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1 SCOPE AND PURPOSE

- 1.1 This method describes a procedure for testing pacifiers and similar products described in item 27 of Part II of Schedule I to the Hazardous Products Act (HPA) to determine if they meet the applicable requirements set out in the Hazardous Products (Pacifiers) Regulations. Specifically, the method is intended to verify that a pacifier or similar product is designed and constructed in such a manner as to protect the user, under reasonably foreseeable conditions, from obstruction of the pharyngeal orifice, strangulation, ingestion or aspiration of the product or any part or component thereof, or wounding. Since the numerical values of performance measures are based upon regulatory requirements, the tolerances for these values have been chosen such that no test parameter is applied to the product that results in a more severe condition than that specified in the regulation.

2 APPLICABLE DOCUMENTS


- 2.1 The Hazardous Products Act (HPA).
- 2.2 HPA, Hazardous Products (Pacifiers) Regulations (C.930) hereinafter referred to as the Regulations.
- 2.3 PSL Project Report 2001: 0639 New Method: TEST PROCEDURE FOR PACIFIERS AND OTHER SIMILAR CONSUMER PRODUCTS.
- 2.4 General Guidelines for Evaluating and Expressing the Uncertainty of Accredited Laboratories' Measurement Results, CLAS Reference Document 5, May 1999.

3 SAMPLING

- 3.1 The following test procedure should be conducted on 10 sample elements.

4 APPARATUS

- 4.1 38 mm (± 0.1 mm) diameter disk with a plane face.
- 4.2 Clamp suitable for grasping and holding the nipple of the pacifier.
- 4.3 Clamp suitable for grasping and holding the pacifier handle.
- 4.4 Clamp suitable for grasping and holding the pacifier guard or shield.
- 4.5 Force adjustable nipple clamp, as illustrated in Figure 10.
- 4.6 Force gauge with a precision of 0.1 N.
- 4.7 Hotplate or suitable heating element.
- 4.8 Marker, water resistant ink.
- 4.9 Metric measuring device with a precision of 1 mm.
- 4.10 Guard template, as illustrated in Figure 1.


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- 4.11 Stainless steel container, minimum 3 L.
- 4.12 Stop watch with a precision of 0.1 sec.
- 4.13 Test stand to attach clamps.
- 4.14 A mass, which when added to the mass of the clamp, will lie within $0.980 \text{ kg} \pm 0.015 \text{ kg}$.
- 4.15 A mass, which when added to the mass of the clamp, will lie within $4.54 \text{ kg} \pm 0.10 \text{ kg}$.
- 4.16 Truncated Right Circular Cylinder (Small Parts Cylinder), as illustrated in Figure 2.
- 4.17 Wire mesh or steamer-type retaining basket.
- 4.18 Thermometer with a precision of 1°C .

5 TESTING PROCEDURE

- 5.1 Note and record if the product meet the requirements in 4(1) and 4(2) of the regulations.
- 5.2 Label each sample element with an identifying mark (for later use as a test orientation reference point) using a water resistant ink marker. Refer to Figure 6.
- 5.3 Note and record whether any ring or handle of the pacifier is hinged, collapsible or flexible, or if the handle is a knob-type that isn't hinged, collapsible or flexible.
- 5.4 Note and record whether there is a loop of cord or other material attached to the pacifier. If any such attachment is present, measure and record the circumference of the item to the nearest 1 mm.
- 5.5 **Protrusion Test:**(Note 1)
 - 5.5.1 Secure the pacifier, with the axis of the nipple horizontal or vertical, such that the guard or shield is held fixed. Any hinged handle or ring shall have its hinge axis horizontal and shall be allowed to rotate under the influence of its own weight.
 - 5.5.2 Attach a 38 mm diameter disk with a plane face to a force gauge so that the axis of the force gauge passes through the centre of the disk and the plane face is normal to this axis. Align the axis of the force gauge with that of the pacifier (axis of the nipple) and move the plane face of the disk towards the protrusion on the pacifier (Figure 9 shows a horizontal orientation). Allow any flexible component to buckle or bend and continue the motion towards the guard or shield until the force gauge indicates 8.9 N ($8.9 \text{ N} \pm 0.1 \text{ N}$). A pacifier which has a ring, handle or other protrusion which is fabricated from a nonrigid material, but which does not deflect under the influence of its own weight, may be manually deflected as the plane face is brought towards it, if by doing so, its

Note 1: This Protrusion Test is applicable to pacifiers that have a handle, including a knob-like handle, that is not hinged, collapsible or flexible. The Protrusion Test is taken from the United States Code of Federal Regulations, Title 16 Part 1511.4. The requirements for protrusion will be revised to eventually include all designs of pacifiers.

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resistance to deflection is not greater than the resistance it would offer if it wasn't deflected.

5.5.3 While maintaining the 8.9 N (8.9 N ± 0.1 N) load, measure the protrusion distance from the plane face of the disk to the face of the shield at the base of the nipple as illustrated by Figure 9.

5.5.4 Repeat steps 5.5.1 through 5.5.3 with the remaining sample elements.

5.5.5 Results

5.5.5.1 Record the protrusion distance for each sample element tested.

5.6 Nipple tear:

5.6.1 If, at any time during the following tests of 5.7 and 5.8, a tear or break visibly appears on the nipple around the immediate vicinity of the clamp, cease testing. The tests of 5.7 and 5.8 must be repeated in their entirety using the clamp described in Figure 10 on 10 pristine sample elements of the same sample. Using this clamp and one or two or as many extra pristine sample elements are necessary, determine the minimum applied clamping force at which slippage between the clamp and nipple does not occur. Record this force. Increase this clamping force by 25% and apply it to the nipples, as required, of 10 pristine sample elements of the same sample in performing tests 5.7 and 5.8.

5.7 Guard Test:

5.7.1 Place the pacifier in the guard template, illustrated in Figure 1, with the nipple of the pacifier centered in the opening of the template (see *Note 2 and Figure 3*). Attach the nipple clamp to the nipple. Gradually apply a mass (0.980 kg ± 0.015 kg including the mass of the clamp) to the nipple clamp within 2 seconds and allow the load to hang freely for 10 seconds (±1 sec). See Figure 4.


5.7.2 Note whether the guard or shield passed through the opening in the template.

5.7.3 Repeat steps 5.7.1 and 5.7.2 with the remaining sample elements.

5.7.4 Results

5.7.4.1 Record whether the guard or shield of any pacifier passed through the opening in the template.

Note 2: For pacifiers with non-circular mouth guards or shields, place the pacifier on the template with the nipple of the pacifier centered in the opening of the template with the major axis of the mouth guard or shield aligned with the major axis of the opening in the template, as illustrated in Figure 3.


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5.8 Structural Integrity Test:

Note: Perform the following three structural integrity tests (5.8.1 - 5.8.3) consecutively on the same sample element prior to testing the next sample element. Doing so reduces the stress incurred by the nipple from the frequent clamping and unclamping action of the test equipment.

- 5.8.1 Attach a nipple clamp to the nipple of the pacifier and affix the clamp to the test stand. Gradually apply a mass ($4.54 \text{ kg} \pm 0.10 \text{ kg}$ including the mass of the clamp) to the handle of the pacifier over a period of 10 seconds ($\pm 2 \text{ sec}$) such that the load is applied axially to the nipple. Allow the load to hang freely for 10 seconds ($\pm 0.5 \text{ sec}$). See Figure 5. Observe any damage or separation of parts or components. Store the components that have separated for further evaluation in step 5.8.6. Discontinue testing (only for the specific sample element under test) if the nipple or handle has detached.
- 5.8.2 Clamp the guard or shield of the pacifier on the test stand in a fixed position using the test orientation guide shown in Figure 6, and attach a mass ($4.54 \text{ kg} \pm 0.10 \text{ kg}$ including the mass of the clamp) to the handle of the pacifier (*Note 3*). Gradually apply the load over a period of 10 seconds ($\pm 2 \text{ sec}$) such that the load is applied at right angles to the axis of the nipple. Allow the load to hang freely for 10 seconds ($\pm 0.5 \text{ sec}$). See Figure 7. Observe any damage or separation of parts or components. Store the components that have separated for further evaluation in step 5.8.6. Discontinue testing (only for the specific sample element under test) if the handle has detached.
- 5.8.3 Clamp the guard or shield of the pacifier on the test stand in a fixed position using the same guard orientation as that used in step 5.8.2. Attach a clamp to the nipple of the pacifier. Gradually apply a mass ($4.54 \text{ kg} \pm 0.10 \text{ kg}$ including the mass of the clamp) to the nipple clamp over a period of 10 seconds ($\pm 2 \text{ sec}$) such that the load is applied at right angles to the axis of the nipple. Allow the load to hang freely for 10 seconds ($\pm 0.5 \text{ sec}$). See Figure 8. Observe any damage or separation of parts or components. Store the components that have separated for further evaluation in step 5.8.6. Discontinue testing (only for the specific sample element under test) if the nipple has detached.
- 5.8.4 Place all sample elements in a wire mesh or steamer-type retaining basket and immerse the basket in boiling water for 10 ± 0.5 minutes. Remove the pacifiers from the boiling water and allow to cool in air at $20 \pm 3^\circ\text{C}$ for 15 minutes ± 0.5 minutes. Repeat steps 5.8.1 through 5.8.3.

Note 3: If the 4.5 kg load cannot be attached to the handle, then a suitable clamp should be used, provided that the test weight and the clamp do not exceed $4.5 \text{ kg} \pm 0.1 \text{ kg}$ in weight and do not alter the structural integrity of the handle.

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5.8.5 Repeat the entire procedure described in step 5.8.4 an additional nine times (*Note 4*).

5.8.6 Observe whether any part or component that has separated or broken free from the pacifier can be totally enclosed, in a non-compressed state, into the truncated right circular cylinder.

5.8.7 Results

5.8.7.1 Record the details of any damage to each sample element including reference to the exact stage of testing (test and boil number).

6 QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES

6.1 Ensure that all measuring instruments are functional and are calibrated with traceability to national or international standards.


6.2 Testing and the results obtained according to this method include uncertainty associated with the:

(i) uncertainty of any or all calibrations by an accredited calibration laboratory of the apparatus stated and used in this method,

(ii) standard uncertainty or standard deviation of a series of repeated measurements of masses or with instruments stated and used in this method (documented in the Equipment Record binder),

(iii) a coverage factor ($k = 2$) to express an expanded uncertainty ($U = ku_c$, where u_c is the combined standard uncertainty) for a level of confidence of approximately 95%, assuming normal distribution (Reference: General Guidelines for Evaluating and Expressing the Uncertainty of Accredited Laboratories' Measurement Results, CLAS Reference Document 5, May 1999).


Note 4: In proceeding with steps 5.8.2 and 5.8.3 after each boil/cool cycle, rotate the pacifier's guard or shield 90 degrees clockwise about the axis of the nipple, as shown in Figure 6, prior to clamping the guard or shield in a fixed position.

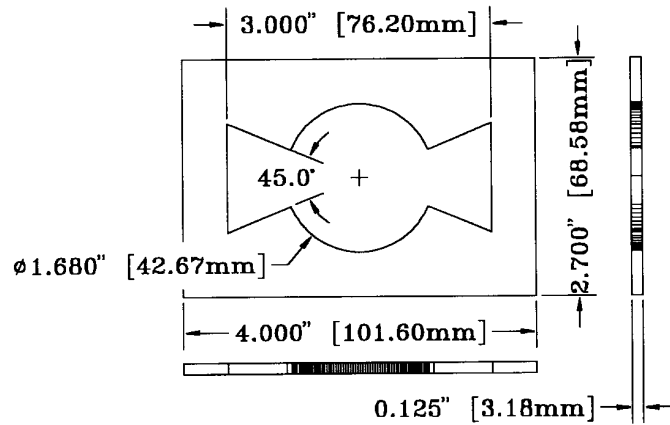
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7 TEST REPORT

7.1 The test report should contain the following information:

- 7.1.1 A description of the product to include, brand, style, country of origin, photo and UPC.
- 7.1.2 The number of sample elements tested.
- 7.1.3 The results of the tests (conducted in the sequence presented in section 5 of this test method) with specific details for any non-compliances or potential problems observed.
- 7.1.4 If required, the minimum applied clamping force as per 5.6.1 at which slippage does not occur, and it's value increased by 25%.
- 7.1.5 The analyst's name and signature as well as the name(s) and signature(s) of the reviewer(s).

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NOTE:

1. Radius of all edges of opening to be 0.030 inches/0.762 mm
2. Material to be Aluminum Plate
3. Dimensional Tolerance ± 0.005 inches/0.127 mm

FIGURE 1. GUARD TEMPLATE

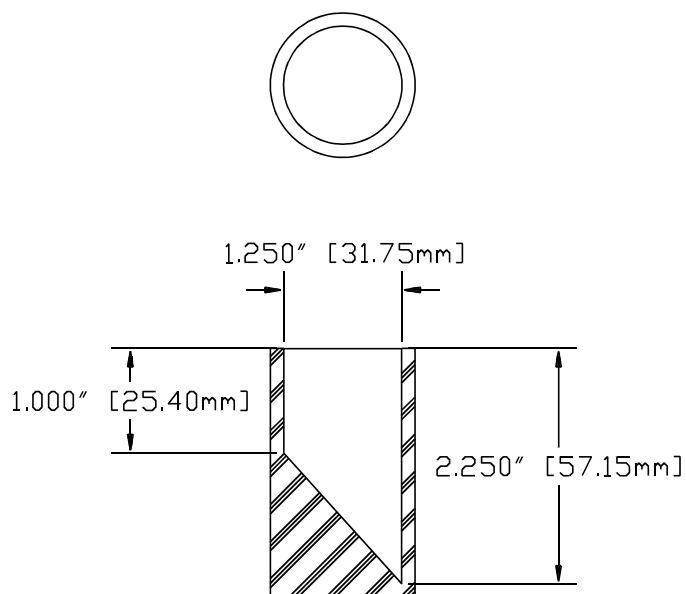



FIGURE 2. TRUNCATED RIGHT CIRCULAR CYLINDER

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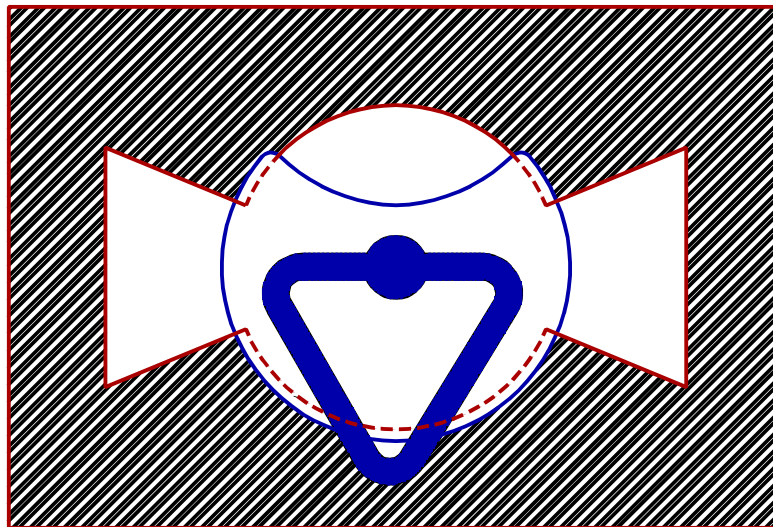


FIGURE 3. PACIFIER ON GUARD TEMPLATE (procedure 5.7.1, Note 2)

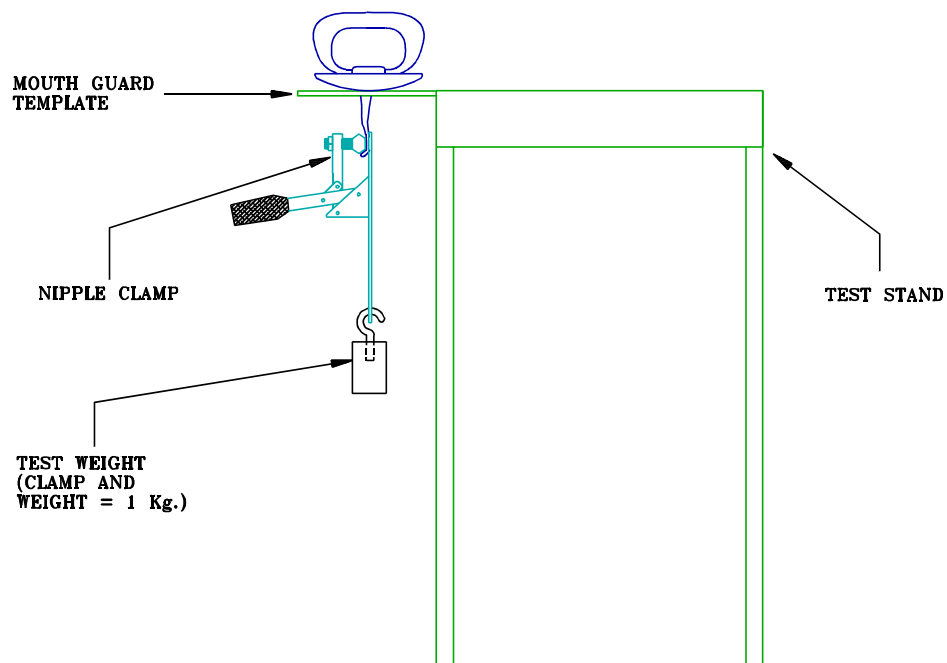



FIGURE 4. GUARD TEST

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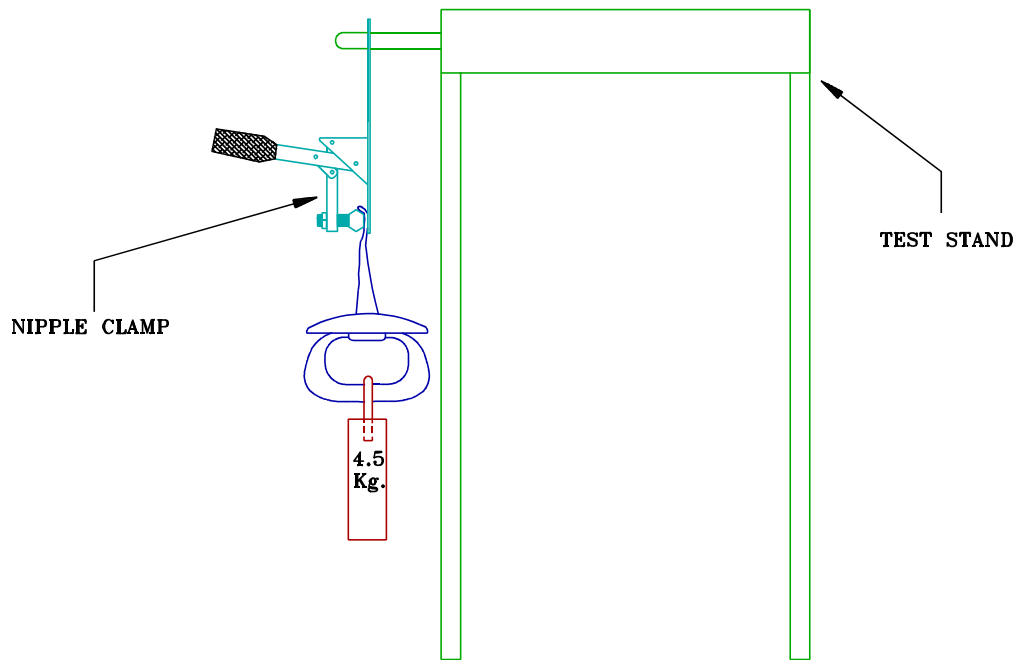


FIGURE 5. STRUCTURAL INTEGRITY TEST (procedure 5.8.1)

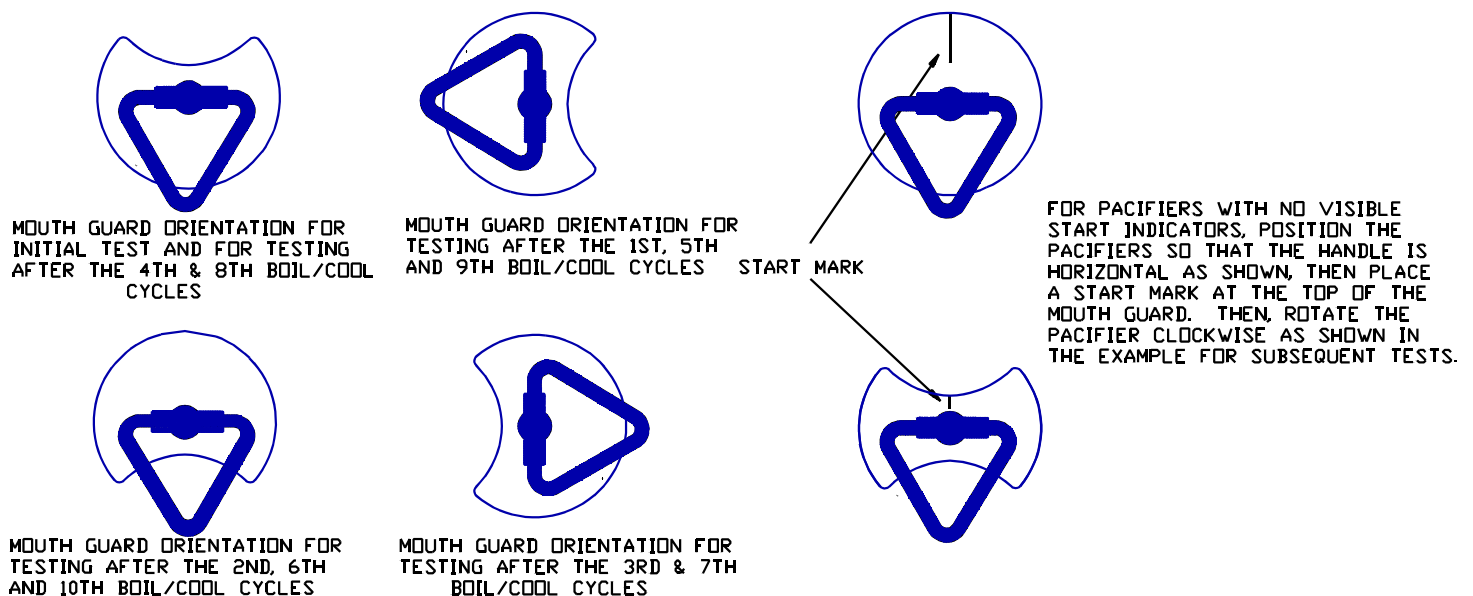



FIGURE 6. ORIENTATION OF GUARD OR SHIELD FOR STRUCTURAL INTEGRITY TESTS

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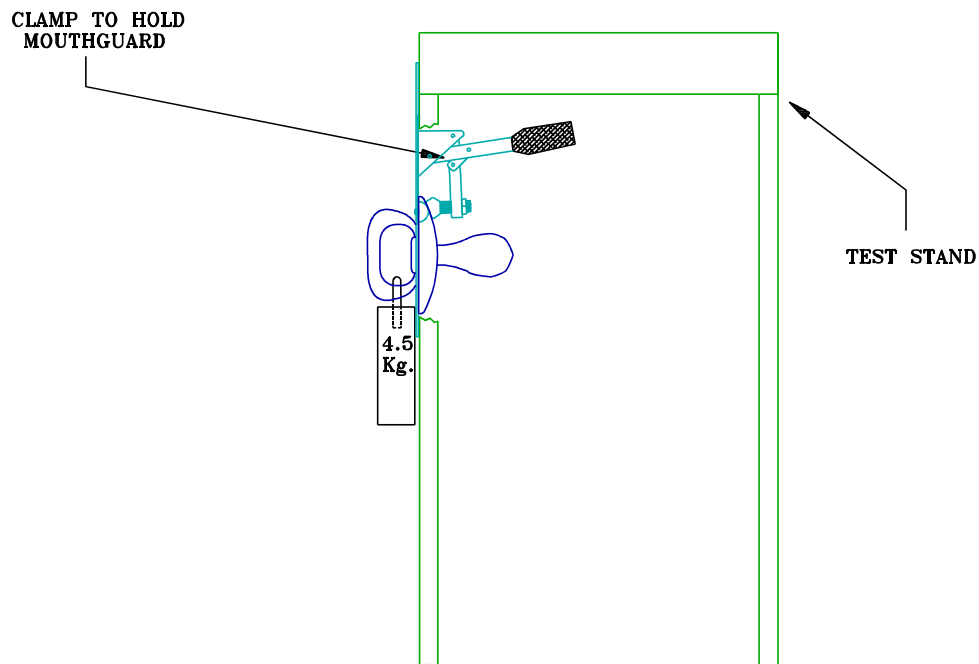


FIGURE 7. STRUCTURAL INTEGRITY TEST (procedure 5.8.2)

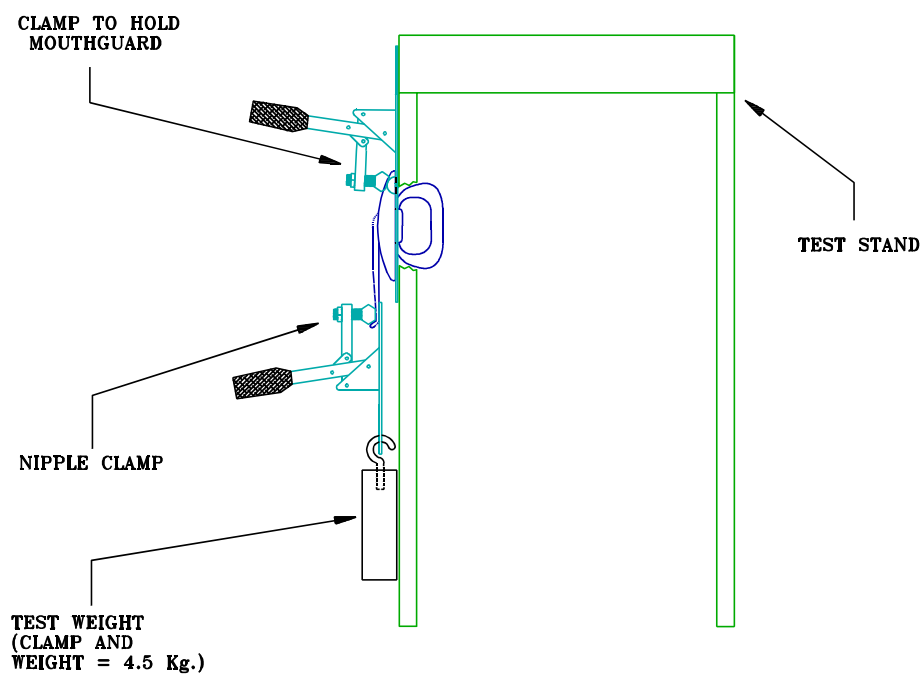



FIGURE 8. STRUCTURAL INTEGRITY TEST (procedure 5.8.3)

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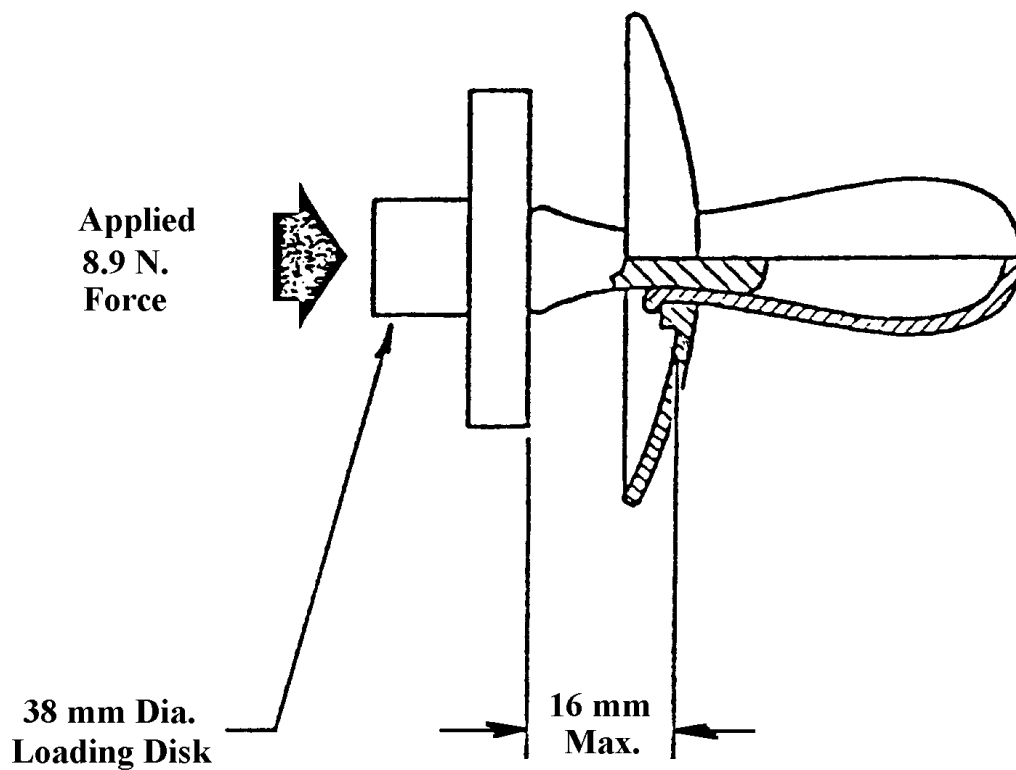



FIGURE 9. DIMENSIONAL REQUIREMENT IN PROTRUSION TEST

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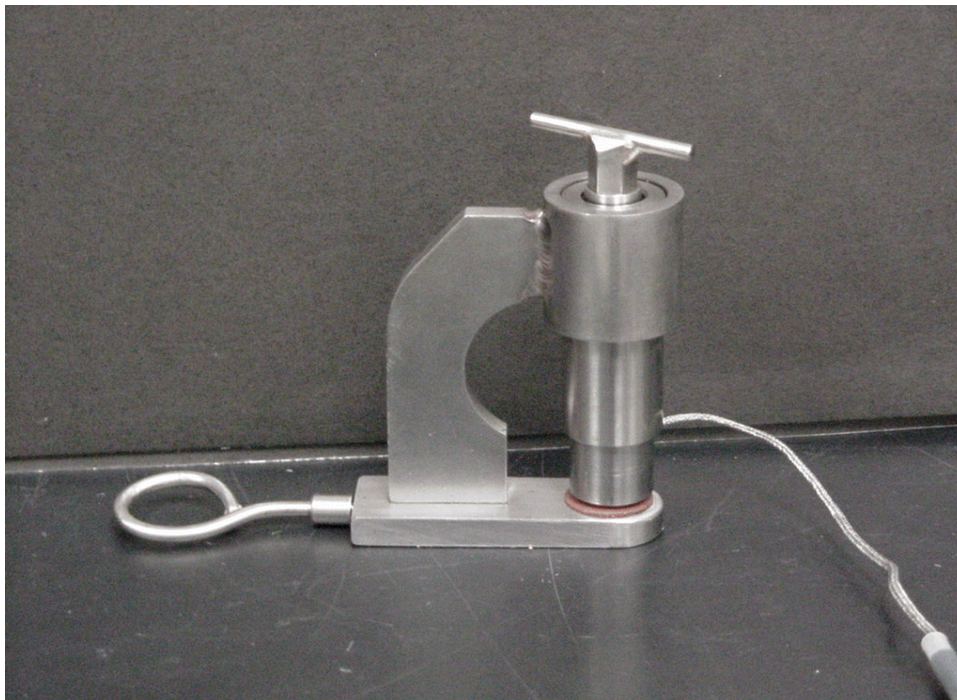


FIGURE 10. FORCE ADJUSTABLE NIPPLE CLAMP

Mass of clamp used by PSL: 252 grams. Mass of clamp used combined with test mass shall remain within the tolerance(s) specified in the method for applying load(s).
 Nominal clamp contact diameter: 12.7 mm (0.5 inch).

..... END