optima view®
TIMESCO

Video Laryngoscope for Reusable Blades



Operator's Manual

I.VL.002/2 March 2023

Contents

1 Overview 4
1.1 Product Information 4
1.2 Intended Purpose 4
1.3 Indications 4
1.4 Contraindications 4
1.5 Specifications & Performance Characteristics 4
1.6 Environments of Intended Use 5
1.7 Product Listing & Compatible Accessories 6
1.8 Warnings & Cautions 6
2 Operation 7
2.1 Device Setup 7
2.2 Device Usage 7
Operation of Device 7
Blade Attachment 8
Blade Removal 8
2.3 Device Functions 8
Device Interface 8
Button Functions 8
3 Reprocessing & Storage 9
3.1 Cleaning 9
Video Laryngoscope Handle 9
Blades 9
3.2 Disinfection 9
Video Laryngoscope Handle 10
Blades 10
3.3 Storage 10
4 Maintenance 11
5 Manufacturer Guarantee 11
6 Electromagnetic Compatibility 12
6.1 Electromagnetic Emissions 12
6.2 Electromagnetic Immunity 12/13
7 Regulatory 14

1 Overview

1.1 Product Information

The Timesco Optima View Reusable Blade Video Laryngoscope consists of a reusable video laryngoscope handle which is utilised with compatible reusable blades to illuminate and visualise the airway to aid in intubations. The video laryngoscope handle incorporates a colour LCD screen which displays the view from the top of the blade curvature where an LED and camera is housed. The design intent of the Optima View video laryngoscope and reusable blades is to leverage established rigid laryngoscopy techniques with an optimal view of the airways to enable efficient intubations.

1.2 Intended Purpose

Timesco video laryngoscopes are intended for use by qualified professionals to obtain a clear, unobstructed view of the airway and vocal cords for medical procedures.

1.3 Indications

Timesco video laryngoscopes are intended to aid in medical procedures such as intubations, which are typically pre-surgical or pre-treatment procedures. The device is indicated to lift the epiglottis to expose the glottis, enabling tracheal intubation or oral examination.

1.4 Contraindications

- The video laryngoscope is contraindicated for uses outside of the stated intended use and indications.
- The device is contraindicated for use with non-compatible blades or accessories.
- The device is contraindicated in environments where an electromagnetic field would adversely affect the performance of the device or other devices.

1.5 Specifications & Performance Characteristics

Table 1 Specifications & Performance Characteristics

General		Technical	
Size	233mm x 101mm x 135mm	Display	3.75" LCD Colour Display
Weight	290g	Camera Resolution	2.0M Pixels
Handle Material	Medical Grade Thermoplastic & Steel Alloy[1]	Screen Rotation	180° (left/right), 120° (up/down)
Blade Protection Rating	IPX8	Lens Angle	50°-60°
		Illuminance	≥800 LUX
		Operating Time	≥120 minutes[2]
Blade Material	Medical Grade Steel Alloy[1]	Storage Capacity	~10hrs video or 70k+ photos

[1] *Devices not manufactured using latex.*
[2] *Typical operating time in optimal conditions, battery life may vary during use.*

1.6 Environments of Intended Use

The Optima View video laryngoscope is intended to be used only be qualified healthcare professionals.

Device usage outside of environmental specifications may result in deterioration of safety and performance.

Do not use in an environment with a high electromagnetic field.

Do not use in the presence of flammable mixtures.

The Timesco video laryngoscope is intended to be used in professional healthcare environments such as hospitals. The Optima View video laryngoscope is indicated for use and storage in environments as outlined below.

Table 2 Environmental Specification

	Operating Conditions	Transportation & Storage Conditions
Temperature	5 - 40°C	-20 - 60°C
Humidity	20 - 80%	10 – 95%
Atmospheric Pressure	860 – 1060 hPa	500 – 1060 hPa

For electromagnetic compatibility, refer to Section 6 of this operator's manual.

1.7 Product Listing & Compatible Accessories

Do not use any other accessories or blades which are not listed here with the Optima View Video Laryngoscope. Only use the specified compatible accessories.

The Timesco Optima View Reusable Blade Video Laryngoscope is intended to be used only with the following accessories. The video laryngoscope, blades, charger and cables are provided non-sterile.

Table 3 Product & Compatible Accessories Listing

Video Laryngoscope	
4000.300.50	Optima View Video Laryngoscope Handle and LCD Display 3.75" For Reusable Blades
Cables & Charger	
4000.900.10	Optima View HDMI Cable
4000.900.11	Optima View USB Cable
4000.900.12	Optima View 5V/2A Adapter
Blades	
4500.150.10	Optima View Video Laryngoscope Macintosh Blade 1
4500.150.15	Optima View Video Laryngoscope Macintosh Blade 2
4500.150.20	Optima View Video Laryngoscope Macintosh Blade 3
4500.150.25	Optima View Video Laryngoscope Macintosh Blade 4
4500.150.30	Optima View Video Laryngoscope Macintosh Blade 5
4500.185.03	Optima View Video Laryngoscope Miller Blade 00
4500.185.05	Optima View Video Laryngoscope Miller Blade 0
4500.185.10	Optima View Video Laryngoscope Miller Blade 1

1.8 Warnings & Cautions

Throughout the manual, pay attention to sections labelled with the caution symbol for safe and efficacious use of the device.

2 Operation

2.1 Device Setup

Ensure that the device has been cleaned & disinfected in accordance with Timesco instructions and dry prior to use. Ensure that local handling procedures are followed at all times when handling disinfected devices.

Unpack and check the device for any signs of damage which may have occurred during shipment. Contact Timesco in the case of device damage.

2.2 Device Usage

Only qualified and trained professionals may use this device.

Check the video laryngoscope is adequately charged and functional at the preparatory stages prior to the procedure and attachment of blade. Report any malfunction to Timesco.

Always prepare additional compatible reusable blades or an alternative device in case of failure.

Only use the specified compatible Optima View reusable blades.

Ensure the Optima View reusable blade is securely attached onto the video laryngoscope. Do not use the blade if secure attachment is not possible. A warning is displayed on the screen when the blade is not securely attached onto the handle.

The Optima View reusable blades must be cleaned prior to and after each patient use. Non-compliance to Timesco reprocessing instructions may result in degraded performance and/or cross-infection.



Figure 1 Operation of device.

Operation of Device

1. Turn on the device by pressing and holding the Power button for 1 second. The device will power on and the live feed will be displayed on the screen momentarily. Rotate the screen for optimal viewing angles.

2. Quick press to take a photo, long press to start and end a video.

Blade Attachment

Attach the reusable blade onto the video laryngoscope by hooking it onto the handle, then securely engaging the blade.

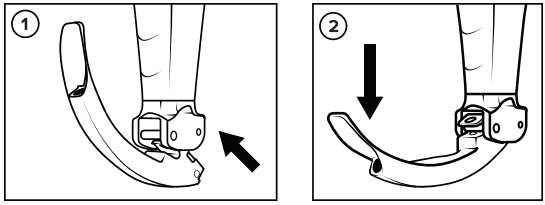


Figure 2 Blade attachment & check of secure fitting.

Blade Removal

To remove the blade, disengage the blade and unhook the blade from the handle. Prepare the blade and handle for reprocessing in a timely manner.

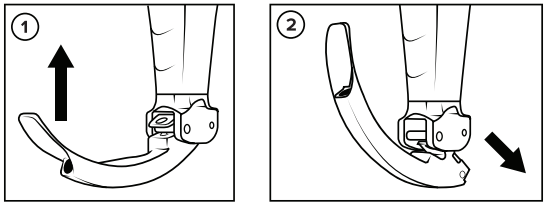


Figure 3 Blade removal.

2.3 Device Functions

Device Interface

The device interface shows a status of the battery percentage as well as the time and date on the bottom of the screen. When the battery level reaches 20% and 10%, warnings will appear on the screen to inform the user of the battery status.

Button Functions

The table below outlines the button functions for the Optima View Video Laryngoscope.

Table 4 Button Functions

Button Marking	Function(s)
⏻	Turn On / Off
M	• Open Menu • When in the menu: Select • When viewing image/video playback: Play
△	Navigate Up
▽	• Navigate Down • Re-format (long Press)
📷	• Capture Image • Start / End Video (Long Press) • When in the menu: Return • When viewing image/video playback: Delete (Long Press)

3 Reprocessing & Storage

3.1 Cleaning



Only healthcare professionals trained in reprocessing medical equipment may reprocess this device. Reprocess the device in accordance with Timesco instructions.



Ensure the device is powered off and disconnected from the charging cable prior to cleaning and disinfection.



Do not immerse the video laryngoscope handle into any liquid. Take care not to allow any ingress of liquid into the device, especially in relation to open ports and device joints.



Do not use any abrasive material such as steel wool, xylene or acetone solvents to clean the device.

Video Laryngoscope Handle

Disinfect the video laryngoscope with new 75% alcohol wipes. Ensure that the wipe is in contact with all the device surfaces and a minimum contact time of 1 minute.

Blades

Clean the video laryngoscope with 75% alcohol wipes. Repeat the cleaning process until all soiling is removed. Rinse the blade with deionised water for 2 minutes and wipe dry.

Soak the blade in the enzymatic cleaning detergent in accordance with the detergent manufacturer's specification. Wipe the blade at least 5 times and then clean the blade in an ultrasonic cleaner in the enzymatic detergent for 5-10 minutes.

This process has been validated using Metrex EmPower (Concentration 1: 128) at a temperature of 20-40°C, with soaking time of at least 1 minute.

Flush the blade under high-pressure water for 10 seconds and wipe the blade dry with sterile gauze.

3.2 Disinfection



Do not disinfect under high temperature and high pressure.



Do not disinfect with high concentration organic acid or non-organic acid.



Do not use any chemical substance containing chloral formamide, phenol derivative or anionic surfactant for disinfection.



The device surface may change colour if it is cleaned by a disinfectant containing acetaldehyde and amine.

Video Laryngoscope Handle

Clean the video laryngoscope with 75% alcohol wipes. Repeat the cleaning process until all soiling is removed prior to commencement of the disinfection step.



Do not disinfect under high temperature and high pressure.



Do not disinfect with strong alkaline/acidic disinfectant.



Do not soak in medical alcohol or iodophor.



Do not keep the device in the presence of acetone, butanone and other organic solvents.

Blades

Immerse the blades into a disinfectant solution in accordance to the solution manufacturer's specifications. After the final usage each day, the disinfection time must be extended by 30 mins.

This process has been validated using MetriCide 28 Long-life Activated Dialdehyde Solution (2.5% Concentration) at the temperature of 25°C, with soaking time of 90 minutes.

Rinse the blade in a container with 5L sterile water, wiping the blade thoroughly with sterile gauze. Conduct the rinse step three times, ensuring no residual disinfectant.

Dry the blade using sterile gauze or clean compressed air.

Prior to usage each day, the blade needs to be disinfected for at least 20 minutes in the above disinfectant or in accordance to the disinfectant solution manufacturer's specifications, then washed and dried before first usage.

3.3 Storage



Ensure the device is completely dry prior to storage.

Post cleaning and disinfection, the device should be air dried or wiped dry with a clean lint free cloth. Decontaminated devices should be packaged immediately upon completion of drying and should be stored in accordance with local guidelines.

4 Maintenance

Do not attempt to dismantle or disassemble the video laryngoscope.

Routine maintenance of the Optima View Video Laryngoscope ensures the longevity of device safety and performance. The power adaptor is specified to have an input of 100-240V at 50/60Hz, ensure power input is within this range. Timesco recommend the below maintenance procedures:

Table 5 Maintenance Procedures

<table>
<tr><th>Maintenance Procedure</th><th>Interval / Situation</th><th>Description</th></tr>
<tr><td>Battery Check</td><td>Annual / Suspected Battery Issue</td><td>1. Charge the video laryngoscope continuously until fully charged.
2. Disconnect the device from the power adaptor.
3. Turn on the device and start a timer/note the time.
4. Verify the battery warnings appear at 20% and 10%.
5. The timed battery life will provide an indication of battery condition:
<table>
<tr><th>Time to Battery Depletion</th><th>Battery Condition</th></tr>
<tr><td>120+ minutes</td><td>Excellent</td></tr>
<tr><td>30-120 minutes</td><td>Good</td></tr>
<tr><td><30 minutes</td><td>Close to end of life</td></tr>
</table></td></tr>
<tr><td>Battery Optimisation</td><td>Not used for >3 months</td><td>1. Charge the video laryngoscope continuously for 8 hours.
2. Disconnect the device from the power adaptor.
3. Turn the device on, and keep on until the battery is depleted.
4. Charge the device continuously for 8 hours.</td></tr>
</table>

5 Manufacturer Guarantee

Do not return contaminated devices back to Timesco. Always clean and disinfect before returning any device to Timesco.

The Timesco Optima View Video Laryngoscope is supplied with a 1-year guarantee excluding accidental damage such as damage to the screen, damage from dropping and any form of water damage or ingress.

This guarantee is only upheld based on the below:

- Only products supplied by Timesco are covered.
- The Operator's Manual is wholly complied with to ensure device usage as intended by Timesco.
- Any returned devices under the guaranteed claim are cleaned and disinfected in accordance with Section 3.

6 Electromagnetic Compatibility

The Timesco Optima View Video Laryngoscope has been tested to be in compliance to the IEC 60601-1-2 / EN 60601-1-2 standards which specify the electromagnetic compatibility (EMC) requirements for medical electrical equipment. The device is also in compliance with applicable essential performance requirements specified in IEC 60601-1, IEC 60601-2-18 & EN 60601-2-18 standards. Results of the testing show that the essential performance of the system is not affected under the test conditions described in the following tables.

6.1 Electromagnetic Emissions

The device is intended for use in the electromagnetic environment specified below, therefore the user of the device should ensure that it is used in such an environment.

Table 6 Electromagnetic Emissions Tests, Compliance Level & Notes

Manufacturer's Declaration		
Emissions Test	Compliance Level	Notes
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

6.2 Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below, therefore the user of the device should ensure that it is used in such an environment.

Table 7 Electromagnetic Immunity Tests, Compliance Level & Notes

Manufacturer's Declaration		
Immunity Test	**Compliance Level**	**Notes**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±15 kV air	Compliant. Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF Immunity IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz 80% AM at 1kHz	Compliant.
Electrical Fast Transient Bursts IEC 61000-4-4	±2 kV for power supply line	Applicable to charger only - Compliant. Mains power quality should be that of a typical hospital environment.
Surge Immunity IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	

Conducted RF Immunity IEC 61000-4-6	3 V RMS 150 kHz - 80 MHz 6 V RMS in ISM bands 150 kHz - 80 MHz 80% AM at 1 kHz	Applicable to charger only - Compliant. Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distances d (m): $d=1.2\sqrt{p}$ $d=1.2\sqrt{p}$ (80MHz – 800MHz) $d=2.3\sqrt{p}$ (800MHz – 2.5GHz) There may be interference in the vicinity of the equipment marked with the following symbol: 
Magnetic Immunity IEC 61000-4-8	30 A/m 50Hz / 60Hz	Compliant. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT, last 0.5 cycles (At UT, >95% dip) 40 % UT, last 5 cycles (At UT, 60% dip) 70% UT, last 25 cycles (At UT, 30% dip) < 5 % UT, last 5s (At UT, >95% dip)	Applicable to charger only - Compliant. Mains power quality should be that of a typical hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.

7 Regulatory

Report any serious incident or adverse event to Timesco and the competent authority of the member state or national regulatory body.

CE This product complies with EN 60601-1 and EN 60601-1-2 safety standards. The CE mark indicates that it meets the requirements of Regulations (EU) 2017/745.



The Optima View Blades are classified as a BF type applied part in accordance with section 8.3 of IEC 60601-1.



Device disposal should be done in accordance with applicable Waste Electrical and Electronic Equipment requirements and local guidelines.



Caution: Federal (USA) Law restricts this device to sale by or on the order of a licensed practitioner.

Not all Timesco Healthcare products shown or described in this manual are available for commercial sale in all countries.
Information in this manual may change at any time without notice.
For the most up-to-date information contact Timesco.

Email: info@timesco.com
Phone: +44 (0)1268 297700
Website: Timesco.com



Timesco Healthcare Ltd
Timesco House, 3 Carnival Park, Carnival Close, Basildon, Essex, SS14 3WN, UK

EC REP

Advena Ltd. Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

For the most up-to-date information contact Timesco.

Email: info@timesco.com
Phone: +44 (0)1268 297700
Website: Timesco.com