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Reference Manual Book 5: Laboratory Policies and Procedures  
Part B: Test Method Section

**Method M09: Pacifiers and Other Similar Consumer Products**

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## 1. SCOPE

This method describes procedures for testing pacifiers and similar products to determine if they meet the applicable requirements set out in the Pacifiers Regulations (SOR/2016-184), under the *Canada Consumer Product Safety Act (S.C. 2010, c.21)*. Section 2, *Toxic Substance and Section 3 Limit of volatile N-nitrosamines*, of the Pacifier Regulations are not covered by this test method. 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, with the understanding that uncertainty of measurement is always present. The product is evaluated by performing the following test sections in sequence:

- 4.1 ADVERTISING AND LABELLING
- 4.2 MARKING OF PACIFIERS FOR TESTING PURPOSES AND IDENTIFYING THE COMPONENTS OF THE PACIFIER
- 4.3 PROTRUSION TEST
- 4.4 GUARD TEST
- 4.5 STRUCTURAL INTEGRITY TEST
- 4.6 SMALL COMPONENTS
- 4.7 SHARP EDGES AND SHARP POINTS

## 2. APPLICABLE DOCUMENTS

- 2.1. *Canada Consumer Product Safety Act (S.C. 2010, c.21)*.
- 2.2. *Pacifiers Regulations (SOR/2016-184)* hereinafter referred to as the Regulations.
- 2.3. *Method M00.1: Small Components*.
- 2.4. *Method M00.2: Sharp Edges*.
- 2.5. *Method M00.3: Sharp Points*.
- 2.6. The United States Code of Federal Regulations, Title 16 Part 1511.4.
- 2.7. SOP 36: Verification of Engineering Section Test Equipment.

## 3. SAMPLING

- 3.1. The following test procedures should be conducted on the number of sample elements provided or received (typically ten), unless otherwise requested by the client.



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## 4. TESTING PROCEDURES

### 4.1. ADVERTISING AND LABELLING<sup>1</sup>

4.1.1. Note and record whether the product meets the requirements of subsections 6(1) and 6(2) of the Regulations:

**Reference to Canada Consumer Product Safety Act or Regulations**

6 (1) Written information that appears on a pacifier, that accompanies one or that is in any advertisement for one must not make any direct or indirect reference to the *Canada Consumer Product Safety Act* or these Regulations.

(2) Any written information that appears on or that accompanies a pacifier, and any advertisement of one, must not make representations in respect of the use of or modification to the pacifier that would result in the failure of the pacifier to meet a requirement of these Regulations.

### 4.2. MARKING OF PACIFIERS FOR TESTING PURPOSES AND IDENTIFYING THE COMPONENTS OF THE PACIFIER

#### 4.2.1. Scope

This section describes the procedure for marking the pacifiers for testing purposes and identifying the components of the pacifier.

#### 4.2.2. Apparatus

- 4.2.2.1. A marker with water resistant ink.
- 4.2.2.2. A measuring device with a resolution of 1 mm or better.

#### 4.2.3. Procedure

- 4.2.3.1. Label each sample element (e.g. SE1, SE2, SE3, etc.). Mark each sample element with a start indicator as an identifying mark for later use (in procedure 4.5 Structural Integrity Test) using a water resistant ink marker. For pacifiers with no visible start indicators, position the pacifier so that the handle is horizontal, and then place a mark at the top of the mouth guard (see Figure 1).
- 4.2.3.2. Note 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.

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<sup>1</sup> Section 6 of the Regulations.



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4.2.3.3. Note 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.

4.2.4. Results

4.2.4.1. 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.

4.2.4.2. Record whether there is a cord or other material attached to the pacifier and, if applicable, the length to the nearest 1 mm.

**4.3. PROTRUSION TEST<sup>2</sup>**

4.3.1. Scope

This section describes the procedure for determining the distance of a protrusion from the face of the guard or shield opposite from the nipple.

4.3.2. Apparatus

4.3.2.1. A device suitable for holding the pacifier guard or shield such that the guard or shield is fixed and the nipple is vertical.

4.3.2.2. A mass or device with a plane surface that is 0.88 kg ± 0.02 kg.

4.3.2.3. A measuring device with a resolution of 0.1 mm or better capable of taking internal measurements, such as an inside caliper.

4.3.3. Procedure

4.3.3.1. Secure the pacifier, with the nipple facing downwards and the axis of the nipple 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.

4.3.3.2. Using a mass or device with a plane surface, slowly apply the 0.88 kg ± 0.02 kg load towards the protrusion on the pacifier in a direction normal and central to the plane surface, in alignment with the axis of the nipple (see Figure 2). Allow any

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<sup>2</sup> The Protrusion Test is taken from the United States Code of Federal Regulations, Title 16 Part 1511.4 and is only intended to be applicable to pacifiers that have a "handle, including a knob-like handle that is not hinged, collapsible or flexible" when tested against this Standard. However, when testing according to this method all types of pacifiers will be tested according to the Protrusion Test.



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flexible component to buckle or bend and continue the load application until the  $0.88 \text{ kg} \pm 0.02 \text{ kg}$  of loading is applied. A pacifier that has a ring, handle or other protrusion which does not deflect under the influence of its own weight, may be manually deflected.

4.3.3.3. While maintaining the  $0.88 \text{ kg} \pm 0.02 \text{ kg}$  load, measure the protrusion distance<sup>3</sup> from the plane face of the load to the face of the shield at the base of the nipple as illustrated by Figure 2.

4.3.3.4. Repeat steps 4.3.3.1 through 4.3.3.3 with the remaining sample elements.

#### 4.3.4. Results

4.3.4.1. Record the protrusion distance for each sample element tested.

### 4.4. GUARD TEST

**Note:** Perform the following guard test (4.4.3.1 to 4.4.3.5) on each sample element. If the nipple or handle of a sample element completely detaches, discontinue testing of that one sample element but finish testing the remaining sample elements. If a partial separation is observed, continue testing.

#### 4.4.1. Scope

This section describes the procedure for determining whether the guard or shield of any pacifier passes through the opening in the guard template.

#### 4.4.2. Apparatus

4.4.2.1. Guard template (see Figure 3).

4.4.2.2. Clamp suitable for grasping and holding the nipple of the pacifier.

4.4.2.3. A mass, when added to the mass of the clamp, that is  $0.97 \text{ kg} \pm 0.02 \text{ kg}$ .

4.4.2.4. A stopwatch with a resolution of 0.1 seconds or better.

#### 4.4.3. Procedure

4.4.3.1. Attach the nipple clamp to the nipple.

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<sup>3</sup> The premise behind this measurement is to obtain the potential distance that the pacifier (nipple component) can be pressed into a child throat in the event of a force being applied.



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- 4.4.3.2. Place the pacifier in the guard template with the nipple of the pacifier centered in the opening of the template. For pacifiers with non-circular mouth guards or shields, place the pacifier on the template as shown in Figure 4.
- 4.4.3.3. Gradually apply a mass ( $0.97 \text{ kg} \pm 0.02 \text{ kg}$  including the mass of the clamp) to the nipple clamp within 5 seconds ( $\pm 1 \text{ s}$ ) and allow the load to hang freely for 10 seconds ( $\pm 1 \text{ s}$ ). See Figure 5.
- 4.4.3.4. Note whether the guard or shield passed through the opening in the template.
- 4.4.3.5. Repeat steps 4.4.3.1 through 4.4.3.4 with the remaining sample elements.

#### 4.4.4. Results

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

### 4.5. STRUCTURAL INTEGRITY TEST

**Note:** Perform the following three structural integrity tests (4.5.3.1 to 4.5.3.6) 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. If the nipple or handle of a sample element completely detaches, discontinue testing of that one sample element but finish testing the remaining sample elements. If a partial separation is observed, continue testing.

#### 4.5.1. Scope

This section describes the procedure for determining whether any part of the pacifier sustains damage after repeatedly applying a load of  $4.54 \text{ kg} \pm 0.09 \text{ kg}$  to its nipple and handle and subjecting the pacifier to 10 boiling cycles of 10 minutes ( $\pm 30 \text{ s}$ ) each.

#### 4.5.2. Apparatus

- 4.5.2.1. Clamp suitable for grasping and holding the nipple of the pacifier.
- 4.5.2.2. Clamp suitable for grasping and holding the pacifier handle.
- 4.5.2.3. Clamp suitable for grasping and holding the pacifier guard or shield.
- 4.5.2.4. Cord (or similar product) suitable for grasping and holding a knob-like handle.
- 4.5.2.5. Hotplate or suitable heating element.



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- 4.5.2.6. Large container for boiling water.
- 4.5.2.7. A stopwatch with a resolution of 0.1 seconds or better.
- 4.5.2.8. Test stand to attach clamps.
- 4.5.2.9. A mass, when added to the mass of the clamp, that is  $4.54 \text{ kg} \pm 0.09 \text{ kg}$ .
- 4.5.2.10. Wire mesh or steamer-type retaining basket.
- 4.5.2.11. Temperature measuring device with a resolution of  $0.1^{\circ}\text{C}$  or better.

4.5.3.Procedure

- 4.5.3.1. Attach a nipple clamp to the nipple of the pacifier and affix the nipple clamp to the test stand. See Figure 6. If the pacifier only has a knob, attach a knob clamp to the knob and affix the knob clamp to the test stand (see Figure 7). If the knob is constructed such that it cannot be grasped by the knob clamp follow one of three procedures below, attempting them in order:
  - 4.5.3.1.1. Attempt to tie a short length of cord (or similar product) around the knob to form a loop and affix the cord to the test stand as you would with a knob clamp (see Figure 7). If successful, take a photo of the pacifier and proceed to 4.5.3.2.
  - 4.5.3.1.2. If a cord cannot be tied around the knob, attempt to tie the cord to the pacifier guard if it has holes that would allow this to be done (see Figure 8). If successful, take a photo of the pacifier and proceed to 4.5.3.2.
  - 4.5.3.1.3. If neither a cord nor the knob clamp can be attached to the knob or guard, record that it cannot be grasped and proceed to 4.5.3.5.
- 4.5.3.2. Gradually apply a  $4.54 \text{ kg} \pm 0.09 \text{ kg}$  mass (including the mass of the nipple clamp in the case of a knob) to the pacifier over a period of 10 seconds ( $\pm 2 \text{ s}$ ) such that the load is applied axially to the nipple. Allow the load to hang freely for 10 seconds ( $\pm 0.5 \text{ s}$ ). Observe any damage. Store any components that have separated for further evaluation in steps 4.6 and 4.7. Discontinue testing the specific sample element under test if the nipple or handle completely detaches, but continue testing if only a partial separation is observed.
- 4.5.3.3. Clamp the guard or shield of the pacifier on the test stand in a fixed position (see Figure 9). If the pacifier has a cord tied to the pacifier guard from step 4.5.3.1, skip 4.5.3.4 and proceed to 4.5.3.5, otherwise continue with testing.



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- 4.5.3.4. Gradually apply a 4.54 kg  $\pm$  0.09 kg mass (including the mass of the knob clamp) to the handle or knob of the pacifier over a period of 10 seconds ( $\pm$  2 s) 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 s). See Figure 9. Observe any damage. Store any components that have separated for further evaluation in steps 4.6 and 4.7. Discontinue testing the specific sample element under test if the handle detaches, but continue testing if only a partial separation is observed.
- 4.5.3.5. 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 4.5.3.3.
- 4.5.3.6. Gradually apply a 4.54 kg  $\pm$  0.09 kg mass (including the mass of the nipple clamp) to the nipple over a period of 10 seconds ( $\pm$  2 s) 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 s). See Figure 10. Observe any damage. Store any components that have separated for further evaluation in steps 4.6 and 4.7. Discontinue testing the specific sample element under test if the nipple detaches, but continue testing if only a partial separation is observed.
- 4.5.3.7. Place all sample elements in a wire mesh or steamer-type retaining basket and immerse the basket in boiling water for 10 minutes ( $\pm$  30 s). Remove the pacifiers from the boiling water and allow them to cool in air at 21.0 °C  $\pm$  5°C for 15 minutes ( $\pm$  30 s).
- 4.5.3.8. Repeat steps 4.5.3.1 through 4.5.3.7 an additional 9 times for a total of 10 boil/cool cycles. Repeat steps 4.5.3.1 through 4.5.3.6 once more after the 10<sup>th</sup> boil/cool cycle for a total of 11 force applications. In proceeding with steps 4.5.3.3 and 4.5.3.5 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 11, prior to clamping the guard or shield in a fixed position.

4.5.4. Results

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

**4.6. SMALL COMPONENTS**

4.6.1. Scope

This section describes the procedure for testing all product components that are suspected of being able to fit in the Small Parts Cylinder.



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4.6.2. Apparatus

- 4.6.2.1. Small Parts Cylinder (Figure 12).

4.6.3. Procedure

- 4.6.3.1. Conduct this test as described in *Method M00.1: Small Components* on any components that were detached during testing in section 4.5. Do not perform sections 5.2.1 and 5.2.2 of *Method M00.1: Small Components*. These sections apply only to detached components of toys.
- 4.6.3.2. Results
- 4.6.3.3. Record if any part or component that has separated from the pacifier can be totally enclosed, in a non-compressed state, into the small parts cylinder -- as per *Method M00.1: Small Components*.

**4.7. SHARP EDGES AND SHARP POINTS**

4.7.1. Scope

This section describes the procedure for determining whether every part of the product that is made of metal, wood, plastic, or a similar hard material, and any cut edge of any metal tubing, are free of sharp edges and sharp points.

4.7.2. Apparatus

- 4.7.2.1. Sharp Edge Tester.
- 4.7.2.2. Sharp Point Tester.

4.7.3. Procedure

- 4.7.3.1. Examine every part of the product that is made of metal, wood, plastic, or a similar hard material, any cut edge of any metal, and any detached component found in section 4.5 of this test method. Conduct this test as described in *Method M00.2: Sharp Edges*, and *Method M00.3: Sharp Points*.

**Note:** For any crack or other defect that cannot be evaluated by using the sharp edge or sharp point test method, identify the locations and photograph the defect. Consult with the project leader to determine if further testing is required.

4.7.4. Results





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- 4.7.4.1. Record the location of any sharp edge, whether it cut the test tape, and the length of the cut – as per *Method M002: Sharp Edges*
- 4.7.4.2. Record the location on the product of any projections, corners and any surface deformations that activated the sharp point tester – as per *Method M00.3: Sharp Points*.

## **5. QUALITY ASSURANCE/QUALITY CONTROL PROCEDURES**

- 5.1. Ensure that all measuring instruments are functional, verified, and are calibrated with traceability to national or international standards.

## **6. TEST REPORT**

- 6.1. The test report at a minimum shall contain the following information:

- 6.1.1. Name, number, effective date of the test method, and any deviations from the documented test procedure.
- 6.1.2. A description of the product to include (where available), brand, style, country of origin, photo, UPC and other pertinent information.
- 6.1.3. The number of sample elements tested.
- 6.1.4. The results of the tests with specific details for any potential problems observed:
  - 6.1.4.1. Whether the product meets the requirements of subsections 6(1) and 6(2) of the Regulations
  - 6.1.4.2. 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.
  - 6.1.4.3. Whether there is a cord or other material attached to the pacifier. If any such attachment is present, report the length of the item to the nearest 1 mm.
  - 6.1.4.4. The greatest protrusion distance tested.
  - 6.1.4.5. Whether the guard or shield of any pacifier passed through the opening in the guard template.
  - 6.1.4.6. The details of any damage to each sample element including reference to the exact stage of testing (test and boil **cycle** number).



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- 6.1.4.7. If any part or component that has separated from the pacifier can be totally enclosed, in a non-compressed state, into the small parts cylinder.
- 6.1.4.8. The location of any sharp edge, whether it cuts the test tape, and the length of the cut.
- 6.1.4.9. The location on the product of any projections, corners and any surface deformations that activated the sharp point tester.
- 6.1.5. The analyst's name and signature, as well as the name(s) and signature(s) of the reviewer(s).

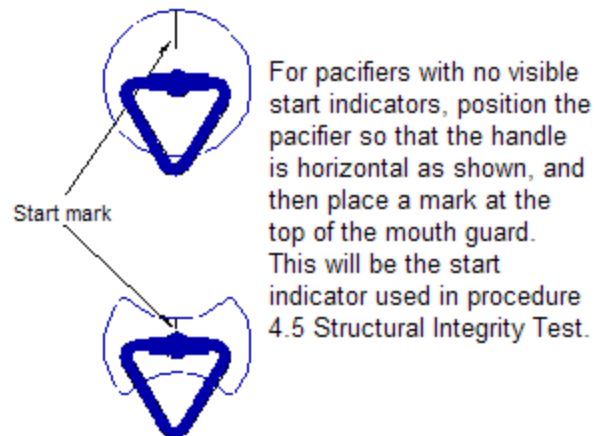


Figure 1 - Marking of a pacifier with no visible start indicator



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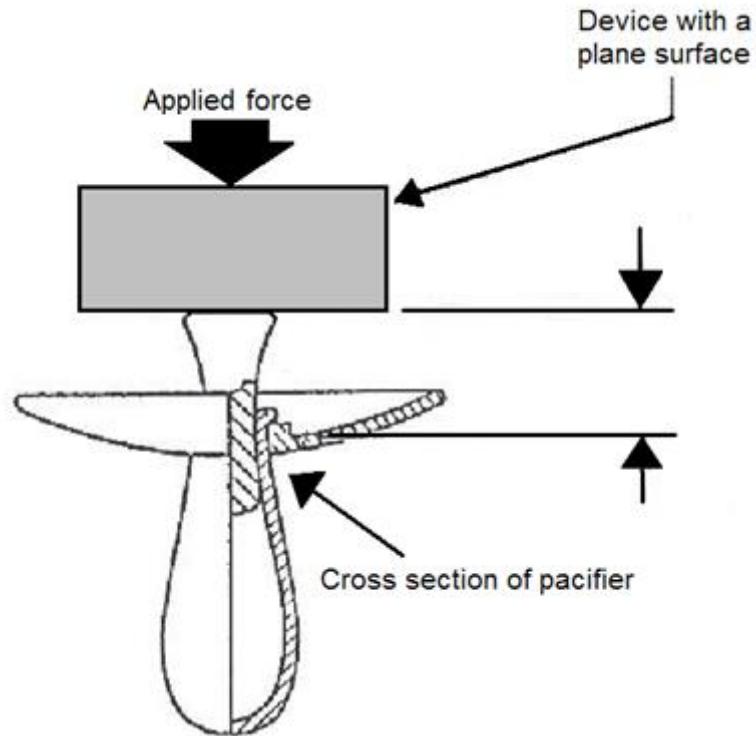


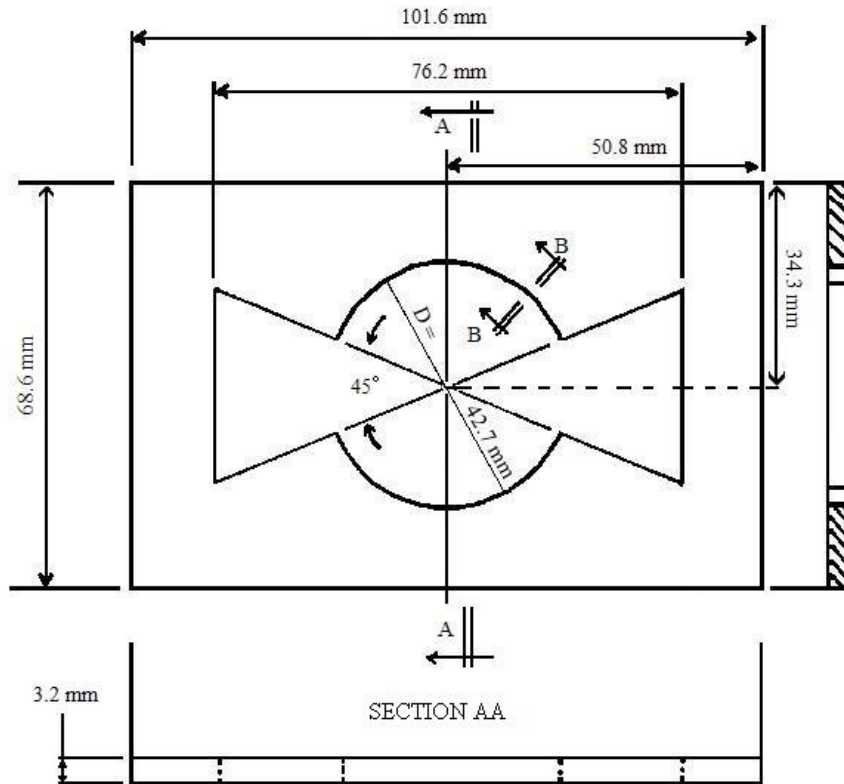
Figure 2 - Dimensional requirement in protrusion test



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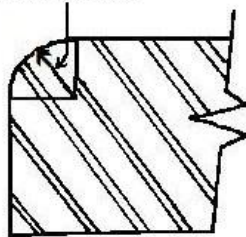
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ENLARGED SECTION BB

RADIUS: 0.76 mm



NOTES

1. Radius of all edges of opening: 0.76 mm
2. Material to be aluminum plate
3. Dimensional tolerance:  $\pm 0.13$  mm



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Figure 3 - Guard template

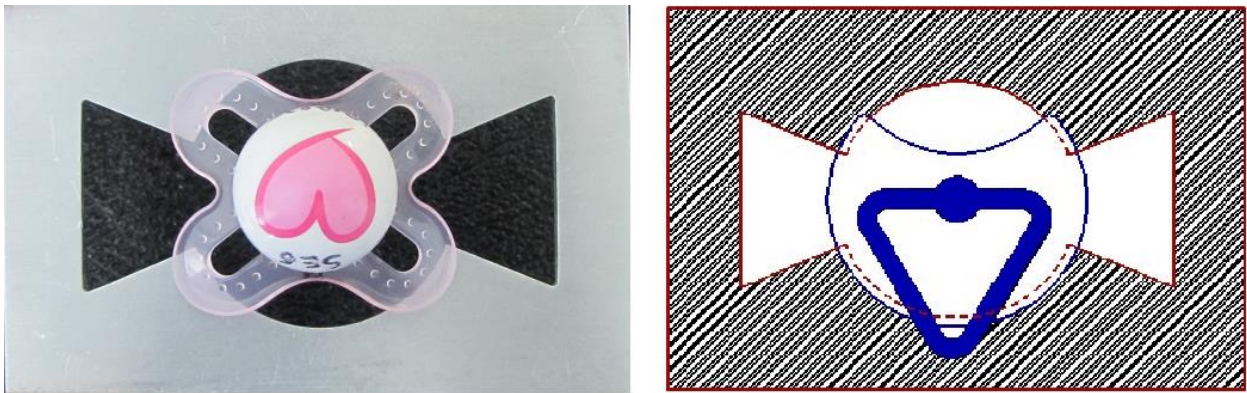


Figure 4 – Example of different shaped pacifiers on the guard template

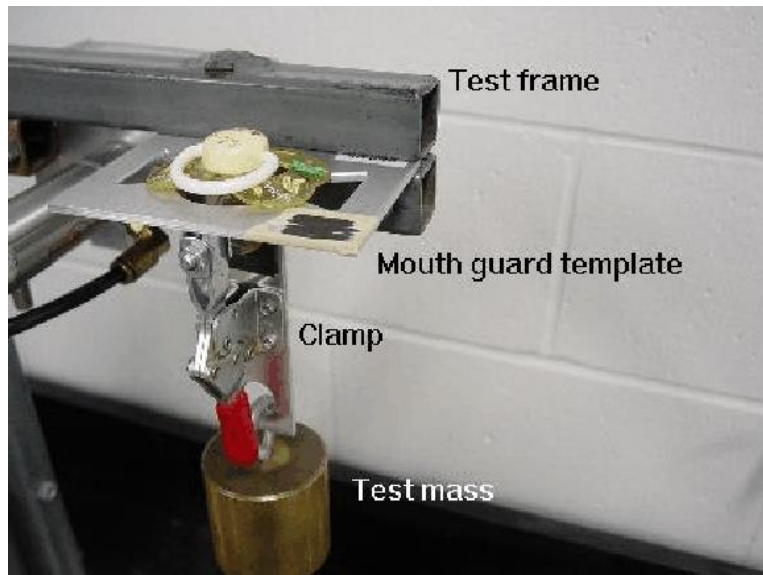


Figure 5 - Guard test



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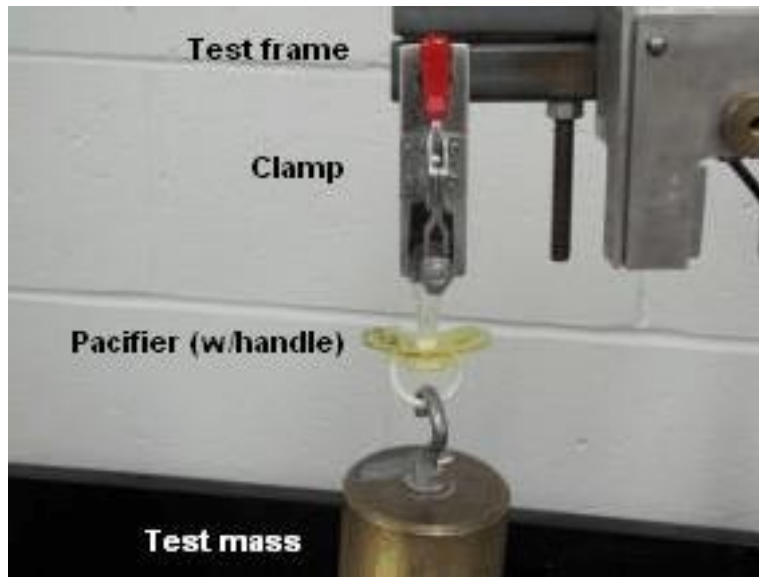


Figure 6 - Structural integrity test (pacifier with handle)

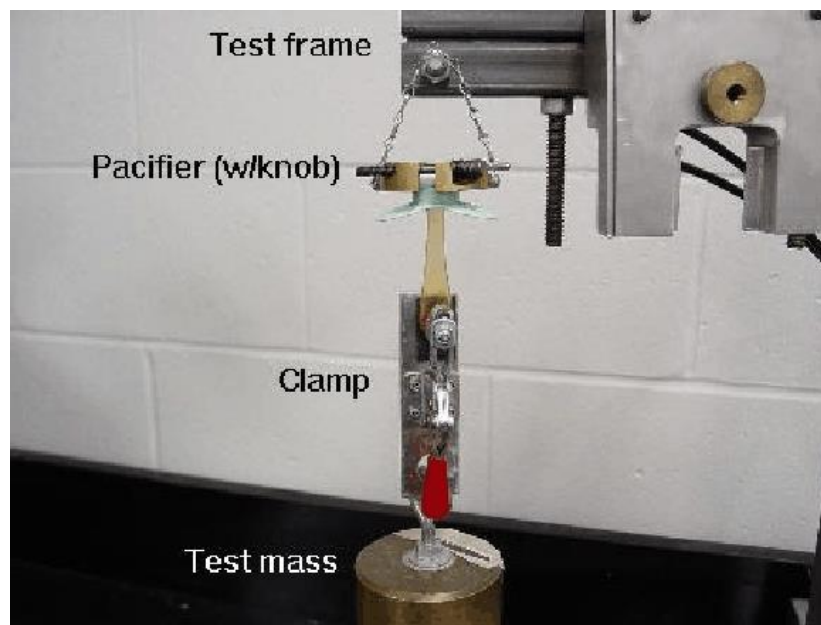


Figure 7 - Structural integrity test (pacifier with knob)



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Figure 8 - Pacifier guard tied using cord

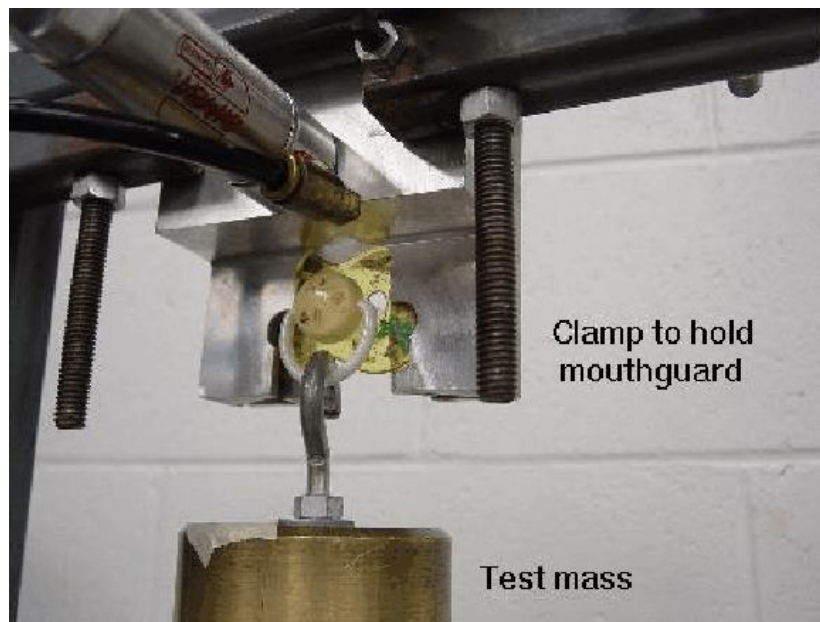


Figure 9 - Structural integrity test (handle test)



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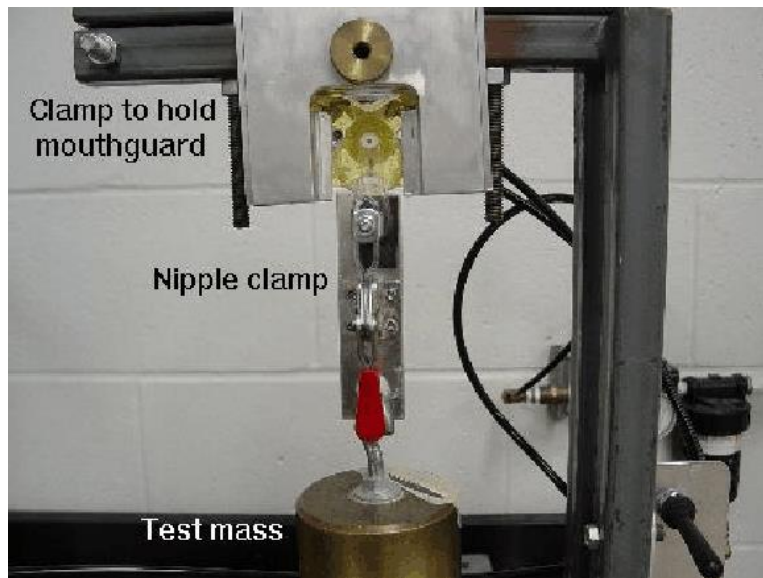


Figure 10 - Structural integrity test (nipple test)

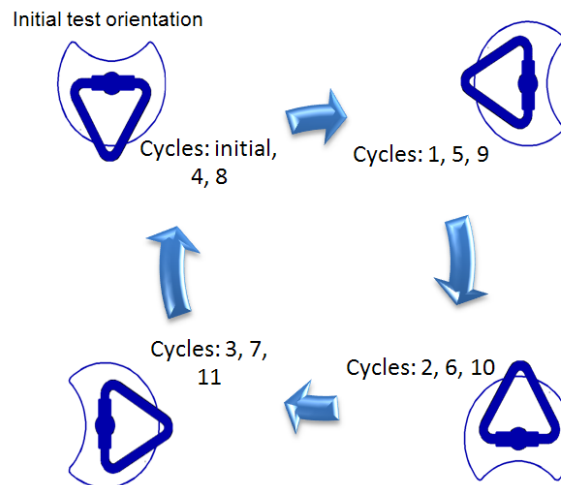


Figure 11 - Orientation of guard or shield for structural integrity tests





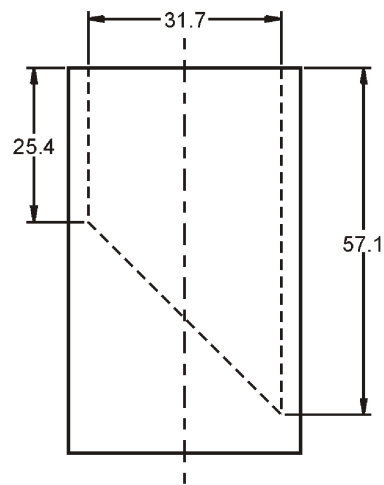
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- Notes:
- Not to scale
  - All dimensions in mm

**Figure 12 - Small parts cylinder**