

non-circular guards or shields, align the major axis of the guard or shield with the major axis of the opening in the fixture. Apply a tensile force to the pacifier nipple in the direction shown. The force shall be applied gradually attaining but not exceeding 2.0 pounds (8.9 newtons) within a period of 5 seconds and maintained at 2.0 pounds for an additional 10 seconds. Any pacifier which can be completely drawn through an opening with dimensions no greater than those of Figure 1(a) by such a force shall fail the test in this part.

(b) *Ventilation holes.* The pacifier guard or shield shall contain at least two holes symmetrically located and each being at least 0.20 inches (5 millimeters) in minor dimension. The edge of any hole shall be no closer than 0.20 inches (5 millimeters) to the perimeter of the pacifier guard or shield.

#### § 1511.4 Protrusions.

(a) *Protrusions limitation.* No protrusion from the face of the guard or shield opposite from the nipple shall exceed 0.63 inches (16mm) when measured in accordance with the procedure specified in paragraph (b) of this section.

(b) *Protrusion test.* Secure the pacifier by clamping the nipple with its axis horizontal. For pacifiers with hinged handles or rings the orientation of the hinge axis shall be horizontal. A plane surface shall be applied to any protrusion from the guard or shield with a force gradually attaining but not exceeding 2.0 pounds (8.9 newtons) applied in a direction along the axis of the nipple. The normal of the plane surface shall be maintained parallel to the axis of the nipple. Any protrusion shall be allowed to flex or rotate about its hinge as the plane surface is applied to it. Measure the distance from the plane surface to the guard or shield at the base of the nipple.

#### § 1511.5 Structural integrity tests.

(a) *Nipple.* Hold the pacifier by the shield or guard, grasp the nipple end of the pacifier and gradually apply a tensile force to the pacifier nipple in any possible direction. The force shall be applied gradually, attaining but not exceeding 10.0 pounds (44.5 newtons) with-

in a period of 5 seconds and maintained at 10.0 pounds for an additional 10 seconds.

(b) *Handle or ring.* Hold the pacifier by the shield or guard or base of the nipple, and push or pull on the handle or ring in any possible direction. The force shall be applied gradually attaining but not exceeding 10.0 pounds (44.5 newtons) within a period of 5 seconds and maintained at 10.0 pounds for an additional 10 seconds.

(c) *Heat cycle deterioration.* After the testing prescribed in paragraphs (a) and (b) of this section, all pacifiers shall be subject to the following: submerge the pacifier in boiling water for 5 minutes and then remove the pacifier and allow it to cool for 5 minutes in room temperature air, 60° to 80 °F. (16° to 27 °C). After the cooling period, re-submerge the pacifier in the boiling water for 5 minutes. The process shall be repeated for a total of 6 boiling/cooling cycles. After the sixth cycle, the pacifier shall again be subjected to the structural tests in paragraphs (a) and (b) of this section and section 1511.3.

(d) *Small parts.* Any components or fragments which are released as a result of the tests specified in paragraphs (a), (b) and (c) of this section shall be placed in the truncated cylinder shown in Figure 2, such that the component or fragment is in the lowest position in the cylinder. If the uppermost edge of the component or fragment is below the plane of the top of the cylinder, the pacifier shall fail the test in this section.

#### § 1511.6 Ribbons, strings, cords, or other attachments.

A pacifier shall not be sold or distributed with any ribbon, string, cord, chain, twine, leather, yarn or similar attachments.

#### § 1511.7 Labeling.

(a) As required by paragraphs (b) and (c) of this section, pacifiers shall be labeled with the statement: "Warning—Do Not Tie Pacifier Around Child's Neck as it Presents a Strangulation Danger."

(b) The labeling statement required by paragraph (a) of this section shall appear legibly and conspicuously on

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any retail display carton containing two or more pacifiers.

(c) Each individually packaged pacifier shall bear the labeling statement required in paragraph (a) of this section on the package legibly and conspicuously.

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**§ 1511.8 Metric references.**

For purposes of compliance with the test procedure prescribed by this §500.46, the English figures shall be used. The metric approximations are provided in parentheses for convenience and information only.