Video-laringoscoapele HugeMed

Siguranță
- Lame de unică folosință ambalate la vid.
- Ecranul este ranforsat pentru protecție împotriva spargerii.
- Nu există posibilitatea infecției încrucișate la utilizarea lamelor de unică folosință.
- Lentile anti-aburire, mâner antimicrobian.
- Lamele de unică folosință sunt construite utilizând materiale speciale pentru a preveni ruperea, partea care fixează lamele de consolă poate suporta presiuni de peste 300 kg.
- Lamele reutilizabile fabricate din oțel inoxidabil 316 de calitate medicală au avantajul unei rezistențe ridicate la flexiune, nu prezintă riscul de rupere; au trecut cu succes testul de impermeabilitate fiind clasificate IPX8, astfel, pot fi dezinfectate prin scufundare totală în apă.

Rapiditate
- Ușoare, portabile.
- Instalare și intubare mai rapide.
- O îndepărtare mai eficientă a lamelor normale sau retractabile.

Înaltă definiție
- Ecranul de 3,5 inci anti-reflexii cu vizualizare completă dispune de capacități înalte de vizualizare la fiecare intubare
- Camere de 2,0 megapixeli cu vizualizare îmbunătățită

Ușurință
- Acumulator litiu-ion reîncărcabil
- Buton cu o singură apăsare pentru înregistrare.

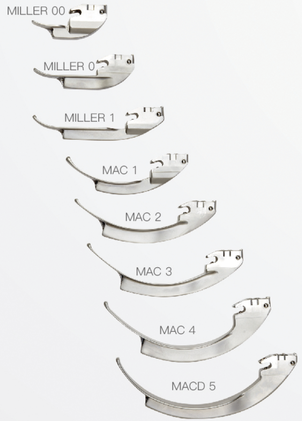
Un bun raport calitate-preț
- Lame de unică folosință ieftine.
- Lame reutilizabile din oțel inoxidabil 316 de calitate medicală rezistente la 1000 de utilizări.







Video-laringoscopul reutilizabil HugeMed VL3R



Video-laringoscopul de unică folosință HugeMed VL3D



Toate mărimile de lame într-o singură unitate

Florina Iustina Ionescu
Digitally signed by Florina Iustina Ionescu
T=Manager, C=RO, S=ARAD, L=ARAD, O=Spitalul Clinic Judetean de Urgenta Arad, OU=Administrativ, E=ionescuscm@yahoo.ro, SERIALNUMBER=201104209FIII1, G=Florina Iustina, SN=Ionescu, CN=Florina Iustina Ionescu
Certificare autentificitate
Computerul meu
2020.05.27 14:08

Safety, Intubation, V

O ușoară intubare a căilor respiratorii dificile!
- Incidența intubărilor dificile nedetectate este estimată a fi peste 3%. Unul dintre factorii care contribuie la intubările dificile este slaba vizualizare a glotei.
- Video-laringoscopul HugeMed oferă o mai bună vizualizare la intubările dificile.

Ratele scăzute de succes al intubației și curba de învățare largă au fost îmbunătățite!
- De obicei, curba de învățare cu o formare adecvată pentru HugeMed VL este relativ redusă.
- Ratele de succes ale intubării utilizând HugeMed VL sunt mai ridicate în comparație cu celelalte produse.



Subsemnatul, **Suciu Brăduț-Crișan**, traducător autorizat de către Ministerul de Justiției cu autorizația nr. **30426/2010**, certific exactitatea prezentei traduceri in limba română cu textul inscrisului în limba engleză, care mi-a fost prezentat.

Traducator autorizat :

Suciu Brăduț-Crișan
Traducător interpret autorizat
Engleză - Aut. Nr.30426/2010
CNP 1810514260084
MINISTERUL JUSTIȚIEI
TÂRGU MUREȘ • ROMÂNIA

HugeMed VL3R Video Laryngoscope
Operating Instructions

HugeMed, Co., LTD
8F, Block A, Tempus Building
1st Qingshuihe Road, Luohu District
Shenzhen City, Guangdong, China
www.HugeMed.net

Guide Book

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HugeMed VL3R Video Laryngoscope Operating Instructions

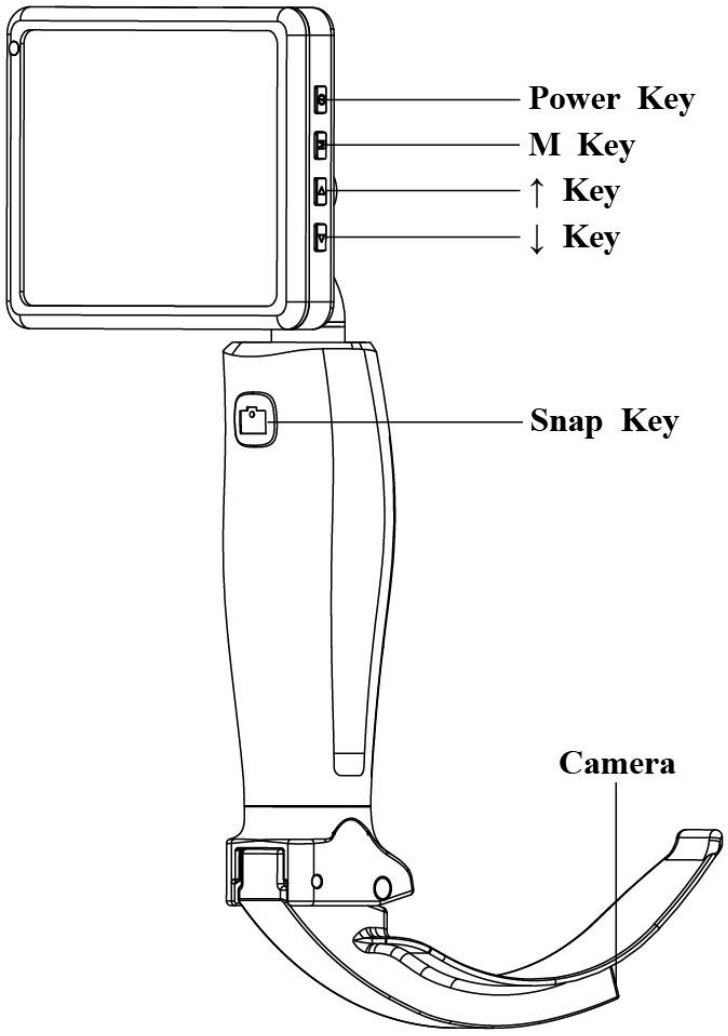
Welcome to use VL3R handheld video laryngoscope. With its advanced module design , high resolution images, professional lighting system and recording capabilities, this device represents a state-of-the-art solution to both average and difficult intubation procedures in different environments.
While the VL3R is fairly intuitive to assemble and operate, these instructions will serve as a reference for operation and maintenance of the device. Please read the instructions carefully before attempting to operate the VL3R.

Ⅰ. Device Assembly and Disassembly

1. Select the appropriate VL3R video blade according to patient oral cavity size .
2. Assembly :position the blade connection point to the video handle mounting block and snap together by pushing down the tip of the blade.
3. Disassembly : reverse action of Step 2 by pulling up the tip of the blade to separate the blade connection from the handle mounting block.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Ⅱ. Operating the VL3R Display



1. Power Key: Switch on/off the device ;
2. M key: menu key / video play Pause key / Enter / time selection.
3. ↑ key: last image or video / increase value .
4. ↓ key: next image or video / Decrease value .
5. Snap key : short press camera / long press video / return .
6. Camera : for being filmed .

1. Pressing the power button for 3.5 seconds, the system will power up and display the" HugeMed "logo for a few seconds, and will then fully functional. If a video blade is appropriately fitted to the handle, an image from the camera will appear on the screen. If the screen read" Video blade is not connected!",please check if the handle connection has fitted well with blade tip , or turn off and restart the device.
2. Upon turning on the display , in the lower left hand corner of the screen will be a small battery symbol icon indicating the power level of the monitor's internal rechargeable lithium battery. The date and time will also be displayed.
3. If the battery is low in power and in need of recharging, there will be reminder like "Reminder : Low battery! Please charge in time! The system will be shut down in 15 minutes! until the device is either recharged with the external mini-USB recharger cord, or power is eventually exhausted and the monitor turns itself off.

Ⅲ. VL3R System Operation Guidance

The VL3R is designed to be used with standard laryngoscopy technique similar to that of direct laryngoscopy. Please refer to qualified instructors who provide specialized training in endotracheal intubation techniques before attempting to use this device with human subjects. The static images and video for respiratory and tracheal intubation procedures can be recorded and automatically saved to the SD card inside the display .

1.Warming up ：

- Cleaning：The blade and handle should be appropriately cleaned and/or sterilized before use (see cleaning instructions in PART IV).
- While the blade electrical component generates heat to the camera lens which will help clear lens fogging immediate after open up especially while in the warm and humid conditions of the airway,

2. Recording static images: :

- Press short the snap key on the handle for picture shooting. When there appears icon "" images are automatically saved to the SD card under a ".JPG" file format.
  NOTE: static l images cannot be recorded and saved while the device is recording video.

3. Recording Video loops:

- Press long(2 seconds) the snap key to initiate recording. The action is noted by an ongoing blinking "Recording " on the display. A recording time counting will also be displayed.
- Press the same button a second time to end the recording. The video file will automatically be saved to the SD card under an ".MP4" format.。

4. Reviewing images and videos:

- Both static images and video loops can be reviewed by pressing the" M" menu button for selecting "Image view" or "Video play" to preview .
- Each file is individually identified by a date/time stamp.

5. Exiting video :

- Press "M" menu button to pause video review play ; press "snap" key to end up video review .

6. Setting up Time and Date

- press "M" Menu key and select "Time Setting " .
- Press Up or Down arrow buttons to amend date and time value .
- Press M" Menu key to confirm the changes and then the upper right corner of the display will show the change

IV、Cleaning Instruction

Please carefully follow the below operating instructions from the manufacturer before you do cleaning/sterilization.

1. Handle & Display Cleaning

- The display is not waterproof and should not be merged or exposed to excessive amounts of fluids. The face of the unit, including the front control buttons, is sealed and can be cleaned with anti-microbial solution wipes. Cleaning of the remainder of the unit should be done carefully to avoid introducing liquids into the interior of the monitor.

2. Blade Cleaning

Given its electrical components, the VL3R blade should not be exposed to extremely high or low temperatures during cleaning. The blade can be sterilized through:

- Anti-microbial soaking
- low-temperature sterilizing with hydrogen peroxide gas plasma

V、Battery use and battery maintenance

The VL3R system is equipped with rechargeable lithium ion batteries. These batteries are designed to independently provide optimal power to the display and the video blades, and can be fully recharged many times with minimal loss in performance.

1. Charging

It is not accessible other than to connect to a charger via the mini-USB charging port on the top of the display. The LED on the upper left of the display will illuminate GREEN when the battery is charging, and will cease when the battery is fully charged.

- When the power is nearly consumed up ,there will be reminder 5 minutes beforehand .
- Consumption time of one full charge in continuous use: 2 hours (average)
- Time to recharge: 8 hours from fully discharged state
- Span life: up to 3 years (average)

2. Maintenance

The VL3R monitor can be continuously attached to the charger for long periods of time . Lithium ion batteries also do not have “memory” characteristics, and do not require deep discharging and recharging to maintain peak functionality

Note: Allowing rechargeable lithium batteries to fully discharge can damage the battery and reduce performance significantly. Full discharge of the batteries should be avoided.

VI. Electromagnetic Compatibility

Notice

- VL3R conforms with IEC 60601-1-2 relevant requirements of the standard electromagnetic compatibility;user should install and use in accordance with electromagnetic Compatibility random file provided;
- Portable and mobile RF communication equipment may affect VL3R performance, so to avoid the use of strong electromagnetic interference such as near the cell phones, microwave ovens and the like;
- Guidelines and manufacturer's statement are detailed in the annex.

Warning

- VL3R should not be close to or stacked with other equipment; if it must be close to or stacked use, it should be observed to verify normal operation in the configuration when using;
- A Class of equipment intended for use in industrial environments, because of VL3R conduction and radiation harassment, in other environments it is essential to ensure that EMC may have the potential difficulties or not;

- Except for the manufacturer VL3R internal components as spare parts to sell cables, the use of accessories and cables provisions may result in increased or reduced VL3R emitted immunity.

Annex：

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">VL3R is intended to be used in the electromagnetic environment specified below; the purchaser or user should ensure that it is used in such an electromagnetic environment:</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment - Guidelines</th></tr>
<tr><td>RF Transmitter
GB 4824</td><td>Group 1</td><td>VL3R only for its internal functions and uses radio frequency energy. Therefore, it is the very low radio frequency transmitter, and the possibility of interference in nearby electronic equipment is small.</td></tr>
<tr><td>RF Transmitter
GB 4824</td><td>A Class</td><td rowspan="3">VL3R suitable for use in non-residential and is not directly connected to all facilities for residential home in the public low-voltage power supply network.</td></tr>
<tr><td>Harmonic emission
GB 17625.1</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations / flicker emission
GB 17625.2</td><td>Not applicable</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity			
VL3R is intended to use in the electromagnetic environment specified below, the purchaser or user should ensure that it is used in such an electromagnetic environment:			
Immunity Test	**IEC 60601 Test level**	**compliance level**	**Electromagnetic environment - Guidelines**
Electrostatic discharge GB/T 17626.2	±6kVcontact ischarge ±8 kV air discharge	±6kVcontact discharge ±8 kV air discharge	Floors should be wood, concrete or ceramic tile. If the ground is covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient burst GB/T 17626.4	±2kV to Power line	±2kV to Power line	Mains power quality should have a typical commercial or hospital environment using
Surging GB/T 17626.5	±1 kV Wire to Wire ±2 kV Wire to earth	±1 kV Wire to Wire ±2 kV Wire to earth	Mains power quality should have a typical commercial or hospital environment using
Power input line voltage dips, short interruptions and voltage variations GB/T 17626.11	<5 % U_T,Duration of 0.5 cycles （ on the basis of U_T,>95% voltage sag） 40 % U_T,Duration of 5 cycles （ on the basis of U_T,60% voltage sag） 70 % U_T，Duration of 25 cycles （ on the basis of U_T,30% voltage sag） <5 % U_T,Continued 5s （ on the basis of U_T,>95% voltage sag）	<5 % UT,Duration of 0.5 cycles （ on the basis of UT,>95% voltage sag） 40 % UT,Duration of 5 cycles （ on the basis of UT,60% voltage sag） 70 % UT，Duration of 25 cycles （ on the basis of UT,30% voltage sag） <5 % UT,Continued 5s （ on the basis of UT,>95% voltage sag）	Mains power should have the quality of a typical commercial or hospital environment use. If the user needs VL3R continuous operation during power interruption, its recommended VL3R use an uninterruptible power supply or battery-powered
Power frequency magnetic field（50/60Hz） GB/T 17626.8	3A/m	3A/m,50/60Hz	Power frequency magnetic field should have a typical place in a typical commercial or hospital environment characteristic of the level of power frequency magnetic field

Remark：U_T is the AC voltage before applying the test voltage

Guidance and Statement of Electromagnetic Immunity

The VL3R should be used under stipulated electromagnetic environment. Customer or user shall ensure using VL3R under the following stipulated electromagnetic environment.

Immunity test	IEC 60601Test Level	Compliance level	Electromagnetic environment – Guide
Conduction immunity GB/T 17626.6 Radiation immunity GB/T 17626.3	3 V(Valid Value) 150 kHz ~ 80 MHz 3 V/m 80 MHz ~ 2.5 GHz	3 V (Valid Value) 3 V/m	Portable and mobile RF communications equipment must be used outside the equipment and / or systems (including cable) of any parts the prescribed distance. The separation distance is based on the transmitter frequency to choose the right formula calculated. The suggested calculation formula of isolation distance is: $d = 1.2\sqrt{P}$ 80M ~ 800MHz $d = 2.3\sqrt{P}$ 800M ~ 2.5GHz Among them, P is the Nominal maximum output power of transmitters, its unit is watt; d is the recommended isolation distance, its unit is meter. The field strength of RF transmitter is obtained via electromagnetic field measurements ***a*** ,in every frequency range ***b*** must be less than line level. It may appear interference by the equipment marked the following sign: 

Note 1: Use higher frequency band formula between 80 MHz and 800 MHz

Note 2: The above guidance does not apply to all cases, because material structure, objects and persons can absorb and reflect the electromagnetic wave and then affect the electromagnetic transmission.

[a] The field strength of Radio (honeycomb and wireless) mobile phone's base stations and ground mobile radio receivers, the antenna devices, FM and AM radio, television broadcast is unable to use pure theory for the accurate estimation. In order to evaluate the electromagnetic environment produced by fixed RF transmitters, we should consider method of electromagnetic field measurement. If the measured field strength of working environment of VL3R exceeded the stipulated RF level, we must observe whether VL3R can work normally. Once abnormal situation was found, we must take corresponding measures, such as changing the direction of VL3R or moving it to other places.

[b] When the frequency range is between 150 k and 80 Mhz, the field strength shall be less than 3 V/m.

Recommended Distance Between VL3R and Portable/Mobile RF Communication Equipment

The VL3R can be used in the electromagnetic environment where RF interference can be controlled. In order to avoid electromagnetic interference, the customer or user should ensure that the VL3R and portable/mobile RF communications equipment maintain the minimum recommended distance. The following recommended distance is calculated according to the maximum output power of communication equipment.

The transmitter's maximum output power (W)	Calculate isolation distance according to the transmitter frequency (m)		
	150 kHz ～ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ～ 800 MHz $d = 1.2\sqrt{P}$	800 MHz～ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

If the transmitter's maximum output power is not within the above range, we can estimate isolation distance by corresponding equation in column. P in the equation is the maximum output power given by transmitter manufacturer. The unit is watt.

Note 1: Use the higher frequency band formula between 80 M and 800 MHz.

Note 2: The above guidance does not apply to all cases, because material structure, objects and persons can absorb and reflect the electromagnetic wave and then affect the electromagnetic transmission.

VII. Troubleshooting

HugeMed VL3R systems are generally reliable and simple to operate, requiring minimal maintenance for extended periods. However, the following is offered to help deal with unexpected device conditions:

1) Display is non-functional, shows no sign of power
- Check for proper power
- Check the connection between blade and handle .
- Restart if necessary .

2) Display is powered, but shows blue screen
- Check the connection between blade and handle .
- Restart if necessary .

3) Image appears on screen, but is grainy or dim
- Ensure that handle battery is adequately charged
- Check all blade and handle connections
- Ensure that lenses on camera and LEDs on blade are clean, and not contaminated

Ⅷ .HugeMed VL3R Limited Quality Warranty

HugeMed warrants its VL3R Products to be free of defects in materials or production and offer 12 months guarantee under normal use from date of purchase . Details are as follows:

What is Covered: Replacement of All Parts.
What is Not Covered: Transportation charges to and from HugeMed; damage caused by abuse, misuse, accident or negligence.
To Obtain Warranty Service: Please contact HugeMed Customer Support which will check and evaluate the situation. If it is appropriate, HugeMed will issue an RGA authorization and number. A form will be sent to be completed and returned with the defective product.

An RGA number is valid for 30 days after issuance. Any returns beyond 30-day period will expire and will not be authorized and will not be accepted.

HugeMed VL3R Professional Care Extended Warranty

HugeMed;s Professional Care Extended Warranty covers all VL3R products against defects in material or workmanship for a period of 1 to 3 years from date of shipment to the customer. This extended warranty is available only to the original purchaser of the VL3R system or components, and is not transferable. This care extended may be purchased on an annual basis or for 3 year period. This optional package may also be extended for up to three (3) years after the completion of the initial Extended Warranty period, accumulating a maximum of six years of coverage.

If additional equipment is added to the original VL3R system, an extended warranty package can be purchased independently .

If a VL3R system fails for any reason during the extended warranty period, HugeMed will repair or replace the failed component of the VL3R system within the next business day after notification to our customer service department. The customer agrees to return the defective VL3R product to HugeMed within 3 business days upon receipt of the replacement unit .
This extended warranty does not apply to product that has been damaged due to obvious mishandling or as a result of modification by an unauthorized HugeMed repair station or person.

HugeMed VL3R Warranty Registration

HugeMed products do not contain a warranty registration card, however to obtain warranty service it is a good practice to register your product in order to obtain supplemental information. Warranty registration information is kept strictly confidential and is not available to any other organizations.

Organization (institution) _____

Title_____

First Name _____

Last Name _____

Address _____

City _____

State/Zip Code _____

Country Code _____

Email Address _____

Product Number(On Label) _____

Product Name _____

Quantity _____

Serial Number / Lot Number _____

Distributors purchased from_____

Date of Purchase _____

Mail or Fax Warranty Registration to

Shenzhen HugeMed Medical Technical Development Co., LTD

8F, Block A, Tempus Building, 1st Qingshuihe Road, Luohu District, Shenzhen City ,Guangdong, China

Tel : +86-755-22275866,22275899 Fax : +86-755-22275833 E-mail:server@hugemed.net

EC Declaration of Conformity

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

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

We, the manufacturer, herewith declare that the products

Video Laryngoscope

Model:VL3R;VL3D;VL3D Plus;VL3S;VL3H;VLRM;VLDM

VLRM-01;VLRM-02;VLRM-03;VLRM-04;VLRM-05;VLRM-06;VLRM-07;VLRM-08;VLRM-09;
VLDM-01;VLDM-02;VLDM-03;VLDM-04;VLDM-05;VLDM-06;VLDM-07;VLDM-08;VLDM-09;
(Including system components and accessories)
UMDNS-Code: **12293**

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 Rule 5 of the Directive 93/42/EEC. It bears the mark

Applicable Standard(s):

Risk Management:	EN ISO 14971:2012		
Safety:	EN 60601-1:2006/A12:2014	EN ISO 7376-2009	EN 60601-1-2:2015
Software:	EN 62304:2006/AC:2008		
Usability:	EN 62366:2008	EN 60601-1-6:2010	
Biological Evaluation:	EN ISO 10993-1:2009/ AC:2010		
Label:	EN ISO 15223-1:2016	EN 1041:2008	

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 Qingshuihe Road, Luohu District, Shenzhen 518023, P.R China

Shenzhen,4/1/2019 TAN YONG HONG

Place, date *Legally binding signature, Function*