Designation: ~~F2213 – 06 (Reapproved 2011)~~ F2213 – 17

Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment[1]

This standard is issued under the fixed designation F2213; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers the measurement of the magnetically induced torque produced by the static magnetic field in the magnetic resonance environment on medical devices and the comparison of that torque ~~to the equivalent torque applied by the gravitational force to the implant.~~a user-specified acceptance criterion.

1.2 This test method does not address other possible safety issues which ~~include~~ may include, but are not limited ~~to issues of magnetically induced force due to spatial gradients in the static magnetic field, RF heating, induced heating,~~ to, magnetically induced deflection force, tissue heating, device malfunction, imaging artifacts, acoustic noise, interaction among devices, and the functionality of the device and the MR system.

1.3 The torque considered here is the magneto-static torque due to the interaction of the MRI static magnetic field with the magnetization ~~in~~of the implant. The dynamic torque due to interaction of the static field with eddy currents induced in a rotating device is not addressed in this test method. ~~Currents~~ Torque induced by currents in lead wires ~~may induce a torque as well.~~is not addressed by this standard.

1.4 The ~~sensitivity of the torque measurement apparatus must be greater than~~methods in this standard are applicable for MR systems with a horizontal magnetic field. Not all of the methods described in this standard are applicable for use in an MR system with a vertical magnetic field. The Suspension Method and the Low Friction Surface Method require gravity to be orthogonal to the magnetically induced torsion and may not be performed using a vertical magnetic field. The Torsional Spring and Pulley Methods can be adapted to work in a vertical magnetic field, however the example apparatus are not appropriate for ~~1/10 the "gravity torque," the product of the device's maximum linear dimension and its weight.~~use in a vertical magnetic field. The Calculation Based on Measured Displacement Force Method is independent of the MR system and thus could be used for an MR system with a vertical magnetic field.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate ~~safety~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

F2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants

F2182 Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging

[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

2.2 *Other Standards:*[3]

IEC 60601-2-33 ~~Ed. 2.0 Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis, 2002~~Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

ISO ~~13485:2003(E)~~13485 Medical ~~Devices—Quality Management Systems—Requirements for Regulatory Purposes, definition 3.7~~devices -- Quality management systems -- Requirements for regulatory purposes[4]

ISO TS 10974 Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

3. Terminology

3.1 ~~*Definitions—*~~*Definitions:*~~For the purposes of this test method, the definitions in 3.1.1 – 3.1.18 shall apply:~~

3.1.1 *diamagnetic ~~material—~~material, n—*a material whose relative permeability is less than unity.

3.1.2 *ferromagnetic ~~material—~~material, n—*a material whose magnetic moments are ordered and parallel producing magnetization in one direction.

3.1.3 *magnetic induction or magnetic flux density (B in ~~T)—~~T), n—*that magnetic vector quantity which at any point in a magnetic field is measured either by the mechanical force experienced by an element of electric current at the point, or by the electromotive force induced in an elementary loop during any change in flux linkages with the loop at the point. The magnetic induction is frequently referred to as the magnetic field. B_0 is the static field in an MR system. Plain type indicates a scalar (for example, B) and bold type indicates a vector (for example, $\boldsymbol{B}$).

3.1.4 *magnetic field strength (H in ~~A/m)—~~A/m), n—*strength of the applied magnetic field.

3.1.5 *magnetic resonance ~~(MR)—~~(MR), n—*resonant absorption of electromagnetic energy by an ensemble of atomic particle situated in a magnetic field.

~~3.1.6 *magnetic resonance diagnostic device—*a device intended for general diagnostic use to present images which reflect the spatial distribution or magnetic resonance spectra, or both, which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images or spectra, or both, may also be produced.~~

3.1.6 *magnetic resonance (MR) ~~environment—~~environment, n—*volume within the 0.50 mT (5 gauss (G)) line of an MR system, which includes the entire ~~three-dimensional~~ three-dimensional volume of space surrounding the MR scanner. For cases where the 0.50 mT line is contained within the Faraday shielded volume, the entire room shall be considered the MR environment.

3.1.7 *magnetic resonance ~~equipment—~~equipment, n—*medical electrical equipment which is intended for ~~in-vivo~~magnetic resonance examination of a patient. The MR equipment comprises all parts in hardware and software from the supply mains to the display monitor. The MR equipment is a Programmable Electrical Medical System (PEMS). **IEC 60601-2-33**

~~3.1.9 *magnetic resonance examination (MR Examination)—*process of acquiring data by magnetic resonance from a patient.~~

3.1.8 *magnetic resonance imaging ~~(MRI)—~~(MRI), n—*imaging technique that uses static and ~~time-varying~~ time-varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei.

3.1.9 *magnetic resonance system (MR ~~System)—~~System), n—*ensemble of MR equipment, accessories including means for display, control, energy supplies, and the MR environment.

IEC ~~60601-2-33~~60601-2-33

3.1.10 *magnetically induced displacement ~~force—~~force, n—*force produced when a magnetic object is exposed to the spatial gradient of a magnetic field. This force will tend to cause the object to translate in the gradient field.

3.1.11 *magnetically induced ~~torque—~~torque, n—*torque produced when a magnetic object is exposed to a magnetic field. This torque will tend to cause the object to align itself along the magnetic field in an equilibrium direction that induces no torque.

3.1.12 *magnetization (M in ~~T)—~~T), n—*magnetic moment per unit ~~volume.~~volume

3.1.13 *medical ~~device—~~device, n—*any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or ~~calilbrator,~~calibrator, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

~~(1) diagnosis, prevention, monitoring, treatment, or alleviation of disease,~~
~~(2) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury,~~
~~(3) investigation, replacement, modification, or support of the anatomy or of a physiological process,~~
~~(4) supporting or sustaining life,~~
~~(5) control of conception,~~
~~(6) disinfection of medical devices, and~~
~~(7) providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.~~

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Specifically, definition 3.11.

(1) diagnosis, prevention, monitoring, treatment, or alleviation of disease;
(2) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury;
(3) investigation, replacement, modification, or support of the anatomy or of a physiological process;
(4) supporting or sustaining life;
(5) control of conception;
(6) disinfection of medical devices; and
(7) providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

ISO 13485

3.1.14 *paramagnetic ~~material~~ material, n*—a material having a relative permeability which is slightly greater than unity, and which is practically independent of the magnetizing force.

3.1.15 *passive ~~implant~~ implant, n*—an implant that serves its function without the supply of electrical power.

3.1.16 *tesla, ~~(T)~~ (T), n*—the SI unit of magnetic induction equal to 10^4 gauss (G).

4. Summary of Test Method

4.1 The static magnetic field associated with an MR system produces a torque on a device that acts to align the long axis of the object with the direction of the magnetic field. Five methods for measurement or assessment of magnetically induced torque are given in this standard: the Suspension Method, the Low Friction Surface Method, the Torsional Spring Method, the Pulley Method, and the Calculation Based on Measured Displacement Force Method.

4.2 The Suspension Method and the Low Friction Surface Method are not appropriate for devices for which the magnetically induced torque is expected to be greater than the torque due to gravity.

4.3 The Low Friction Surface Method is performed by placing the device on a low friction non-metallic, non-conductive surface as near as practical to the isocenter of the MR system. The device is then rotated in defined angular increments while alignment or rotation of the device with the static magnetic field is observed. If rotation of the device is not observed, an upper bound on the magnetically induced torque is estimated using the coefficient of friction between the surface and the device and the weight of the device. If alignment or rotation of the device is observed, then either the Torsional Spring Method or the Pulley Method shall be performed. The coefficient of friction is calculated from the device weight and the angle of repose (the angle in which the implant is on the verge of sliding off the low friction surface) which is measured outside the MR environment.

4.4 The ~~static field in a magnetic resonance system produces a torque on a device that acts to align the long axis of the object with the magnetic field. The torque is evaluated using a torsional pendulum method.~~ Torsion Spring Method determines the magnetically induced torque using a torsion pendulum. A device is placed on a holder suspended by a ~~torsional~~torsion spring. The apparatus is placed in the center of the magnetic resonance equipment magnet where the magnetic field is uniform. The torque is determined from the measurement of the deflection angle of the holder from its equilibrium position. The frame holding the spring and holder assembly is rotated and the torque as a function of angle of the implant is determined. The maximal magnetic torque is compared to the worst case ~~gravity~~gravitational torque, defined as the product of the maximum linear dimension of the device and the device weight.

4.5 The Pulley Method allows determination of the maximum magnetically induced torque of the device using a low friction pulley attached to a rotating platform. The device is fixed on the platform while positioning the device to be centered as near as practical to isocenter of the MR system. Using a lightweight string attached to the pulley and a force gauge, the platform is rotated by pulling the force gauge in a direct line away from the torque fixture. The maximum torque is determined by using the maximum reading from the force gauge.

4.6 The Suspension Method is a qualitative method that is performed by suspending the device by a lightweight string in a location as near as practical to the isocenter of the MR system. The device is then rotated in defined angular increments while movement or rotation of the device to align with the static magnetic field is observed. If rotation of the device is not observed, the magnetically induced torque is small and no further evaluation is required. If rotation of the device is observed, then the Low Friction Surface Method, the Torsional Spring Method, or the Pulley Method shall be performed.

4.7 The Calculation Based on Measured Displacement Force Method provides an upper bound for the magnetically induced torque based on magnetically induced displacement force measurements using Test Method F2052. This method is most appropriate for devices which are composed of only one material; however it may also be used with devices composed of multiple materials (see 7.8.2.2). This method is not appropriate for devices that contain magnets or ferromagnetic material.

5. Significance and Use

5.1 This test method is one of those required to determine if the presence of a medical device may cause injury ~~during a magnetic resonance examination and~~ in the magnetic resonance environment. Other safety issues which should be addressed include but may not be limited to magnetically induced force (see Test Method F2052~~) and~~), RF heating (see Test Method F2182~~)~~.

~~The terms and icons in Practice~~), and image artifact (see Test Method ~~F2503~~F2119 ~~should be used to mark the device for safety in the magnetic resonance environment.~~). ISO TS 10974 addresses hazards produced by active implantable medical devices in the MR Environment.

5.2 The terms MR Conditional, MR Safe, and MR Unsafe together with the corresponding icons in Practice F2503 shall be used to mark the device for safety in the MR environment.

5.3 ~~If the maximal~~ The acceptance criterion associated with this test shall be justified. If the maximum magnetically induced torque is less than the product of the longest dimension of the medical device and its weight, then the magnetically induced ~~deflection~~ torque is less than the worst case torque on the device due to gravity. For this condition, it is assumed that any risk imposed by the application of the magnetically induced torque is no greater than any risk imposed by normal daily activity in the Earth's gravitational field. This is ~~conservative; it~~conservative. It is possible that greater torques also would not pose a ~~hazard to the patient.~~hazard. (For example, device position with respect to adjacent tissue, tissue ingrowth, or other mechanisms may act to prevent device movement or forces produced by a magnetically induced torque that are greater than the torque due to gravity from causing harm to adjacent tissue.)

5.4 This test method alone is not sufficient for determining if an implant is safe in the MR environment.

~~5.4 The sensitivity of the torque measurement apparatus must be greater than 1/10 the "gravity torque," the product of device weight and the largest linear dimension.~~

5.5 The magnetically induced torque considered ~~here~~ in this standard is the magneto-static torque due to the interaction of the MRI static magnetic field with the magnetization in the implant. The dynamic torque due to interaction of the static field with eddy currents induced in a rotating device is not addressed in this test method. Currents in lead wires may induce a torque as well.

~~**6. Apparatus**~~

~~6.1 The test fixture is depicted in Fig. 1. It consists of a sturdy structure supporting a holding platform supported by a torsional spring. Materials should be non-ferromagnetic. The device may be taped or otherwise attached to the holding platform. The supporting structure will have fixed to it a protractor with 1° graduated markings and the holding platform will have a marker so that the angle between the basket and the support structure can be measured. The supporting structure is rotated with the turning knob. The equilibrium angle between the supporting structure and the holding platform outside the magnetic field represents the zero torque angle. The torque inside the magnet is equal to the product of the deflection angle and spring constant. The torsional spring diameter should be chosen so that the maximal deflection angle is less than 25°. A photograph of a torque apparatus is shown in Fig. 2.~~

6. Test Specimens

6.1 For purposes of device qualification, the device evaluated according to this test method should be representative of manufactured devices. The device should be sterilized, unless sterilization is not expected to affect the relevant properties of the device (for example: magnetic susceptibility, weight)

6.2 For purposes of device qualification, any alteration from the finished condition should be reported. For instance, if sections are removed from the device for testing or if the device has not been sterilized, this should be reported.

~~**7. Test Specimens**~~

~~7.1 For purposes of device qualification, the device evaluated according to this test method should be representative of manufactured devices that have been processed to a finished condition (for example, sterilized).~~

~~7.2 For purposes of device qualification, any alteration from the finished condition should be reported. For instance, if sections are cut from the device for testing, this should be reported.~~

7. Procedure

7.1 *Selection of Test Device:*

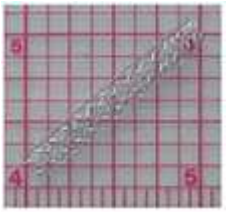

FIG. 1 Example of Low Friction Apparatus Including Device (i.e., Stent)

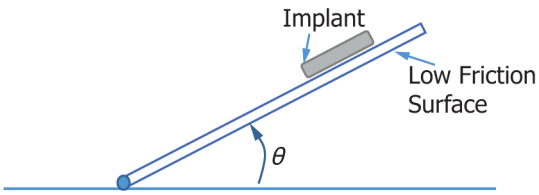

FIG. 2 Diagram of Angle of Repose (Θ) Measurement Method

7.1.1 The test sample shall be worst case for the device under test. Provide a rationale for the selection of the test sample as worst case. For instance, for devices that are available in multiple sizes and/or configurations, provide a rationale supporting the chosen test sample as worst case for the entire range of device sizes and/or configurations.

7.1.1.1 It might be appropriate to test only a relevant section of a device (for example, for a flexible device with only a small metallic portion, test only the metallic portion of the device). A justification for the selected portion of the device shall be provided. Mass, linear dimension, and material magnetic susceptibility shall be considered. The worst case combination will likely include components with the greatest product of the implant mass and the maximum linear dimension when compared to other product combinations.

7.2 *Test Device Orientation:*

7.2.1 The test device shall be tested with each principal axis of the test device oriented parallel to the MR system's static magnetic field, unless a rationale for a specific worst case orientation is determined. Such a rationale may include consideration of the clinically possible orientations of the test device in relation to B_0. Note, it is possible for the worst case orientation to be with the principal axes of the test device at an oblique(s) angle with respect to B_0. Also, lead wires should be arranged in a manner that is worst case or representative of the *in vivo* configuration. If applicable, the effect of current in lead wires should be considered.

7.3 *Coordinate System:*

7.3.1 Use a right handed Cartesian coordinate system with origin (x=y=z=0) at the isocenter of the MR system. The *z*-axis is parallel to the MR system bore with the positive direction pointing from the patient table into the bore. The *y*-axis is vertical with the positive direction up.

7.4 *The Low Friction Surface Method:*

7.4.1 The Low Friction Surface Method apparatus consists of a low friction non-metallic, non-conductive surface as shown in Fig. 1.

7.4.2 *Determination of Coefficient of Friction Between the Implant and the Low Friction Surface:*

7.4.2.1 Perform this process outside the MR environment where the earth's magnetic field is the only magnetic field acting on the device.

7.4.2.2 Place the test device on the surface (an acrylic sheet, for example). If the device has sides with varied friction characteristics, use the side with lower friction. Fix one end of the low friction surface so that it will not slide when the other end is lifted.

7.4.2.3 Slowly raise the surface until it reaches the angle of repose (the angle at which the device is on the verge of sliding) as shown in Fig. 2. This will require raising the device to an angle at which the test device does slide and then repeating the process to determine the angle of repose. Make sure the device slides and does not roll.

7.4.2.4 Calculate the coefficient of friction (μ) using Eq 1.

$$\mu = \tan\theta_s \tag{1}$$

where:

θ_s = angle of repose or angle where the implant is on the verge of sliding.

7.4.3 *Procedure for Low Friction Surface Method:*

7.4.3.1 Place the test device on the low friction surface that is positioned on the x-z plane (the horizontal surface) as near as practical to the isocenter of the MR system (x=y=z=0). Orient the test device so that one principal axis is aligned in the z-direction.

7.4.3.2 Rotate the test device in 45° increments about the isocenter (on the x-z plane) until a full 360° of rotation is completed. After each 45° rotation, observe the test object for alignment or rotation of the device with the static magnetic field. Record any motion of the test device.

7.4.3.3 Repeat 7.4.3.1 and 7.4.3.2 two additional times for the other two principal axes of the test device.

7.4.3.4 If no motion is observed and the device remained motionless, then the magnetically induced torque is less than the product of the friction force between the device and the low friction surface and the longest dimension of the device, as defined in Eq 2 and which may be calculated from the device length, weight, and coefficient of friction determined in 7.4.2.

$$\tau_{magnetic} < L\,F_f \tag{2}$$

where:

$\tau_{magnetic}$ = magnetically induced torque,
L = longest dimension of the test device, and
F_f = friction force between the test device and the low friction surface.

The friction force, F_f, between the test device and the low friction surface is given in Eq 3.

$$F_f = \mu m g \quad (3)$$

where:

F_f = friction force between the test device and the low friction surface,
μ = coefficient of friction between the test device and the low friction surface (determined in 7.4.2),
m = mass of the device, and
g = acceleration due to gravity.

and Eq 2 becomes:

$$\tau_{magnetic} < L \mu m g \quad (4)$$

7.4.3.5 If magnetically induced torque is observed and the device rotates to align with the static magnetic field, then further testing according to the Torsional Spring Method or the Pulley Method shall be conducted.

7.5 ~~Fig. 1 depicts the test fixture, which is placed in the middle of the magnet where the magnetic field is uniform. The test device is placed on the holding platform with one of its principal axes in the vertical direction. The entire apparatus is placed in the center of the magnet in the region of uniform magnetic field. Rotate the fixed base and measure the deflection of the device with respect to the base at 10° increments for angles between 0° and 360°. Note that at angular values where the angular derivative of the torque changes sign, there will be an abrupt change in deflection angle as the device swings to the next equilibrium position. Try to measure the deflection angle as close as possible to this swing so that the maximal torque will be determined.~~*Torsional Spring Method:*

7.5.1 Example test fixtures are depicted in Figs. 3-5. A sturdy structure supporting a holding platform supported by a torsion spring is used. Apparatus materials shall be non-ferromagnetic.

7.5.1.1 The test device may be taped or otherwise attached to the holding platform.

7.5.1.2 An angle measurement tool (a protractor, for example) with the ability to measure in 1° increments shall be attached to the apparatus in order to be able to measure the angle of rotation of the torsional spring.

7.5.1.3 The equilibrium angle of the torsion spring outside the MR system's static magnetic field represents the zero torque angle.

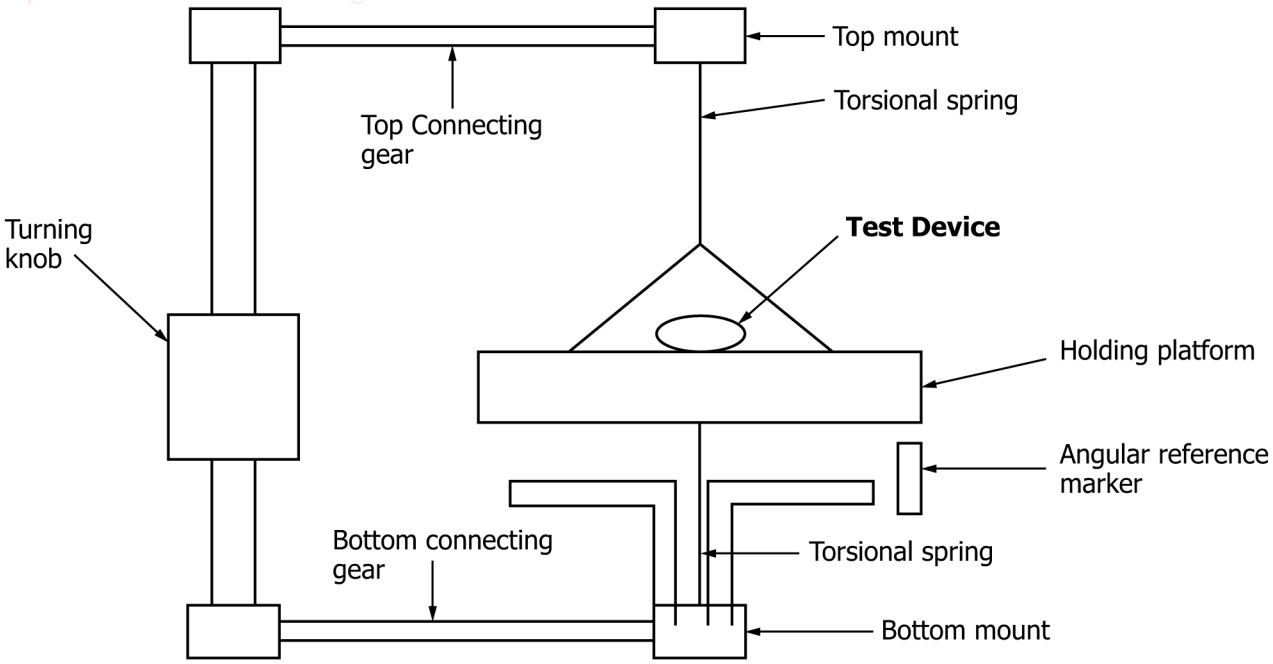

FIG. 3 Diagram of Example of Torsion Spring Apparatus

NOTE 1—The angular reference marker is used to locate the angular marks on protractors connected to the bottom mount and the holding platform.