



PVL-I PLUS
Pocket Video Laryngoscopes
USER MANUAL



PVL-I-02 Plus

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Manufacturer Information

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Chinese Patents

The PVL-I Plus Video Laryngoscope technology is protected under Chinese Patents. Applied Chinese Patents:

ZL201620082375.1	ZL201821478272.2
ZL201620082173.7	ZL201920305262.7
ZL201630543506.7	ZL201920301295.4
ZL201720246532.2	ZL202030463721.2
ZL201620573285.2	ZL202021702029.1
ZL201730166005.6	ZL202021703805.x
ZL201721893598.7	ZL202021702028.7
ZL201721128421.8	ZL202030465715.0
ZL202030465767.8	ZL202030463720.8

Information in this User's Manual and Quick Reference Guide may change at any time without notice. For the most up-to-date information, see the online manuals at www.vimed-mac.com.

Trade Mark & Trade Name:



Hebei Vimed Medical Device Company, Ltd. is the owner of above trade mark which is registered in China. All of our video laryngoscope products are marketed under this trade mark.

Pocket VL is a trade name registered in China by the company as well. And registered in Europe as:



Product Information

Name: PVL-I Plus Video Laryngoscope (hereinafter called PVL-I Plus)

Model: PVL-I-01 Plus/PVL-I Plus

The PVL-I Plus Video Laryngoscope (PVL) is designed to present a consistent, clear, real-time view of patient's airway to physicians, and to assist them getting a quicker and safer tracheal intubation.

There are two different models of PVL-I Plus Video Laryngoscope (PVL-I-01 Plus/PVL-I-02 Plus) available for different situation and/or different physicians. PVL-I-01 Plus is designed for pediatrics and PVL-I-02 Plus is designed for adults. Therefore, their Sterile Single-use Blades are also designed differently in size and shape.

The PVL-I-Plus PVL-I Plus Video Laryngoscopes are portable, handheld and user-friendly medical devices. The “Control Key” controls the device’s all functions such as On/Off, Photo-Taking and Video-Recording. Its 3” display monitor can be completely foldable to either side of its handle and two-way rotatable. It also offers clarity for real-time viewing, optimal for image recording and analysis during tracheal intubation or the laryngopharynx examination and treatment. And the digital video output is ideal for display video recordings. The Sterile Single-use Blade are available in a wide range of configuration and size, allow clinicians to meet the requirements of patients ranging in size from preterm to morbidly obese. The device also incorporates a rechargeable 18500AA lithium battery and anti-fog mechanism. The 18500AA battery is interchangeable. The water-resistance of PVL handle is IPX7 and IPX4 for the 3” monitor.

Model & Size Difference

As mentioned above, the PVL-I-01 Plus is designed for pediatrics (see Fig. 1) and PVL-I-02 Plus for adults (see Fig. 2) respectively. They must be used with the Sterile Single-use Blade (hereinafter called SSB) to conduct the intubation. There are 8 different sizes of SSB available for being used with the PVL-I Plus video laryngoscopes. Details are described in Table 1.

Table 1 matching the PVL-I Plus with the Sterile Single-use Blades

Models of PVL-I Plus	Sizes of the sterile Single-used blade
PVL-I-01 Plus	Mac-00, Mac-0, Mac-1
PVL-I-02 Plus	Mac-2, Mac-3, Mac-4, Mac-3D, Mac-3M



Fig. 1 PVL-I-01 Plus



Fig. 2 PVL-I-02 Plus

PVL-I Plus Video Laryngoscope Components and Configuration

Table 2 PVL-I-01 Plus (Pediatric) standard configuration

Components	Qty/Unit	Model & Sizes	Code	Remarks
PVL-I Plus video laryngoscope	1pcs	PVL-I-01Plus	2101000	For baby & infant
18500A Li-ion Battery	2pcs	3.7 VDC 2040 mAh	2100323	Rechargeable
Data cable	1pcs	USB	2100328	
Battery Charger	1pcs	For 18500A	2100326	
Adaptor for the Charger	1pcs	EU standard	2100327	
Packing box	1pcs	Carton	2100329	
Sterile Single-use Blade	-	Mac-00	3101304	Ordered separately
Sterile Single-use Blade	-	Mac-0	3101305	Ordered separately
Sterile Single-use Blade	-	Mac-1	3102301	Ordered separately

Table 3 PVL-I-02 Plus (Adult) standard configuration

Components	Qty/Unit	Model & Sizes	Code	Remarks
PVL-I Plus video laryngoscope	1pcs	PVL-I-02 Plus	2102000	For adult patients
18500A Li-ion Battery	2pcs	3.7 VDC 2040 mAh	2100323	Rechargeable
Data cable	1pcs	USB	2100328	
Charger pack	1pcs	For 18500A	2100326	
Adaptor for the Charger	1pcs	EU standard	2100327	
Packing box	1pcs	Carton	2100329	
Sterile Single-use Blade	-	Mac-2	3102302	Ordered separately
Sterile Single-use Blade	-	Mac-3	3102303	Ordered separately
Sterile Single-use Blade	-	Mac-4	3102304	Ordered separately
Sterile Single-use Blade	-	Mac-3D	3102305	Ordered separately
Sterile Single-use Blade	-	Mac-3M	3102306	Ordered separately

PVL-I-02 Plus Major Parts Typical Diagram

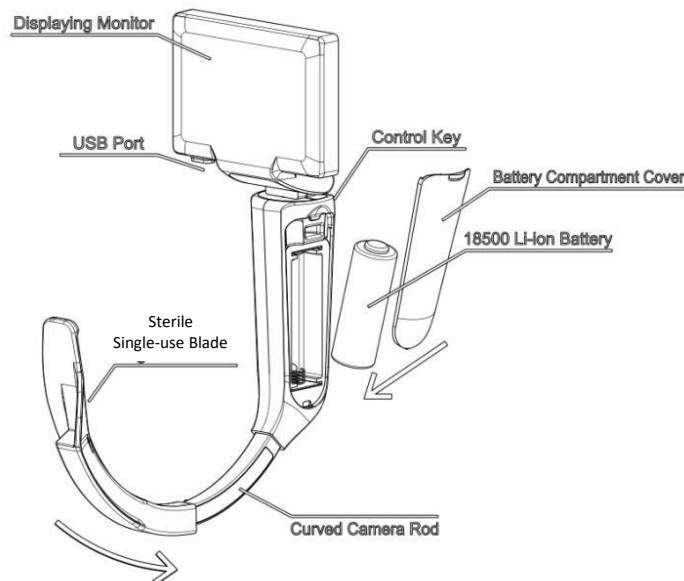


Fig. 3 PVL-I-02 Plus KEY & PARTS TYPICAL DIAGRAM

Other Accessories



Fig.4 Charger & Adaptor



Fig.5 Batteries

Control Key & Function

Table 4 “Control Key” and its functions

PVL-I PLUS Current Status	Control-Key’s Operating mode	Aim at
OFF	Long-press 2-3 Sec	Turning on PVL-I Plus
ON	Long-press 2-3 Sec	Turning off PVL-I Plus
ON	Short press once	Photo-taking
ON	Continuously short press twice	Video-Recording
Video recording	Short press once	Stop video recording

Transportation and Storage

The PVL-I Plus video laryngoscope and its components must be operated and stored under the environmental conditions specified as following:

Operating Condition

Temperature:+5°C ~ +40°C (41°F~104°F)

Relative Humidity:0 – 80%

Atmospheric pressure:.....86 - 106kPa

Shipping and Storage Conditions

Temperature: -40°C ~ +55°C (-40°F~131°F)

Relative Humidity:0 - 93%

Atmospheric pressure:86 - 106kPa

General Device Specification

Classification: I

Safety: Class II

Battery Power (18500A Li-ion rechargeable): 2040mAh, 3.7Vd.c.

Operation Time: ≥240 min per fully charged 18500A Li-ion Battery

Display Monitor: 3”

Video Aspect Ratio: 4:3

Voltage Input: DC 3.7V

Current Input: 310± 10mA

Max Power: 2W

Illumination: > 300lx

Charging mode adapter input: 100-240Va.c. 50/60Hz 0.4A

Charging mode adapter output: 5Vd.c. 2.1A

Type of Protection Against Electric Shock: Class II for adapter or internally powered equipment

Degree of Protection against Electric Shock: Type B applied parts

Interchangeable Battery Power: 18500A Li-ion rechargeable batteries

Mode of operation: Continuous

Applied Part: Sterile Single-use Blade

Warnings and Cautions

- A. This User Manual is applicable to both PVL-I-01 Plus & PVL-I-02 Plus video laryngoscopes. Every user must carefully read this manual before operating it.
- B. For the first time using PVL-I Plus, please make sure all of the components are fully furnished, and in good condition. If not, please contact the manufacturer and/or the distributors as soon as possible.
- C. Before using the PVL-I Plus, please make sure the equipped 18500A Li-ion battery is fully charged. For the first time of charging the battery, it may take up to 6 hrs. Please use the equipped battery charger pack only.
- D. There is a battery power level indicator displayed on the screen. The battery power level is measured in term of “3 bars”. When the battery is fully charged, there will be “3 bars” displayed on the display monitor. When there is “no bar” displayed on the indicator and the color of the battery symbol becomes red and “blinking”, please replace the battery with a fully charged one immediately.
- E. For PVL-I Plus Video Laryngoscopes, there are 8 different sizes ‘Sterile Single-use Blade’ which are compatible with each of them. Before using the PVL-I Plus Video Laryngoscopes, please make sure:
 - a) The Sterile Single-use Blade is suitable to the patient and compatible with the PVL-I Plus Video Laryngoscope.
 - b) The package of the ‘Sterile Single-use Blade’ is in good shape, if the package is broken, please get a new one. Dispose the use ‘Sterile Single-use Blade’ as medical waste.
- F. Do not expose the PVL-I Plus video laryngoscope to humidity over 93%.
- G. Do not expose the PVL-I Plus video laryngoscope to temperatures over +55°C (131°F).
- H. Do not extrude data transmission cable.
- I. Do not heat or burn the 18500A lithium-ion battery.
- J. Instructions to check the outer surface of the ‘Sterile Single-use Blade’ for rough surfaces, sharp edges or protrusions which may cause a safety hazard before using them.
- K. Do not disinfect the PVL-I Plus video laryngoscope using devices such as autoclaves, ultrasonic clears, or pasteurizers. Use of such methods to disinfect video laryngoscope will cause permanent damage and void the manufacturer warranty. Refer to the disinfection instructions.
- L. If you need details about circuit diagram and component information, please contact us.
- M. The consumables should be used before expiry date.
- N. The light-emitting area surrounding the camera of the video laryngoscope may exceed 41°C as part of normal operation. However, Continuous contact with the area surrounding the camera is unlikely because the product is typically not held stationary for an extended period of time exceeding 1 minute.

Note: Typical intubations are less than 1 minute in duration.

Applications

The PVL-I Plus Video Laryngoscope is the perfect tool for physicians and other healthcare professionals who need to effectively operate on difficult airways. The device is easy to use, learn, and teach. It integrates easily into standard ICU, ER, Respiration and Anesthesia departments of any medical institution. The device is also ideal for mobile patient transport units such as ambulances and helicopters.

The PVL-I Plus Video Laryngoscope makes intubation easier & safer. The advanced data recording unit helps confirm tube placement in clinical practices. Multiple blades, from preterm to morbidly obese, can meet any clinical requirements. Additionally, it is useful for verification of endotracheal (ET) position, nasal intubation, ET exchange, and teaching.

Intended Use

The PVL-I Plus Video Laryngoscope is intended for use by qualified medical professionals to obtain a clear, real-time view of the patient's airway during tube placement medical procedures.

A Caution

The PVL-I Plus Video Laryngoscope should be used only by individuals who have been trained and authorized by a physician or by health care providers who have been trained and authorized by the institution providing patient care.

Allergic to PC material, use PVL-I Plus Video Laryngoscopes with caution due to their Sterile Single-use Blade are made of PC (polycarbonate).

Notice to Operators

All operators should read this user manual in its entirety before operating the device. Failure to do so may damage the device and/or jeopardize the medical procedure.

Keep the user manual safe, operate the device according to this manual strictly.

Do not overcharge the 18500A Li-ion batteries.

Without the authorization from the manufacturer, no organizations or individuals may repair or dismantle the device or its parts. Otherwise, the product warranty will be void immediately.

The 18500A lithium-ion battery is rechargeable, reusable and recyclable, do not disassemble, refit, or dispose the lithium battery arbitrarily.

Ensure high level of battery charged before operating.

The PVL-I Plus is a precise instrument, handle with care.

Applicable Procedures

Normal or restricted oropharyngeal visualization and assessment of the oropharynx

Trauma airways - excellent when dealing with blood and secretions in the airway

Airway management in morbidly obese patients

Preterm and newborn or neonatal intubations

Re-intubation in Intensive Care Unit (ICU) settings Supervision and documentation of the laryngoscopy

Laryngoscopic foreign body removal

Awake intubation for difficult airway management

Teaching the anatomy of the airway in medical school

Clinical Application Tips

The intubation procedure may vary from patient to patient depending on the users' skill, experience and preference. Practical training of using PVL-I Plus Video Laryngoscope on a mannequin before clinical application is highly recommended. And the same technique may not be suitable for using PVL-I-01 Plus to conduct the intubation on pediatrics.

How to use the PVL-I Plus

Important: Intubation with the PVL-I Plus video laryngoscopes should only be performed by or under direct supervision of trained medical personnel. In order to optimal use of the PVL-I Plus, the following points are for reference only:

- a) If possible, please place the patient's head and neck in an optimal position for the chosen intubation technique. A suitable Sterile Single-use Blade should be chosen in accordance with the patient's weight and shape and the chosen technique.
- b) Look into the patient's mouth, hold the PVL-I Plus video laryngoscopes with the left hand, and insert the blade of PVL-I Plus into the patient's mouth according to the used technique.
- c) Move the blade of PVL-I Plus slowly to push the patient's tongue to the left, get the blade gently down to the central position.
- d) Advance the tip of the blade of PVL-I Plus into the vallecular gently.

- e) When the epiglottis appears on the monitor, slightly lift the anatomy forwards and upwards to obtain a direct or indirect view of the glottis. If the PVL-I Plus placed at an optimal position, the view of glottis should be appeared on the upper central section of the monitor.
- f) Slowly and a traumatically insert the tube through vocal cords. The tube placement can be performed easily by watching the display monitor of PVL-I Plus.
- g) Indirectly view the intubation through the vocal cords from the PVL-I Plus. If the intubation performed properly, the tube will enter from the right-hand side of the monitor and slowly approach the vocal cords.
- h) By using the PVL-I Plus, the user can easily and quickly get a clear view of the patient's glottis due to the ergonomically designed curve of the SSB. For performing a quicker and safer intubation, a stylet should be used to shape the distal part of the tube with a 120° angle or even smaller is highly recommended. However, using Mac-3M to perform an intubation, the intubation may be completed without a stylet.

IMPORTANT!

- ★ Please do not insert the PVL-I Plus VL blade too deep in the patients' mouth in the very beginning. Otherwise, the view of epiglottis can be easily missed.
- ★ The PVL-I Plus video laryngoscopes are designed to be inserted down the midline of the tongue to the epiglottis. It can be used to lift the epiglottis, expose the glottis, and guide the medical intubation correctly.

Getting Started

Initial Inspection

Upon receiving the device and packing list, inspect the components of PVL-I Plus Video Laryngoscope for any obvious physical damage that may have incurred during transportation. We recommend that the inspection be performed by a qualified professional who is familiar with electronic medical device. To verify that you have received the appropriate components, refer to the packing list included with the device. If any of the components are missed or damaged, notify the carrier and contact us immediately at 086-316-3081859, 3081860, or contact your local distributor immediately.

Preparing for First Use

Prior to using the PVL-I Plus Video Laryngoscope for the first time, perform the following steps:

Charge the Battery

There is a battery compartment inside the PVL-I Plus Video Laryngoscope's handle, where an 18500A Li-ion rechargeable battery can be placed to provide power to the PVL-I Plus Video Laryngoscope and the display monitor. The 18500A battery should be charged separately with the specially equipped battery charger pack. The video laryngoscope cannot be operational while charging the battery unless another fully charged battery placed inside the chamber. To charge the 18500A battery, its charger must be connected to a wall socket.

IMPORTANT! The 18500A battery must be fully charged prior to its first use.

For optimal battery life

There is a battery power level indicator displayed on the monitor's screen in term of "bars"; when there is only one "bar" left on the indicator and the "bar" is in "red" and "blinking", please replace the battery with a fully charged one and charge the empty battery immediately. The battery should be charged with the equipped charger only at room temperature, between 5°C~40°C(41°F~104°F).

Proper Charging Procedure

- (1) Using the charger especially furnished with the PVL-I Plus Video Laryngoscope only to charge the 18500A battery.
- (2) There are two charging modes available: charging one battery or charging two batteries together.
- (3) Placing the battery or batteries into the charger's charging compartment, make sure the battery's

- anode is on the right position.
- (4) Connecting the charger to an adaptor (output 5VDC, 1000mA), and plugging the transformer into wall socket (100~240V, 50~ 60Hz).
 - (5) The charging status indicator will turn red, indicating that the charging cycle has begun. When the battery is fully charged, the charge status indicator will turn green.



Fig. 6

IMPORTANT! The USB port on the display monitor and the equipped USB cable are used for data communication only, not for charging. If charged properly, a genuine 18500A battery can be charged 300 times.

There are two charging modes available. This one is charging the single 18500A battery (see Fig. 6) . Placing one battery into the charger's charging compartment, make sure the battery's anode is on the right position. Then follow **Proper Charging Procedure** to complete the charging process.



Fig. 7

There are two charging modes available: This one is charging two 18500A batteries together (see Fig. 7). Place two batteries into the charger's charging compartments and make sure the battery's anode is on the right position. Then follow **Proper Charging Procedure** to complete the charging process.

Preparation (Loading and unloading batteries)

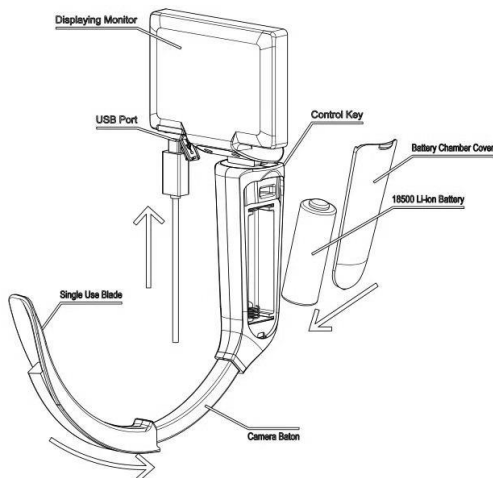


Fig. 8 PVL-I-02 Plus Typical Parts Diagram

There is a battery compartment inside the PVL-I Plus video laryngoscope's handle with a removable cover. There is a rechargeable 18500A Li-ion battery placed inside the battery compartment. When replacing a low power level battery with a fully charged one, please pull to open the cover of the battery compartment (see Fig. 9), then take out the "empty" battery (see Fig. 10). To reload a fully charged one in the battery compartment, just reverse the operation as in Fig.10. Then put the cover back to close the battery compartment, just reverse the operation as in Fig. 9.

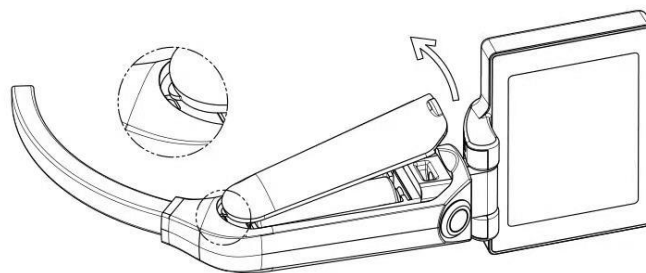


Fig. 9 PVL-I-02 Plus Typical Diagram-Opening the battery compartment

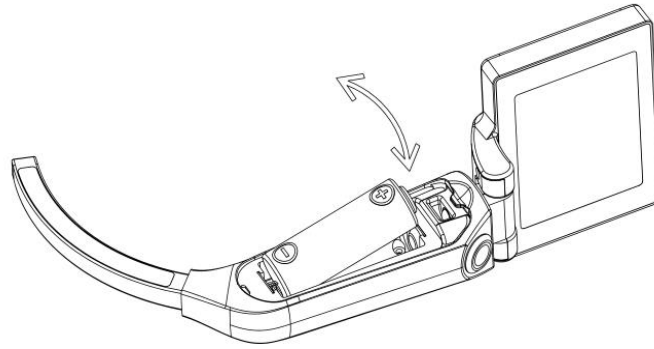


Fig. 10 PVL-I-02 Plus Typical Diagram of Loading/Unloading the battery

Perform a Functional Check

To perform a functional check, please refer to Table 5 “Control Key” and its functions.

Prior to the first use of PVL-I Plus Video Laryngoscope, please perform the following functional check to assure that the PVL-I Plus Video Laryngoscope is working properly and its quality is up to the standard. Please contact with a customer care representative if your PVL-I Plus Video Laryngoscope does not function as described below:

- (1) Slide a fully charged 18500A battery into the compartment (chamber) inside the PVL handle, make sure the plus points (anode) to the right position, and assemble the PVL-I Plus accordingly.
- (2) Long pressing the “Control Key” for 2-3 seconds to turn on the PVL-I Plus, both the display monitor and the led light of the video laryngoscope will be on.
- (3) Short pressing the “Control Key” once, a photo picture is taken. A camera sign appears on the screen briefly.
- (4) Quickly short press the “Control Key” twice, to start video recording. There is a “red dot” on the screen.
- (5) Short pressing the “Control Key” once, to stop video recording. The “red dot” will disappear from the screen.
- (6) Long pressing the “Control Key” for 3-5 seconds to turn off the video laryngoscope both the display monitor and the led light of the video laryngoscope will be off.

Verify that the logo is displayed on the monitor screen.

Important Note: The logo will display on screen for a few seconds when powering on, then the system is ready to work, and the battery level and real time are displayed on screen.

Time Settings

The PVL-I Plus Video Laryngoscope’s display “Time” has been preset in the factory before shipped out. The standard time applied is Beijing’s local time or one’s local time if requested to do so. The users from the other time zones can reset the display “Time” to their local time by performing the following steps:

- (1) Put a fully charged 18500A battery into the battery compartment of PVL-I Plus;
- (2) Connect the PVL-I Plus to a computer with the equipped data cable, please connect the PVL-I Plus first, then connect the computer;
- (3) Turn on the power of PVL-I Plus;
- (4) Find out “My Computer” on the desktop of the computer and open it;
- (5) The TF card of the PVL-I Plus appears on the screen as a “USB flashing disk”
- (6) Find out “USB flashing disk” and open it. Its drive will be installed automatically.
- (7) If nothing happens, please wait for a while or reconnect the PVL-I Plus VL to the computer again.
- (8) In the opened “USB flashing disk” create a new file “rtc.txt”
- (9) Then key in the “Right Time” into the file as following: 20160101152201 which means: year=2016, month=01(Jan.), day=01, hour=15(24hour), minute=22, second=01.
- (10) Save the file immediately and log out the “USB flashing disk”;
- (11) Unplug the USB cable from the PVL-I Plus VL, the set time will be automatically updated in it.

Data Retrieval

Connect the PVL-I Plus to a computer with the equipped data cable. **Please connect the PVL-I Plus first, then to the computer.** To retrieve the data recorded in the PVL-I Plus into the computer just like reading the data from the U disk.

Battery power indication

There is a battery power level indicator displayed on the screen of display monitor in term of “bars”; when there is only one “bar” left on the indicator and the “bar” is in “red” and “blinking”, please replace the battery with a fully charged one and charge the empty battery immediately. When the battery is fully charged, there will be 3 “bars” displayed. A fully charged 18500A battery can power the PVL-I Plus continuously work at least 200 minutes.

The folding of PVL-I Plus

The display monitor of PVL-I Plus video laryngoscopes can be smoothly rotated in two different directions and easily folded down to the side of PVL-I Plus video laryngoscopes’ handle. The folded PVL-I Plus video laryngoscopes can be carried by physicians. Refer to Figure 11 and Figure 12 for details. The display monitor’s two-way rotation is as following:

Horizontal rotation: $\geq 300^\circ$;

Vertical rotation: $\geq 200^\circ$.

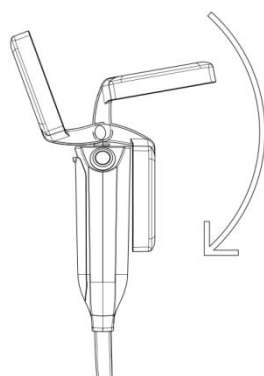


Figure 11 Fold down displaying monitor

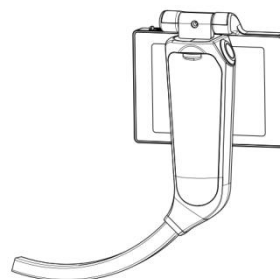


Figure 12 Folded displaying monitor

Attaching the Sterile Single-use Blade to the PVL-I Plus video laryngoscope

Before using PVL-I Plus video laryngoscope, attach the Sterile Single-use Blade to the PVL-I Plus video laryngoscope firmly and properly. Follow the proper attaching procedure as below:

- (1) Unpack the package bag of Sterile Single-use Blade and make sure the package is in good condition.
- (2) Take out the Sterile Single-use Blade carefully.
- (3) Insert the curved camera rod of PVL-I Plus into the opening of the Sterile Single-use Blade.
- (4) Ensure the position lock of the Sterile Single-use Blade is compact and seamless with the video laryngoscope.

Caution: Damages may be caused by improper connection and excessive force.

Make sure the selected Sterile Single-use Blade is a good match for the PVL-I Plus video laryngoscope and it is suitable to the patient.

Detaching the Sterile Single-use Blade from the PVL-I Plus video laryngoscope

After using the PVL-I Plus video laryngoscope to complete the intubation, the used Sterile Single-use Blade should be disposed as medical waste. Follow the proper procedures to detach the used Sterile Single-use Blade from the PVL-I Plus video laryngoscope:

- (1) Prizing the position lock of the Sterile Single-use Blade with left thumb.
- (2) Removing the used Sterile Single-use Blade from the PVL-I Plus video laryngoscope.

(3) Dispose it as medical waste by following proper procedure.

The Features of Sterile Single-use Blade

- (1) Imported Germany medical grade polymer.
- (2) Ergonomic curve design.
- (3) Durable material ensures the safety of applying the Sterile Single-use Blade to rescue a conscious patient.
- (4) Enclosed design prevents the cross infection of infectious disease.
- (5) Anti-fogging technology guarantees a clear view to the observer during the intubation.

Selecting the right Sterile Single-Use Blade for PVL-I Plus

Make sure to select the right Sterile Single-use Blade which best fit your patients. Please refer to the compatibility of the PVL-I plus and their Sterile Single-use Blade in table 5.

Table 5 Match the PVL-I Plus with its Sterile Single-use Blade

Blade Size	PVL model	Clinical Application	Remarks
Mac-00	PVL-I-01 Plus	Preterm & New born	1.5-5Kg
Mac-0		Baby and infant	5-15Kg
Mac-1		newborn	15-25Kg
Mac-2	PVL-I-02 Plus	Children & Adult female	25-60Kg
Mac-3		Adult male	60-90Kg
Mac-4		Big and tall guys	≥90Kg
Mac-3D		For difficult airway	
Mac-3M		Cross over between video- and direct laryngoscopy. Can be used without a stylet.	

Cleaning, Disinfecting, and Maintenance

Cleaning and disinfecting are very important factors to maintain the PVL-I plus in good condition. Make sure the PVL-I plus are clean and disinfected before each use. Examine the PVL-I plus periodically to make sure they are functioning correctly.

Important Notes:

- ① Clean and disinfect the PVL-I Plus with 75% medical grade ethanol and wipe them only.
- ② When disinfecting the PVL-I Plus Video Laryngoscopes' handles by soaking them in the disinfectants, the battery must be removed from its compartment and leave the compartment open. The level of disinfectant solution must be lower than the PVL-I plus' "Control Key".

General Maintenance Information

Periodic inspection should be performed to ensure safe and effective operation. We recommend that a qualified user perform a full visual inspection of all components at least every six months.

The following items should be checked carefully:

- ✧ External damage;
- ✧ All functions;
- ✧ Damage to the power supply;
- ✧ Connectors and cable insulation integrity

To ensure patient safety, the users should perform a routine inspection of the PVL-I Plus video laryngoscope before each use to ensure that all components are free of rough surface, sharp edges, protrusions, or cracks. If inspection reveals any faults in the components, please contact us or your local distributor immediately.

Caution: Risk of permanent equipment damage.

- (1) Do not expose video laryngoscope to any temperature above 55°C.
- (2) Do not soak the PVL-I Plus' display monitor and "control key" in any disinfectants solution.

Disinfection Instructions

- (1) Disinfect the components of the PVL-I plus according to the disinfecting procedure of this manual.
- (2) Do not disinfect the PVL-I plus with strong acid or alkaline disinfectants.
- (3) Do not expose the PVL-I plus to places with organic solvent, such as acetone and butanone.
- (4) Do not expose the PVL-I plus to places where the temperature is above 55°C.
- (5) Never soak the display monitor of the PVL-I plus in any kind of disinfectants.
- (6) Cleaning the glass of camera window whenever necessary to ensure the optimal observing view after disinfection.

Disinfection Procedure for PVL-I Plus (Wipe clean)

- (1) Take off the Sterile Single-use Blade from the PVL-I plus after every use.
- (2) Wipe the PVL-I plus with medical wiper properly, for example, 75% ethanol medical wipers.
- (3) Start from the front end of the PVL-I plus (the end with camera lens).
- (4) Apply the wiper gently to cover the whole the PVL-I plus including the display monitor.
- (5) Do not wipe the PVL-I plus back and forth with the same wiper.
- (6) Dispose the used medical wipers as the medical waste.
- (7) The sterilization of the PVL-I plus can also be done with EO, as long as control the temperature under 50°C.

Cleaning the Data Transmission Cable


Using a soft and lint-free wiper gently wipe the data transmission cable with IPA (70% isopropyl alcohol), bleach (100ppm), or a mild detergent and water.



Warning

- (1) The PVL-I Plus video laryngoscopes should be cleaned and disinfected before first use and after each use.
- (2) The PVL-I Plus video laryngoscopes is partially water resistance, IPX7 for the handle, IPX4 for the monitor.
- (3) The PVL-I Plus video laryngoscopes cannot withstand any kind of automated cleaning and ultrasonic cleaning.
- (4) The blade is for Single-use only. Discard the blade after each procedure.
- (5) Test all PVL-I Plus video laryngoscopes before use.
- (6) Follow the cleaning and sterilization methods as stated in the User manual.
- (7) If any doubts about the cleaning and disinfection process, please contact the local authorized representative or the manufacturer.
- (8) Do not use iodide solutions or bleach on the unit.
- (9) Repair and service of the PVL-I Plus video laryngoscopes can only be done by the authorized technicians.

General Cleaning, Disinfection and Maintenance instructions (Table 6)










INSTRUCTIONS	
Limitations on reprocessing	Repeated using has minimal effect on the performance of the PVL-I Plus video laryngoscope (PVL). The life time of PVL is normally determined by wear and damage due to its clinical use.
Initial treatment at point of use	<ol style="list-style-type: none"> 1. Pull off the used blade from the PVL handle and discard the blade as medical waste. 2. During clinical application, if body fluid or secretions contaminate the PVL handle or its monitor, please clean and disinfect the PVL-I Plus immediately in order to prevent the buildup of bioburden, development of biofilms, and drying of secretions. The PVL-I Plus must be properly cleaned and disinfected after each use. <p>★ Using soft cloth to scrub the monitor, do not immerse the monitor and the “control key” in the water or alcohol, do not rinse the screen (PVL-I only).</p> <p>★ Using soft cloth with alcohol to scrub the handle, dry the handle with soft cloth.</p> <ol style="list-style-type: none"> 3. Each used PVL must be properly cleaned, disinfected and dried. Then keep the dried and disinfected PVL in a safe and clean place for next use.
Preparation before cleaning	No particular requirements if disinfect the PVL-I Plus with a soft cloth and 75% medical Ethanol to wipe clean it. If dipping the PVL handle in disinfectant solution, the cover of battery compartment and the battery must be removed. Do not immerse the monitor and the “control button” in any solution.
Cleaning: Manual	<p>Manual cleaning should be conducted immediately after each use to prevent any soil from drying on the PVL-I Plus. Soil that remains on the PVL-I Plus may interfere with the ability of the sterilization process to effectively kill or inactivate microorganisms and allow biofilm to develop.</p> <ul style="list-style-type: none"> ● Use a soft cloth with 75% medical grade alcohol to scrub the surface of PVL-I Plus. ● Use a soft brush to clean any soil in gaps, joints etc. ● Thoroughly wipe the surface of the PVL-I Plus until soil and organic matter have been visibly removed (In case of heavy soiling more than one wipe may have to be used). <p> Do not use an excessively wet cloth!</p>
Manual Disinfection	<p>After cleaning, visually inspect all surfaces for complete removal of soil and fluids. If ANY soil or fluid is still visible, repeat manual cleaning process.</p> <p>We recommend using 75% alcohol, sodiumdichloroisocyanurate or chlorine dioxide (ClO₂) as the disinfectants.</p> <p>Wipe the PVL-I Plus completely for at least 2 times with damp cloth with suitable and effective disinfectant solution.</p>
Drying	Allow the PVL-I Plus to air dry. Ensure the PVL-I Plus is completely dry before stored it.
Inspection and maintenance	<p>Maintenance of the PVL-I Plus can only be done by qualified users.</p> <p>Inspect every surface area, major part and connection for damage or deterioration.</p> <p>Slide a Sterile Single-use blade on the PVL-I Plus, turn on its power and check the function of PVL-I Plus in proper working condition.</p>
Packaging	The PVL-I Plus video laryngoscope should be packed according to the hospital protocols.
Storage	<p>The PVL-I Plus should be stored in a well-ventilated, clean and dry area.</p> <p>If not used, please check the mechanical functions of PVL and battery every week.</p> <p>For the storage, make sure “First in, first out” rule applied properly.</p>

Trouble Shooting (Table 9)

#	Malfunction	Troubleshooting Method
1	The Device doesn't work while powering on.	Take the battery out and reload the battery correctly. If the problem persisted, please contact your distributor immediately.
2	The fogging displays on the screen of monitor	Check the Sterile Single-use Blade, replace the blade when necessary.
3	Stain displayed on screen of monitor	Check if there are stains on the screen of the monitor or single-use external shell or the camera protection glass.
4	It cannot be connected with data transmission.	Use the cable furnished with video laryngoscope only, ensure the cable is connected properly.
5	No storing function	Check the PVL-I Plus' TF card and make sure there is enough data space available for recording, download the files to a computer and release the data space if necessary.
6	Turns off automatically after charging or connecting with computer.	Check the connection and restart. The charging power is checked automatically by system, and it will power off when wrong connection is detected.

If the troubleshooting methods above do not work, or malfunction persists, please contact us or your local distributor immediately.

Symbol Directory (Table 10)

Symbol	Meaning
---	Direct current
	Class II Electric shock protection
	Power on/off
	manufacturer
	Caution
	Type B applied part
	Date for production
	Consultant with IFU
	Dispose by local law or regulation
	Series Number

Limited Warranty

The warranty obligations of Hebei Vimed Medical Device Company, Ltd. (hereinafter called Vimed Medical) for PVL-I Plus Video Laryngoscope are limited to the terms set forth below:

What is covered?

This limited warranty covers defects in materials and workmanship in this product.

What is not covered?

This limited warranty does not cover any damage, deterioration or malfunction resulting from any alteration, modification, improper or unreasonable use or maintenance, misuse, abuse, accident, neglect, exposure to excess moisture, fire, lightning, power surges, or other acts of nature. This limited warranty does not cover any damage, deterioration or malfunction resulting from any unauthorized tampering with this product, any repairs attempted by anyone unauthorized by Vimed Medical to make such repairs, or any other cause which does not relate directly to a defect in materials and/or workmanship of this product. This limited warranty does not cover Consumable items.

How Long this Coverage Lasts?

The standard limited warranty for PVL-I Plus video laryngoscope product is two (2) years from the date of original purchase.

Who is covered?

Only the original purchaser of this product is covered under this limited warranty. This limited warranty is not transferable to subsequent purchasers or owners of this product.

What Vimed Medical will do?

Vimed Medical will, at its sole option, provide a replacement unit to satisfy a proper claim under this limited warranty.

How to Obtain a Remedy under This Limited Warranty?

To obtain a remedy under this limited warranty, you must contact either the authorized Vimed Medical distributor from whom you purchased this product or Vimed Medical's office in China.

Limitation of Liability

THE MAXIMUM LIABILITY OF VIMED MEDICAL UNDER THIS LIMITED WARRANTY SHALL NOT EXCEED THE ACTUAL PURCHASE PRICE PAID FOR THE PRODUCT. TO THE MAXIMUM EXTENT PERMITTED BY LAW, VIMED MEDICAL IS NOT RESPONSIBLE FOR DIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR CONDITION, OR UNDER ANY OTHER LEGAL THEORY.

Other Conditions

This limited warranty is void if (i) the label bearing the serial number of this product has been removed or defaced, (ii) the product is not distributed by Vimed Medical or (iii) this product is not purchased from an authorized Vimed Medical distributor.

Your rights under this limited warranty are not diminished if you do not complete and return the product registration form or complete and submit the online product registration form. However, your original Invoice of Purchasing must be presented when requesting a replacement.

Vimed Medical thanks you for purchasing a Vimac video laryngoscope product. We hope it will give you years of satisfaction.

Hebei Vimed Medical Device Company, Ltd.