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Assisted surgical medical equipment and assisted surgical medical system employing robotic technology

采用机器人技术的辅助手术设备和辅助手术系统

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Assisted surgical medical equipment and assisted surgical medical system employing robotic technology

1 Scope

This Standard specifies the terms and definitions, requirements and test methods for assisted surgical medical equipment and assisted surgical medical system employing robotic technology.

This Standard applies to assisted surgical medical equipment and assisted surgical medical system employing robotic technology (hereinafter referred to as "RA equipment").

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

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

GB/T 12642, Industrial robots - Performance criteria and related test methods

GB/T 12643, Robots and robotic devices - Vocabulary

GB/T 14710, Environmental requirement and test methods for medical electrical equipment

YY/T 0043, Medical suture needle

YY 0167, Non-absorbable surgical suture

YY/T 1686, Medical electrical equipment employing robotic technology - Classification

Figure 2 -- Orientation accuracy and repeatability

3.3 Positioning repeatability

The degree of consistency of the attained positions that the same command pose arrives repeatedly n times from the same direction. The value of the sphere radius RP_1, with the cluster center as the center of the sphere, is shown in Figure 1.

[GB/T 12642-2013, Definition 7.2.2]

3.4 Orientation repeatability

The degree of consistency of the attained orientations that the same command pose responses repeatedly n times from the same direction (RP_a, RP_b, RP_c), which is shown in Figure 2.

[GB/T 12642-2013, Definition 7.2.2]

3.5 Master-slave operation distance accuracy

The difference between the theoretical movement distance of the end effector reference point and the average actual movement distance under master-slave operation.

Note: The theoretical movement distance depends on the movement distance of the master equipment reference point and the mapping relation of the master-slave movement.

3.6 Master-slave operation distance repeatability

The degree of consistency of the actual movement distance of the end effector reference point, when the master equipment reference point repeatedly moves in the same direction n times under the master-slave operation.

3.7 Master-slave operation orientation accuracy

The difference between the average orientation of the master equipment reference frame and the average orientation of the end effector reference frame under master-slave operation.

3.8 Master-slave operation orientation repeatability

The degree of consistency of the attained orientations of the end effector reference frame, when the orientation of the master equipment reference frame moves repeatedly in the same direction for n times, under master-slave operation.

3.9 Pose

3.17 End effector

The equipment that is installed at the mechanical interface for the RA equipment to complete its surgical tasks.

3.18 End effector reference point

The reference point that is set on the end effector for a certain purpose. In the test, the geometric center of the last joint axis of the end effector is generally used as the measurement reference point.

[GB/T 12643-2013/ISO 8373:2012, definition 4.9]

3.19 End effector reference frame

The reference frame that is set on the end effector for a certain purpose. During the test, it is generally defined at the end effector reference point.

3.20 Master equipment reference point

The reference point that is set on the master equipment in order to reflect the information of the doctor's hand operation during the operation. During the test, the intersection of several joint axes at the end of the master equipment is generally used as the measurement reference point.

3.21 Master equipment reference frame

The reference frame that is set on the master equipment in order to reflect the information of the doctor's hand operation during the operation. During the test, it is generally defined at the master equipment reference point.

3.22 Mechanical interface

The component, on the mounting surface of the RA equipment, that is allowed to connect detachable accessories and components, or is operated by the RA equipment movement.

Note 1: The mechanical interface can be used to attach sterile items.

Note 2: The mechanical interface can provide insulation and other functions (such as aseptic boundaries) to meet basic security requirements.

Note 3: The RA equipment may have zero, one or more mechanical interfaces.

Note: Rewrite IEC 80601-2-77.

3.23 Master-slave control

The positioning repeatability shall meet the manufacturer's regulations in the accompanying documents.

4.2.1.4 Orientation repeatability

The orientation repeatability shall meet the manufacturer's regulations in the accompanying documents.

4.2.2 Master-slave operation accuracy and master-slave operation repeatability

4.2.2.1 Master-slave operation distance accuracy

The master-slave operation distance accuracy shall meet the manufacturer's regulations in the accompanying documents.

4.2.2.2 Master-slave operation distance repeatability

The master-slave operation distance repeatability shall meet the manufacturer's regulations in the accompanying documents.

4.2.2.3 Master-slave operation orientation accuracy

The master-slave operation orientation accuracy shall meet the manufacturer's regulations in the accompanying documents.

4.2.2.4 Master-slave operation orientation repeatability

The master-slave operation orientation repeatability shall meet the manufacturer's regulations in the accompanying documents.

4.3 RA equipment positioning accuracy under navigation guidance

4.3.1 RA equipment positioning accuracy under navigation guidance

The positioning accuracy shall meet the manufacturer's regulations in the accompanying documents.

4.3.2 RA equipment positioning repeatability under navigation guidance

The positioning repeatability shall meet the manufacturer's regulations in the accompanying documents.

4.3.3 RA equipment system accuracy under navigation guidance

The system accuracy shall meet the manufacturer's regulations in the accompanying documents.

damp and heat storage) and mechanical environment test (vibration test, collision test); the final test shall be performed after all the tests are completed.

The test items of the environmental test are specified by the manufacturer, and should include at least 4.2 Master-slave control RA equipment accuracy, and 4.3.2 RA equipment positioning repeatability under navigation guidance.

4.8 Safety requirements

In addition to the following contents which implement the requirements of this Standard, GB 9706.1 is applicable.

6.1 External marking of equipment or equipment components

6.1v) Protective packaging

Supplement:

If the disposable applied part cannot be marked, it shall be marked on the independent outer packaging of the applied part, or marked at the adjacent connection point of the applied part of the RA equipment.

6.1l) Classification

Supplement:

If the RA equipment needs to be marked with IP classification, and a protective cover is required to meet the IP classification requirements, the IP symbol shall be marked on the protective cover.

6.8.2 Instruction manual

Supplement:

In addition to the general requirements, the following warnings and safety instructions shall be added, if applicable:

1) Warning: If the RA equipment is an F-type applied part, then, the applied part of other medical electrical equipment that is used in conjunction with this RA equipment shall be BF-type or CF-type;

2) Warning: When other ME equipment is used with surgical tools of the RA equipment, patient leakage current may be superimposed;

3) Warning: When the RA equipment is used with laser equipment, advice on its safe use shall be provided, including avoiding potential injuries, such as wearing appropriate personal protective equipment, or inserting appropriate filters for the surgical tools of the RA equipment;

f) The result shall meet the requirements of 4.3.1.

5.3.2 RA equipment positioning repeatability under navigation guidance

Test requirements for RA equipment positioning repeatability under navigation guidance:

a) Connect and start the RA equipment according to the requirements of the manual;

b) Install the calibration finger on the end mechanism as required; control the movement of the RA equipment to place the calibration finger measuring point at any position A in the effective workspace; use a three-dimensional measuring instrument to measure the position coordinates A_0 (X_{A0}, Y_{A0}, Z_{A0}) of the current calibration finger measuring point;

c) Control the movement of the RA equipment, so that the calibration finger measuring point is placed at any different position B in the effective workspace; use the software to record the current pose of the RA equipment; use a three-dimensional measuring instrument to measure the position coordinates of the current calibration finger measuring point B_0 (X_{B0}, Y_{B0}, Z_{B0});

d) Control the movement of the RA equipment to move the calibration finger measuring point to the position A; record the position coordinate A_1 (X_{A1}, Y_{A1}, Z_{A1}) again in the same way;

e) Control the movement of the RA equipment to move the calibration finger measuring point to the position B; record the position coordinate B_1 (X_{B1}, Y_{B1}, Z_{B1}) again in the same way;

f) Repeat steps d) and e) to obtain position coordinates A_i (X_{Ai}, Y_{Ai}, Z_{Ai}) and B_i (X_{Bi}, Y_{Bi}, Z_{Bi}), i = 1, 2, 3, 4, 5;

g) Calculate the spatial distance $AOAi = \sqrt{(XAO - XAi)2 + (YAO - YAi)2 + (ZAO - ZAi)2}$, $BOBi = \sqrt{(XBO - XBi)\,2 + (YBO - YBi)2 + (ZBO - ZBi)2}$, (i = 1, 2, 3, 4, 5), which is the RA equipment positioning repeatability;

h) The result shall meet the requirements of 4.3.2.

5.3.3 RA equipment system accuracy under navigation guidance

Test requirements for the RA equipment system accuracy under navigation guidance:

Test requirements for translational clamping force in the working state of the end instrument:

a) The RA equipment is equipped with a needle holder surgical instrument; a No. 7 suture that meets the requirements of YY 0167 is clamped at the front 1/3 of the head of the needle holder;

b) Run the RA equipment; make the needle holder completely closed;

c) Apply the translational clamping force that is specified by the manufacturer in the direction parallel to the principal axis of the needle holder pliers; the suture must not slip off.

5.5.2.2 Driving torque

Test requirements for the driving torque in the working state of the end instrument:

a) The RA equipment is equipped with a needle holder surgical instrument; the midpoint of a suture straight round needle that meets the requirements of YY/T 0043 is clamped at the front 1/3 of the head of the needle holder;

b) Run the RA equipment; make the suture straight round needle perpendicular to the direction of the plier, and the needle holder completely closed;

c) Apply the torque that is specified by the manufacturer to the suture straight round needle parallel to the direction of the plier; the suture needle shall not be displaced.

Note: During the test, select the suture needle of corresponding specifications according to the surgical indications of the RA equipment.

5.6 Master-slave control time delay

Test requirements for the master-slave control time delay of the RA equipment:

a) Connect the moving parts of the linear motion generator to the operating handle of the master equipment through a rigid connecting rod, so that it can control the master equipment reference point to move along the measured direction (Figure 9);

b) Under the master-slave control mapping ratio of 1:1, control the motion generator to make the master equipment reference point move according to the following requirements: the master equipment reference point accelerates from the static state to 80% of the rated velocity (or the velocity that is give in the standard) within 200 ms; after moving at a uniform velocity

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