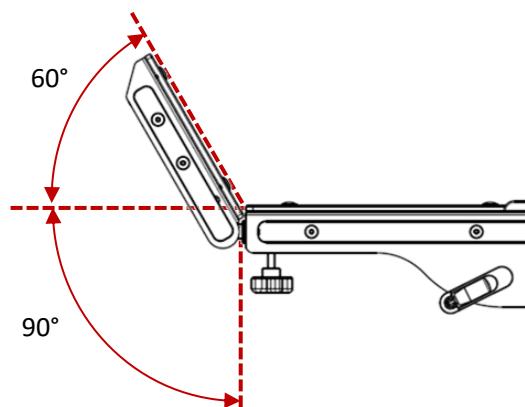


## 4.5 Operation of the Head Plate

- Firmly hold the head plate and the adjustment lever (1) of the head plate with both hands;
- Raise or lower the head plate to a suitable position;
- Release the head plate and the adjustment lever of the head plate.



The adjustment angle range of the head plate is shown in the following figure.



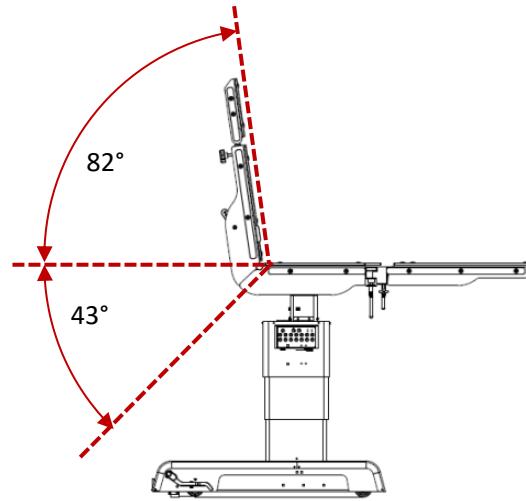
### Warning

- After installing the head plate, make sure that the head plate is installed safely and securely to prevent the head plate from falling off and causing equipment damage or personal injury.

## 4.6 Operation of the Back Plate

Press the Startup button and the Adjustment Button of the back plate at the same time to fold the plate.

The adjustment angle range of the back plate is shown in the following figure.



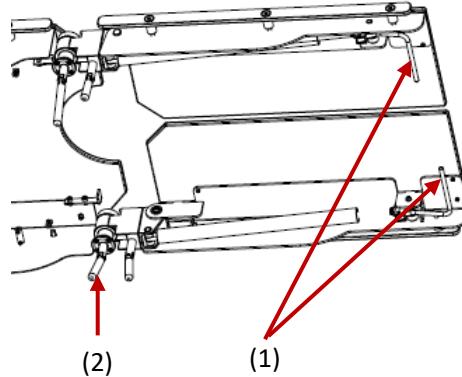
## 4.7 Operation of the Leg Plate



- Before adjusting the leg plate, make sure that there are no objects under the leg plate.

### 1) Upper/lower adjustment of the leg plate

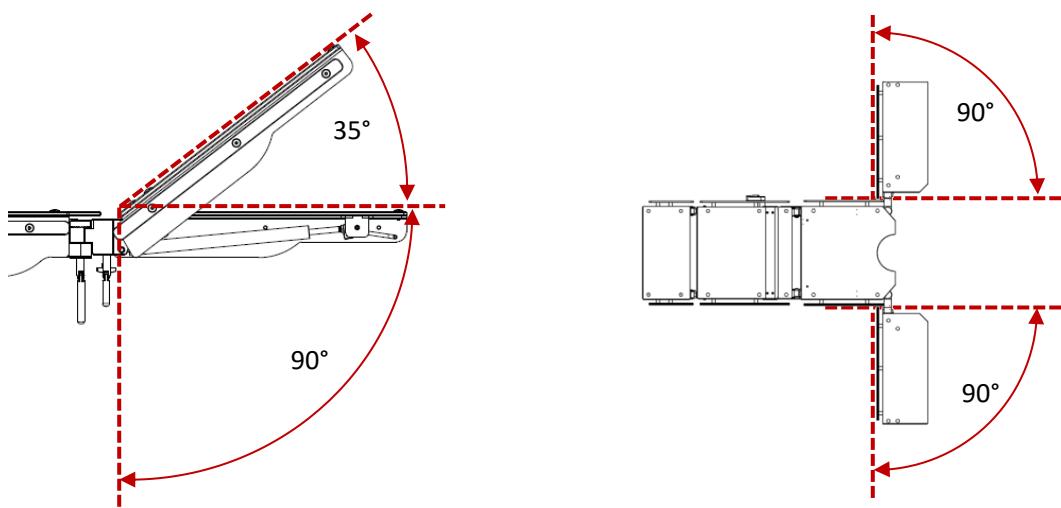
- Firmly hold the leg plate with both hands, and press the adjustment lever (1) of the leg plate.
- Raise or lower the leg plate to a suitable position.
- Release the leg plate and the adjustment lever of the leg plate.



### 2) Level adjustment of the leg plate

- Firmly hold the leg plate and loosen the horizontal locking wrench (2) for the leg plate in a counterclockwise direction;
- Adjust the leg plate left and right to a suitable position;
- Tighten the horizontal locking wrench (2).

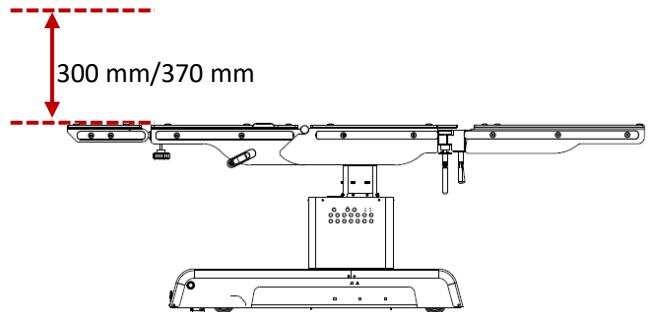
The adjustment angle range of the leg plate is shown in the following figure.



## 4.8 Lifting Operation

Press the Startup button and the Lifting Up/Down button at the same time to lift the operating table up or down.

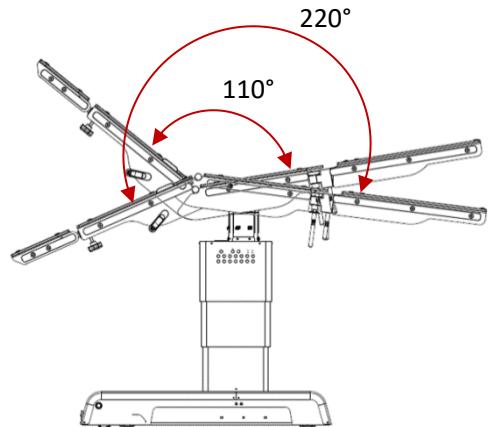
The lifting range is shown in the following figure.



## 4.9 Forward/Backward Buckling Operation with One Key

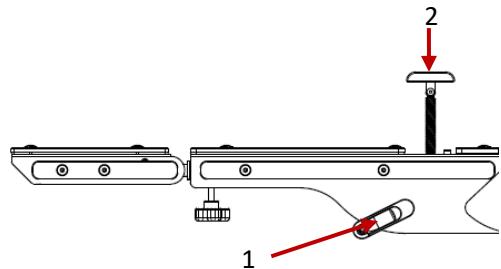
Press the Startup button and the Forward/Backward Buckling button at the same time to adjust the operating table.

The adjustment range is shown in the following figure.

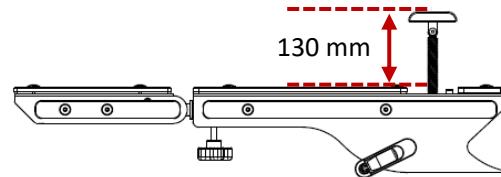


## 4.10 Operation of the Waist Elevator

Rotate the rocker (1) behind the waist elevator; this operation can raise and lower the waist elevator (2).



The adjustment range is shown in the following figure.



## Chapter 5 Troubleshooting



### Warning

- This chapter is limited to specified users to fix simple failures. If you encounter a failure that is not included in this chapter, or the failure cannot be eliminated after you try the troubleshooting methods listed below, please contact the user service organization specified by Shenzhen Comen Medical Instruments Co., Ltd. Do not repair the equipment without authorization.
- Repairs can only be done by authorized personnel of Shenzhen Comen Medical Instruments Co., Ltd. Repairs performed by unauthorized personnel may cause personal injury or equipment damage.
- Repairs must be strictly based on the technical data provided by Shenzhen Comen Medical Instruments Co., Ltd. If you need relevant technical data, please contact the user service organization specified by Shenzhen Comen Medical Instruments Co., Ltd. or your local agent.

Source	Possible Cause	Countermeasures
The power plug is connected, but all light sources are off	The power switch is not turned on or the emergency stop switch is not turned on.	Turn on the emergency stop switch and the power switch.
	The wire connection is poor or faulty.	Check whether the wires in the outer cover are disconnected or fused, and take appropriate action.
	The fuse is blown.	Contact the personnel authorized by Comen to replace the fuse.
	Power supply is not connected.	Connect to the power supply.

## 6.1 Overview

The equipment can be fitted with a built-in rechargeable battery. When connected to an AC power supply, the battery will be charged automatically, regardless of whether the equipment is turned on or not, until it is fully charged. In the event of a sudden power failure, the system will automatically use the battery to power the equipment without interrupting the equipment's status or functionality. After the AC power supply is cut off, the battery indicator flashes to indicate that the battery is being used for power supply and the operation of the equipment is not affected.

### Attention

- During storage and transportation, or when the table is not used for long periods, press the emergency stop switch of the operating table to turn off the battery output.
- If the equipment has a built-in battery, the battery must be charged after each use to ensure that the battery has sufficient power reserve.
- When the battery voltage is lower than 23V and the voltage does not rise after charging, it indicates that the battery has been damaged. Please contact Comen or the local agent to replace the battery.
- When the operating table functions become intermittent or unresponsive, or the battery indicator reports a low battery indication, it indicates that the battery is too low to drive the operating table. Please charge the battery. If the behavior continues to occur after charging, please contact the Comen after-sales service.

### Warning

- Incorrect replacement or fitting of lead-acid batteries will lead to unacceptable risks.
- Non-professional replacement of lead-acid batteries may cause risks.
- The battery electrolyte is harmful. When the battery electrolyte gets into your skin or eyes, you should immediately rinse the skin or eyes with clean water and consult a physician.
- Keep the battery out of the reach of children.
- When the equipment is being powered by battery, the equipment will automatically power off when the battery is low.

## 6.2 Battery Installation

### Warning

- If you need to install batteries, please contact Comen's local after-sales service.
- Only use batteries specified by the manufacturer.
- Do not remove the battery while the equipment is being used.

## 6.3 Optimization and Inspection of the Battery Performance

- Optimization of the battery performance

When the battery is used for the first time, it should be subjected to at least two complete optimization cycles. A complete optimization cycle shall be uninterrupted charging until the battery is fully charged, and discharging until the equipment automatically shuts down.

When optimizing the battery, you should ensure that:

- 1) Disconnect all connections between the equipment and the patient and stop all functions.
- 2) The battery to be optimized should be fitted to the battery box.
- 3) When charging the battery, ensure that the battery is charged for more than 8 hours without interruption. The battery indicator on the side panel goes out in the shutdown state, indicating that the battery is fully charged.
- 4) Disconnect the AC power and use the battery to power the equipment until the battery is discharged and the equipment automatically shuts down.
- 5) The battery optimization is over.

- Inspection of the battery performance

The service life of the battery varies with storage, usage environment, battery discharge frequency and usage time. Even if the battery is not used, its performance will gradually decrease.

The following describes the battery inspection steps:

- 1) First, determine whether the battery is damaged. When using battery power supply, if it cannot be turned on or cannot be charged (abnormal charging indicator), it means that the battery is damaged or there is no battery in the battery box.
- 2) Check whether the battery can be charged normally when the battery is connected to AC power.

- 3) Disconnect all connections between the equipment and the patient and stop all functions.
- 4) When charging the battery, ensure that the battery is charged for more than 8 hours without interruption. The battery indicator on the side panel goes out in the shutdown state, indicating that the battery is fully charged.
- 5) Disconnect the AC power and use the battery to power the equipment until the battery is discharged and the equipment automatically shuts down, and record the discharge start time and discharge end time.
- 6) The length of the discharge time reflects the battery performance.
- 7) When the discharge time drops below 50% of the initial value, the battery shall be replaced.



#### Attention

- If the battery is stored without use for long periods, in order to extend the life of the rechargeable battery, it is recommended to charge it once a month to prevent the battery from over-discharging.
- The battery life depends on the configuration and operation of the equipment. For example, frequent operation of the operating table will reduce the battery's power supply time.

## 6.4 Battery Recycling

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If the battery is obviously damaged or the battery cannot be charged, it shall be replaced, and the discarded old battery shall be properly recycled. Moreover, it shall be handled according to the corresponding laws and regulations or hospital rules and regulations.



#### Warning

- Do not disassemble or short-circuit the battery or throw it into a fire, otherwise it may cause the battery to catch fire, explode, leak harmful gas or lead to other hazards.

# Chapter 7 Cleaning and Disinfection

Only use the materials and methods approved by Comen listed in this chapter to clean or disinfect the operating table. Comen does not provide any guarantee for damage caused by using unapproved materials or methods.

Comen is not responsible for the effectiveness of the listed chemicals or methods as a means of infection control. For infection control methods, please consult your hospital's infection prevention department or epidemiologists, or refer to all local policies applicable to your hospital and country.

## 7.1 Overview

Please keep your equipment and accessories free of dust. After each cleaning, check the equipment carefully. If you find any signs of aging or damage, stop using it immediately. If you need to send it back to the Comen company for repairs, please clean it first. Please observe the following precautions:

- ✧ Follow the manufacturer's instructions to dilute detergents and disinfectants, or use the lowest possible concentration.
- ✧ Do not let liquid enter the housing.
- ✧ Do not let the operating table and its parts immerse in liquid for a long time.
- ✧ Do not use abrasive materials, bleaching powder, and any strong solvents (such as acetone or detergents containing acetone).



### Warning

- **Use only the detergents and disinfectants recommended in this manual. The use of other detergents and disinfectants can cause equipment damage or lead to safety hazards.**
- **Before cleaning the operating table, you must turn off the power and disconnect the AC power supply.**
- **Do not use EtO (ethylene oxide) to disinfect the operating table.**
- **Do not let the disinfectant remain on any surface and accessories of the operating table, please wipe it off immediately with a damp cloth.**
- **Detergents cannot be mixed; otherwise dangerous gases will be generated.**

- This chapter only introduces the cleaning methods of reusable accessories. Disposable accessories cannot be cleaned and disinfected and used again to avoid cross-infection.
- In order to protect the environment, disposable accessories must be recycled or properly disposed of.
- After cleaning, if there are signs of damage or aging of the cable, the cable shall be replaced with a new one.
- The operating table and all accessories cannot be autoclaved.
- Do not use any cleaning solutions other than those recommended here, which may cause permanent damage to the equipment, accessories and cables.



#### Caution

- If you accidentally pour liquid on the operating table or accessories, please contact the maintenance personnel or Comen immediately.

## 7.2 Cleaning and Disinfection of the Operating Table

The operating table shall be kept clean. It is recommended to clean the outer surface of the table frequently. In particular, in areas with severe environmental conditions such as windy or dusty, the frequency of cleaning shall be increased. In addition, in order to avoid cross-infection, it is necessary to clean the accessories regularly. Please consult or understand the hospital's regulations on equipment cleaning before cleaning.

➤ Cleaning steps:

- 1) Turn off the power first and disconnect the power cord.
- 2) Use a soft cloth to absorb the proper amount of detergent, wring it out and wipe the body of the operating table.
- 3) Use a soft cloth to absorb the proper amount of detergent, wring it out and wipe the controller panel of the operating table.
- 4) If necessary, use a soft, dry cloth to wipe off excess detergent.
- 5) Place the equipment in a cool and ventilated environment to air dry naturally.

The disinfection operation may cause a certain degree of damage to the equipment. It is recommended that the equipment be disinfected only when necessary in the hospital maintenance plan. Before disinfecting the operating table, please clean the operating table first.

➤ Available detergents/disinfectant:

Detergent	Disinfectant
Weak basic solvent (soapy water)	Aldehydes
All-purpose cleaner	Quaternary compound
Clean water	Guanidine compound
/	2% alkaline glutaraldehyde (applicable for metal parts)

Note: All-purpose cleaner generally refers to the cleaner mainly composed of surfactants and phosphates.

➤ Detergents/disinfectant not applicable:

- Detergents/disinfectant containing alcohol
- Detergents/disinfectant containing or releasing chlorine (not applicable to metal parts)
- Halides (e.g., fluorine, chloride, bromide and iodide)
- Things that will scratch the surface of the bed (e.g., cleaning ball and wire brush)
- Organic solvent (benzene, diluent)
- Water containing metallic impurities

# Chapter 8 Maintenance

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## 8.1 Maintenance inspection

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Before the operating table is used or it has been continuously used for 6 -12 months or after each maintenance or upgrade, a complete inspection of the equipment, including functional safety inspections, must be performed by trained and qualified technical maintenance personnel.

Inspection items shall include:

- 1) Check whether the operating environment and power supply of the operating table meet the requirements;
- 2) Check the operating table and accessories for mechanical damage;
- 3) Check whether the power cord is free from abrasion and has good insulation performance;
- 4) Check all equipment functions that may be used for the patient and ensure that the equipment is in a good operating condition;
- 5) Check whether the accessories used are those specified by the manufacturer;
- 6) Check whether the battery performance is good;
- 7) Check whether the wiring impedance and leakage current meet the requirements;
- 8) Confirm that the operating table has been cleaned and disinfected;
- 9) The appearance of the operating table shall be upright, uniform in color, and there shall be no obvious bumps, cracks, and sharp edges;
- 10) The texts and markings of the operating table shall be clear and accurate, and firmly stuck;
- 11) The operation of each control part shall be flexible, stable and reliable, with no jitter and no loose fasteners;
- 12) The hydraulic system of the operating table shall be leak-free

If there is any indication of a functional impairment of the operating table is found, do not use this equipment to perform any operations on the patient. Please contact the biomedical engineer of the hospital or Comen.

All safety inspections or repairs requiring the disassembly of equipment shall be carried out by professional maintenance personnel. The use of the non-professional personnel may result in the failure of the function of the equipment or the existence of safety hazards, and may endanger personal safety.

Comen will conditionally provide circuit diagrams upon user's request to help users find appropriate and qualified technicians to repair those parts of the equipment that the Comen company classified as user-serviceable.



### Warning

- The hospital or institution using this equipment shall establish a comprehensive maintenance plan, otherwise it may cause the failure of equipment functions and unpredictable consequences, and may endanger personal safety.

## 8.2 Maintenance Plan

### 8.2.1 Maintenance

The following tasks can only be completed by professional maintenance personnel approved by Comen. When the following maintenance is required, please contact the maintenance personnel in time. Before testing or maintenance, the operating table must be cleaned and disinfected.

Testing and maintenance items	Frequency
Carry out safety inspection according to IEC 60601-1	At least once every two years. After the equipment is dropped, or the power supply is replaced, or when required, it shall be checked.
Mechanical/hydraulic system	Carry out safety inspection and necessary maintenance once a year; The hydraulic oil shall be replaced after the first 2-year use, and then every 5 years.
Battery	See the appropriate section relating to the battery.

### 8.2.2 Service Life of Accessories

The service life of the parts and accessories of this equipment is 10 years.

## Appendix I Accessories

When this equipment is used, Comen recommends the following accessories.



### Warning

- Please use the accessory models specified by Comen. Using other accessories may damage the equipment.
- Disposable accessories can only be used once. Repeated use may result in reduced performance or cross-infection.

No.	Name
1.	Anesthesia Screen
2.	Light Circular Clamp
3.	Rotatable Hand Support
4.	Head Ring
5.	Open Head Ring
6.	Ophthalmology Head Pad
7.	Concave headrest
8.	Prone Position Protection Cushion
9.	Thyroid Cushion
10.	Universal Head Cushion
11.	Semi-circular Supporting Pad
12.	Chest Cushion
13.	Limb Fixture Cushion
14.	Arm Support Pad
15.	Heel Pad
16.	Operating Table Fixation Strap ( for Wrist)
17.	Operating Table Fixation Strap ( for Ankle)
18.	Operating Table Fixation Strap ( for Body)
19.	Rhombus-shaped Pad
20.	Universal square Pad
21.	Tunnel Pad

Accessories

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22.	Pressure Relief Cushion
23.	Combined Prone Position Support Pad
24.	Double Deck Hand Support
25.	Handrail
26.	Waste Bin
27.	Instrument tray
28.	Knee Support
29.	Stirrup-shaped Leg Plate
30.	Hand bracket for lateral position
31.	Shoulder opening surgical frame
32.	Multi-Articulated Arm Support
33.	Upper arm support plate
34.	Doctor's Head Frame
35.	Fixture
36.	Square Fixture
37.	X-ray film tray
38.	IV Pole
39.	Leg support
40.	Shoulder/body support
41.	Foot plate

## Appendix II Product Specifications

### 1) Product Type

Name	Type
CE classification according to MDR	Class I
Classification in accordance with the electric shock protection type	Class I (external power supply), built-in power supply
Classification in accordance with the degree of electric shock protection	Type B (mattress)
Explosion protection level	Explosion protection is not provided (ordinary equipment), and flammable respiratory agents cannot be used.
Classification in accordance with the degree of protection against liquid ingress	IPX4
Classification in accordance with the degree of safety when used in the case of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide	Equipment that cannot be used in the presence of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide
Classification in accordance with the operation mode	Intermittent operation, operate for 10 minutes, and rest for 20 minutes
Whether there is an applied part to protect against defibrillation discharge effect	None
Whether there is a signal output or input part	None
Permanently installed equipment or non-permanently installed equipment	Non-permanently installed equipment
Compliance with relevant standards	Medical Device Regulation (EU) 2017/745, Directive 2011/65/EU, ISO 14971, ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 780, ISO 20417, ISO 15223-1, IEC 60601-1, IEC 60601-1-2, IEC 60601-2-46, IEC 60601-1-6, IEC 62366-1, IEC 62304

## 2) Physical Specifications

Name	Specification		
Table surface size (excluding mattress)	Length: 2050 mm ± 50 mm		
	Width: 510 mm ± 50 mm (excluding side rail)		
	Height range	WH1/WH1A: Min: 670 mm±50 mm, Max: 1040 mm±50 mm	
		WH2/WH2A: Min: 500 mm±50 mm, Max: 800 mm±50 mm	
	Weight: 250 kg ± 10 kg		

Accessories rated load			
Supporting part	Rated load	Supporting part	Rated load
Head board	22 kg	Hip board	62 kg
Arm supporting board	23 kg	Left leg board	56 kg
Upper trunk board	30 kg	Right leg board	56 kg
Lower trunk board	31 kg		

Load bearing specification	
Lifting limit load	WH1/WH1A/WH2/WH2A: 350 kg
Normal position load	WH1/WH1A/WH2/WH2A: 280 kg

## 3) Electrical Specifications

AC power supply	
Name	Power supply environment
Power input	100-240V ~ , 50Hz/60Hz
Rated current	5.5A-2.8A
Fuse	T6.3AL 250V, 5*20
Power cord	5m
Built-in battery	
Voltage	24V DC (12V×2)
Capacity	13Ah (10 hours)
Fuse	T15AL 250V, 5 x20
Charging time	≤10h
Power supply time	About 50 operations

## 4) Environmental Specifications

Working environment	
Temperature	+5°C ~ +40°C
Relative humidity	15% ~ 95%, non-condensing
Atmospheric pressure	70 kPa ~ 106 kPa
Storage and transportation environment	
Temperature	-40°C ~ +55°C
Relative humidity	10% ~ 95%, non-condensing
Atmospheric pressure	50 kPa ~ 106 kPa
Transport conditions	During transportation, the operating table must be protected from severe shock, vibration, and rain and snow.
Storage conditions	The operating table shall be stored in a dry and well-ventilated room with no corrosive gases.

## 5) Parameter Specifications

Braking mode	Electronically controlled hydraulic brake or manual brake
Driving mode	Hydraulic electric control
	Mechanical control
Control mode	Hand control: Wired button control mode
	Side control: Integrated in the column
	Foot control
Vertical longitudinal slide	Max 320 mm±10 mm
Trendelenburg / reverse Trendelenburg	Max 30° / Max 30°±5°
Lateral tilt (left / right )	Max 22° / Max 22°±5°
Fold up / fold down of the head plate	Max 60° / Max 90°±5°
Fold up / fold down of the back plate	Max 82° / Max 43°±5°
Waist elevator	130 mm±10 mm
Fold up / fold down of the leg plate	Max 35° / Max 90°±5°
Outward rotation of the leg plate	0° ~ 90°±5°
Lifting distance	WH1/WH1A: 0 ~ 370 mm±50 mm

	WH2/WH2A: 0 ~ 300 mm±50 mm
One key forward/backward buckling	Forward buckling: 220°±5° (reverse Trendelenburg 20°, back plate folds down 20°)
	Backward buckling: 110°±5° (Trendelenburg 30°, back plate folds up 40°)
"0" button	Trendelenburg / reverse Trendelenburg, lateral tilt, and the back plate returns to the original position
The adjustment range of the table	Vertical: no more than 15 mm
	Level: no more than 10 mm
	Lateral: no more than 18 mm
Foot control	Able to realize Trendelenburg / reverse Trendelenburg, lateral tilt and lifting function
Brake	Hydraulic brake
Movement function	The operating table is equipped with movable casters and brake; when the brake is locked, there shall be no movement at a thrust of 200N
Stability of movements	The operating table should have stable transitions of various movements without any shaking.
Emergency stop	The operating table is equipped with a one-button emergency stop function
Data storage and recording	Failures data saved

## 6) Hydraulic System Specifications

Hydraulic system		
Hydraulic pump	Hydraulic working medium	Hydraulic oil (+ antioxidant and rust inhibitor) YA-N32 hydraulic oil or GB11120L-TSA32 steam turbine oil
	Rated working pressure	21Mpa
	Operating working pressure	10Mpa±10%
Hydraulic Leakage	When hydraulic leakage lasts for 5 hours, the downward distance of the table should not exceed 8 mm.	
Connector and installation method	Hose connector	Withholding type hose connector (with good pulling resistance and sealing performance)
	Installation method	Threaded (tubular) mounting connection

## 7) Warning

Low battery shutdown delay time	5 minutes after the first low battery warning
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## Appendix III EMC



### Attention

- The WH1/WH1A/WH2/WH2A operating table meets the requirements of electromagnetic compatibility in the IEC 60601-1-2 and IEC 60601-2-46 standards.
- Users shall install and use the electromagnetic compatibility information provided in the accompanying file.
- Portable and mobile RF communication equipment may affect the performance of the WH1/WH1A/WH2/WH2A operating table. Avoid strong electromagnetic interference during use, such as near mobile phones, microwave ovens, etc.
- See the attachments below in the manual for the guidance and manufacturer's declaration.



### Warning

- The WH1/WH1A/WH2/WH2A operating table shall not be used close to other equipment. If they must be used close to each other, all devices shall be observed to verify that they can operate normally in the configuration used.
- Class A equipment is intended for use in industrial environments. Due to conducted emissions and radiated emissions in the WH1/WH1A/WH2/WH2A operating table, it may be potentially difficult to ensure electromagnetic compatibility in other environments.
- In addition to the cables sold by the manufacturer of the WH1/WH1A/WH2/WH2A operating table as spare parts for internal components, the use of accessories and cables outside the regulations may result in increased emission or reduced immunity of the WH1/WH1A/WH2/WH2A operating table.
- Even if other equipment meet the emission requirements of corresponding national standards, the equipment or system may still be interfered by other equipment.

<b>Cable information</b>				
<b>No.</b>	<b>Name</b>	<b>Cable length (m)</b>	<b>Shield Radio Signal or not</b>	<b>Remark</b>
1	AC power cord	5.0	No	/
2	Hand control cable	3.5	No	/
3	Grounding wire	5.0	No	/

During and after non-transient phenomena, the operating table maintains the basic safety and essential performance: Support a patient without unintended movement (motorized or not) to avoid an unacceptable risk in a single fault condition.

Table 1

<b>Guidance and manufacturer's declaration - electromagnetic emission</b>		
The WH1/WH1A/WH2/WH2A operating table is intended for use in the electromagnetic environment specified below. The customer or the user of the WH1/WH1A/WH2/WH2A operating table 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 WH1/WH1A/WH2/WH2A operating table uses RF energy only for its internal functions. 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 WH1/WH1A/WH2/WH2A operating table is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity			
The WH1/WH1A/WH2/WH2A operating table is intended for use in the electromagnetic environment specified below. The customer or user of the WH1/WH1A/WH2/WH2A operating table should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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	± 2 kV for power supply lines ± 1 kV for input/output lines 100 kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for input/output lines 100 kHz repetition frequency	Mains power quality should meet the requirements of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Mains power quality should meet the requirements of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % $U_T$ ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % $U_T$ ; 1 cycle and 70 % $U_T$ ; 25/30 cycles Single phase: at 0°  0 % $U_T$ ; 250/300 cycles	0 % $U_T$ ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % $U_T$ ; 1 cycle and 70 % $U_T$ ; 25/30 cycles Single phase: at 0°  0 % $U_T$ ; 250/300 cycles	Mains power quality should meet the requirements of a typical commercial or hospital environment. If the user of the WH1/WH1A/WH2/WH2A operating table requires continued operation during power interruptions, it is recommended that the WH1/WH1A/WH2/WH2A operating table be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m	Power frequency magnetic fields should have the magnetic characteristic of a typical location in a typical commercial or hospital environment.
NOTE: $U_T$ is the a.c. mains voltage prior to the application of the test level.			

Table 3

<b>Guidance and manufacturer declaration - electromagnetic immunity</b>			
The WH1/WH1A/WH2/WH2A operating table is intended for use in the electromagnetic environment specified below. The customer or the user of the WH1/WH1A/WH2/WH2A operating table should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Conducted RF IEC 61000-4-6	3V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the WH1/WH1A/WH2/WH2A operating table, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz	3V/m	<p><b>Recommended separation distance</b></p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz} \sim 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz} \sim 2.7 \text{ GHz}$ <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur near the equipment marked with the following symbol:</p> 
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects and people.</p> <p>a) Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones</p>			

and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the WH1/WH1A/WH2/WH2A operating table is used exceeds the applicable RF compliance level above, the WH1/WH1A/WH2/WH2A operating table should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the WH1/WH1A/WH2/WH2A operating table.

b) Over the frequency range 0.15 MHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4

<b>Recommended separation distances between portable and mobile RF communications equipment and the WH1/WH1A/WH2/WH2A Operating Table</b>			
<b>Rated maximum output power of transmitter W</b>	<b>Separation distance according to frequency of transmitter m</b>		
	<b>150 kHz ~ 80 MHz</b>	<b>80 MHz ~ 800 MHz</b>	<b>800 MHz ~ 2.7 GHz</b>
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters 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 rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range is applied.

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

Table 5

Declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28V/m	28 V/m
	710 MHz	**Pulse			
	745 MHz	Modulation: 217Hz	0.2 W	9V/m	9 V/m
	780 MHz				
	810 MHz	**Pulse			
	870 MHz	Modulation: 18Hz	2 W	28 V/m	28 V/m
	930 MHz				
	1720 MHz	**Pulse			
	1845 MHz	Modulation: 217Hz	2 W	28 V/m	28 V/m
	1970 MHz				
	2450 MHz	**Pulse			
	Modulation: 217Hz	2 W	28 V/m	28 V/m	
	5240 MHz	**Pulse			
	5500 MHz	Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	5785 MHz				
<p>Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.</p> <p>Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.</p>					

## Appendix IV Toxic and Hazardous Substances or Elements in the Product

Part name		Lead Pb	Mercury Hg	Cadmium Cd	Hexavalent chromium Cr (VI)	Polybrominated biphenyls PBB	Polybrominated diphenyl ethers PBDE
Equipment housing	Metal element	×	0	0	×	0	0
	Table surface	0	0	0	0	0	0
	FRP cover	0	0	0	×	0	0
	Label	0	0	0	0	0	0
Main unit	column	0	0	0	×	0	0
	Main unit hardware	0	0	0	×	0	0
	Cylinder	0	0	0	×	0	0
	Pipeline	0	0	0	0	0	0
	Solenoid valve	0	0	0	0	0	0
	Fuel pump	0	0	0	0	0	0
	Internal cable	0	0	0	0	0	0
Packaging	PCBA	×	0	0	0	0	0
	Packaging material	×	×	0	0	×	×
Universal	Connector	0	0	0	×	0	0
	Power cord	0	0	0	0	0	0
Battery	Lead-acid battery	×	×	×	×	×	×

Toxic and Hazardous Substances or Elements in the Product

Accessorie	Metal element	x	0	0	x	0	0
	Sheet	0	0	0	0	0	0
	Pad	0	0	0	0	0	0
Remark	<p>O: It indicates that the content of this toxic and hazardous substance in all homogeneous materials of this part is below the limit requirement stipulated in SJ/T 11363-2006.</p> <p>x: It indicates that the content of this toxic and hazardous substance in at least one homogeneous material of this part exceeds the limit requirement stipulated in SJ/T 11363-2006.</p>						

## Appendix V Consideration for Environmentally Conscious Design

### 1. Instructions for Minimizing Environmental Impact during Normal Use

This part is compiled based on the requirements of *Clause 4 Protection of Environment, 4.5.2 Instructions for minimizing environmental impact during normal use* of IEC 60601-1-9.

According to the requirements of this clause, the manufacturer shall provide instructions for minimizing the environmental impact of the ME equipment during normal use in the accompanying documents.

The instructions cover the following items (Table 1).

**Table 1 The requirements of Clause 4.5.2 and Instructions provided by manufacturer**

The requirements of Clause 4.5.2	Instructions provided by manufacturer
1) Instructions on how to install the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;	Try to keep the integrity of the non-disposable packing materials and put away the packing materials for future use or put into the specified location where complying with the rules and regulations of the local government and the hospital. Avoid overusing the cleaning reagents and other substances. For the reusable accessories, clean them with specified reagent and put away, and for the disposable ones, deal with them together and put into the specified location where complying with the rules and regulations of the local government and the hospital. If not specified, please follow the rules and regulations of the local government and the hospital.
2) Instructions on how to use and maintain the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;	Use the specified accessories and cleaning and disinfection reagent to avoid harm to the machine and accessories and reduction of the service life. Use the medical device strictly according to the instruction manual. And for maintaining the medical device, always dilute according to the manufacturer's instructions or use lowest possible concentration. Never use bleach. Do not mix disinfecting solutions (such as bleach and ammonia) as this may result in hazardous or poisonous gases or liquids. When there is a need to maintain, please follow the Instruction for Use or follow the rules and regulations of the Hospital.
3) Consumption during NORMAL USE (e.g. energy, consumable materials/parts, disposables, water, gasses,	During normal use of this device, it will consume electricity (alternate current and direct current-battery). The disposables are also consumed and shall be disposed

chemicals/reagents etc.);	according to the rules of the local government and the hospital. For cleaning or disinfection for the cables and machine, the water and ethanol or isopropanol will be used and the waste liquid shall be thrown according to the rules of the local government and the hospital.
4) Emissions during NORMAL USE (e.g. WASTE water, WASTE consumable materials, acoustic energy, heat, gasses, vapours, particulates, HAZARDOUS SUBSTANCES and other WASTE);	During normal use, it is expected there will be some consumption of the medical device. To avoid unnecessary consumption such as acoustic energy, heat, gases, hazardous substances, etc., it's recommended that on the premise of normal operation, turn off the unused functions to reduce the unnecessary heat emission and electricity consumption.
5) Information on the location within the ME EQUIPMENT of HAZARDOUS SUBSTANCES, radioactive sources and induced radioactive materials.	The battery is located inside the table column. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.

## 2. Information for End of Life Management

This part is compiled based on *Clause 4 Protection of Environment, 4.5.3 Information for end of life management* of IEC 60601-1-9.

According to the requirements of this clause, the manufacturer shall provide the responsible organization with information for the proper disposal of the ME equipment at *End of Life* (EOL). And the manufacturer shall make available information to waste treatment facilities necessary for the environmentally responsible management of end of life ME equipment.

The information shall contain the following items (Table 2).

**Table 2 The requirements of Clause 4.5.3 and Instructions provided by manufacturer**

The requirements of Clause 4.5.3	Instructions provided by manufacturer
1) The location of components and parts within the ME equipment that contain stored energy or pose other hazards that can result in an unacceptable risk to disassemblers or others and methods for controlling such risks.	The battery is located inside the table column. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.
2) The identity and location of hazardous substances requiring special handling and treatment	The battery is located inside the table column. Capacitors may contain stored energy or may pose

	other hazards, assembled on the PCB boards within the device.
3) Disassembly instructions sufficient for the safe removal of these hazardous substances including radioactive sources and induced radioactive materials within the ME equipment.	<p>For other hazards that may result in unacceptable risk, the main concern is the handling with battery: Risk of fire, explosion, or burns. Do not crush, puncture, disassemble or short circuit the battery. Do not dispose of the battery in fire or water. Do not place the battery in an environment whose temperature is above 60°C (140°F). Store the battery in the -20°C (-4°F) to 60°C (140°F) environment. Use the specified charger only. Read instructions for use. Maximum Recommended Ambient temperature is 45°C (125°F).</p> <p>Dispose of used batteries promptly and in an environmentally-responsible manner. Do not dispose of the battery in normal waste containers. Consult your hospital administrator to find out about local arrangements.</p> <p>As for disposing of the medical device, to avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the medical device appropriately before disposing of it in accordance with your country's laws for equipment containing electrical and electronic parts. For disposal of parts and accessories such as thermometers, where not otherwise specified, follow local regulations regarding disposal of hospital waste.</p>