ICS 11.040.01
CCS C41

Social Organization Standard

T/GBA 013—2023

Robotic ultrasound for teleoperation-General technical specification

远程超声机器人 通用技术条件

(English Translation)

Issue date: 2023-12-25 Implementation date: 2023-12-30

Issued by Guangdong-Hong Kong-Macao Greater Bay Area Standards Innovation Alliance

Contents

Foreword

This stabdard is drafted in accordance with the rules set forth in GB/T 1.1-2020 *Directives for Standardization -- Part 1: Rules for the Structure and Drafting of Standardizing Documents.*

This staandard is proposed by MGI Imabot Shenzhen Medical Co., Ltd.

This standard is prepared by the Guangdong-Hong Kong-Macao Greater Bay Area Standards Innovation Alliance.

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This is the first release.

Robotic ultrasound for teleoperation-General technical specification

1 Scope

This standard specifies the general technical requirements for remote ultrasonic robots, including terms and definitions, technical requirements, functional requirements, inspection requirements, packaging, marking, storage and transportation.

This standard is applicable to the design, development, testing, packaging and transportation of remote ultrasonic robot systems.

2 Normative references

The contents in the following documents constitute the indispensable clauses of this document through normative references in the text. Among them, the reference document with date, only the version corresponding to this date is applicable to this document; For undated reference documents, the latest version (including all amendments) is applicable to this document.

GB 10152-2009 *B-type ultrasonic diagnostic equipment*

GB 9706.1-2020 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance*

GB 9706.237-2020 *Medical electrical equipment*

GB 4793.1-2007 *Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: General requirements*

GB/T 191-2008 *Packaging and storage and transportation pictorial marking*

YY/T 1712-2021 *Assisted surgical equipment and assisted surgical systems using robotic technology*

YY 0767-2009 *Ultrasound color blood flow imaging system*

YY 9706.102-2021 *Medical electrical equipment*

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Remote ultrasonic robot

Based on robot master-slave control technology, using the network to control interaction and multi-channel data transmission between master and slave devices, achieving a real-time ultrasound diagnostic system that is the same or close to traditional devices.

3.2 Doctor-end master device

Used for real-time control of the patient-end slave device, and receiving the returned ultrasound images or audio and video data, referred to as "doctor-end".

3.3 Patient-end slave device

Used to receive and execute the control instructions of the doctor-end master device in real time, and upload ultrasound images or audio and video data, referred to as "patient-end".

3.4 Effective workspace

The space range that can be swept by the reference point of the end effector of the slave device and can achieve the manufacturer's intended purpose.

[Source: YY/T 1712-2021, *Terms and Definitions 3.13*]

3.5 Master-slavecontrol time delay

The delay time for the slave device to reproduce the movement of the master device.

[Source: YY/T 1712-2021, *Terms and Definitions 3.24*]

3.6 Protective stopping time

The longest time consumed by the protective stop after the patient-end motion device comes into contact and collides with the environment.

3.7 Stable contact force

The force exerted when the patient's terminal actuator is in stable contact with the human body under normal working conditions.

3.8 Protective contact force

The maximum contact force for protective stop after the patient's terminal motion device comes into contact or collision with the environment.

3.9 Rated velocity

The maximum speed that the patient's terminal can reach during normal operation.

[Source: YY/T 1712-2021, *Terms and Definitions 3.16*]

3.10 End effector

The device installed at the end of the robotic arm to enable the patient's terminal to complete the ultrasound examination.

[Source: YY/T 1712-2021, *Terms and Definitions 3.17*]

4 Performance requirements

4.1 Operating principle of remote ultrasound robot

The remote ultrasound robot consists of a doctor's terminal and a patient's terminal. After connecting through the network, the ultrasound doctor operates the haptic probe at the doctor's terminal to perform scanning operations. The control system collects the position and pressure information during the doctor's operation and transmits it to the patient's terminal. The patient's terminal controls the robot's motion system to complete the specific part of the ultrasound scanning action. During the examination, the ultrasound doctor can see the ultrasound images collected and transmitted by the patient's terminal in real time

on the doctor's terminal screen, and can adjust the parameters of the patient's terminal ultrasound equipment in real time by controlling the doctor's terminal ultrasound keyboard. In addition, the doctor and patient can interact in real time through the audio and video system.

The composition of the remote ultrasound robot system is as follows:

a) The doctor's end active device, which includes the main control computer, motion control system, force sensing system, ultrasound control system, audio and video system, ultrasound image display system, power system, etc.

b) The patient's end passive device, which includes the main control computer, motion execution system, force sensing system, ultrasound imaging system, audio and video system, power system, etc.

4.2 Appearance and Structure

The requirements for the appearance and structure of the device are as follows:

a) The outer surface of the device should be clean, without scratches, cracks and other defects;

b) The text and symbols on the panel should be clear, easy to recognize, and durable;

c) The control and adjustment structure should be flexible, reliable, and there should be no looseness in the fastening parts.

4.3 Ultrasound Module Performance Requirements

The performance requirements for the ultrasound module are as follows:

a) The performance of the B-type ultrasound imaging system should comply with GB 10152-2009;

b) The performance of the ultrasound color blood flow imaging system should comply with YY 0767-2009;

c) The performance of the ultrasound spectrum Doppler imaging system should comply with YY 0767-2009.

4.4 Equipment Safety Requirements

The safety requirements for the equipment are as follows:

a) The safety requirements should comply with GB 9706.1-2020, GB 9706.237-2020;

b) The electromagnetic compatibility requirements should comply with YY 9706.102-2021 and GB 9706.237-2020 Article 202.6.

4.5 Control Performance

4.5.1 Master-Slave Control Position Accuracy

The nominal value of the master-slave control X, Y direction position accuracy is ±1mm, and the actual value should not be greater than the nominal value.

4.5.2 Master-Slave Control Position Repeatability

The nominal value of the master-slave control X, Y direction position repeatability is 0.1mm, and the actual value should not be greater than the nominal value.

4.5.3 Master-Slave Control Attitude Accuracy

The nominal value of the master-slave control attitude accuracy is ±1°, and the actual value should not be greater than the nominal value.

4.5.4 Master-Slave Control Attitude Repeatability

The nominal value of the master-slave control attitude repeatability is 0.5°, and the actual value should not be greater than the nominal value.

4.5.5 Master-Slave Control Stable Contact Force Control Accuracy

The range of the master-slave control stable contact force is 3N-40N, and the accuracy at the set value should meet the nominal value of ±3N, and the actual value should not be greater than the nominal value.

4.5.6 Master-Slave Control Effective Working Range

The requirements for the effective working range of the slave device are as follows:

a) The nominal value of the effective working range of the end effector of the master-slave control slave device is L600mm*W300mm*H350mm, and the actual value should not be less than the nominal value;

b) The nominal value of the maximum deflection angle of the end of the end effector of the master-slave control slave device from the vertical direction is ±70°, and the maximum rotation angle of the end is ±170°, and the actual value should not be less than the nominal value.

4.5.7 Master-Slave Control Delay Time

The nominal value of the master-slave control delay time is 250ms, and the actual value should not be greater than the nominal value.

4.5.8 Safe Contact Force

The nominal value of the safe contact force during the movement of the slave device is 120N, and the actual value should not be greater than the nominal value.

4.5.9 Protective stop time

The nominal value of the protective stop time after the driven device motion collides is 500ms, and the measured value should not be greater than the nominal value.

4.5.10 Rated speed

The rated speed requirements of the driven device are as follows:

a) The nominal value of the rated linear speed of the driven device in the X and Y directions is 375mm/s; the nominal value of the rated speed in the Z direction is 125mm/s downward and 375mm/s upward, and the measured value should not be greater than the nominal value;

b) The nominal value of the rated angular speed of the driven device in the RX and RY directions is 0.75rad/s, and the measured value should not be greater than the nominal value.

4.6 Device operation network indicators

4.6.1 Transmission rate

The minimum uplink and downlink network speed required for normal operation of the device is 20Mbps, and the measured value should not be less than the nominal value.

4.6.2 Transmission delay

The maximum end-to-end network delay required for normal operation of the device is 100ms, and the measured value should not be greater than the nominal value.

4.6.3 Transmission reliability

The packet loss rate required for normal operation of the device is less than 5%, and the measured value should not be greater than the nominal value.

5 Functional requirements

5.1 Device functions

5.1.1 Device management

The device should have the following management functions:

a) The ability to connect and manage devices at the doctor's end and the patient's end;

b) The control software at the doctor's end/patient's end can perform self-check after startup, and can give prompts if the self-check is abnormal;

c) The device at the doctor's end and the patient's end can be paired and connected through the network, and can realize real-time motion control of the mechanical arm, dynamic image transmission, real-time adjustment of ultrasound parameters, and audio and video communication;

d) The doctor's end supports viewing the online list of patient's end devices.

5.1.2 Device Connection

The device should have the following connection functions:

a) The doctor's end supports selecting a specific patient's end to establish a network connection, and can give a prompt after the connection is successful;

b) The doctor's end/patient's end supports disconnecting from the existing patient's end/doctor's end connection.

5.2 Software Function

5.2.1 Account Management

Account management should have the following functions:

a) The doctor's end has the function of creating, modifying, and deleting accounts;

b) The doctor's end/patient's end account login function;

c) The doctor's end/patient's end account password modification function.

5.2.2 Data Management

Data management should have the following functions:

a) The doctor's end/patient's end supports searching and browsing patient information;

b) The patient's end supports browsing and sending patient data;

c) The doctor's end supports managing ultrasound examination data;

d) The doctor's end supports editing, previewing, viewing, and sending reports.

5.2.3 Log Function

The log function should have the following functions:

a) The doctor's end/patient's end supports recording device operation usage data;

b) The doctor's end/patient's end supports log viewing, exporting, downloading.

5.2.4 Data Transmission and Reception

The doctor's end/patient's end should support the transmission and reception of different format files such as pictures and videos.

5.3 Remote Control and Transmission

5.3.1 Remote Control Function

Remote control should have the following functions:

a) The doctor's end supports real-time adjustment of ultrasound parameters;

b) The doctor's end supports displaying the patient's end ultrasound system interface;

c) The doctor's end supports the selection of different ultrasound probe types, and sets a stable contact force upper limit threshold for different probe types.

5.3.2 Robotic Arm Function

The robotic arm should have the following functions:

a) The doctor's end supports remote control of the movement and rotation of the probe at the end of the robotic arm through the operation module;

b) The doctor's end supports remote control of the downward pressure of the probe at the end of the robotic arm by pressing down the operation panel, and the stable contact downward pressure will not exceed the set contact force upper limit threshold;

c) After the doctor's end is connected to the patient's end, when conducting examinations of the thyroid, carotid artery and other parts, the robotic arm is restricted from making deflection movements towards the face.

5.3.3 Audio and Video Function

The audio and video system should have the following functions:

a) The doctor's end supports clear and smooth display of the patient's end live audio and video;

b) The patient's end supports clear and smooth display of the doctor's end live audio and video.

5.4 Safety Requirements

5.4.1 Data Storage Requirements

Patient information data should be encrypted and stored in the database, and ultrasound image data should be saved after information desensitization.

5.4.2 User Access Control

The software should have permission management function, provide system user identity verification, and not allow use if user identity verification fails.

5.4.3 User Types and Permissions

The software should have permission management function, provide system user login, do not allow login for users without permission, and should support login for different types of users, and different types of users have different permissions.

5.4.4 Network environment detection function

The device should have the following network environment detection functions:

a) The doctor/patient end should have the ability to perceive the current network situation, be able to timely monitor network performance indicators and display the current network signal condition;

b) The software should monitor the network environment in real time, and take effective security protection measures in time when the network environment is poor.

5.4.5 Device safety control function

To prevent clinical accidents caused by the inability to control the robotic arm due to system failure or network abnormality, the device should have safety control functions:

a) The device should automatically detect the device status and network status at a frequency of ≤6s. When it detects that its own device has a fault that affects clinical operations, it automatically stops the robotic arm from working;

b) The robotic arm should detect its own status and network status at a frequency of ≤ 6s. When it detects a fault that affects clinical operations, it immediately stops working;

c) The patient end should have an emergency stop switch button. In an emergency, press the button to force the robotic arm to stop working.

6 Test method

6.1 Test conditions

6.1.1 Environmental conditions

The environmental conditions for the use of the remote ultrasound robot doctor/patient end are as follows:

a) Environmental temperature: 0° C~40° C;

b) Relative humidity: 30%RH~80%RH, no condensation;

c) Atmospheric pressure: 70kPa~106kPa.

6.1.2 Power conditions

The power conditions for the use of the remote ultrasound robot doctor/patient end are as follows:

a) Power voltage: 220V~240V AC, voltage fluctuation range does not exceed the nominal value ±10%;

b) Power frequency: 50Hz/60Hz.

6.1.3 Test conditions

The remote ultrasound robot doctor/patient end test should first meet the following conditions:

a) The remote ultrasound robot completes installation and debugging according to the instructions;

b) The device establishes a connection through the network;

c) The requirements for the test body film should comply with the regulations in Appendix A (informational appendix) of GB 10152-2009;

d) During the test, try to avoid external vibrations, noise, electromagnetic fields and other physical interferences, so as not to affect the normal progress of various tests.

6.2 Control performance test

6.2.1 Master-slave control position accuracy test

The steps for the device master-slave control position accuracy test are as follows:

a) Under the rated speed condition of the patient-end mechanical arm, apply a certain size of force along the horizontal and vertical directions of the doctor-end control module from the starting end to the end, and measure the distance moved by the patient-end mechanical arm end in the horizontal direction;

b) Repeat the measurement 5 times, and take the average value of the 5 measurements as the measurement result;

c) The above measurement results should meet the requirements of 4.5.1.

6.2.2 Master-slave control position repeatability test

The steps for the device master-slave control position repeatability test are as follows:

a) Under the rated speed condition of the patient-end mechanical arm, the doctor-end sends instructions to move a fixed distance along the horizontal and vertical directions, and measures the distance moved by the patient-end mechanical arm end in the horizontal direction during this process;

b) Repeat the measurement 5 times, and take the average value of the 5 measurements as the measurement result;

c) The above measurement results should meet the requirements of 4.5.2.

6.2.3 Master-slave control attitude accuracy test

The steps of the master-slave control attitude accuracy test are as follows:

a) Within the rated motion range of the patient's end robot arm, control the doctor's end operation module to move to any inclined angle in the vertical position, during this process the patient's end robot arm should respond to the control of the doctor's end operation module, record the inclined angles of the doctor's end operation module and the patient's end robot arm respectively and calculate the difference;

b) Within the rated motion range of the patient's end robot arm, control the doctor's end operation module to rotate to any angle, record the rotation angles of the doctor's end operation module and the patient's end robot arm respectively and calculate the difference;

c) Repeat the above two processes 5 times, take the average of the 5 measurements as the measurement result;

d) The above measurement results should meet the requirements of 4.5.3.

6.2.4 Master-slave control attitude repeatability test

The steps of the master-slave control attitude repeatability test are as follows:

a) Within the rated motion range of the patient's end robot arm, control the doctor's end to send any inclined angle motion command, measure the inclined angle of the robot arm end during this process;

b) Within the rated motion range of the patient's end robot arm, control the doctor's end to send any rotation command, measure the rotation angle of the robot arm end during this process;

c) Repeat the above two processes 5 times, take the average of the 5 measurements as the measurement result;

d) The above measurement results should meet the requirements of 4.5.4.

6.2.5 Master-slave control stable contact force control accuracy test

The steps of the equipment master-slave control stable contact force control accuracy test are as follows:

a) Within the rated downward pressure range of the patient's end robot arm, press down the doctor's end control module with a certain size of downward pressure, and record the pressure value of the patient's end after stabilization;

b) Repeat the measurement 5 times, and take the average value of the 5 measurements as the measurement result;

c) The above measurement results should meet the requirements of 4.5.5.

6.2.6 Master-slave control effective working range test

The steps of the equipment master-slave control effective working range test are as follows:

a) Within the rated movement range of the patient's end robot arm, the doctor's end operation module controls the patient's end robot arm end to move to the limit position in each direction along the horizontal transverse, horizontal longitudinal and vertical directions, and measures and records the limit distance of the robot arm end moving in each direction;

b) The doctor's end operation module controls the patient's end robot arm end to deflect to the maximum tilt angle in the horizontal direction along the vertical direction, and measures and records the maximum tilt angle of the robot arm end at this time;

c) The doctor's end operation module controls the patient's end robot arm end to rotate to the maximum angle in the clockwise and counterclockwise directions, and measures and records the maximum rotation angle of the robot arm end in the clockwise and counterclockwise directions;

d) The above measurement results should meet the requirements of 4.5.6.

6.2.7 Master-slave control delay time test

The steps of the equipment master-slave control delay time test are as follows:

a) Under the condition of the rated movement speed of the patient's end mechanical arm, quickly move the doctor's end operation module to any inclined angle from the vertical position, record the time of this process, and at the same time record the time of the mechanical arm moving from the vertical position to the end position, and calculate the difference between the two times;

b) Repeat the measurement 5 times and take the average of the 5 measurements;

c) The above measurement results should meet the requirements of 4.5.7.

6.2.8 Safety Contact Force Test

The steps of the equipment safety contact force test are as follows:

a) Under the condition of the rated safety contact force of the patient's end mechanical arm, send a motion command at the rated speed to the patient's end mechanical arm, causing the mechanical arm to collide with a rigid object in the horizontal transverse, horizontal longitudinal, and vertical directions until the mechanical arm stops for protection, measure and record the peak force size during the collision process in each direction;

b) Repeat the measurement 5 times in each direction, and take the maximum peak force in each direction as the safety contact force during the movement of the patient's end mechanical arm;

c) The above measurement results should meet the requirements of 4.5.8.

6.2.9 Protective Stop Time Test

The steps of the equipment protective stop time test are as follows:

a) Under the condition of the rated safety contact force of the patient's end mechanical arm, send a motion command at the rated speed to the patient's end mechanical arm, causing the mechanical arm to move vertically downwards and collide with a rigid object, measure and record the time difference from the beginning of the mechanical arm colliding with the rigid object to the mechanical arm stopping;

b) Repeat the measurement 5 times, and take the maximum of the 5 measurements as the protective stop time;

c) The above measurement results should meet the requirements of 4.5.9.

6.2.10 Rated speed test

The steps for the rated speed test of the equipment are as follows:

a) Under the rated motion speed condition of the patient's end mechanical arm, the doctor's end sends motion instructions to the patient's end mechanical arm along the horizontal, vertical, and vertical directions within a fixed distance, and records the motion time of the mechanical arm during this process, and calculates the rated linear speed of the mechanical arm in each direction with distance and time;

b) The doctor's end sends motion instructions from the vertical direction to a fixed angle in the horizontal direction to the patient's end mechanical arm, records the motion time of the mechanical arm during this process, and calculates the rated angular speed of the mechanical arm with angle and time;

c) Repeat the above test steps 5 times, and take the maximum value of the linear speed and angular speed in the 5 measurements as the rated speed of the mechanical arm;

d) The above measurement results should meet the requirements of 4.5.10.

7 Packaging, marking, storage and transportation

7.1 Packaging

The packaging requirements of the equipment are as follows:

a) The packing box should be able to adapt to common transportation conditions;

b) The equipment should be securely fixed in the packing box;

c) The packing box should be moisture-proof and shock-proof.

7.2 Marking

7.2.1 Identification

The identification requirements of the equipment are as follows:

a) The rated supply voltage of the power supply should be marked near the power supply;

b) The on-off of the switch, the function of the button, the cables for the installation and connection of the equipment, and the installation of the spare parts should all be clearly and explicitly marked;

c) Dangerous operating devices or procedures should be marked with warning signs in conspicuous places, and highlighted in the instructions for use;

d) Symbols represented by graphics should comply with the requirements of GB 4793.1-2007 Table 1;

e) The markings on the panel should be clear, under normal use and the manufacturer's specified cleaning methods, the text, symbols, and signs should be able to maintain clarity and firmness for a long time.

7.2.2 Equipment Markings

The following markings should be in the appropriate positions on the equipment:

a) Product model, production date, number, and manufacturer;

b) Nominal voltage, nominal frequency;

c) Equipment dimensions: height × width × depth;

d) Equipment weight;

e) Warning instructions on the inner and outer surfaces of the equipment should be marked near it, or marked on the relevant parts or near them.

7.2.3 Box Markings

The following markings should be on the equipment box:

a) Product model, name, and quantity;

b) Box dimensions: length × width × height;

c) Gross weight of the box;

d) Boxing date;

e) There should be collision, handling warnings, and other signs or words in visible places, and the sign illustrations should comply with the regulations of GB/T 191—2008.

7.3 Storage

Under transportation or storage conditions, the equipment should be able to be placed under the following environmental conditions:

a) Ambient temperature: -20° C~55° C;

b) Relative humidity: 10% RH ~95% RH, no condensation.

7.4 Transportation

Transportation requirements of the equipment:

a) The packaged equipment can be transported by air, sea, and land transportation, and direct rain and snow should be avoided during transportation;

b) The equipment should be stored in the warehouse during transit at stations and docks to avoid prolonged exposure to the sun.

8 Random file

8.1 Overview

Random files refer to files that come with the equipment or accessories, which include important information provided for the equipment assembler, installer, and user, including but not limited to the following:

a) Random technical documents are considered part of the equipment and should at least include product manuals, product certificates, and packing list documents;

b) Explanations of warning instructions and warning symbols (marked on the equipment) should be given in the random technical documents.

8.2 Product manual

8.2.1 Product technical condition description

The product manual should provide all the information necessary for the equipment to operate under its technical conditions, and should at least include:

a) Installation and disassembly methods;

b) Basic working principles and operation instructions;

c) Main functions and their technical requirements;

d) Function description of each part;

e) Cable connections between parts;

f) Working voltage range, power frequency range, and power consumption;

g) Temperature and humidity range of the working environment and storage environment;

h) Dimensions and weight;

i) Identification and use of operation control devices;

j) Explanation of display and alarm information.

8.2.2 Product maintenance and repair technical description

The product manual should provide all the technical information needed for equipment maintenance and repair, and should at least include:

a) Equipment composition diagram;

b) Method of main component replacement and debugging;

c) Safety precautions for use;

d) Common fault handling;

e) Daily maintenance, inspection, upkeep, and cleaning;

f) Power supply, signal, and cable connection diagram;

g) Detailed name and address of the manufacturer;

h) Contact information for technical and maintenance services.

8.3 Product Certificate of Conformity

The product certificate of conformity should provide all the information of the factory inspection of the equipment, it should at least include:

a) Equipment model, serial number;

b) Production date;

c) Inspection qualification mark.

8.4 Packing list document

The packing list document should provide all the information in the equipment packaging box, it should at least include:

a) Equipment, detailed list of accessories, quantity;

b) Product certificate of conformity;

c) Equipment warranty card.