



Company & Product presentation

Shenzhen HugeMed Medical Technical Development Co., Ltd

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- **Market information**
- **Product introduction**
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Company Profile



Company Profile

Who we are:

HugeMed was founded in 2014, and focus on R&D, manufacturer and sales of visual airway management solution now.

Location: Shenzhen: advantages in HR, electronic parts, tooling....

Management background: SK Medical (belonged to Mindray now)

R&D background: Experienced in medical equipment development.

Certification: Shenzhen High-tech enterprise

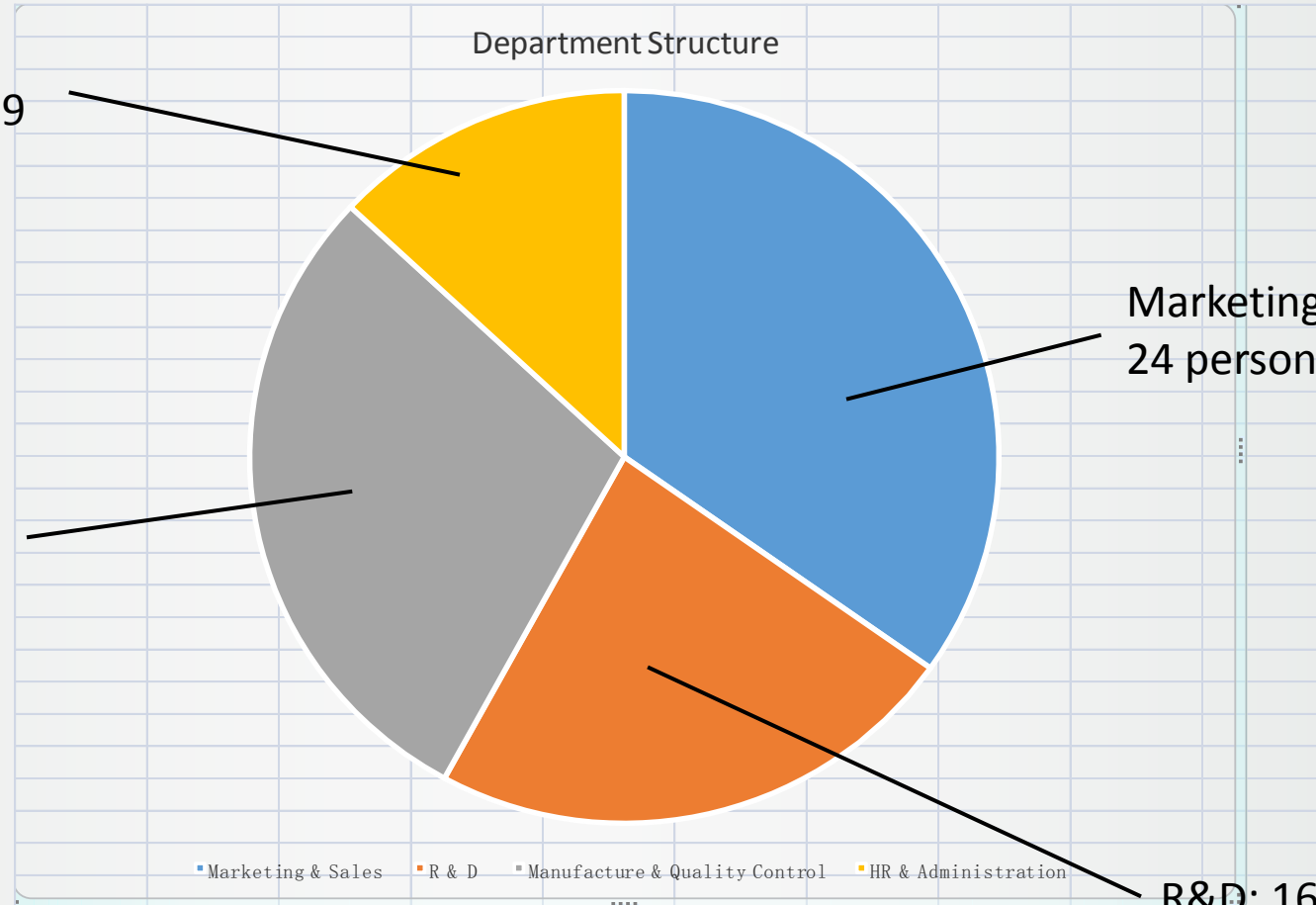


Department Structure

Staff: 69 persons

HR & Administration & Purchasing & Regulatory: 9 persons

Manufacture & QC & Storage: 20 persons



Marketing & Sales: 24 persons

R&D: 16 persons

Production line



Strict Quality Control Process

Voltage Checking



Blade Checking



Waterproof Checking



Resolution Checking



ISO 13485

Korea GMP

Manufacture and Quality Control

Excellent Quality System and Certifications



REGISTRATION NO. 04716Q1000255

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of Shenzhen HugeMed Medical Technical Development Co., Ltd. Registered Address: 6B, Block A, Tempus Building, 1st Qingshahe Road, Luohu District, Shenzhen City, Guangdong, China - Postcode: 518023 Manufacturing Address: 6B, Block A, Tempus Building, 1st Qingshahe Road, Luohu District, Shenzhen City, Guangdong, China

Has been assessed and conformed to the following standard(s) YY/T 0287-2003 (id. ISO 13485:2003)

The certificate is valid for the following scope: The Design, Development, Production, and Service of Video Laryngoscope (VL3D, VL3R) . (Export Only)

Date of issue: August 05, 2016
Date of expiry: March 01, 2019

Director: *[Signature]*

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: The Certificate Information are available on the official website of Certification and Accreditation Administration of the People's Republic of China (www.cca.gov.cn) or the Website of CNAS (www.cnas.com.cn). Add: 8F, Block A, China Lian Building, No. 2000, Guoding Road, Beijing, 100011, CHINA. TEL: 010-52012000

EC Declaration of Conformity

Manufacturer: Shenzhen HugeMed Medical Technical Development Co., LTD
8F, Block A, Tempus Building, 1st Qingshahe Road, Luohu District, Shenzhen 518023, P.R. China

Whose single Authorized Representative: Shanghai International Holding Corp. GmbH
(Europe)
Elffestrasse 80,20537 Hamburg, Germany

We, the manufacturer, herewith declare that the products Anesthesia Video Laryngoscope Model: VL3R, VL3D (including system components and accessories) (AECOCs-Code: 1229) meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

IEC 60601-1 Report No.: 17047017 001
IEC 60601-2 Report No.: 17054208 001

Following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

Shenzhen HugeMed Medical Technical Development Co., Ltd
8F, Block A, Tempus Building, 1st Qingshahe Road, Luohu District, Shenzhen 518023, P.R. China

Shenzhen, 11/11/2015. TAN YONG HONG
Legally binding signature, Function

Place, date

医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号
Certificate No.: YS220170167

产品名称: 麻醉视频喉镜
Product(s): Video Laryngoscope

规格型号
Model: 1. VL3R, 2. VL3D

产品注册证备案凭证号
Registration certificate(s): 粤械注准 20172540103

生产企业: 深圳中宏医疗技术有限公司
Manufacturer: Shenzhen HugeMed Medical Technical Development Co., LTD

生产企业住所: 深圳市罗湖区清水河一海晏路大厦A栋8B
Address of manufacturer: 8B, Block A, Tempus Building, 1st Qingshahe River Road, Luohu District, Shenzhen, Guangdong Province, P.R. China.

生产许可备案凭证号
Manufacturing License(s): 粤食药监械生产许 20172961 号

兹证明上述产品已按中国生产标准注册。
This is to certify that the above products have been registered to be manufactured and sold in China.



2017 年 / Year 04 月 / Month 27 日 / Day

(此证明书从发证时起有效期 2 年)
(This certificate is valid for two years from the date of issuance)

CERTIFICATE OF FDA REGISTRATION



HEREBY CERTIFY THAT

Shenzhen HugeMed Medical Technical Development Co., LTD

FDA US AGENT
IRC USA
www.IRC-US.com

HAS SUCCESSFULLY COMPLETED THE FDA REGISTRATION

FOR OWNER/OPERATOR NUMBER: 10052108

MDL	Product Code	510K ?	Class	GMP/UDI Exempt?	Device Name
D267908	CCW	Exempt	Class I	No.	Video Laryngoscope;VL3R / VL3D
D267909	LRC	Exempt	Class I	No.	Reusable Blade ;Disposable Blade ;B3R/B3D

Cherie Mack
PRINCIPAL ENGINEER
CERTIFICATE NO.:IRC-SH-1606


IRC
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- ISO 13485
- South Korea GMP
- Chinese FDA
- TUV CE
- US FDA



Market



Market Opportunity

1

In global, 80% of surgeries are general anesthesia operations, which need airway intubation

2

Visible and mini-invasive treatment are trend of airway management

3

Video laryngoscopes are being used more and more nowadays

Market Volume

Anesthesia Video Laryngoscope Market

Video laryngoscopy-assisted tracheal intubation devices have become substitutes to conventional laryngoscopes since recent past. These systems provide a clear image of the vocal cords and larynx on a display monitor, enabling control of the endotracheal tube (ETT) in its trajectory toward the airway. These devices display facilitates fast view, accurate ETT placement in difficult airways, avoiding complications resulting from improper tube placement. Anesthesia video laryngoscopy systems improves the view with laryngoscopy along with improved initial success rates, and help in the management of challenging intubations in order to improve care and reduce harm to patients.

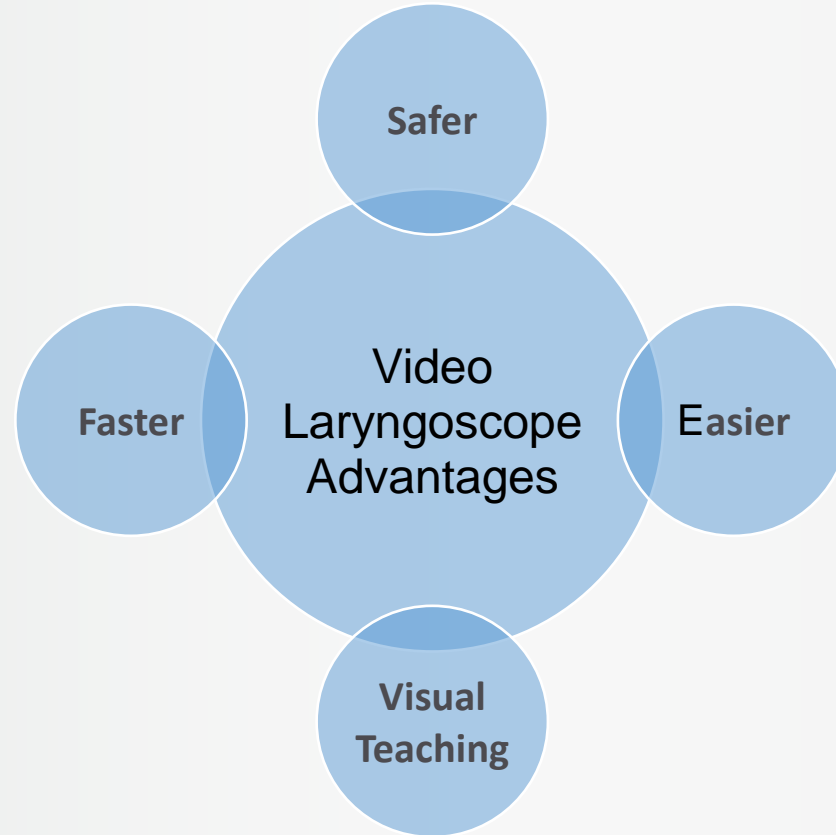
The global anesthesia video laryngoscope market size was valued at US\$ 194.5 million in 2017, and is expected to witness a robust CAGR of 13.2% over the forecast period (2018 - 2026).

Global Video Laryngoscopes Market: Region-wise Outlook

Depending on geographic regions, the global video laryngoscopes market is segmented into seven key regions: North America, Latin America, Eastern Europe, Western Europe, Asia Pacific Excluding Japan, Japan, and Middle East & Africa. North America is estimated to be the largest player in global video laryngoscopes market due to increase in the prevalence of cancer and other disorders related to the larynx. Europe and Japan are anticipated to be the most lucrative market during the forecast period owing to the increased adoption of minimally invasive instruments and high investment in the healthcare facilities.

Video V.S Direct Laryngoscope

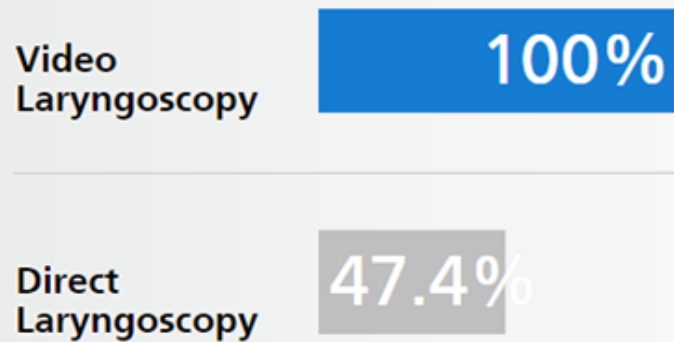
- Compare with traditional laryngoscope, video laryngoscope has its advantages.



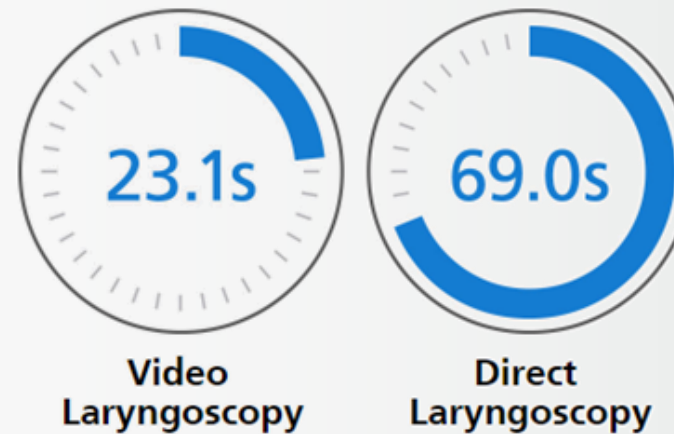
Advantages: Faster

STATISTICS

FIRST-PASS SUCCESS



TIME-TO-INTUBATE



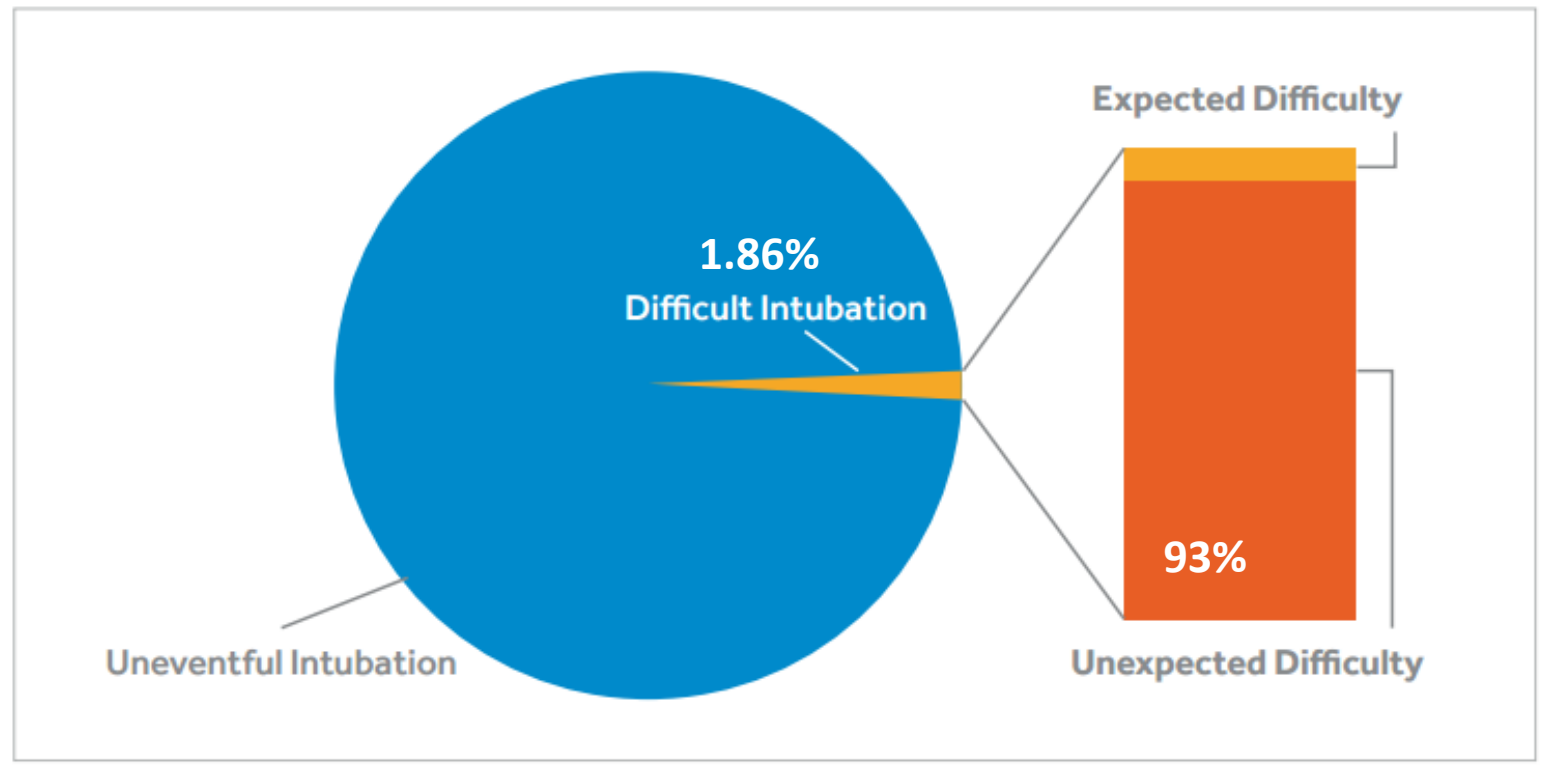
Conclusion:

In novice users, video laryngoscopy with a MAC blade improves success rate and time-to-intubate when compared with direct laryngoscopy with a MAC blade. 1

1. Ambrosio, Art, et al. "Difficult Airway Management for Novice Physicians: A Randomized Trial Comparing Direct and Video-Assisted Laryngoscopy." *Otolaryngology—Head and Neck Surgery* 150.5 (2014): 775-778.

Denmark Clinical resaerch date:3.

FIGURE 1. Frequency of unexpected difficult intubations. In total, 1.86% of intubations were difficult, and 93% of those were unexpected. Data adapted from Norskov et al, 2015.¹



3. Norskov AK, Rosenstock CV, Wetterslev J, Astrup G, Afshari A, Lundstrom LH. Diagnostic accuracy of anaesthesiologists' prediction of difficult airway management in daily clinical practice: a cohort study of 188 064 patients registered in the Danish Anaesthesia Database. *Anaesthesia*. Mar 2015;70(3):272-281.

Advantages: Safer

Unexpected difficult intubations happen in an instant — can cause long-term complications for patients.

Serious Complication:

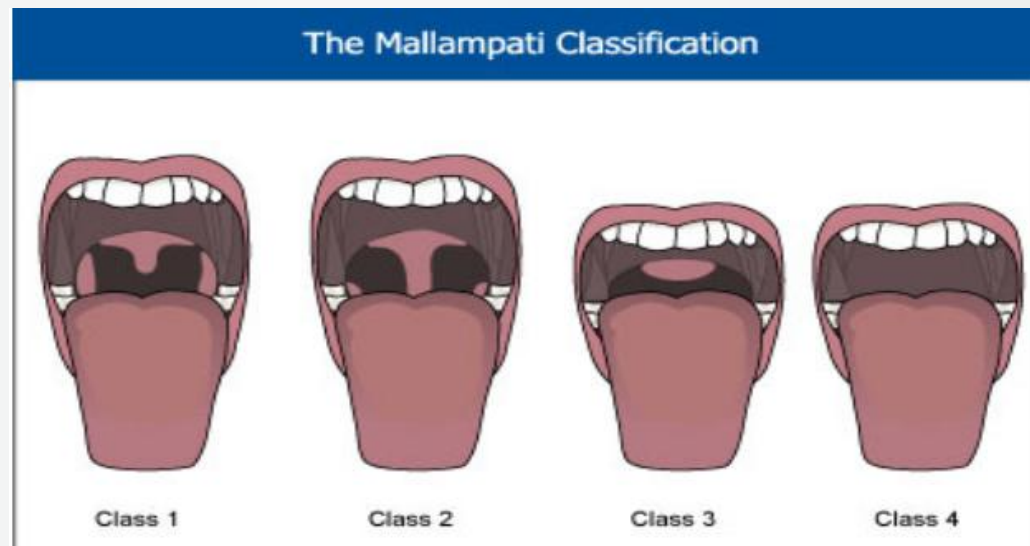
Consequences of difficult intubations can be catastrophic, leading to such as respiratory and cardiac arrest, airway damage and tooth injury, brain damage, or death.....

Complication result: (Research data from an audit in the U.K).²

- approximately 80% of airway-related incidents resulted in a full recovery,
- 2% resulted in brain damage
- 12% finally resulted in patient death.

² Royal College of Anaesthetists and the Difficult Airway Society. Major Complications of Airway Management in the United Kingdom. 2011.

- **Better glottic exposure to make difficult airway not difficult.**
The Mallampati classification of 99% patient could reach to Class I ~2 with video laryngoscope, at least reduce 1 class.
- **Less requirement of patient position**
- **A safe distance between the operator and the patient can be maintained, reducing cross-contamination.**
- **Shorter learning time**



Video Laryngoscope usage department

Emergency Room



ICU Room



Operation Room



NICU Room



Product Introduction



Video laryngoscope series



**Reusable
VL3R**



**Disposable
VL3D**



**Flexible Type
VL3S**



**Rigid
VL3H**

New Video laryngoscope

Advanced Video Laryngoscopy:
Real-time recording. LCD clarity.



Coming soon!!!!



Portable dis-connection type

Beside 8 inch monitor design meet most in-hospital requirement

New Single-use Ureteroscope

Single-Use

Flexible video uretero-roscope

12 Inch Touch Screen

AV, HDMI, VGA, DVI, SDI



Dual Buttons
For snap/Video capture

Self Locker
For reducing surgeon fatigue

True 1: 1
Torque ratio

Flexible Sheath
3.6Fr working channel
9.5Fr slim diameter shaft

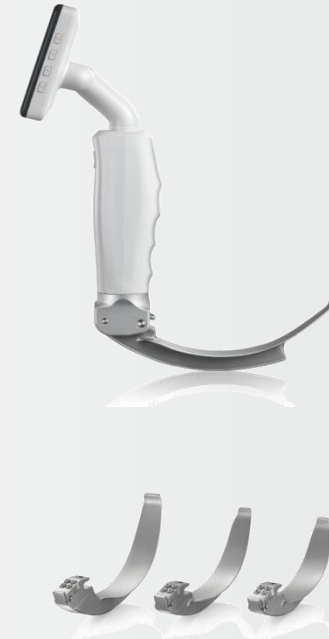
Passive Deflection
For easier navigation of lower pole

Coming soon!!!!

Single-use Ureteroscope



HugeMed VL3D Video Laryngoscope
(Disposable blade)
Mac2/Mac3/Mac4
Optional: Mac1/Mac5



HugeMed VL3R Video Laryngoscope
(Reusable blade)
Mac2/Mac3/Mac4
Optional: Miller00/miller0/miller1/Mac1/Mac5

HugeMed VL3D Video Laryngoscope Advantages

Large Screen

- ◆ 3.5 Inch full view
- ◆ Rotatable screen



Portable Design

- ◆ Anti-microbial handle
- ◆ Rechargeable battery working time:150 minutes
- ◆ USB&HDMI port available.



Snap button

- ◆ Taking photo and video recording
- ◆ Integrated 8G memory card



High Resolution CMOS Camera

- ◆ 2.0M Pixel
- ◆ 640*480 LCD screen.
- ◆ Anti-fog camera
- ◆ 800Lux LED illumination



5 Sized of disposable blade

- ◆ Anti-fog Function
- ◆ Available for pediatric, adult, obese and difficult airway.



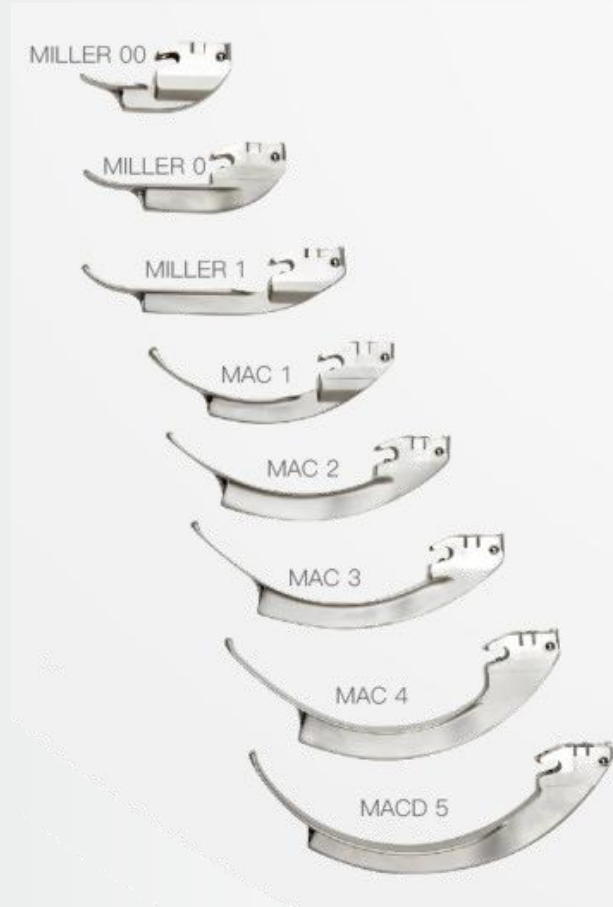
High Cost- Effective

lower price than other brands with same function, save your budget and guarantee your profit well.





HugeMed Resuable
Video Laryngoscope VL3R

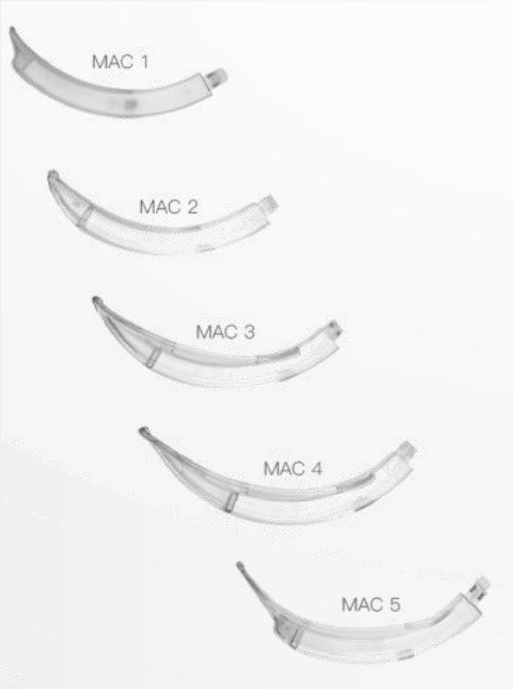


Model	Length mm(LxWxH)	Applicable patient
Miller 00	72X16X30	Newborn
Miller 0	84X17X30	Newborn
Miller 1	110X18X30	Infant
Mac 1	101X18X34	Infant
Mac 2	117X23X37	child
Mac 3	130X24X39	Adult
Mac 4	138X26X49	Obese airway
Mac 5	150X25X52	Diffcult airway

HugeMed disposable blade series



HugeMed Disposable Video Laryngoscope VL3D



Model	Length mm(LxWxH)	Applicable patient
Mac 1	95X28X12.5	Infant
Mac 2	110X29X13	child
Mac 3	120X27X13	Adult
Mac 4	135X22X14	Obese airway
Mac 5	120X29X16	Diffcult airway

HugeMed Video Laryngoscope V.S. Other Brands

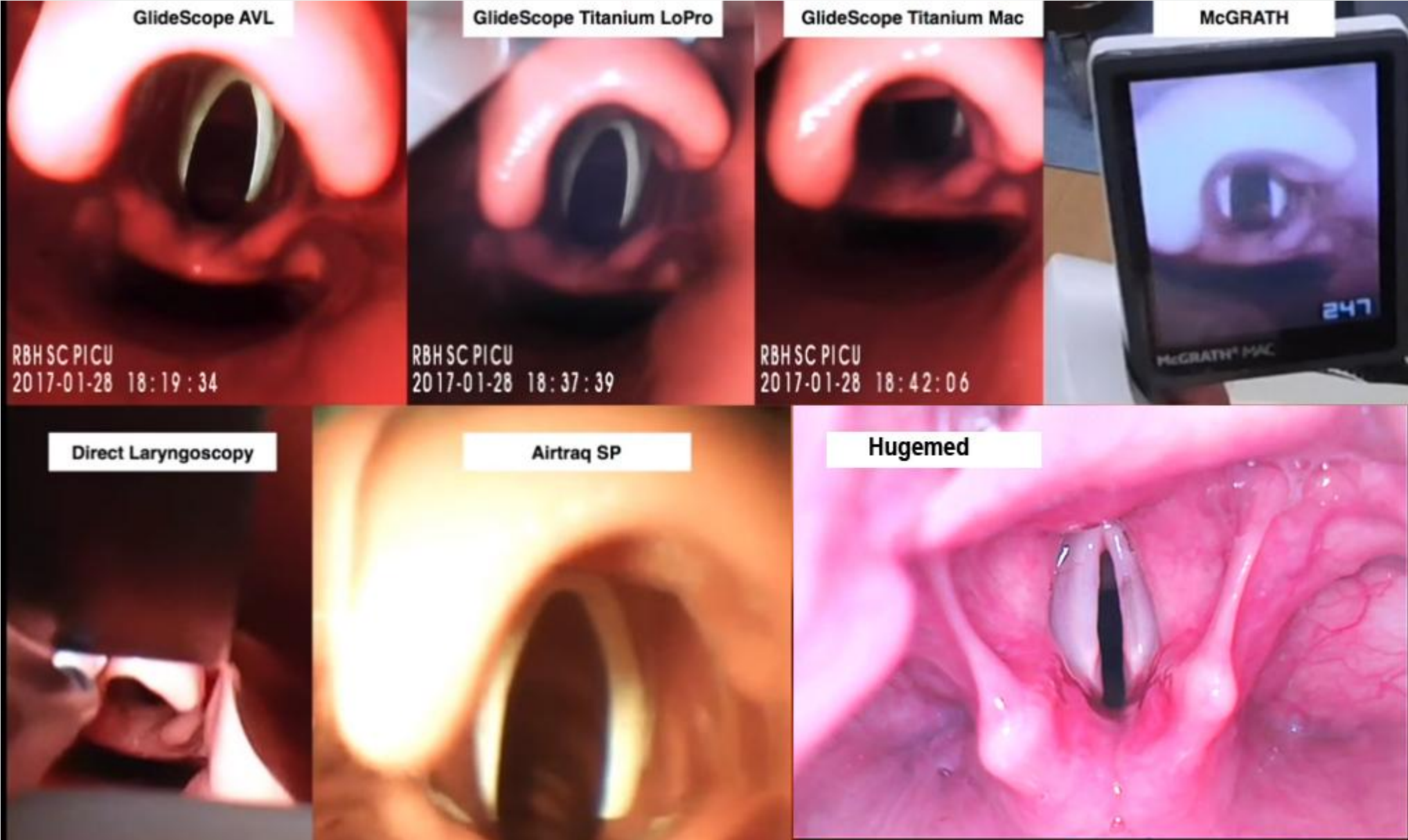
		 HugeMed	 Glidescope®	 STORZ KARL STORZ – ENDOSKOPE	 KingVISION™	 McGRATH®
Product Image						
Display	Size	3.5"	3.5"	3.5"	2.4"	2.5"
	Resolution	640*480	320*240	320*240	640*480	/
	Pixel	2.0M Pixels	/	/	0.2M Pixels	0.1M Pixels
Battery	Rechargeable	YES	YES	YES	NO	NO
	Working Time	150-200 Minutes	100 Minutes	60 Minutes	80 Minutes	250 Minutes
Photo / Video Capture		YES	NO	YES	NO	NO
Blade	Reusable	Yes 8 types	NO	YES 8 types	NO	NO
	Disposable	YES 5 types	Yes 4 types	Yes 5 types	Yes 3 Types	NO 4 Types
Price		Cost-efficient	Very High	Very High	High	High

Key features: high-definition; rechargeable lithium battery; picture/video function, competitive price.

Image quality



Comparison of Image quality



Flexible type— video laryngoscope



VL3S Flexible Video laryngoscope

optical system	field of field	100°
	depth of field	3-50mm
insertion section	insertion tube outer diameter	2.8mm 3.9mm 5.2mm 5.8mm
	distal end out diameter	
	working length	650mm
Instrument Channel	channel Inner diameter	1.2mm 2.2mm 2.6mm
	minmum Visible length	3mm form the dital to end
bending section	angulation range	160 up 130 down



Rigid type— video laryngoscope



Size: 3 types (Infant-flexible, Adult-flexible, Adult/ un-bending)

PARTS	PARAMETER		
	Infant (flexible)	Adult (flexible)	Adult (un-bending)
Field Angle	100±10%	100±10%	60±5%
Depth of Focus	3-50mm	3-50mm	20-50mm
Resolution	640*480	640*480	640*480
Display	3.5"	3.5"	3.5"
Pixels	400*400	400*400	640*480
Illuminance	≥400LUX	≥400LUX	≥400LUX
Weight	330g	340g	350g
Swivel Up and Down	0°~130°	0°~130°	0°~130°
Swivel Left and Right	0°~270°	0°~270°	0°~270°
Rigid Tube Diameter	3mm	3.9mm	5.0mm
Rigid Tube Radian	80mm>R>50mm	80mm>R>50mm	R=55mm, R=65mm, R=75mm
Rigid Tube Length	L=300	380mm	380mm

Global activities



HugeMed Global Sales Network



HugeMed Products have been selling in more than 50 countries/ territories all over the world

Overseas promotion

Korea Workshop



Germany Workshop



Overseas promotion

Turkey Workshop



Saudi Arabia Workshop



Overseas promotion

Indonesia Workshop



Thailand Workshop



HugeMed Chinese Exhibition

2018 Shanghai CMEF



2018 ShenZhen CMEF
Hugemed



Agent Overseas promotion



2018 21th Iran Health



2018 Indonesia Hospital Expo



THANK YOU

The background features several overlapping, semi-transparent blue geometric shapes, primarily triangles and quadrilaterals, that create a sense of depth and movement. These shapes are positioned on the right side of the slide, extending from the top right corner towards the bottom left.