

LMA™ Classic Performance Tests

Conduct all of the performance tests prior to each use of the device. Failure of any one test indicates that the device is past its useful life and should NOT be used. Consult the instruction manual for more complete information and for additional details on insertion technique and pre-use performance testing.

Test 1. Visual Inspection:

Discoloration

Examine the transparency of the airway tube. Discoloration of the airway tube through age or contamination, for example with iodine, prevents easy visualization of fluids entering the airway tube. The transparency of the tube is an important safety feature of the LMA™ airway.



Breakage

Examine the surface of the LMA™ for damage, including cuts, tears, or scratches. The airway tube can be bitten as a result of an inadequate bite-block. Once sustained, this type of damage will tend to propagate, as will nicks from sharp objects or cleaning instruments.



Tube Kinking

Flex the tube up to, but not beyond 180°. Do not use the LMA™ if the tube kinks when flexed through 180°.

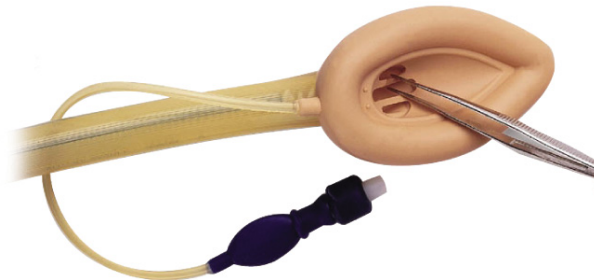


Blockage

Examine the interior of the airway tube to ensure that it is free from blockage or loose particles. Any particles present in the tube, or on the exterior of the tube or mask should be removed as they may be inflated by the patient after insertion.

Aperture Breakage

Examine the aperture in the mask. Gently probe the two flexible bars traversing the mask aperture to ensure they are not broken or otherwise damaged. Aggressive cleaning can damage the aperture bars. If the aperture bars are not intact, the epiglottis may obstruct the airway.



Crazing

Non-recommended cleaning solutions can cause severe damage. Extreme crazing and cracking caused by chemical degradation can cause weakening of the connector. An LMA™ airway with a damaged connector should not be used.

Note: Cleaning solution that is not adequately rinsed off the plastic 15 mm connector can cause the connector to craze during the autoclave cycle.



Test 2. Deflation and Inflation:

Cuff Leakage

Fully deflate the cuff so that the cuff walls are tightly flattened against each other. The cuff walls should remain tightly flattened against each other. Do not use the LMA™ airway if the cuff walls reinflate immediately and spontaneously even if only slightly. Inflate the cuff with air from complete vacuum to 50% over-inflation as shown in the table below:

TEST CUFF OVER-INFLATION VOLUMES	
LMA™ Size	Air Volume*
1	6 mL
1½	10 mL
2	15 mL
2½	21 mL
3	30 mL
4	45 mL
5	60 mL
6	75 mL

* Inflate the cuff with these volumes for testing only.

Any tendency of the cuff to deflate indicates the presence of a leak and should be evident within two minutes. Examine the symmetry of the inflated cuff. There should be no uneven bulging at either end or on the sides. Do not use the LMA™ airway if cuff leakage is present or there is uneven bulging of the cuff (as seen below).



Irregular Balloon

While the LMA™ airway remains 50% over-inflated, examine the blue inflation indicator balloon. The balloon shape should be elliptical, not spherical, and not bulging. Do not use the LMA™ airway if the inflation balloon is spherical or irregularly shaped (as seen below).

