American National Standard/
American Dental Association
Specification No. 63

Root Canal Barbed Broaches and Rasps

American Dental Association
Council on Scientific Affairs 2006

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 63 FOR ROOT CANAL BARBED BROACHES AND RASPS

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 63 for Root Canal Barbed Broaches and Rasps. This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products (formerly Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment). The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the specifications, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. The American National Standards Institute granted approval of ADA Specification No. 63 as an American National Standard on November 29, 2006.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: Frank Lentine (chairman), Lentine Enterprises, Ltd., Taylor, MI; Gerald Glickman, Baylor College of Dentistry, Dallas, TX; Lonnie Graybill, Miltex Instrument Co., York, PA; John Ingle, American Association of Endodontists, San Diego, CA; Nick Lenz, Endodent, Inc., Duarte, CA; Neill Luebke, Brookfield, WI; Spiro Megremis, American Dental Association, Chicago, IL; Robert Postal, Medidentia, Woodside, NY; Michael Sobotka, Charles B. Schwed Co., Key Gardens, NY; and Timothy Svec, The University of Texas, Houston, TX.

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FOREWORD

(This foreword does not form a part of ANSI/ADA Specification No. 63 for Root Canal Barbed Broaches and Rasps).

This revision to ANSI /ADA Specification No. 63 eliminates the referencing of specific materials for compliance with the requirement that the selected material allow the instruments to meet the requirements of this specification. The revision requires that an appropriate material be utilized that allows for adherence to the requirements of this specification.

The other significant change was removal of the Boiling Water test for corrosion. The Autoclave test was determined to be sufficient to test the effects of water. Minor editorial corrections are included.

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1 SCOPE AND CLASSIFICATION

1.1 Scope

This specification is for root canal instruments for hand use utilized in endodontic preparation.

1.2 Type

The instruments covered by this specification shall be of the following types and shall be made from an appropriate material which allows for adherence to the requirements of this specification.

I. Barbed Broach;

II. Rasp.

2 APPLICABLE SPECIFICATIONS AND REGULATIONS

2.1 Specifications

ANSI/ADA Specification No. 28-2002 for Root Canal Files and Reamers Type K for Hand Use & Addendum.

(ANSI/ADA standards may be purchased from the American Dental Association, Dept. of Standards Administration, 211 E. Chicago Ave., Chicago, IL 60611).

IEEE/ASTM SI 10-2002 for Use of the International System of Units (SI): The Modern Metric System.

(IEEE Standards are available from IEEE, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855).

ASTM B16/B16M-05 Standard Specification for Free-Cutting Brass Rod, Bar and Shapes for Use in Screw Machines.

(ASTM Standards are available from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428).

ISO 3630-1:1992, Dental root canal instruments-Part 1: Files, reamers, barbed broaches, rasps, paste carriers, explorers and cotton broaches.

(ISO dentistry standards may be purchased from the American Dental Association, Dept. of Standards Administration, 211 E. Chicago Ave., Chicago, IL 60611).

2.2 Regulations

Quality Systems requirements (QSR) issued by the Food and Drug Administration.

(Available from http://www.fda.gov/cdrh/qsr/contnt.html).

3 REQUIREMENTS

3.1 Dimensions

3.1.1 Length

The length of the instrument, as measured from the tip to the junction with the handle, shall be nominal length with a

tolerance of ± 0.5 mm when tested as specified in 5.2.2.1.

3.1.2 Core Diameter

The diameters and tolerances for the tapered core section of the instrument designated as C_3 and $C_{10.5}$ for all sizes and types shall be as shown in Table 1, Table 2 and Figure 1, when tested as specified in 5.2.2.2.

3.1.3 Barbed Dimensions

3.1.3.1 Barb location

The barb locations are such that the first barb shall be no greater than 1.0 mm from the tip and the last barb shall be no less than 9.0 mm from the tip when tested as specified in 5.2.2.3.

3.1.3.2 Barb height

The barb height is referenced for information and is tested as specified in 5.2.2.4.

3.1.3.3 Number of Barbs

The minimum number of barbs in the working length shall be 36 for Type I and 50 for Type II when tested as specified in 5.2.2.5.

3.1.4 Tip

The tip length of the instrument shall be no greater than the distance to the first barb when tested as specified in 5.2.2.6. Shape of the tip is optional.

3.2 Handles

Handle, when affixed to the shaft, shall be fabricated of material of a quality suitable to withstand normal operative procedures. Operative end shall be securely and permanently affixed in the handle when tested as specified in 5.3.2.2 and 5.3.2.3. Handles shall be able to be autoclaved and dry heat sterilized without losing the shape of the handle or without bleaching out the color when tested as specified in 5.3.2.1.

3.3 Resistance to Fracture by Twisting

The maximum torsion strength before failure and the angular deflection at failure of each size Type I shall not be less than that give in Table 3 and of each size Type II shall not be less than that given in Table 4 when tested as specified in 5.4.

3.4 Stiffness

The stiffness of all instruments shall not be greater than that given in Table 5 for each size of Type I and in Table 6 for each size of rasp when tested as specified in 5.5.

3.5 Resistance to Corrosion

The stainless steel instruments shall not show evidence of corrosion of their surface when subjected to the corrosion test as described in 5.6.

3.6 Color Coding

When individual instruments or instrument packages are color-coded, the color coding for the respective nominal sizes shall be as shown in Table 7.

3.7 Heat Effects of Sterilization

Following one cycle of sterilization by autoclave and dry heat, the instruments shall comply with requirements specified in 3.2, 3.3 and 3.4 when treated as specified in 5.3.2.1.

3.8 Compliance

For dimensions tested by the method described in 5, more than 90% of the tested samples shall comply with the provisions of 3.1. The sampling plan is as follows.

3.8.1 Compliance Criteria

If all 10 instruments pass, product passed. If 8 or less instruments pass, product fails. If 9 instruments pass, test 5 additional instruments. When 5 additional instruments must be tested, all 5 must pass.

4 SAMPLING AND INSPECTION

4.1 Sampling

Not less than fifty (50) instruments of each nominal size and type to be tested shall be procured to determine compliance with this specification. See Table 8 for distribution of testing samples.

4.2 Inspection

Visual inspection, without magnification, shall be used in establishing that the samples selected are free from corrosion.

5 TEST EQUIPMENT, PROCEDURES AND COMPLIANCE

5.1 Test Conditions

Equipment and material shall be conditioned at 20° ± 5°C for a period of at least ten (10) hours prior to testing.

5.2 Dimensions

The dimensions of ten (10) instruments of each size and type shall be determined as follows:

5.2.1 Equipment

The diameters, heights, number of barbs, tapers, lengths and tips of each point shall be measured using a shadowgraph, optical comparator, measuring microscope, or other suitable device capable of measuring with the accuracy of ± 0.002 mm or ± 1 degree.

5.2.2 Procedure

5.2.2.1 Length

Using a millimeter scale of sufficient accuracy, position the instrument to measure the full length from the tip to the junction of the handle. These same instruments should be used for 5.6.

5.2.2.2 Core Diameter

If present, remove the handles with a suitable wire cutter at the point where the handle is attached to the instrument. These same instruments are used for 5.2.2.3 through 5.2.2.6. The instrument to be measured shall be inserted into a suitable holder for the shank. Measure C_3 and $C_{10.5}$.

5.2.2.3 Barb Location

Use the same set-up as described in 5.2.2.2. Rotate the instrument to locate and position the full view of the barb closest to the tip. Measure the distance from the tip to the base of that first barb. Rotate the instrument further to locate and position the full view of the barb most distant from the tip. Measure the distance from the tip to the extended edge of the last barb.

5.2.2.4 Barb Height

Use the same set-up as described in 5.2.2.2. Rotate the instrument to locate the barb nearest the point of 3 mm from the tip. Measure the vertical distance from the barb base to the extended edge. Barb height is a referenced dimension. This procedure is intended as information only.

5.2.2.5 Number of Barbs

Use the same set-up as described in 5.2.2.2. Rotating the instrument, count the number of barbs from the tip to the end of the working length.

5.2.2.6 Tip

Use the same set-up as described in 5.2.2.2. Rotate the instrument to locate the first barb. Visually determine the point at which the tip and shank core meet.

5.3 Handles

The retention of the handle to the instrument after sterilization shall be determined as follows. See 5.3.2.1.

5.3.1 Equipment

A Steam autoclave;

B Dry heat sterilizer.

For the pull test use a stationary collar for knob support, a Jacobs chuck or any other suitable chucking device to grasp operative end of the instrument, and a maximum load. See Figure 2 for suggested test fixture. For the twist test use equipment described under 5.5.1 and mounted as described in 5.3.2.3.

5.3.2 Procedure

Ten (10) instruments of each size and type shall be tested for handle pull strength and ten (10) instruments of each size and type shall be tested for handle twist strength.

5.3.2.1 Sterilization

A set of each type and thirty (30) of each size shall be autoclaved under pressure of 0.22 mNm^{-2} at 136° ± 2°C for twenty (20) minutes and dry heat sterilized at 180° ± 5°C for thirty (30) minutes at the set temperature. Ten (10) of these instruments shall be saved for 5.4.2 and 5.5.2

5.3.2.2 Pull Strength

Measure and record length of operative portion. Insert instrument through collar. Attach chucking device to grasp operative end leaving 3 mm of the shank exposed. Add axial mass of 2.25 kg. Measure and record the length of the operative portion. There shall be no difference in length from those previously recorded.

5.3.2.3 Twist Strength

Mount the handle into the chucking device of the torque meter. The chuck must grip the handle along the section that

does not include the inserted instrument shank. Insert the operative portion of the instrument leaving 3 mm of the shank exposed. Rotate the torque meter until the instrument slips within the handle or until the minimum torque is obtained. Record torque reading obtained when slippage occurs or note “pass” if the minimum torque is reached without failure. It should be noted that for shank diameters up to 0.60 mm, the shank may twist before slippage within the handle.

5.3.3 Compliance

5.3.3.1 Heat Effects of Sterilization

The handles, upon visual examination, without magnification, shall meet the requirements of 3.2.

5.3.3.2 Handle Retention

The tested instruments shall have no axial movement from the handle when pulled with a minimum mass of 2.25 kg. The tested instruments shall not twist within the handle when torque recorded is less than 35.3 mNm.

5.4 Resistance to Fracture by Twisting

A sample of ten (10) instruments of each size and type of which five (5) sterilized and five (5) unsterilized, shall be tested for resistance to fracture by twisting.

5.4.1 Equipment

The testing equipment shall be capable of measuring the torque with an accuracy of ± 0.10 mNm and the angular deflection with an accuracy of $\pm 2^{0}$. The equipment described below shall be used for compliance testing and is presented as the preferred type of equipment for all purposes. The equipment as shown in Figure 3 shall consist of a reversible geared motor revolving at a speed of 2 RPM which drives a test instrument by means of a separate hardened steel chuck. It should also consist of a torque measuring device fixed on two linear ball bearings.

Mounted to the shaft of the device should be a chuck with jaws made of brass (70 % copper-30 % zinc) used to clamp the test instrument at the tip along a length of 3 mm. The chuck is shown in Figure 4. A separate amplifier and digital display controls the operation of the motor and records the torque and angular deflection. The circuitry of the amplifier should be able to retain for display, the maximum torque and the angular deflection at the failure point. A strip chart recorder is recommended to aid in the recording process.

5.4.2 Procedure

Calibrate the device for the torque range of the instrument size to be tested. The instrument shall have its handle removed with a suitable wire cutter at the point at which the handle is attached to the instrument shaft. Set the instrument shank into the driving chuck leaving a maximum of 1 mm of the shank outside of the chuck. Tighten the chuck. Slowly slide the torque device along the linear ball bearing until the tip of the instrument enters 3 mm in the brass jaws. Check to make sure that the instrument is straight and centered into the jaws. Tighten the chuck.

Since clamping will probably induce a pre-stress on the instrument, the gear motor must be activated in steps until the torque digital display or the strip chart recorder shows a reading of zero. After ensuring that the geared motor is set for clockwise rotation as viewed from the instrument shank end, activate the device. The test device will cease operation when the instrument fails. The maximum torque and angular deflection at failure shall be recorded for each instrument tested.

5.4.3 Compliance

The minimum torque and angular deflection allowable for the various types and sizes is given in Table 3 and 4.

5.5 Stiffness

A sample of ten (10) instruments, five (5) sterilized and five (5) unsterilized, of each size and type shall be tested for stiffness.

5.5.1 Equipment

The equipment as described in 5.3.1 shall be used with the modification of the clamping jaws and the bending device of catch pin as shown in Figure 5. The amplifier of the device must be capable of obtaining a preselected angular deflection (45^{0}) at which point the test stops. The testing equipment shall be capable of measuring with an accuracy of ± 0.10 mNm.

5.5.2 Procedure

Calibrate the device for the torque range of the instrument size to be tested. The instrument to be tested shall have its handle removed with a suitable wire cutter at the point at which the handle is attached to the instrument shaft. Set the device to stop the angular deflection at 45^{0}. Place the chuck onto the shaft of the torque meter device. Set the tip of the instrument into the jaws of the chuck perpendicular to the axis of the motor. When the tip enters 3 mm into the brass jaws, tighten the chuck. Mount the catch pin onto the gear motor shaft. Slide the torque device along the linear ball bearing until the instrument is located above the rotating pin. Adjust the catch pin until it lightly touches the instrument by incrementally rotating the gear motor in the proper direction. The torque reading must show zero. Activate the test device. The test will automatically cease when the angular deflection has reach 45^{0}. The torque at 45^{0} shall be recorded for each instrument tested.

5.5.3 Compliance

The bending moment at an angular deflection of 45° shall not be greater than those values given in Table 5 for Type I and in Table 6 for Type II. Test results comparing sterilized and not sterilized instruments shall not show any significant difference in values.

5.6 Corrosion Tests

Ten (10) instruments shall be tested for corrosion resistance by autoclave method.

5.6.1 Equipment

Autoclave of the non-vacuum type capable of being operated at 136 ± 2°C and 0.22 ± 0.02 mNm^{-2} .
Distilled or deionized water.

5.6.2 Preparation

Scrub the instrument using soap and warm water. Rinse thoroughly in distilled or deionized water and dry.

5.6.3 Procedure

Place the instrument, unwrapped, in the tray of the autoclave. Use fresh distilled or deionized water and steam autoclave for a twenty (20) minute cycle. Upon completion, open the door, remove the tray and allow the instruments to cool to room temperature. Repeat the cycle four times for a total of five cycles.

6 PREPARATION FOR DELIVERY

6.1 Packaging

The instruments shall be prepared and packaged in accordance with the Quality Systems Requirements (QSR) regulations of the Food and Drug Administration.

6.2 Marking

The container shall be clearly marked with or contain the following Information.

A Type of instruments and product identification;

B Length of operative end;

C Nominal size of instruments (The first digit “0" may he omitted for sizes less than 100);

D Name of manufacturer or distributor;

E Packaging date (coded or in clear), expressed (if applicable) in accordance with ISO 8601;

F Number of instruments in unit package;

G Material of the operative end:

H Whether the instruments are sterile;

I When the package is marked sterile, the wording: “Sterility is not guaranteed after opening of the package", or equivalent shall be present.

Table 1. Barbed Broach (Type 1) Dimensions (mm).

Nominal size	Tip	C_3	$C_{10.5}$	Barb Height (Ref.)	Tolerance (±)
020	.12	.15	.22	.075	.02
025	.14	.17	.24	.085	.02
030	.16	.19	.26	.095	.02
035	.18	.21	.28	.105	.03
040	.21	.24	.31	.120	.03
050	.25	.28	.35	.140	.04
060	.29	.32	.39	.160	.04

Table 2. Rasp (Type II) Dimensions) (mm).

Nominal Size	Tip + 0.02, - 0	C_3 + 0.03, - 0	$C_{10.5}$ + 0.03, - 0	Barb Height (Ref.)	Color
025	0.15	0.20	0.31	0.05	White
030	0.18	0.23	0.34	0.06	Yellow
035	0.21	0.26	0.37	0.07	Red
040	0.24	0.29	0.40	0.08	Blue
045	0.27	0.32	0.43	0.09	Green
050	0.30	0.35	0.46	0.10	Black

Table 3. Barbed Broach (Type I) – Twist Torque and Angular Deflection.

Nominal Size	Minimum Values for Clockwise Rotation	
	Torque (mNm)	Angular Deflection
020	0.49	90°
025	0.59	90°
030	0.76	90°
035	0.98	90°
040	1.18	90°
050	1.96	90°
060	3.43	90°

Table 4. Rasps (Type II) – Twist Torque and Angular Deflection.

Size	Minimum Value for Clockwise Rotation	
	Torque (mNm)	Angular Deflection
025	0.76	90°
030	0.98	90°
035	1.18	90°
040	1.96	90°
045	2.55	90°
050	3.43	90°

Table 5. Stiffness (Bending Moment) Barbed Broach (Type I).
(Maximum Values at 45°)

ISO Size	Bending Torque (mNm)
020	2.45
025	2.94
030	3.93
035	4.91
040	7.85
050	11.78
060	16.68

Table 6. Stiffness (Bending Moment) Rasps (Type II).
(Maximum Values At 45°)

Size	Bending Torque (mNm)
025	4.91
030	6.87
035	8.83
040	13.74
045	16.68
050	20.61

Table 7. Color Coding.

Nominal Size	Color	Abbreviation
020	Purple	PUR
025	White	WH
030	Yellow	YEL
035	Red	RED
040	Blue	BLUE
045/050	Green	GRN
050/060	Black	BLK

Notes to Table 7:

Type 1:

size 045 - Green

size 050 - Black

Type 2:

size 050 - Green

size 060 - Black

Table 8. Test Sample Distribution.

(50 Samples of Each Size and Type)

Requirement	Test Procedure		
	Group Of 20		Group Of 30
	10 Samples	10 Samples	
3.1 Dimensions	5.2.2.1.	5.2.2.2	
		5.2.2.3	
		5.2.2.4	
		5.2.2.5	
3.2 Handles			5.3.2.1
			5.3.2.2 (10 Only)
			5.3.2.3 (10 Only)
3.3 Twist		5.4.2. (5 Only)	5.4.2. (5 Only)
3.4 Stiffness		5.5.2. (5 Only)	5.5.2. (5 Only)
3.5 Corrosion	5.6.1		

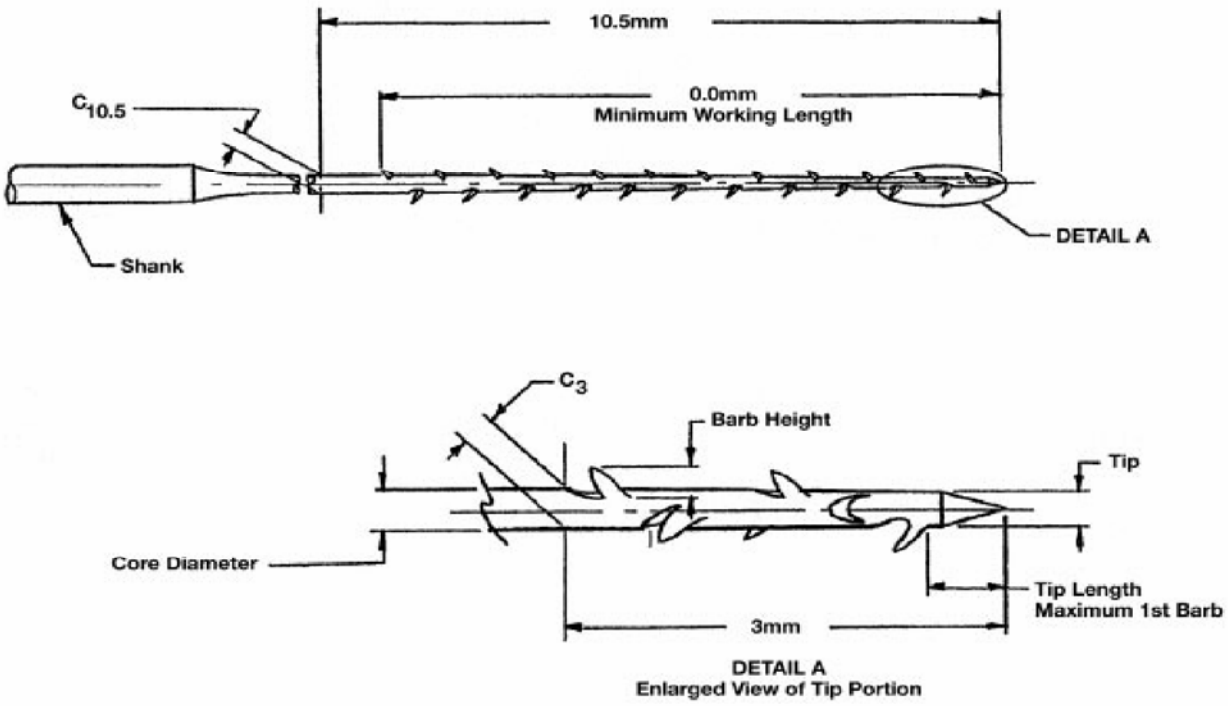

Figure 1. Dimensions

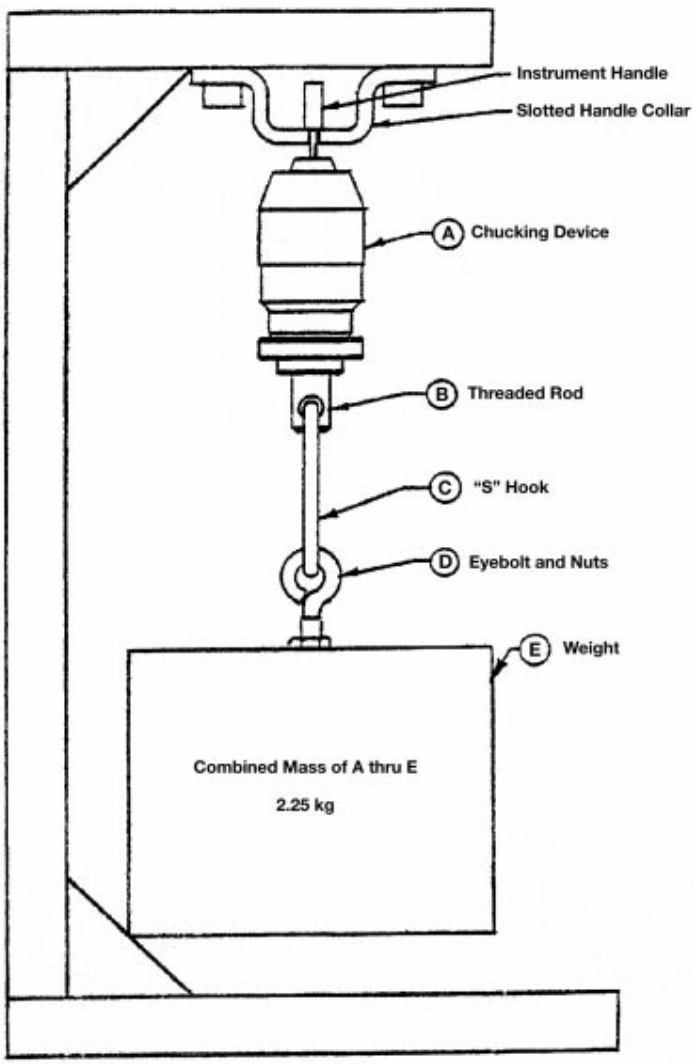

Figure 2. Handle Pull Strength Fixture

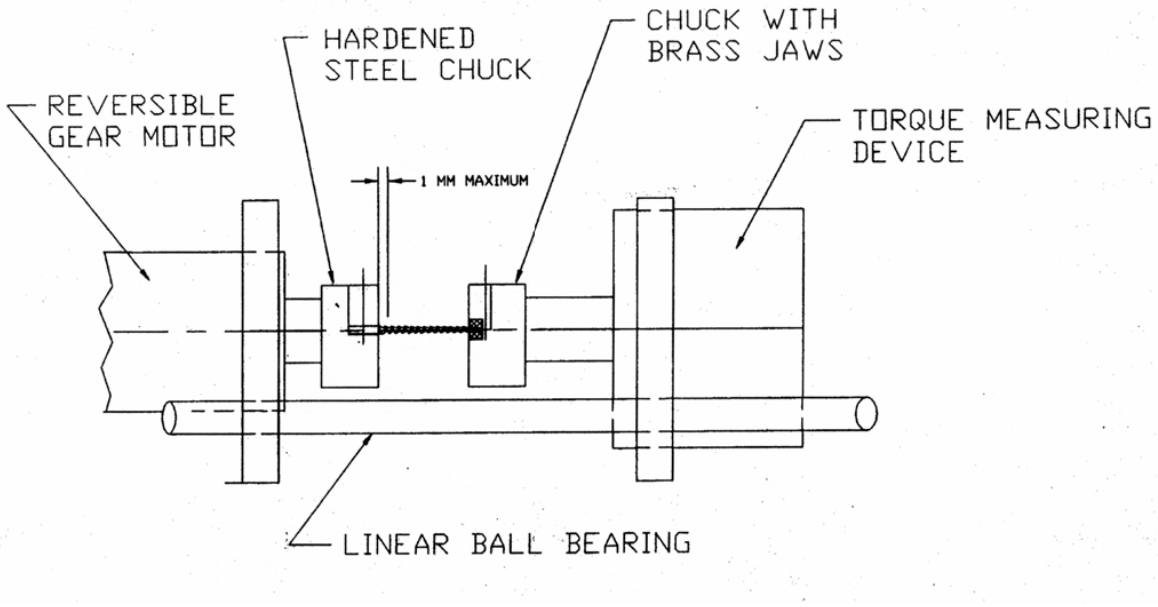

Figure 3. Test Equipment for Twist Testing

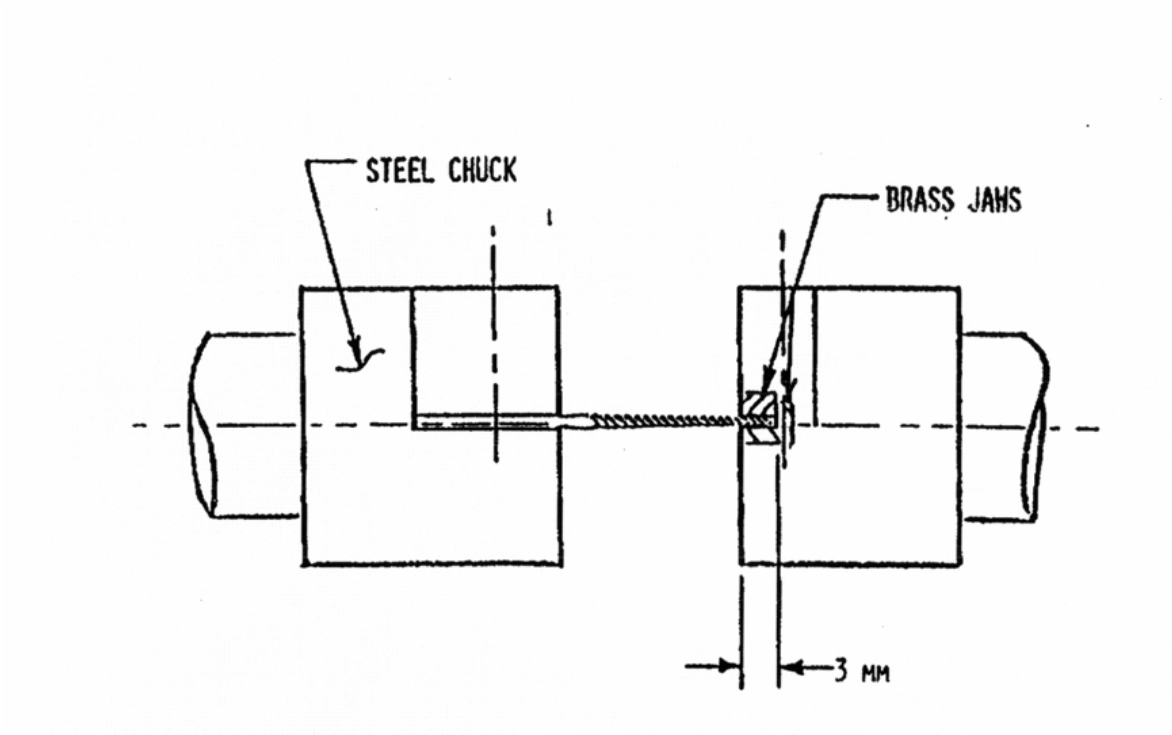

Figure 4. Twist Test Chuck Detail

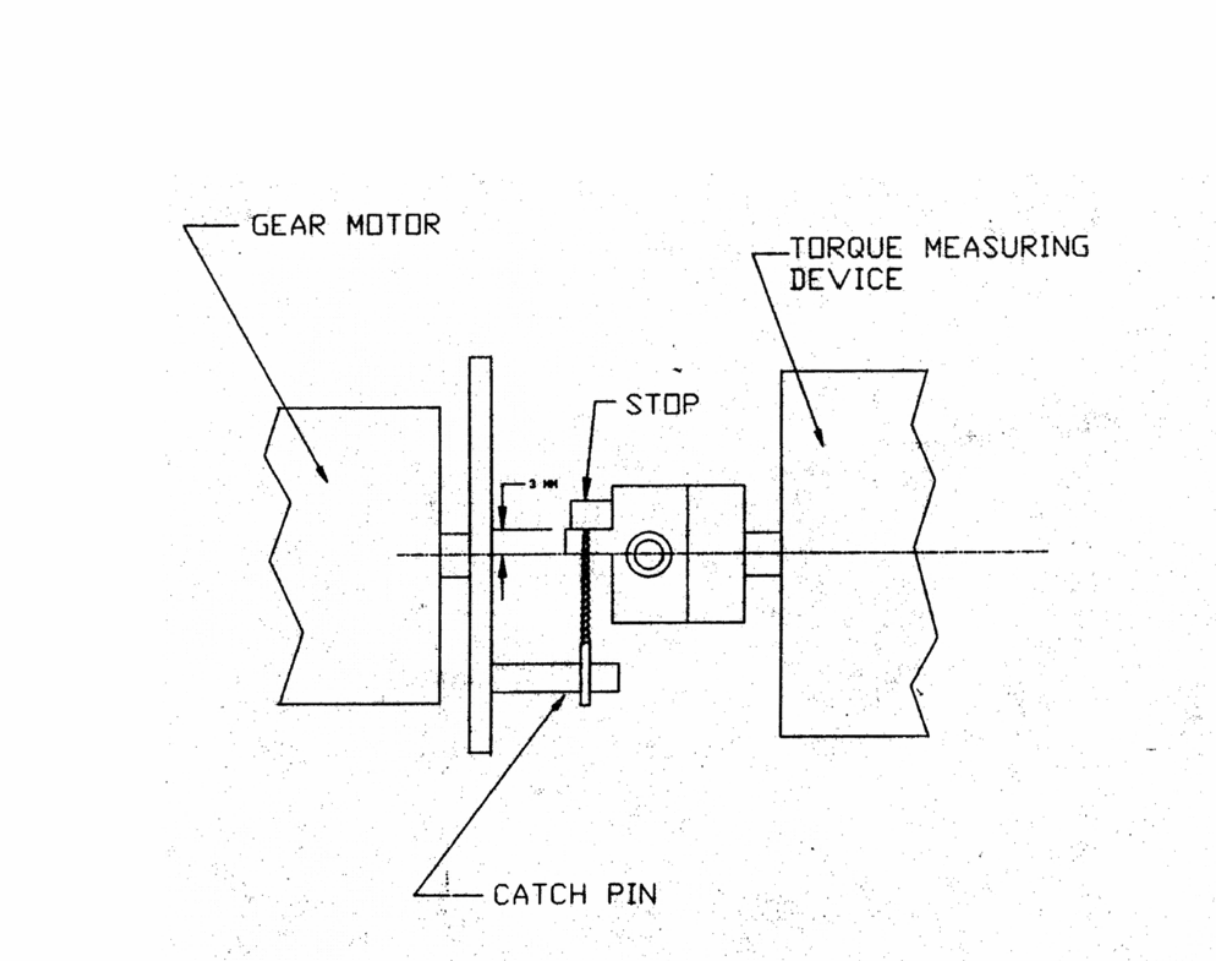

Figure 5. Bending Test Fixture

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