

**YUANHUA ROBOTICS, PERCEPTION & AI TECHNOLOGIES
(HK) LIMITED**

**Safety and performance information
Of
Robotic Orthopaedic Surgical Systems**

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Address:

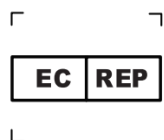
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Manufacturing date: See the label

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1. SAFETY INFORMATION

Please read this Instruction for Use of our robotic orthopaedic surgical systems carefully before use. To ensure safe operation of the device, be sure to follow the instruction for use and safety information provided in this manual and keep the device operating in a safe environment.














This manual contains the following types of safety information.

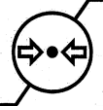









 CAUTION	<p>Caution symbols are used to inform matters requiring attention in operation and use.</p> <p>Relevant scenarios are detailed in a box similar to this one.</p>
 WARNING	<p>Warning symbols are used to inform the operation requirements that must be followed. Otherwise, it may cause personal injury or device damage.</p> <p>Relevant scenarios are detailed in a box similar to this one.</p>
 PROHIBITION	<p>Prohibition symbols are used to inform the actions that are prohibited.</p> <p>Relevant scenarios are detailed in a box similar to this one.</p>







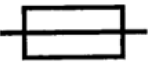


2. DESCRIPTION OF SYMBOLS

2.1 KEY SYMBOLS AND SYSTEM CONTROL BUTTONS

SYMBOL	DESCRIPTION
	FOLLOW THIS INSTRUCTION FOR USE
	CONSULT INSTRUMENT FOR USE
	GENERAL WARNING SIGN
	WARNING! ELECTRICITY
	CAUTION! REFER TO THE ACCOMPANYING DOCUMENT
	WARNING! HAND PINCHING
	WARNING! MECHANICAL INJURY
	TYPE B APPLIED PART
	AC
	MANUFACTURER
	EU AUTHORIZED REPRESENTATIVE
	MANUFACTURING DATE

SYMBOL	DESCRIPTION
	SERIAL NUMBER
	CATALOG NUMBER
	BATCH CODE
	USE-BY DATE
	UDI
	MEDICAL DEVICE
	CE MARK
	UP
	KEEP DRY
	DO NOT ROLL
	DO NOT STACK
	TEMPERATURE LIMITATION
	HUMIDITY LIMITATION

SYMBOL	DESCRIPTION
	ATMOSPHERIC PRESSURE LIMITATION
	Non-sterile
	Do not use of package is damaged and consult instructions for use
	Do not re-use
	EMERGENCY STOP
	PROTECTIVE GROUNDING
	<p>Control panel of robotic arm cart</p> <ul style="list-style-type: none"> 🔒 Double click to lock the robotic arm. At this time, the robotic arm cannot move; 🔓 Double click to unlock the robotic arm. At this time, the robotic arm can be dragged freely; ▲ Double click to lower the fixed pillar and raise the robotic arm cart. At this time, the robotic arm cart is fixed and cannot move; ▼ Double click to raise he fixed pillar and lower the robotic arm cart. At this time, the robotic arm cart can move; <p>Intermediate system shutdown button: Press and hold this button twice to shut down the robotic arm car.</p>
	Emergency stop button of robotic arm cart: Press the emergency stop button in case of emergency. At this time, the robotic arm will stop moving.
	<p>Robotic arm start button: After the robotic arm cart is started, click the robotic arm start button. At this time, a brake test of the robotic arm will be performed.</p> <p> During the brake test of the mechanical arm, ensure that there is no obstacle within 1m horizontal and vertical distance.</p>

SYMBOL	DESCRIPTION
	<p>Electric interface button behind the body of robotic arm cart: Electric interface 1: 14.4V DC power supply, power supply for Surgical powered drills. Electric interface 2: 14.4V DC power supply, power supply for Surgical powered drills.</p>
	<p>This button is located behind the body of the master console cart. Click this button to start the computer of master console cart. Press and hold this button to force off the computer of master console cart.</p>
	<p>USB connector</p>
	<p>No stepping on surface</p>
	<p>Normal use ground slope $\leq 5^\circ$</p>
	<p>FOOT Switch</p>
	<p>Fuse</p>
	<p>General symbol for recover/recyclable</p>
	<p>The following definition of the WEEE label applies to EU member states only</p>

3. PRODUCT DESCRIPTION

3.1 PRODUCT NAME AND MODEL

Name: Robotic Orthopaedic Surgical Systems

Model: YUANHUA-TKA
YUANHUA

3.2 MAIN STRUCTURE AND PERFORMANCE

3.2.1 PERFORMANCE PARAMETERS

3.2.1.1 Normal working requirements

Intended place of use: hospital

3.2.1.1.1 Climate conditions:

Ambient temperature range: 15°C ~ 30°C

relative humidity rang: 20% ~ 80%RH

atmospheric pressure range: 700hPa ~ 1060hPa

altitude: ≤ 3000m


3.2.1.1.2 Electrical safety characteristics:

- (1) Category by electric shock proof type: Class I;
- (2) Category by electric shock proof level: Type B applied part
- (3) Category by protection degree against incoming liquid: Foot switch IPX8;
- (4) Category by operation mode: the host runs continuously. The Surgical powered drills run for a short time, stop working after cold start and 1min of operation, work again after cooling for 3min, and then run in cycle;
- (5) Specified voltage and frequency of the device: AC100-120/200-240V 50/60Hz;
- (6) Input power of the device: 1200VA

3.2.1.1.3 Other working conditions:

- (1) This product should be placed to prevent moisture and direct contact with liquid;
- (2) This product should be kept away from strong electromagnetic field interference sources; this product may produce electromagnetic interference with other devices through the power cord, so the ground terminal of the power jack should be well grounded;

- (3) There should be no corrosive gases in the environment where this product is placed;
- (4) The working surface on which this product is placed should be solid and stable, without strong or continuous vibration or obvious displacement;
- (5) The working environment of this product should be equipped with a reliable grounding system. Poor grounding will directly affect service life and safety in use of this product;
- (6) There should be no obstacles around this product to ensure normal component assembly and normal operation of robotic arm and disconnecting device, etc.
- (7) This product is prohibited from being used for other purposes unrelated to its intended functions;
- (8) This product is prohibited from being used in an environment with flammable anesthetic gas.
- (9) To avoid the risk of electric shock, this product must be connected to a power supply network with protective grounding device.

 WARNING	<ul style="list-style-type: none"> ● This product must be used when the above work requirements are met.
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3.2.1.1.4 Requirements for users:

Requirements:

Surgeons, instrument nurses and follow-up technicians must be trained by professionals to pass the assessment before this product is used in joint replacement surgery.

Requirements for follow-up technicians:

- (1) With certain surgical expertise and operation skills;
- (2) Have a certain understanding of the basic knowledge of computer and robotics, and familiar with the basic operations of computer and robotic arm;

Note 1: Professionals are technicians authorized by the manufacturer

Note 2: Follow-up technicians mainly assist in operating the control panels of master console cart and robotic arm cart.


3.2.1.2 Main technical indicators

SN	Technical indicators
1	Safety performance: Subject to the requirements of IEC60601-1/EN60601-1 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.
2	Electromagnetic compatibility performance: Subject to IEC60601-1-2/EN60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements

	for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
3	Software quality: Subject to ISO/IEC 25000-2014 Systems and Software Engineering - Systems and Software Quality Requirements and Evaluation (SQuaRE).
4	<p>Appearance:</p> <ul style="list-style-type: none"> ● The housing should be level and smooth, uniform in color, free of mechanical damage, surface deformation or other defects; ● All accessible parts should be free of sharp angles, sharp edges, burrs and sharp edges; ● Logo and text should be clear, legible and permanently pasted; <p>Each system should be flexible and reliable, free of fastener looseness, firm and reliable.</p>
5	Software functions: Total knee replacement operative planning software includes four functional modules, namely case management, CT segmentation, landmark selection, and operative planning; intra-operative navigation software for total knee replacement surgery includes five functional modules, namely case management, pre-operative preparation, bone surface registration, intra-operative planning, and navigation-assisted osteotomy; hip replacement operative planning software includes case management, CT segmentation, landmark selection, and operative planning; intra-operative navigation software for hip replacement surgery includes case management, operative planning, pre-operative preparation, bone surface registration and navigation-assisted bone grinding.

4. CYBERSECURITY

4.1 OPERATING ENVIRONMENT

 CAUTION	<ul style="list-style-type: none">● The patient should remain still during the scanning.● When a metal implant is placed in the patient's contralateral joint, there is a need to adjust the position of the patient's contralateral joint to avoid introduction of metal artifacts at the joint or the removal of artifacts by CT.
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4.2 PRECAUTIONS

- When the follow-up technicians leave their posts, they must save the current operation results and close the software.
- The follow-up technicians must reasonably manage the patients' health data to prevent data leakage.
- The follow-up technicians must perform regular data backups.
- No one is allowed to maliciously modify or delete patient health data.
- Users are not allowed to change system configuration at will, software environment and security software must be maintained and updated by the manufacturer's professionals.
- Users are not allowed to install the third-party software unrelated to this product software on the computer system of master console cart without permission, and are not allowed to upgrade the vulnerabilities or patches. They should contact the manufacturer to have professionals address these vulnerabilities or patches.
- The system does not support emergency access to private data, which needs to be queried by yourself.
- Computer system of this product is equipped with a security system. Only authorized USB flash drives can be recognized. Unauthorized USB flash drives and other devices related to USB interfaces should not be used.
- ACCESSORIES, other ME EQUIPMENT and/or non-ME EQUIPMENT that are not specified or allowed by the MANUFACTURER cannot be connected to the MECHANICAL INTERFACES and other interface of the RASE.

5. INTENDED USE, INDICATIONS, CONTRAINDICATIONS AND PRECAUTIONS

5.1 INTENDED USE

This product is used in conjunction with proven joint prostheses and surgical instruments for navigation and positioning of the joint prostheses and surgical tools during adult total knee replacement surgery and adult total hip replacement surgery.

5.2 INDICATIONS

Adult total knee replacement surgery and adult total hip replacement surgery is required in the case that conservative treatment is ineffective for knee osteoarthritis and end-stage knee joint pathological changes, etc.; hip replacement surgery is required in the case that conservative treatment is ineffective for end-stage hip joint diseases.

5.3 CONTRAINDICATIONS

This product is not suitable for the patients who have received adult total knee replacement surgery or adult total hip replacement surgery, and the patients for which the adult total knee replacement surgery or the adult total hip replacement surgery cannot be planned and positioned through images.

5.4 INTENDED USER

This product must be used by the surgeons who are familiar with joint replacement surgery, and such surgeons should receive relevant training on device use.

This product must be used by instrument nurses who are familiar with joint replacement surgery, and such instrument nurses should receive relevant training on device use.

This product must be used with assistance of the follow-up technicians who are familiar with joint replacement surgery, and such follow-up technicians should receive relevant training on device use.

5.5 POTENTIAL COMPLICATIONS:

Serious complications may occur in any surgery, up to and including death. Examples of serious or life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include but are not limited to, one or more of the following: Breakage of pins or fracture on the pins holes, Bleeding, Wound complication, Thromboembolic disease, Ligament injury, Deep periprosthetic joint infection, Periprosthetic fracture, etc. Individual surgical results may vary.


5.6 PRECAUTIONS

- This product is a device used to assist the surgeons in positioning, osteotomy, bone grinding, and cup placement. The surgeons should confirm the operative planning and control the navigation and positioning process during operation.
- This product is only applicable to the operating rooms of medical institutions.
- The operators with color blindness or color feebleness are forbidden to use this product during operation.
- The recommended surgical procedures of this product for adult total knee replacement and adult hip replacement are shown in the table below.

Surgical procedure	Total knee replacement surgery	Hip replacement surgery
Operative position	Supine position	Lateral/supine position
Surgical approach	Medial parapatellar approach	Posterior lateral approach
Surgical site	Knee joint	Hip joint

- The robotic arm cart, Surgical powered drills, navigation and positioning tool kit, and surgical instrument set of this product are used in the patient environment, and the navigator cart and master console cart are not used in the patient environment.
- Before each use, the outer surfaces of all navigation tools in contact with the patient should be inspected to ensure there are no rough surfaces, sharp edges, or protrusions that could cause injury.
- Warning: This device should not be modified without the manufacturer's authorization.
- To avoid danger or environmental pollution, relevant local laws and regulations or the waste disposal procedures of the hospital must be observed when handling the main unit, accessories and packaging materials. The main unit, accessories and packaging materials must be kept out of the reach of children.
- A notice to the user and/or patient: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

6. PRODUCT SOFTWARE






 WARNING	<ul style="list-style-type: none"> ● The number of characters in the user account input box is limited to 4-12, the number of characters in the user name input box is limited to 2-16, the number of characters in the password input box is limited to 6-18, and the number of characters in the patient ID input box is limited to 12-16, and the number of characters in the patient name input box is limited to 2-16. ● In the "dragging" mode, all joints of the robotic arm need to move within the allowable range. If any joint moves to the limit position, a voice warning will be triggered, and the robotic arm will be immediately locked after exceeding the limit position.
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6.1.1 SOLUTIONS FOR CRITICAL SOFTWARE DEFECTS


SN	Critical defects	Solutions
1	Related components are prompted to be "lost" during software running.	Do not block the relevant tracer
2	The patient's CT data cannot be opened in the software normally	Check whether the patient's CT data meets software quality imaging requirements
3	The user login password is forgotten	Contact the administrator or the after-sales service provider
4	The software runs slowly with a lag	Contact the after-sales service provider
5	The software cannot run properly	Contact the after-sales service provider

7. CONNECTION


7.1 SYSTEM CONNECTION

 WARNING	<ul style="list-style-type: none">● Check whether the power cord is damaged and whether the device is functioning properly before use.
 WARNING	<ul style="list-style-type: none">● Never operate with wet hands.
 WARNING	<ul style="list-style-type: none">● Don't connect to the device or components that are not parts of the system.
 WARNING	<ul style="list-style-type: none">● The master console cart and the navigator cart can only be powered by isolated power supply of the robotic arm cart. It is prohibited to use external power supply of the system to supply power to the master console cart and the navigator cart separately.
 WARNING	<ul style="list-style-type: none">● The Surgical powered drills at the end of robotic arm cart can only be powered by the output power of robotic arm cart. It is prohibited to use external power supply of the system to supply power separately.


7.2 POWER ON/OFF METHODS

 WARNING	<ul style="list-style-type: none">● When pulling out the power cord, hold the power socket with one hand and grasp the plug with the other hand to pull it out. Do not only pull the power cord.● Never pull out the power cord with wet hands.
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8. INSTALLATION AND USE INSTRUCTIONS

 WARNING	<p>Carry out the following inspections at least once a month to confirm whether the UPS is faulty:</p> <ul style="list-style-type: none">● When the external power supply is normal and the fuse at the power supply end is not damaged, check whether the system can start up or work normally; if it cannot start up or work normally, the UPS may be faulty.● When the external power supply is interrupted, check whether the system can automatically switch to the UPS power supply mode; if it cannot automatically switch to the UPS power supply mode, the UPS may be faulty.● When the system is started, disconnect power supply and put the system on standby for 10 minutes when the UPS power supply is provided, then connect the power supply and check whether the UPS charging indicator turns green; if it does not turn green, the UPS charging is faulty. <p>If the UPS is faulty, contact the manufacturer for repair or replacement.</p>
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8.1 DEVICE CHARGING


 WARNING	<ul style="list-style-type: none">● This product must be used in conjunction with the tools and accessories specified above. If other tools and accessories are used without the manufacturer's confirmation and approval, the product may not work properly or the product accuracy may be reduced, thereby posing greater surgical risks to the patient.
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9. PRODUCT USE PROCESS


 <p>WARNING</p>	<ul style="list-style-type: none">● When inserting the bone nails and installing the tracer, special attention should be paid to direction and force, and the bone screws should not be reinserted to prevent peripheral fracture.● After the bone nails are inserted and removed, the thread temperature is relatively high, so direct contact with the skin should be avoided.
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10. PRECAUTIONS

10.1 PRODUCT CONFIGURATION

 <p>CAUTION</p>	<ul style="list-style-type: none">● The power cord is provided together with the machine (with a protective ground wire and a three-wire plug).● Assembly shall be subject to relevant content in this Instruction for Use.● All components and accessories of this product are used in conjunction with each other. Please do not replace them without authorization. Use of the components and accessories not provided by our company may lead to abnormality or damage of this product, or even a danger.
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10.2 PRODUCT USE

 <p>WARNING</p>	<ul style="list-style-type: none">● In the process of use, the robotic arm should be always observed for any unexpected movement of the system. In case of any unexpected movement, immediately press the emergency stop button on the robotic arm cart and remove all components in contact with the patient before handling. If necessary, restart the system and repeat the operation process. After operation, relevant information should be fed back to the after-sales service provider in a timely manner, and it will not be used in clinical practice until debugging and normal use.● When the robotic arm is being dragged, sudden acceleration excessive force should be avoided.● If this product malfunctions during use, stop using it immediately and provide timely feedback to the after-sales service provider.● This product is not suitable for removable multi-jack sockets.● The sterile protective cover is disposable, should be disposed of as medical waste after use.● The reflective disk in the navigation and positioning tool kit is disposable, should be disposed of as medical waste after use.● The power cords of power tools should be replaced in regular, and each power cord of the power tools should be replaced after 20 times of sterilization.● During operation, the operating specifications of this product should be strictly followed to ensure that spatial position of the system components and the patient's surgical site are relatively stable.
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	<ul style="list-style-type: none">● After operation, the computer system on master console cart should be shut down first, and then the robotic arm cart should be shut down.● When moving robotic arm cart, master console cart or navigator cart of this product, be careful not to touch people or objects around.● This product is a precision medical device. Do not pull the moving components with force, nor use these parts to hang other objects.● This product should be kept away from strong electromagnetic interference sources such as TV towers and high-voltage lines.
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10.3 ELECTROMAGNETIC COMPATIBILITY

See Appendix 7 for details.

10.4 OTHER PRECAUTIONS


- After scrapping, this product should be disposed of according to national medical waste and electronic waste disposal requirements and should not be discarded at will.
- Any serious adverse event should be reported to the EU competent authority.

11. PRODUCT STORAGE AND TRANSPORTATION


 <p>CAUTION</p>	<ul style="list-style-type: none">● When this product is stored, the robotic arm cart, the master console cart and the navigator cart should be stored separately, and the robotic arm should be restored to the folded position.● The handrails on the robotic arm cart should be used to move the robotic arm cart, the handrails on the master console cart should be used to move the master console cart, and the handrails on the navigator cart should be used to move the navigator cart.
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11.1 PRODUCT TRANSPORTATION


11.2 DAILY MAINTENANCE

 <p>CAUTION</p>	<ul style="list-style-type: none">● Store and transport the instrument as required.● This product is a precision device. Please be careful when moving the robotic arm cart, the master console cart and the navigator cart.● Untrained personnel should not move this device at will.
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11.2.1 CLEANING, DISINFECTION, AND STERILIZATION METHODS


 <p>CAUTION</p>	<ul style="list-style-type: none">● The outer shell of pendulum saw and bone drill can be directly cleaned and wiped with purified water or distilled water. The gaps can be cleaned with a soft brush or rinsed with a high-pressure water gun for 1 minute. Water cannot enter the motor during cleaning.● For all Auxiliary tools in Chapter 8.6.1
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11.2.1.1 Cleaning

 CAUTION	<p>The above recommended sterilization method is the safest and most reliable. The time and temperature should be strictly controlled within the range, otherwise the surgical powered drills will be immediately damaged.</p> <p>Among them, the maximum number of sterilizations that reusable surgical instruments can withstand is 20 times. reflective disk can withstand is 1 times.</p>
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11.2.2 YUANHUA ROBOTICS, PERCEPTION & AI TECHNOLOGIES (HK) LIMITED MAINTENANCE




 WARNING	<ul style="list-style-type: none"> ● Charge this product in strict accordance with requirements to prevent the excessively high or low supply voltage and avoid damage. ● Operate in strict accordance with this Instruction for Use, use this product by a specific personnel. Untrained personnel are prohibited from using it to avoid irreversible damage. ● This product may not be used for other purposes than those specified in this Instruction for Use.
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 CAUTION	<ul style="list-style-type: none"> ● This product should be placed in a clean room without corrosive gas. When this product is not in use, the relative humidity should not be greater than 80%. ● This product should be wiped frequently to remove dust. When it is not used for a long time, it should be powered on for dehumidification and moisture prevention. It should be powered on at least once a week for 2-3 hours each time to avoid moisture damage. ● This product should be protected from dust. ● Periodical maintenance is provided
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 CAUTION	<ul style="list-style-type: none"> ● Before and after use, this product can be wiped with a gauze soaked in water or 75% alcohol.
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12. TROUBLESHOOTING

12.1 PROBLEMS THAT USERS CAN SOLVE THEMSELVES

 CAUTION	<ul style="list-style-type: none">● Before each use of this product, the navigation and positioning tool kit, surgical instrument set, Surgical powered drills and power cord of power tools should be cleaned and sterilized.
 PROHIBITION	<ul style="list-style-type: none">● Users are strictly prohibited from disassembling the machine for maintenance.
 WARNING	<ul style="list-style-type: none">● Before maintenance, the device should be completely turned off and the power cord should be unplugged.

12.2 PROBLEMS SOLVED BY THE AFTER-SALES SERVICE PROVIDER

 PROHIBITION	<ul style="list-style-type: none">● Never violate the Instruction for Use.
 WARNING	<ul style="list-style-type: none">● Under the premise of normal operation, in case of any malfunction of this product, you should contact the after-sales service provider in time, we will provide you with professional technical services.● Technical description indicates, we will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair

13. AFTER-SALE SERVICE GUIDE

Yuanhua Robotics, Perception & AI Technologies (HK) Limited provide product after-sales services for the users of "robotic orthopaedic surgical systems".

The contact information is as follows:

- Name:
YUANHUA ROBOTICS, PERCEPTION & AI TECHNOLOGIES (HK)
LIMITED
- Address:
Floor 20, Block D3, Nanshan Zhi Yuan, #1001 Xueyuan Avenue, Changyuan
Community, Taoyuan Sub-district, Nanshan District, 518055 Shenzhen,
Guangdong, PEOPLE'S REPUBLIC OF CHINA
- Tel: +86-755-2373 6172
- Fax: +86-755-2373 6172

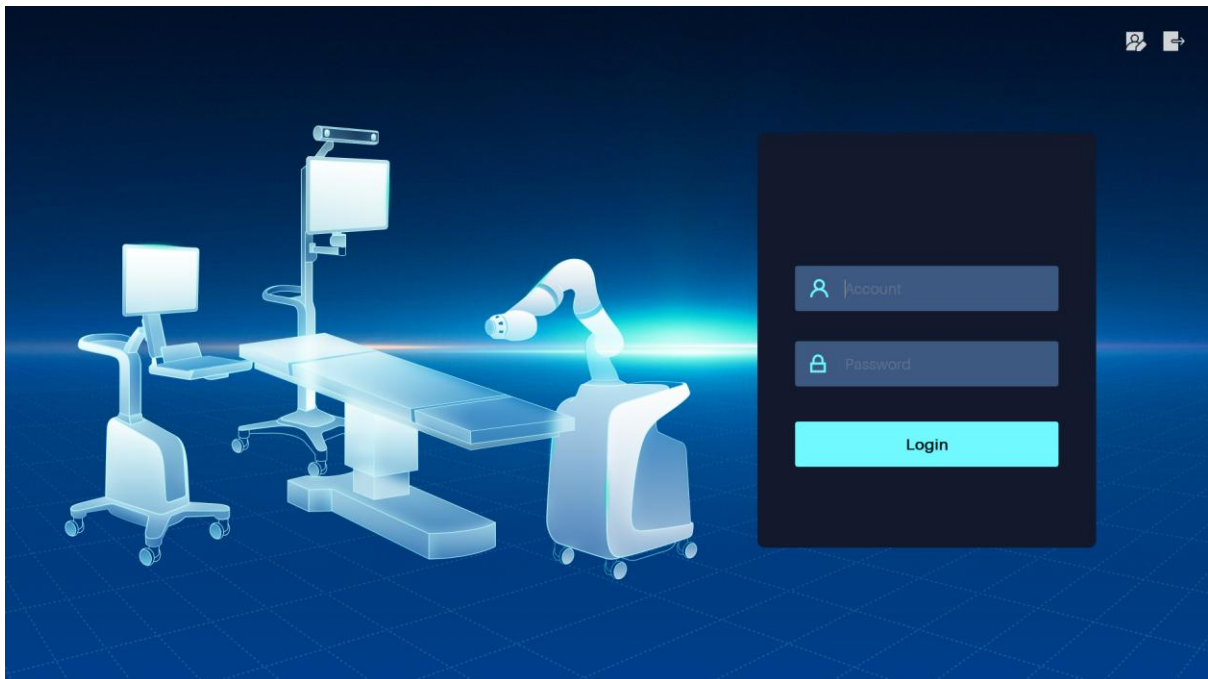
Appendix1: Operating Instruction of TKA Application Part

**OPERATING INSTRUCTION OF TKA
APPLICATION PART**

1. SOFTWARE LOGIN


1.1 USER LOGIN

After the system is started, the login page will automatically be displayed. Enter the authorized user's account and password, and click the “Login” button to log in to the system's indication module selection page. Users are classified into administrators, maintenance users, and common users.



User login

1.2 SOFTWARE LOGIN LOG QUERY

 WARNING	<ul style="list-style-type: none">● The patient's CT data and the operative side must be correct, otherwise it will cause software calculation errors.● The brand of the prosthesis must be consistent with that used by the patient during operation.
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2. LANDMARK SELECTION




- The doctor shall reconfirm the patient's operative plan before operation.


3. PRE-OPERATIVE PREPARATION

Pre-operative preparation includes device placement and surgical instrument calibration.


3.1 DEVICE PLACEMENT

 <p><i>CAUTION</i></p>	<ul style="list-style-type: none">● In getting the femoral head center, please avoid moving the navigator camera and frequently blocking the femoral tracer. Otherwise, the accuracy of getting this landmark will be affected.
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3.2 GET FEMORAL LANDMARK

 <p><i>WARNING</i></p>	<ul style="list-style-type: none">● In getting the landmark points, avoid blocking the femoral tracer or the reflective disk of the current probe.● Ensure that the probe type currently used is the same as the probe identified by the system.● Excessive deviations in the positions of getting the landmark points will affect the point registration results.● Excessive deviations in point registration will affect the point registration results.
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3.3 FEMORAL SURFACE REGISTRATION

 <p><i>CAUTION</i></p>	<p>To ensure the accuracy of registration and osteotomy, please be sure to pay attention to the following:</p> <ul style="list-style-type: none">● If the patient has cartilage on the bone surface, the probe tip shall penetrate through the cartilage.● If the patient has osteoporosis, the probe tip shall not penetrate into the bone.● In getting the surface registration points, avoid blocking the femoral tracer or the reflective disk of the current probe.
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	<ul style="list-style-type: none">● Ensure that the probe type currently used is the same as the probe identified by the system.● If the positions of getting each surface registration points are too close, the system will give a warning prompt. The surface registration points should be as scattered as possible.
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 <i>CAUTION</i>	<ul style="list-style-type: none">● For example, when assessing the patient's gap balance before osteotomy, the doctor should first remove the osteophytes near the patient's knee.● If the patient has already undergone osteotomy on part of the osteotomy plane, when adjusting the operative plan, care should be taken to adjust the resection volume according to the facts.
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3.4 PLANNING ADJUSTMENT


4. NAVIGATION-ASSISTED OSTEOTOMY

4.1 CONTROL MODE OF ROBOTIC ARM.

4.2 TIBIAL OSTEOTOMY

 <i>WARNING</i>	<ul style="list-style-type: none">● When automatic alignment of the robotic arm is enabled, avoid moving the navigator camera and blocking the pendulum saw or the tracer of the model to be aligned.
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Osteotomy view

 <i>WARNING</i>	<ul style="list-style-type: none">● The doctor shall guarantee the safety of the current osteotomy area.● When the robotic arm performs osteotomy operations, avoid blocking the pendulum saw or the tracer of the model to be osteotomized.● The doctor should perform osteotomy operations in accordance with the system's default safety boundaries and avoid expanding the safety boundaries or canceling the protection restrictions of the safety boundaries unless necessary.● If it is necessary to expand the safety boundary or cancel the protective restrictions of the safety boundary during osteotomy, the doctor should guarantee the safety of the current osteotomy area again, otherwise unnecessary soft tissue damage may occur.● When the system prompts that osteotomy is prohibited, the doctor should fine-tune the position of the pendulum saw and continue osteotomy.
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4.3 FEMORAL OSTEOTOMY



CAUTION

- To ensure the accuracy of osteotomy and prevent the tibial tracer from loosening, click the "Checkpoints" button at any time during navigation-assisted osteotomy to perform checkpoints verification.
- To ensure the accuracy of osteotomy and prevent the pendulum saw tracer from loosening, the pendulum saw checkpoint verification can be performed at any time during navigation-assisted osteotomy.

Appendix 2: Operating Instruction of THA Application Part

**OPERATING INSTRUCTION OF THA
APPLICATION PART**

1. SOFTWARE LOGIN

1.1 USER LOGIN



WARNING


- The patient's CT data and the operative side must be correct, otherwise it will cause software calculation errors.
- The brand of the prosthesis must be consistent with that used by the patient during operation.


2. CT SEGMENTATION



- The doctor shall reconfirm the patient's operative plan before operation.


3. ROBOTIC ARM MODULE START

 <p>CAUTION</p>	<p>To ensure the accuracy of post-operative evaluation, the relative position of the femur and acetabulum should be maintained in getting the measurement positions of the proximal femur and the distal femur.</p>
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 <p>WARNING</p>	<p>When checkpoint verification fails, stop further operation for analytical correction, otherwise the accuracy of femoral osteotomy and post-operative evaluation will be reduced.</p>
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After successful verification, you will automatically enter the “Get Landmark” page for femur point registration.

3.1 GET FEMORAL LANDMARK

 <p>WARNING</p>	<ul style="list-style-type: none">● In getting the landmark points, avoid blocking the femoral tracer or the reflective disk of the current probe.● Ensure that the probe type currently used is the same as the probe identified by the system.● Excessive deviations in the positions of getting the landmark points will affect the point registration results.● Excessive deviations in point registration will affect the point registration results.
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3.2 FEMORAL SURFACE REGISTRATION

	<p>To ensure the accuracy of registration and bone grinding, please be sure to pay attention to the following:</p> <ul style="list-style-type: none">● If the patient has cartilage on the bone surface, the probe tip
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<i>CAUTION</i>	<p>shall penetrate through the cartilage.</p> <ul style="list-style-type: none"> ● If the patient has osteoporosis, the probe tip shall not penetrate into the bone. ● If the probe tip and bone surface shift during registration, the system will have a voice warning prompt and the probe tip and bone surface should remain stable. ● In getting the surface registration points, avoid blocking the femoral tracer or the reflective disk of the current probe. ● Ensure that the probe type currently used is the same as the probe identified by the system. ● If the positions of getting each surface registration points are too close, the system will give a warning prompt. The surface registration points should be as scattered as possible.
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3.3 FEMORAL REGISTRATION VERIFICATION

3.4 HIP BONE CHECK

 WARNING	<p>When checkpoints verification fails, stop further operation for analytical correction, otherwise the accuracy of bone grinding and cup placement will be reduced.</p>
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3.5 HIP BONE POINT REGISTRATION

 WARNING	<ul style="list-style-type: none"> ● In getting the landmark points, avoid blocking the hip bone tracer or the reflective disk of the current probe. ● Ensure that the probe type currently used is the same as the probe identified by the system. ● Excessive deviations in the positions of getting the landmark points will affect the point registration results. ● Excessive deviations in point registration will affect the point registration results.
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3.6 HIP BONE SURFACE REGISTRATION



CAUTION


To ensure the accuracy of registration and bone grinding, please be sure to pay attention to the following:


- If the patient has cartilage on the bone surface, the probe tip shall penetrate through the cartilage.
- If the patient has osteoporosis, the probe tip shall not penetrate into the bone.
- In getting the surface registration points, avoid blocking the hip bone tracer or the reflective disk of the current probe.
- Ensure that the probe type currently used is the same as the probe identified by the system.
- If the probe tip and bone surface shift during registration, the system will have a voice warning prompt and the probe tip and bone surface should remain stable.
- If the positions of getting each surface registration points are too close, the system will give a warning prompt. The surface registration points should be as scattered as possible.

3.7 HIP BONE REGISTRATION VERIFICATION


4. NAVIGATION-ASSISTED BONE GRINDING


4.1 CONTROL MODE OF ROBOTIC ARM

 <i>WARNING</i>	<ul style="list-style-type: none">● Ensure that the actual use of the acetabular reamer is consistent with the interface display before alignment. Otherwise, it may lead to excessive bone grinding of the acetabular cup, causing unstable implantation of the acetabular cup or fracture.● When automatic alignment of the robotic arm is enabled, avoid moving the navigator and blocking the end-of-arm guide or the hip bone tracer.● During the alignment of the robotic arm, attention should always be paid to the position relationship between the acetabular reamer and the acetabular reamer rod and between the acetabulum and the surrounding tissues. If there is any abnormality, the foot pedal should be released immediately to stop the alignment process and avoid bone tissue damage.
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 <i>WARNING</i>	<ul style="list-style-type: none">● The doctor shall guarantee the safety of the current bone grinding area.● When the robotic arm performs acetabular grinding, avoid moving the navigator and blocking the end-of-arm guide or the hip bone tracer.● The doctor should perform bone grinding operations in accordance with the system's default safety boundaries and avoid expanding the safety boundaries or canceling the protection restrictions of the safety boundaries unless necessary.● If it is necessary to expand the safety boundary or cancel the protective restrictions of the safety boundary during bone grinding, the doctor should guarantee the safety of the current bone grinding area again, otherwise unnecessary soft tissue damage may occur.● When the system prompts that bone grinding is prohibited, the doctor should fine-tune the position of the acetabular reamer and continue bone grinding.● When the acetabular reamer is located in the acetabulum, grasp the tool before pressing the “Robotic Arm Start” button.
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Acetabular reamer

 <p><i>CAUTION</i></p>	<ul style="list-style-type: none">● To ensure the accuracy of bone grinding and prevent the hip bone tracer from loosening, click the "Checkpoints" button at any time during navigation-assisted bone grinding to perform checkpoint verification.● To ensure the accuracy of bone grinding and prevent the end-of-arm tracer from loosening, the end-of-arm tool checkpoint verification can be performed at any time during navigation-assisted bone grinding.● During bone grinding, if it is confirmed or suspected that the tracer is accidentally touched, checkpoint verification should be carried out immediately. If the verification fails, it proves that the tracer moves relative to the bone and the bone surface needs to be re-registered.
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 <p><i>WARNING</i></p>	<ul style="list-style-type: none">● When the acetabular cup is inserted, the doctor should always pay attention to the position information in the navigation view and should not go beyond the target position.
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Appendix 3: Electromagnetic Compatibility

ELECTROMAGNETIC COMPATIBILITY

The robotic orthopaedic surgical systems are suitable for all facilities that are not directly connected to the public low-voltage power supply network of domestic and residential buildings



Warning

Active medical devices are subject to special EMC precautions and must therefore be installed and used in accordance with these guidelines.



Warning

Portable and mobile communication RF devices may affect the use of medical electrical equipment.



Warning

Except for transducers and cables sold by the manufacturer of the devices or system as spare parts to internal components, the use of accessories, transducers and cables other than those specified may result in increased emission or reduced immunity of the device or system.

The following types of cables must be used to ensure compliance with interference radiation and immunity standards:

Cable overview:

Table 1: Cable Overview

Cable	Length (m)
Power supply cable	2.0
Connecting wire between master console cart and robotic arm cart	5.0
Connecting wire between master console cart and navigator	5.0
Power supply cable of power tools	2.6
Connecting wire of foot pedal	3.0
Control panel wire of robotic arm	9.9

Electromagnetic radiation:



Warning

Devices or systems shall not be used in close proximity to or stacked with other devices, and if they must be used in close proximity or stacked, they shall be observed to verify that they function properly in the available configuration.


Table 2: Electromagnetic Radiation

Guidelines and Manufacturer's Statement - Electromagnetic Radiation		
The robotic orthopaedic surgical systems are intended for use in the environment specified below. The customer or the user should assure that they are used in such an environment.		
Emission test	Conformity	Electromagnetic Environment - Guideline
RF emission CISPR11	Group 1	The robotic orthopaedic surgical systems use RF energy only for their internal functions. As a result, its RF emission is low, and the potential for interference with nearby electronic devices is small
RF emission CISPR11	Class A	The robotic orthopaedic surgical systems are suitable for all facilities that are not directly connected to the public low-voltage power supply network of domestic and residential buildings
Harmonic emission IEC 61000-3-2	NA	
Voltage fluctuation/flicker emission IEC 61000-3-3	NA	

Electromagnetic immunity:

Guidelines and Manufacturer's Statement - Electromagnetic Immunity			
The robotic orthopaedic surgical systems are intended for use in the environment specified below. The purchaser or user shall ensure that it is used in such environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic Environment - Guideline
Electrostatic discharge IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 s	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the robotic orthopaedic surgical systems requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a

			battery
Power frequency magnetic field (50Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidelines and Manufacturer's Statement - Electromagnetic Immunity			
The robotic orthopaedic surgical systems are intended for use in the environment specified below. The purchaser or user shall ensure that it is used in such environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic Environment - Guideline
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz-80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz-800MHz $d=2.3\sqrt{P}$ 800MHz-2.5GHz P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance.
Conducted RF IEC 61000-4-3	3 V/m 80 MHz- 2.5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.			

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones 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 device is used exceeds the applicable RF compliance level above, the robotic orthopaedic surgical systems should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the robotic orthopaedic surgical systems;

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

Recommended separation distance:

Recommended separation distances between portable and mobile RF communications equipment and this product			
This product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz-80MHz $d=1.2\sqrt{P}$	80MHz-800MHz $d=1.2\sqrt{P}$	800MHz-2.5GHz $d=2.3\sqrt{P}$
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 80MHz and 800MHz, the higher frequency range applies.			
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Basic performance during electromagnetic compatibility test:

Item	Basic performance
Planning	The preoperative planning data of the navigation software should not be lost.
Registration	After registration, it can be successfully passed when the user is guided by the navigation software to verify the checkpoints.
System Accuracy	Knee joint application part: Comprehensive navigation and positioning error after system registration: position error is not more than 1mm, attitude error is not more than 1°.
	Application part of hip joint: Comprehensive navigation and positioning error after system registration: position error is not more than 1mm, attitude error is not more than 1°.