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Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shaft and tracheal tube cuffs

Lasers et équipements associés aux lasers — Détermination de la résistance au laser des axe et ballonnet de tubes trachéaux

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 9, *Laser and electro-optical systems*.

This third edition of ISO 11990 cancels and replaces ISO 11990-1:2011 and ISO 11990-2:2010 which have undergone a revision in order to adjust the two documents to each other thereby eliminating redundancies and unintended discrepancies.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

A fire in the airway is always a serious matter. In addition to local damage in the larynx, injury can occur to the lower airway and the parenchymal tissue in the lung. The products of combustion can be blown into the lungs.

Procedures performed in the airway, where a tracheal tube and a laser are used, bring together an oxygen-enriched atmosphere, a fuel and high power, the three ingredients necessary to create a fire. The likelihood that a laser beam will contact the tracheal tube during airway procedures is high. This led to the development of a test method, described in this document, to assist the clinician in determining which tracheal tube shaft was the most laser-resistant under a defined set of conditions.

Unfortunately, fires with tracheal tubes, whose shafts were laser-resistant according to this document have continued to occur. Investigations have shown that the cuff, and not the shaft, of the tracheal tube is the area of lowest laser resistance and most likely to be contacted by the laser beam, even when used according to the manufacturer's instructions. Clinical experience has shown that not only perforation of the part of the shaft below the cuff has happened, but also ignition of the outer surface of the cuff. This could then ignite other parts of the tracheal tube, such as the tip, which is normally unprotected.

Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shaft and tracheal tube cuffs

1 Scope

This document specifies a method of testing the continuous wave (cw) laser resistance of the shaft of a tracheal tube and the cuff regions including the inflation system of tracheal tubes designed to resist ignition by a laser.

NOTE 1 When interpreting these results, the attention of the user is drawn to the fact that the direct applicability of the results of this test method to the clinical situation has not been fully established.

NOTE 2 The attention of the users of products tested by this method is drawn to the fact that the laser will be wavelength sensitive and tested at the wavelength for which it is intended to be used. If tested using other wavelengths, explicitly state the power settings and modes of delivery.

CAUTION — This test method can involve hazardous materials, operations and equipment. This document provides advice on minimizing some of the risks associated with its use but does not purport to address all such risks. It is the responsibility of the user of this document to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11146-1, *Lasers and laser-related equipment — Test methods for laser beam widths, divergence angles and beam propagation ratios — Part 1: Stigmatic and simple astigmatic beams*

ISO 11810, *Lasers and laser-related equipment — Test method and classification for the laser resistance of surgical drapes and/or patient protective covers — Primary ignition, penetration, flame spread and secondary ignition*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

ISO 5361:2016, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 11145:2016, *Optics and photonics — Lasers and laser-related equipment — Vocabulary and symbols*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11810, ISO/IEC Guide 99 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
beam diameter
d_{95}
smallest diameter of a circular aperture in a plane perpendicular to the beam axis that contains 95 % of the total beam power (energy)

[SOURCE: ISO 11145:2016, 3.3.1, modified — The value of contained total beam power has been set to 95 %, and the note to entry has been removed.]

3.2
beam cross-sectional area
A_{95}
smallest completely filled area containing 95 % of the total beam power (energy)

[SOURCE: ISO 11145:2016, 3.2.1, modified — The value of contained total beam power has been set to 95 %, and the note to entry has been removed.]

3.3
combustion
any continuing burning process that occurs in or on the specimen caused by a chemical process of oxidation with the liberation of heat

EXAMPLE Flame, smouldering, rapid evolution of smoke.

[SOURCE: ISO 11810:2015, 3.7]

3.4
cuff
inflatable balloon permanently attached around the tracheal tube near the patient end to provide an effective seal between the tube and the trachea

[SOURCE: ISO 5361:2016, 3.4]

3.5
damage
any change, other than combustion, which can affect the safety of the patient or efficacy of the tracheal tube due to increasing the risk of ignition

EXAMPLE Local heating, melting, creation of holes, pyrolysis.

[SOURCE: ISO 11810:2015, 3.8, modified — “product” has been replaced with “tracheal tube”.]

3.6
flammable
subject to ignition and flaming combustion

[SOURCE: ISO 11810:2015, 3.9]

3.7
ignition
creation of combustion induced by the delivery of power

[SOURCE: ISO 11810:2015, 3.10]

3.8
laser resistance
measure of the ability of a material to withstand laser power without ignition or damage

[SOURCE: ISO 11810:2015, 3.11]

3.9
melting behaviour
softening of a material under the influence of heat (including shrinking, dripping and burning of molten material, etc.)

[SOURCE: ISO 11810:2015, 3.12]

3.10
penetration resistance
ability of a material to prevent the passage of laser energy

[SOURCE: ISO 11810:2015, 3.14]

3.11
shaft
portion of the tracheal tube between the cuff and the machine end of the tube

4 Principle

WARNING — This test method can result in a rocket-like fire involving the tracheal tube. Such a fire can produce intense heat and light and toxic gases.

To simulate worst-case conditions, the material is exposed to laser power of known characteristics in an environment of up to 98 % ± 2 % oxygen.

5 Significance and use of the test

5.1 This document describes a uniform and repeatable test method for measuring the laser resistance of the shaft and the cuff of a tracheal tube. Most of the variables involved in laser ignition of a tracheal tube have been fixed in order to establish a basis for comparison. This test method for measuring can be used to compare tracheal tubes having differing types and designs of laser protection.

5.2 A large number and range of variables are involved in the ignition of a tracheal tube. A change in one variable can affect the outcome of the test. Caution should be observed, since the direct applicability of the results of this test method to the clinical situation has not been fully established.

NOTE 1 This method can be applied to study the effect of changing the test conditions, but this is outside the scope of this document. For example, variation of the breathing-gas flow rate or different breathing-gas mixtures might affect the laser resistance of the shaft and cuff of a tracheal tube.

5.3 Since an oxygen-enriched atmosphere is often present in the clinical situation, either intentionally or unintentionally, the test is performed in an environment of 98 % ± 2 % oxygen.

5.4 A flow rate of 1 l/min of oxygen in a 6,0 mm inner diameter tube was chosen as the most appropriate condition for shaft and cuff ignition and establishment of a fire, based on the work cited in Reference [5].

5.5 The preparation of the specimen shall be in accordance with the manufacturer's instructions for use.

5.6 Use of beam cross-sectional shape other than circular, or mode of laser power delivery other than continuous wave can affect the shaft and cuff ignition characteristics. Also, shafts and cuff of different construction have different laser resistances (see References [5] to [12]).

5.7 The majority of manufacturers of laser-resistant cuffs recommend using isotonic saline or water to fill the cuff. For preliminary testing of leakage of the cuff, filling with air is recommended by most manufacturers. This can cause an air bubble, which, in a typical position of the patient during surgery, is not on the top of the filled cuff, but at the area where the cuff and shaft meet. The test report shall

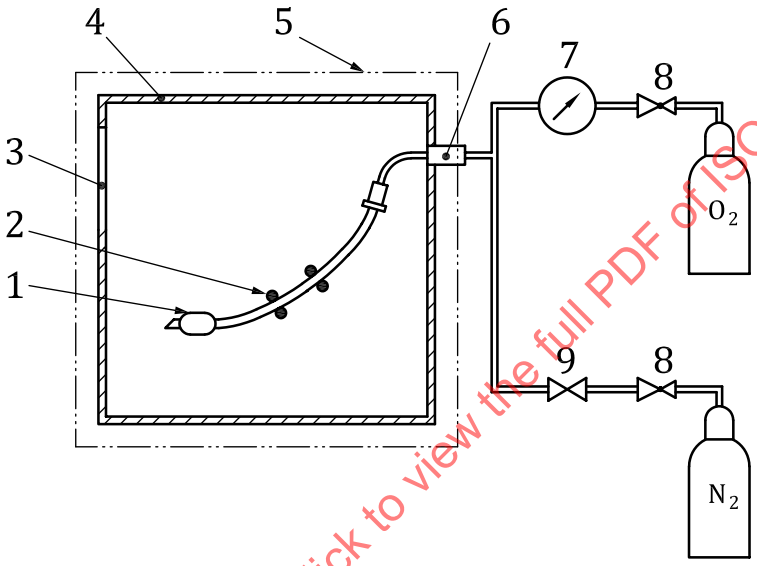
include whether a bubble occurs and, if so, report if the bubble fills out the space between the cuff and the underlying shaft material, and whether the shaft material in the cuff region is laser-resistant or not.

NOTE 2 This method can be applied to study the effect of changing the test conditions, but this is outside the scope of this document.

6 Apparatus

6.1 General

6.1.1 The test apparatus shall consist of a draught-resistant ventilated containment box, specimen holder, specimen rack, laser energy source and associated parts (see Figure 1).



Key

1 test specimen
2 specimen holder using two clamps
3 opening for laser access
4 containment box (lateral view)
5 enclosure cover (maybe multi-piece)
6 flashback arrestor
7 oxygen flow meter and controller
8 pressure regulator with inlet and outlet gauges
9 quick-action inert gas valve

Figure 1 — Typical testing apparatus (schematic)

6.2 Containment box

6.2.1 The containment box controls the environment around the specimen while allowing the laser beam to be directed onto the specimen.

6.2.2 The containment box shall have the following characteristics:

a) rectangular in shape and measures approximately 46 cm × 46 cm × 46 cm;

b) fire-proof and easily cleaned of soot and residue from burned specimens;

c) an opening, or at least one cover or window, to allow access to the test specimen;

d) allow direct access of the laser beam to the specimen;

e) allow observation with video cameras on the top and on all sides of the box; a minimum of three video cameras (one camera positioned above the containment box and two cameras positioned at two of the sides of the containment box) is needed for recording purposes;

f) exhaust the gas and any products of combustion to a safe area;

g) allow cleaning of the box, and cleaning of the covers and/or windows themselves;

h) maintaining an environment of 98 % ± 2 % oxygen around the specimen;

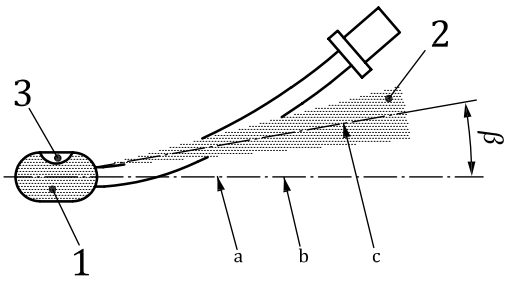
i) it can be rapidly flooded with nitrogen or another gas to extinguish any fire inside the box;

j) the internal surfaces are non-reflective to protect the specimen from reflections.

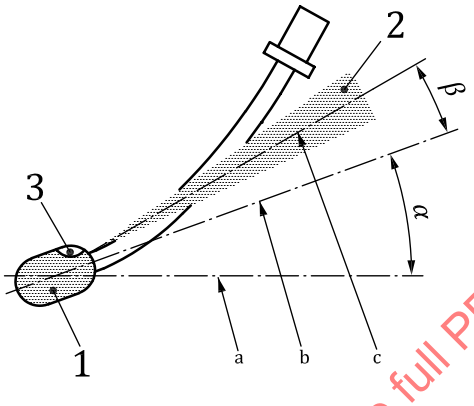
6.2.3 Other configurations may be used, as long as the requirements of the test method as defined herein are not affected.

6.3 Specimen holder

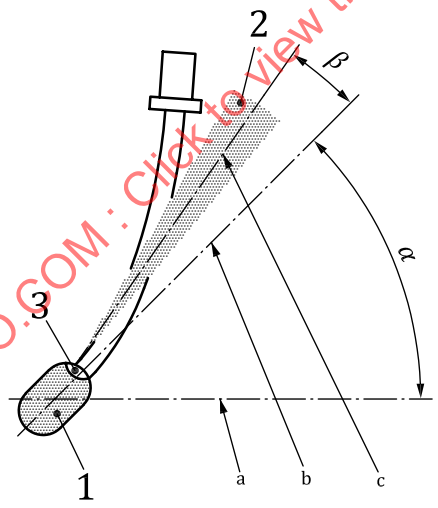
The specimen holder shall allow laser access to the test specimen to be able to allow for different angles of positioning of the tracheal tube and an angle of the laser beam to the tracheal tube cuff. Figure 2 shows these angles (denoted as α and β) which allows the mounting of the test specimen at an angle such that an air bubble, if present, inside the cuff is directed to the connecting area between the cuff and the tube shaft.



a) horizontal alignment: α between 0° and 5°; β = 10°



b) tilted alignment: α between 15° and 20°; β = 10°



c) tilted alignment: α between 40° and 45°; β = 10° (laser beam impacting at the air bubble)

Key

1 cuff of the test specimen
2 laser beam
3 air bubble
α angle between horizontal line and the cuff symmetry axis
β angle between cuff symmetry axis and the optical axis of laser beam
a Horizontal line.
b Cuff symmetry axis.
c Optical axis of laser beam.

Figure 2 — Alignment of test specimen and angle of impact of the laser beam on the cuff

6.4 Lasers and delivery systems

WARNING — Surgical lasers emit radiation of sufficient power to damage living tissue or ignite fires directly or by reflection of radiation. In addition to other precautions, test personnel should be trained in the use of lasers and take proper safety measures based on the type of laser being used. These precautions should include laser-safety eyewear, protective clothing and controlled access to the test area.

6.4.1 Various laser types emitting radiation of wavelengths in the visible and infrared ranges are used during ENT (ear, nose and throat) surgery. Any of these lasers that meet the requirements listed in this test procedure are suitable for use in this test.

6.4.2 The continuous wave laser radiation shall be applied with the same optical quality as it is typically used for a surgical procedure. The system shall provide a beam diameter, d_{95}, of 0,5 mm ± 10 % at the surface of the specimen in accordance with ISO 11146-1.

CAUTION — Cooling or clearing gases shall not be used. Cooling or clearing gases are used by some lasers to maintain the quality of the delivery system. The flow of these gases can alter the measured laser resistance, e.g. by extinguishing nascent fire.

6.5 Power meter

6.5.1 For measuring the power of the laser radiation and for determining the penetration resistance, power meters which provide a measuring range from less than 10 mW to greater than 20 W shall be used. A response time of ≤0,25 s shall be used for the penetration resistance measurements. Testing shall be done at the power density required for the test.

6.5.2 The power of radiation transmitted by these systems shall be verified as accurate as ±10 %. This can be accomplished by use of an external power meter or internal calibration systems.

6.6 Gas supply system

6.6.1 The gas supply system shall provide oxygen to the tracheal tube at a controllable flow rate. Also, the system shall be capable of rapidly flooding the containment box with nitrogen or other inert gas or stopping oxygen flow, or both, to extinguish any burning material. An oxygen flow meter and controller and a quick-action inert gas valve shall be part of this system (see Figure 1). The nitrogen or inert gas supplied shall be at a higher pressure and allow a flow rate of at least an order of magnitude greater than that of the oxygen supplied to the tracheal tube.

6.6.2 Other arrangements, such as an oxygen flood valve for rapidly purging the containment box or an inert gas flooding system for rapid extinguishment of burning material, may be used as long as the requirements of the test method as defined herein are not affected.

6.6.3 Oxygen analyser: any device that can measure the concentration of gaseous oxygen with a repeatability of at least 1 % of full scale and a calibrated accuracy of at least 1 % of full scale is satisfactory. The oxygen sensor shall be positioned so as to minimize the chance of its ignition by any fire in the containment box.

6.7 Environment

6.7.1 Ambient air conditions

The tests under ambient air conditions shall be performed at room temperature of 20 °C ± 3 °C and 20 % ± 2 % relative humidity.

6.7.2 Oxygen enriched atmospheres

The tests shall be performed under oxygen-enriched atmosphere, i.e. at oxygen concentration of 98 % ± 2 %.

The oxygen concentration within the containment box shall be established at the desired level by proportional mixing of nitrogen and oxygen by suitable means.

6.8 Smoke evacuation device

WARNING — Combustion of most materials produces toxic gases such as carbon monoxide, hydrogen chloride and hydrogen cyanide. Also, the smoke produced in such fires contains hazardous particles of carbon, silica, unburned matter and other materials.

6.8.1 A device shall be attached to the containment box to safely remove smoke resulting from a burning specimen but shall be designed to eliminate the chance of drawing fire into the exhaust system. Placing the containment box in a fume hood that exhausts to a safe location satisfies this requirement.

6.8.2 The smoke evacuation device shall not interfere with maintaining the oxygen environment within the containment box. For example, the flow of a fume hood shall not create draughts that would enter or pull gas from the opening for laser access. The smoke evacuation shall not be activated until after the initiation of combustion.

7 Reagents and materials

7.1 **Oxygen**, 98 % ± 2 % (volume fraction) pure.

7.2 **Nitrogen** or **other gas** (i.e. non-oxidizing, non-flammable), 98 % ± 2 % (volume fraction) pure.

8 Preparation of test specimens

8.1 The test specimen shall be any material, device or system used as a tracheal tube, with whatever modifications are used to protect the tracheal tube from laser power.

8.2 Five test specimens shall be used.

8.3 Each test specimen shall be prepared according to the manufacturer's instruction for use. Some devices can require special preparation (e.g. wetting of the tube, filling the cuff with isotonic saline or water, insufflation with inert gas). Measure the outer diameter of the filled cuff.

8.4 The test specimens shall be free from any extraneous materials, as such materials can significantly alter the laser resistance of the tracheal tube.

EXAMPLE Char, ash, soot, blood, mucous, lubricants and other materials.

8.5 The test specimen and apparatus shall be equilibrated at 20 °C ± 3 °C in an oxygen-enriched 98 % ± 2 % atmosphere for 10 min prior to the start of testing.

NOTE 1 This is done to standardize the test conditions rather than to simulate the clinical condition. The ignitability and flammability of most materials do not significantly change between room temperature and body temperature. However, some polymers change their oxygen absorption, and therefore their flammability, with temperature.

NOTE 2 Some materials, such as polymers, absorb oxygen and might have diminished laser resistance if exposed to oxygen for long periods of time.

9 Preparation of apparatus

9.1 Ensure that the containment box is clean (i.e. free of contaminants).

NOTE Contamination can interfere with the performance of the test or evaluation of the results.

9.2 Ensure that the laser is in working order, that its operation is understood, and that personnel protection is in place.

9.3 Ensure that there is adequate oxygen for the test and nitrogen or other gas for extinguishing any resulting fire.

9.4 Have other means of fire extinguishment (e.g. a carbon dioxide fire extinguisher) at hand. Water is not recommended, as it will not extinguish some materials burning in oxygen and, if used, will cause considerable soiling of the containment box and will interfere with interpretation of the results of laser interaction with the specimen. Water is not recommended for use on a fire involving energized electrical equipment.

10 Test methods

10.1 General conditions

10.1.1 Perform the test at 20 °C ± 3 °C.

10.1.2 Insert the specimen in the containment box. Connect the gas supply systems to the apparatus.

10.1.3 Ensure that the opening for laser access is as small as possible, in order to maintain the oxygen-enriched atmosphere but still allow laser access to the specimen.

10.1.4 Ensure that the gas flush is working properly.

10.1.5 Ensure that the smoke evacuation system is working properly and will not affect the gas concentration in the containment box during the test.

10.1.6 Flow oxygen into the containment box at a rate and time period sufficient to establish an environment of 98 % ± 2 % oxygen. This oxygen level shall be verified by use of an oxygen analyser (6.6.3) measuring the environment.

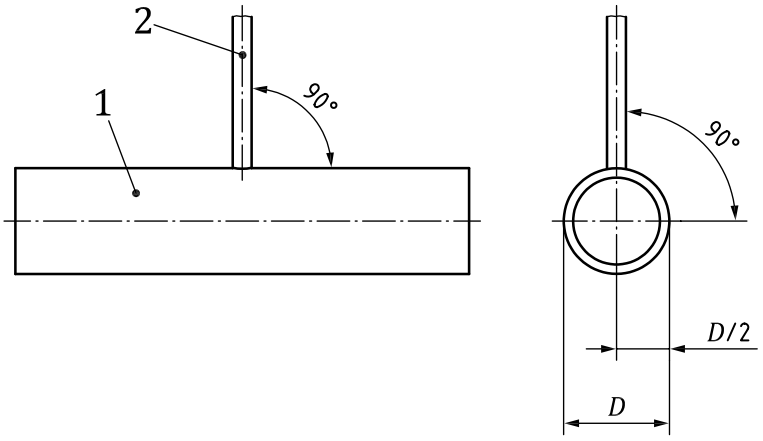
10.2 Shaft

10.2.1 The laser shall be positioned so that

— the laser beam is perpendicular to the surface of the shaft of the test specimen (see Figure 3);

— the beam diameter, d_{95}, measured in accordance with ISO 11146-1, is 0,5 mm ± 10 % at the surface of the test specimen (the beam cross-sectional area, A_{95}, is a critical dimension).

Lateral motion of the laser spot shall be minimized by some form of stabilization.



Key

1 test shaft
2 laser beam
D diameter

Figure 3 — Laser beam firing angle

10.2.2 Verify that the following standardised test parameters are correct during performance of the test:

a) exact positioning of the laser beam;

b) oxygen concentration: (98 ± 2) %;

c) temperature: (20 ± 3) °C;

d) oxygen flow rate: 1 l/min;

e) laser beam diameter d_{95}: 0,5 mm ± 10 %;

f) mode of laser operation: continuous wave.

10.2.3 Starting with a power of 2 W, apply the laser beam to the test specimen for a specified duration of 1 s up to 10 s maximum, using the continuous wave mode of laser operation. Stop the laser beam if ignition, or damage (i.e. melting, perforation, leakage, etc.) occurs or if there is difficulty with the test apparatus. These data shall be reported in addition to the data collected at 10 s.

10.2.4 Increase the laser power in reasonable steps. Repeat the application of the laser beam for each new power level or until ignition or damage occurs as described in 10.2.3. This shall necessitate either the use of a new specimen or, if the construction of the shaft is identical around the whole circumference, rotation of the specimen (at a cool, clean undamaged area) for each new power level to determine the maximum power setting at which ignition or damage did not occur. Once the maximum power setting has been determined, verify the maximum power setting by beginning the testing procedure with the five specimens according to 8.2.

10.3 Cuff

10.3.1 The laser shall be positioned so that:

— the laser beam is applied at a 10° angle (denoted as β in Figure 2) to the cuff symmetry axis and is focused on the connecting area between the cuff and the shaft.