

Fig 1

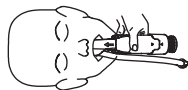


Fig 2

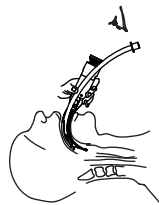


Fig 3

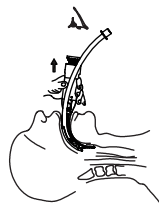


Fig 4

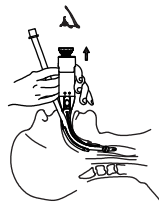
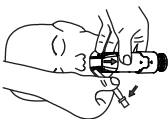


Fig 5



Product Name

Video Laryngoscope

Part Name

Reusable Core

Model No.

TL-65R - II

Components List

- Video Laryngoscope (Reusable Core)1PC
- Eyecup1PC
- Type C Charger1PC

Battery - Reusable Core

Charging time: About 70 minutes.

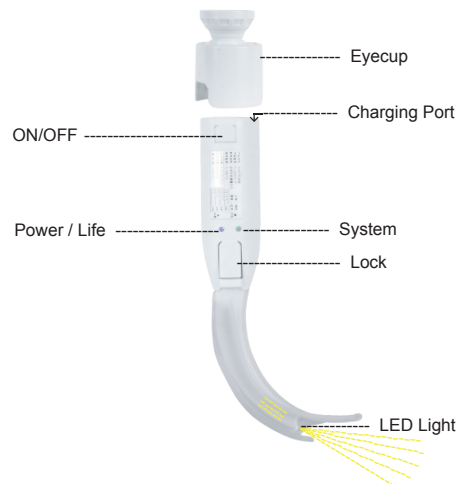
Working time: About 4 hours.

Applicable Scope

This product is a split type video aryngoscope designed to facilitate intubation, laryngeal diagnosis and observation.It needs to work with "Sterile Video Laryngoscope Blade" as a completed set.

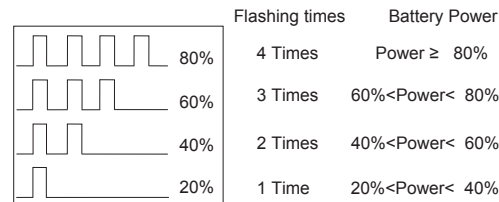
Technique Instruction

1. Instruction



Item	Function	Remark
	ON/OFF	Press 1sec-Turn on / off the core
	Power / Life	Blue light is indicator of power, for power status please refer to Form 2 below. Orange light is indicator of life
	System	Green Light - Normal, No Light - Abnormal
	Charging Port	Please used the charger supplied in the package
	LED Light	Not light--Not turn on or broken. Blinking- Anti-fog and Heating system are starting to work. Steady light- System is ready.

Form 1



Form 2

[When blue light is flashing only one time. It means that the power is less than 20%. It is suggested to charge the core before using.]

[To remind the user, life light (Orange light) will be turned on after used 500 times. It is suggested to replace the core after 500 times used.]

[After turn off the core, the power light will still flash, it means it is saving the data.]

【Manufactured Date】
Reference to the product's label
【Expiration Date】
Within 5 Years (from the manufactured date.)
【Manufacturer】
Shenzhen Tianlang Medical Equipment Co.,LTD
Floor5,C5 Factory Building, Zhu' ao No.2
Industrial Area, Xixiang Sub-district, Bao 'an district ,
Shenzhen, Guangdong , China 518126
【Tel】 +86 755-27696568
【Fax】 +86 755-27678821
【EC REP】: CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo N18 CP 29006,
Málaga-Spain

2. Preparation

- Select the appropriate blade size based on the size ETT to be used. Please refer to Form 3 and Form 4.

Reusable Core	TL-65R-II			
Sterile Video Laryngoscope Blade	TL-602-I	TL-602-II	TL-602-III	TL-602-IV
ETT Size	2.5-3.5mm	4.5-5.0mm	5.5-6.5mm	7.0-8.0mm
Min. mouth opening	13mm	13mm	14mm	15mm

Form3

Reusable Core	TL-65R-II		
Sterile Video Laryngoscope Blade	TL-602-V	TL-602-NI	TL-602-N2
ETT Size	8.5-9.5mm	2.5-6.0mm	6.5-9.5mm
Min. mouth opening	16mm	13mm	13mm

Form4

- Press the reusable core (TL-65R-II) power button 1 second, then the light will be turned on and blinking.
- Insert the reusable core (TL-65R-II) into the blade completely.
- Install the eyecup.
- Only after light stops blinking. User can start to use the video laryngoscope (TL-65R602-II).

NOTE: The light stops blinking(within 5sec) and steady on, the anti-fog system is activated.

If light can not be turn on, please replace a new core.

- Make sure the ETT cuff is empty.
- Lubricate the ETT and place it into the lateral channel of the video laryngoscope (TL-65R602-II).
- Align the tip of the ETT with the end of the lateral channel.
- Appropriately lubricate the blade without contacting the lens.

3. Placement

- Insert the video laryngoscope (TL-65R602-II) along the midline of the patient's mouth, be careful not to squeeze the tongue. In some cases, it may help to insert it by using the same technique as "Guedel airway". (Fig1)

- When the video laryngoscope (TL-65R602-II) is about 45 degrees to the plane, observe the patient's mouth and airway structure through the eyecup. (Fig2)

- Continue to insert until the epiglottis can be seen(Fig3), place the tip of the video laryngoscope (TL-65R602-II) to the epiglottic vallecula. Alternatively, the tip also can be placed under the epiglottis (Miller style).

- Gently lift the video laryngoscope to (TL-65R602-II) expose the vocal cords.

4. ETT Insertion

- Align the glottis in the center of the visual field by gently moving the tip of the video laryngoscope (TL-65R602-II) as needed.

- Gently advance the ETT in the lateral channel until it is visualized passing through the glottis. Check insertion depth. (Fig4)

- Inflate the ETT cuff and make sure the intubation is successful.

5. Laryngoscope Removal

- Connect ETT to the breathing circuit and make sure the connection is proper and secured.

- Separate the ETT from the video laryngoscope (TL-65R602-II) by pulling it laterally from the guiding channel. Remove the video laryngoscope (TL-65R602-II) from the patient's airway following the midline.

- Keep the ETT in the right position during the separation(Fig 5).

6. Core Removal From Blade

- Take out the eyecup and withdraw the reusable core from the blade by press the lock. Make sure the core is clean during the removal.

- Discard the blade properly
- If needed, please recharge the core.

7. Core Cleaning and Disinfection

- The core is used with blade as a set, it is full protected by blade without contact the patient.

- In case the core is contaminated accidentally, please select multi-enzymatic cleaner / neutral-ph soapy water / sodium bicarbonate solution(8% -10%) as cleaners, peracetic acid solution(0.08%) or isopropyl alcohol(70%) as disinfectant, clean and disinfect the core by wipe method. Be sure to follow your institution's specific cleaning procedures in consultation with this manual as below:

- Remove the core from the blade.

- Use clean cotton gauze pads that are saturated with the cleaning solution to wipe down the exterior surfaces of the core. Use soft brushes with the cleaning solution to access areas that cannot be reached with the gauze pads, make sure that all contaminants is cleared.

- Be careful to keep running liquid off these surfaces.

- Caution:










- Do not autoclave.




- Do not soak in liquids.

- Avoid liquid or moisture going inside the core.

- Avoid touching the lens of the core.

Graphic and symbol definitions

	Keep dry
	This side up
	Handle with care
	Forced
	Lot Number
	Manufacture Date
	Expiration Date
	Sterilized by Ethylene Oxide
	Do not reuse

	Type BF applied part
	Attention, see Instruction for use
	Do not use if the package damaged

Warnings

This product are not suitable for the patient whose mouth opening degree less than the Min. mouth opening"(Form 3 and Form4).

Attention

1. The core's service life is 500 times use. Once the service life is finished the core is invalid.

2. The device should only be used by qualified person.

3. Clean away patient's oral secretion before intubation.

4. Do not submerge in liquids.

5. Use only with non-lammable anesthetics.

6. Do not put pressure on the teeth with the device.

7. Do not force the device into the upper airway .

8. Do not insert the core into patient's mouth without loading the blade.

9. It is not in warranty if the device is polluted or invalid due to cleaning or disinfection by user.

Storage and Transport

The product should be stored and transported at temperature 0~50°C. The relative humidity must not exceed 93%. Non-corrosive gases and dry, well -ventilated, clean area. Prevent moisture, heat and direct sunlight

Other

1. Please discard the blade in properly way accordingly to the legal.

2. This product is included the battery, please handle the battery properly before discard.