LMA®

LMA®

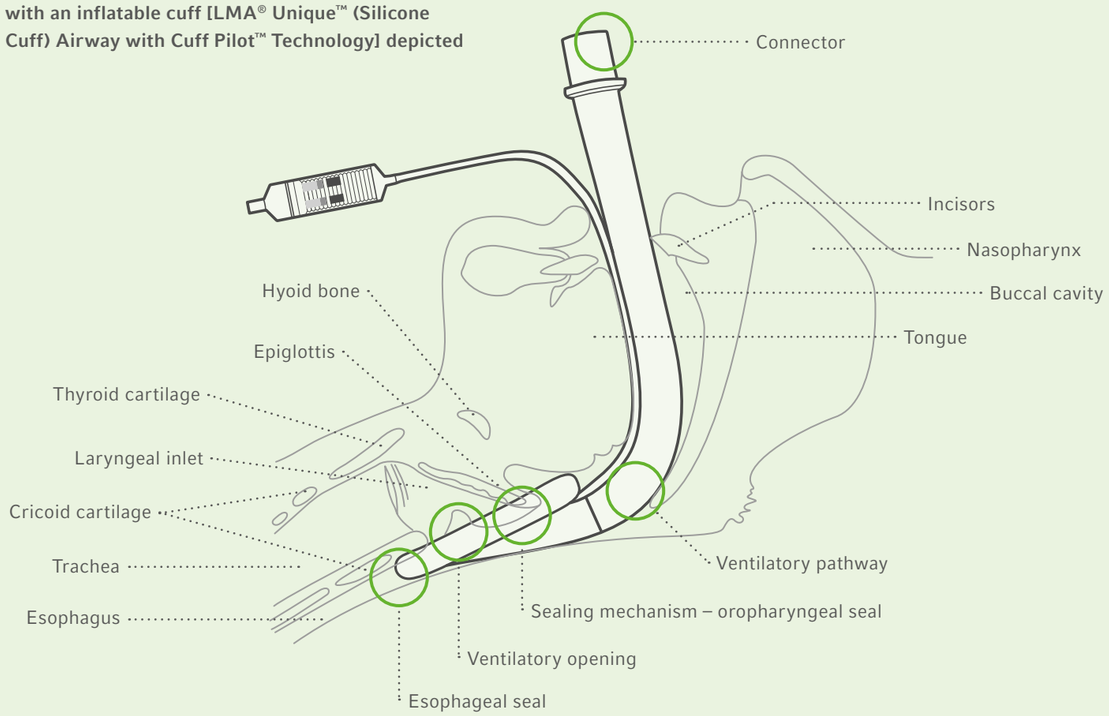
Cuff Pressure Monitoring

Teleflex®

The role of laryngeal masks with inflatable cuffs

- Laryngeal masks, including the family of LMA® Airways, are routinely used to facilitate oxygenation and ventilation during general anesthesia
  - Laryngeal masks are also increasingly used for emergency airway management in the pre-hospital setting
- Optimal use of a laryngeal mask relies on a number of factors, including selecting a device that is the correct size for a given patient, ensuring that the device is inserted to a correct depth, and achieving an adequate seal between the device and the airway anatomy[1]
- The majority of laryngeal masks include an elliptical cuff that is inflated with air following insertion
  - The inflatable cuff encircles the laryngeal inlet, effectively isolating the distal airways
  - Once inflated, the cuff functions to prevent air from leaking to the atmosphere (Figure 1)
- Optimal inflation of the cuff is essential for patient safety
  - Intracuff pressure must be high enough to seal the airway during both spontaneous and assisted ventilation, but be low enough to avoid reducing/occluding blood flow in the laryngopharyngeal mucosa and/or damaging adjacent nerves

Figure 1. *In situ* positioning of a laryngeal mask with an inflatable cuff [LMA® Unique™ (Silicone Cuff) Airway with Cuff Pilot™ Technology] depicted



The complex relationship between cuff inflation volume and cuff pressure

- Typically, the inflation system of a laryngeal mask comprises a cuff, an inflation line, a pilot balloon (which provides an indication of the pressure within the cuff), and a check valve (which prevents leakage of air and maintains intracuff pressure)
- To inflate the cuff, a given volume of air is injected via the inflation line
  - The cuff should be inflated with sufficient air to obtain a low-pressure seal
- Laryngeal mask manufacturers provide recommendations about safe maximum inflation volumes for their devices; however, these are based on the physical properties of the cuff (i.e., the volume to which the cuff can be safely distended without compromising the material)[2]
- Typically, the recommended (i.e., maximum) filling volume is employed in clinical practice, even though it is not an indication of what is suitable for the majority of patients[2]
- Inflating the cuff with the recommended maximum inflation volume often leads to cuff hyperinflation (i.e., a cuff pressure greater than what is recommended)
  - An *in vitro* experiment that used pediatric-sized single-use and reusable laryngeal masks showed that, when starting from a completely deflated cuff, inflation to the maximum recommended volume almost always resulted in an intracuff pressure that was higher than recommended (i.e., >60 cm H_2O)[3]
    - Furthermore, when starting from a resting cuff (i.e., with the pilot balloon valve opened to atmospheric pressure), inflation to the maximum recommended volume resulted in a cuff pressure of >120 cm H_2O for all but one of the devices studied[3]
  - An *in vivo* study that used single-use and reusable laryngeal masks in pediatric patients showed similar results; when starting from a completely deflated cuff, the recommended intracuff pressure (i.e., 60 cm H_2O) was exceeded *"well below"* the recommended maximum inflation volume[4]
    - Indeed, an intracuff pressure of 60 cm H_2O was achieved with approximately one-half of the recommended maximum inflation volume[4]
- An intracuff pressure of 60 cm H_2O and higher may have clinical consequences, including increased leakage around the cuff[5,6]
- Excessive intracuff pressures may also lead to pharyngolaryngeal morbidity, including post-operative sore throat, dysphagia, dysphonia, and/or nerve injury[7-15]

The prevalence of cuff hyperinflation

Table 1. Prevalence of cuff hyperinflation (intracuff pressure ≥60 cm H_2O) in children and adults whose airway was managed with various laryngeal masks (comparative data for endotracheal tubes [ETTs] have been included, where available)

STUDY	SETTING	INSERTION/INFLATION METHOD	MEASUREMENT OF CUFF PRESSURE	DEVICE	INTRACUFF PRESSURE	RATE OF CUFF HYPERINFLATION IN %
Infants and children						
von Ungern-Sternberg BS, et al. 2009[21]	Elective surgery requiring general anesthesia	Inserted unchanged straight from the sterile packaging without further inflation or deflation of the cuff	Measured using a calibrated hand-held manometer following device insertion	LMA® Classic™ Airway (n=87) LMA® Unique™ Airway (n=89) LMA® Flexible™ Airway [single use] (n=115) LMA Flexible Airway [reusable] (n=80) LMA® ProSeal™ Airway (n=61) PROACT Medical Ltd PRO-Breathe® (n=568)	NR	≥60 cm H_2O: 21 (67% for size 1 devices)
Schloss B, et al. 2012[18]	Surgery requiring general anesthesia	Inserted with the cuff partially inflated, as per routine clinical practice, with further inflation as needed to ensure a seal during positive pressure ventilation to a peak inflating pressure of 20–25 cm H_2O	Measured using a hand-held manometer within the first 30 minutes	Ambu® A/S laryngeal mask (n=200)	Mean ± SD: 57 ± 30	≥60 cm H_2O: 53
Martin DP, et al. 2013[22]	Surgery requiring general anesthesia	Inserted with the cuff partially inflated, as per routine clinical practice, with further inflation as needed to ensure a seal during positive pressure ventilation to a peak inflating pressure of 20-25 cm H_2O	Measured using a hand-held manometer immediately after device placement	AES Inc laryngeal mask (n=100)	NR	>60 cm H_2O: 31
Adults						
Rokamp KZ, et al. 2010[16]	Elective surgery requiring general anesthesia	Inflated as per the disposition of the head anesthesiologist (without the use of a manometer or a pressure release valve)	Measured using a cuff pressure gauge following placement of the airway	Ambu® A/S laryngeal mask (n=82)	Median (range): 95 (10–121)	>60 cm H_2O: 68 >120 cm H_2O:† 41
				ETT (n=119)	Median (range): 30 (8–100)	>30 cm H_2O: 45 >40 cm H_2O: 28
Spiro M, et al. 2010[19]	NR	NR	Measured in the operating room	Fannin Ltd single-use laryngeal mask (n=89)	Median: 120	≥60 cm H_2O: 85
Patient population not specified						
Sandhu G, et al. 2012[17]	Surgery requiring general anesthesia	NR	Measured using a hand-held manometer within 30 minutes of device placement	Laryngeal mask (n=34)	NR	≥60 cm H_2O: 97 60–120 cm H_2O: 24 >120 cm H_2O:† 74
				ETT (n=27)	Mean: 39	≥25 cm H_2O: 52
Viernes DC, Joffe AM, et al. 2012[20]	Surgery requiring general anesthesia	NR	Measured using a Compass Lumbar Puncture	Laryngeal masks (n=44)	Median (range): 90 (12–199)	>60 cm H_2O: 68 >120 cm H_2O: 30
				ETT (n=246)	Median (range): 43 (6–199)	>30 cm H_2O: 61 >60 cm H_2O: 23

† The upper limit of the pressure gauge/manometer
NR, not reported; SD, standard deviation

- Cuff hyperinflation may be highly prevalent in the setting of general anesthesia
  - Studies have shown that as many as 97% of patients whose airway was managed with a laryngeal mask had a cuff pressure that exceeded the recommended value of no more than 60 cm H_2O (Table 1)[16-22]
  - Of concern, up to 74% of measurements were more than twice the recommended pressure (i.e., >120 cm H_2O)[16,17,20]
- Cuff hyperinflation is not solely restricted to the use of laryngeal masks, but is also apparent in patients whose airway is managed with a cuffed endotracheal tube (ETT) (Table 1)[16,17,20]

The association between intracuff pressure and airway morbidity

Table 2. Frequency of post-operative pharyngolaryngeal complications according to intracuff pressure in patients whose airway was managed with various laryngeal masks

STUDY	SETTING	LARYNGEAL MASK	INSERTION AND INFLATION METHOD		RATE OF AIRWAY-RELATED ADVERSE EVENTS IN %	
Burgard G, et al. 1996[8]	Gynecological surgery requiring general anesthesia	LMA® Classic™ Airway	Device inserted and inflated with recommended volume of air (25 mL [size 3] or 35 mL [size 4]) **Low-pressure group:** Intracuff pressure released to minimal airtightness pressure **High-pressure group:** Intracuff pressure not released		Low-pressure group (n=100)	High-pressure group (n=100)
				Sore throat (minimal, moderate, or severe) in the recovery room and 4, 8, and 24 hours post-surgery	0, 0, 0, and 0	8, 8, 8, and 5
Nott MR, et al. 1998[12]	Elective surgery requiring general anesthesia	LMA Classic Airway	Inserted using a standard technique (with a slight lateral approach if resistance encountered) Inflation to move the device into the correct position within the pharynx, up to typical volumes for each size **Adjusted group:** Intracuff pressure adjusted after 5 minutes until there was a slight leak to positive pressure at 10–12 cm H_2O (i.e., "just airtight") **Non-adjusted group:** Intracuff pressure left unchanged		Adjusted group (n=412)	Non-adjusted group (n=427)
				Sore throat (mild, moderate, or severe)	7*	16
Seet E, et al. 2010[13]	Short-duration elective ambulatory surgery requiring general anesthesia	LMA Classic Airway	Inserted according to the anesthesiologist's preferred technique and the manufacturer's instructions Inflated at the discretion of the attending anesthesiologist to achieve an audible seal **Pressure-limiting group:** Intracuff pressure reduced to 54–60 cm H_2O if >60 cm H_2O **Routine care group:** Intracuff pressure left unchanged		Pressure-limiting group (n=97)	Routine care group (n=103)
				Any pharyngolaryngeal complications	13*	46
				Sore throat at 1, 2, and 24 hours post-surgery	7, 2***, and 3**	8, 9, and 14
				Dysphagia at 1, 2, and 24 hours post-surgery	1*, 0*, and 2***	13, 13, and %
				Dysphonia 1, 2, and 24 hours post-surgery	5***, 4, and 4	16, 12, and 7
Chantzara G, et al. 2014[9]	Elective urological surgery requiring general anesthesia	LMA® laryngeal mask (distributed by Iamex SA in Greece)	Gradually inflated at the discretion of the anesthesiologist to achieve a seal without audible leak during positive pressure ventilation with a maximum intracuff volume of 30 mL (size 4) and 40 mL (size 5) **Intervention group:** Intracuff pressure maintained at 60 cm H_2O **Observation group:** Intracuff pressure left unchanged		Intervention group (n=60)	Observation group (n=60)
				Any pharyngolaryngeal adverse effects 24 hours post-surgery	8*	35
Kang JE, et al. 2014[10]	Laparoscopic surgery requiring general anesthesia	LMA® Supreme™ Airway	Device inserted with the cuff completely deflated Cuff inflated thereafter **Low-pressure group:** Intracuff pressure limited to 25 cm H_2O **High-pressure group:** Intracuff pressure set to 60 cm H_2O		Low-pressure group (n=49)	High-pressure group (n=52)
				Sore throat on days 1 and 2	4 and 6***	12 and 23
				Dysphagia on days 1 and 2	0*** and 0***	8 and 8
				Dysphonia on days 1 and 2	0 and 0	0 and 2
Vasanth Karthik R, et al. 2014[15]	Short-duration elective surgery requiring general anesthesia	LMA® ProSeal™ Airway	Inserted according to the anesthesiologist's preferred technique Inflated to no more than the maximum recommended volume to achieve a seal without audible leak during positive pressure ventilation with a tidal volume of 8 mL/kg and a peak inspiratory pressure <25 cm H_2O **Pressure-monitored group:** Intracuff pressure reduced to 60 cm H_2O if >60 cm H_2O **Control group:** Intracuff pressure left unchanged		Pressure-monitored group (n=60)	Control group (n=59)
				Any pharyngolaryngeal complications	32	42
				Sore throat at 1, 2, and 24 hours post-surgery	5, 22, and 25	9, 37, and 41
				Dysphagia at 1, 2, and 24 hours post-surgery	3, 12, and 17	8, 20, and 22

- There is a large body of evidence to show that excessive intracuff pressures can have a detrimental effect on a patient's airway
  - Morbidity may manifest as post-operative sore throat, dysphagia, dysphonia, and/or nerve injury[7-15]
- The pharyngeal mucosal perfusion pressure may be exceeded during the use of laryngeal masks[23] and this might lead to cuff pressure-related airway morbidity[24-26]
  - If intracuff pressure exceeds perfusion pressure, the mucosa may become ischemic, leading to tissue damage[24]
- Other types of pressure-related morbidity include cranial nerve injuries (e.g., the lingual, laryngeal, hypoglossal, and glossopharyngeal nerves)[7,11,14]
  - Such injuries are thought to be the result of pressure neuropraxia, with hyperinflation of the cuff being a contributing factor[7,11,14]
- Several randomized controlled trials have been undertaken to study the effect of laryngeal mask cuff pressure on the incidence of post-operative pharyngolaryngeal complaints
  - Data show that a reduction in intracuff pressure results in a decreased rate of airway morbidity (Table 2)[8-10,12,13,15]
  - In one study,[13] reducing intracuff pressure to 54–60 cm H_2O led to a 70% reduction in pharyngolaryngeal complications
- A reduction in the rate of airway morbidity when intracuff pressure is reduced to the recommended maximum has also been observed with cuffed ETTs[27,28]
- Interestingly, rates of sore throat appear to have increased over time, from 13% when the LMA Classic Airway was first described in 1983[29] to rates approaching 50% in recent years[15,30]

Cuff pressure monitoring in clinical practice

- In a clinical setting, intracuff pressure is typically estimated via digital palpation of the pilot balloon
  - Data show that the palpation technique is inaccurate[31] and tends to result in an underestimation of actual intracuff pressure[31,32]
- Clinical endpoints (e.g., appropriate positioning of the device and an adequate seal) may also be used to guide cuff inflation
  - This method is associated with cuff hyperinflation in a majority of patients[6,33] and with increased leakage around the cuff[6]
- In order to avoid cuff hyperinflation, numerous researchers have concluded that intracuff pressure should be routinely monitored/controlled in both adults and children,[3,4,6,8,13,16,19-21,32-34] typically with a pressure manometer
  - Cuff pressure monitoring is considered particularly important in children
    - Because pediatric patients have smaller airway diameters than adults, the effect of swelling of the airway is known to be greater[4,6]
    - Furthermore, with smaller-sized devices (i.e., those used in pediatric patients), small changes in volume can result in large changes in pressure[4]

Table 3. Changes in cuff pressure in certain surgical settings/scenarios

SURGICAL SETTING/SCENARIO	CHANGE IN CUFF PRESSURE
Nitrous oxide anesthesia	The use of nitrous oxide is known to increase intracuff volume and pressure over time, owing to the more rapid diffusion of nitrous oxide (versus air) across the wall of the cuff[35,36‡]
Changes in patient position	Significant increases in cuff pressure have been observed following rotation of the head during surgery[37]
Changes in atmospheric pressure	Increases in cuff pressure have been observed following increases in altitude/elevation,[38] which is relevant during aeromedical transport

- Because changes in intracuff pressure over time are not uncommon, particularly in certain surgical settings/scenarios (Table 3), monitoring should occur throughout the use of a laryngeal mask[4,8,16,33]
- Despite calls for the use of manometry to monitor intracuff pressure, this is not routinely undertaken in many institutions[2-4,6,13,18,21,32,33]
- The lack of uptake of manometers is likely multifactorial
  - Researchers in the United States note that the cost of a commercially available manometer ranges from approximately $US100 to $US400;[13,18,22] in Europe, the cost is estimated to be approximately €100 per unit[16]
    - Based on these prices, the installation of manometers into every operating room would be costly[39] and potentially infeasible[18,22]
    - Additional costs related to the repair, replacement, and maintenance (e.g., calibration) of such devices would also be incurred, as would costs associated with cleaning the devices between each patient[18,22]
  - Medical personnel may consider the use of a manometer time consuming, difficult/cumbersome, and/or inaccurate[40-43]
  - Single measurements of intracuff pressure using external manometers do not provide a continuous assessment of cuff pressure throughout the course of surgery[30]

‡ Diffusion of nitrous oxide is known to differ according to the physical properties of the cuff

Cuff Pilot™ Technology

An integrated pressure indicator

- Effective cuff inflation is about pressure, not volume
- Cuff Pilot™ Technology is an integrated pressure indicator that constantly monitors intracuff pressure and provides at-a-glance manometry of cuff pressure levels
- Cuff Pilot Technology replaces the standard pilot balloon and is being introduced on all single-use LMA® Airways with a silicone cuff
  - Those LMA Airways that include Cuff Pilot Technology can be identified by the inclusion of Cuff Pilot Technology in the product name
- Cuff Pilot Technology provides users with an easy-to-read, 360° view of cuff pressure levels
  - This is achieved using a color-coded scale in which pressure ranges are indicated using specific color zones (Figure 2)

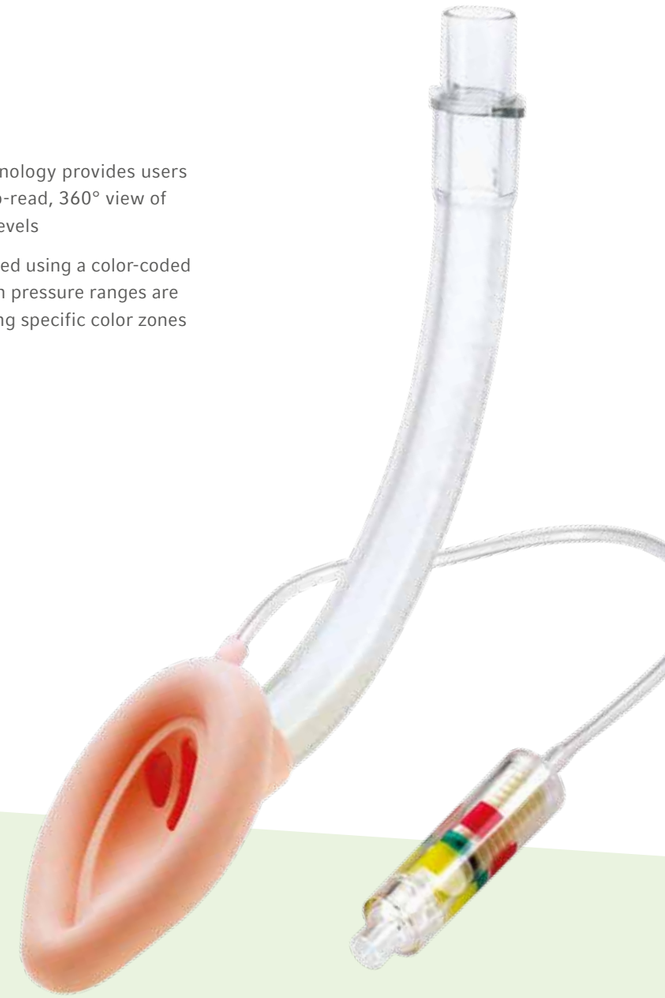


Figure 2. Integrated Cuff Pilot Technology with a color-coded scale to indicate intracuff pressure

Yellow zone
indicates a possible decrease in pressure or under inflation
0–40 cm H_2O

Green zone
indicates the optimal pressure
40–60 cm H_2O

Clear zone
between green and red warns of a change in pressure in its initial stages
60–70 cm H_2O

Red zone
indicates an increase in the cuff pressure or possible over inflation
70+ cm H_2O

Cuff Pilot™ Technology

An integrated pressure indicator

- A number of studies† conducted in pediatric and adult patients have evaluated the accuracy, clinical performance, and tolerability of laryngeal masks that include the integrated Cuff Pilot™ Technology[22,30,44]
  - One study noted that use of Cuff Pilot Technology allowed for an accurate indication of intracuff pressure[22]
  - Another study showed that use of Cuff Pilot Technology resulted in a lower incidence of post-operative pharyngolaryngeal complications, compared with a device without an integrated pressure indicator[30]
- Cuff Pilot Technology can help clinicians avoid many of the potential disadvantages of manometry
  - The use of LMA® Airways with Cuff Pilot Technology will help avoid the need for expenditure related to the purchase, maintenance, repair, cleaning, and storage of manometers, which could result in substantial cost savings
  - The single-use nature of LMA Airways with Cuff Pilot Technology may help reduce the risk of cross-contamination
  - Use of Cuff Pilot Technology helps avoid issues associated with the management, inventory, availability, and calibration of manometers within hospital operating rooms
  - Because Cuff Pilot Technology is integrated into into all single-use LMA Airways with a silicone cuff, it does not require users to take additional steps to determine cuff pressure
  - Cuff Pilot Technology constantly monitors intracuff cuff pressure, as opposed to a manometer, which provides a spot measurement

† The cuff pressure indicator used in the studies cited here was Cuff Pilot Technology, although it was referred to using different brand names.

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