

EXAMVISION



Instruction for Use  
Total & PowerGo

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## Model Overview

This Instruction for Use (IFU) is valid for ExamVision Light system models:

21100 PowerGo v2 GTIN: (01) 05744000230009

21101 Total Pure v2 GTIN: (01) 05744000230016

21102 Total Intense v2 GTIN: (01) 05744000230023

40202 Total Pure v2 w. Coaxial Extender GTIN: (01) 05744000230016

40203 Total Intense v2 w. Coaxial Extender GTIN: (01) 05744000230023



- 1 PowerGo v2
- 2 Total Pure (5000k)  
Total Intense (6500k)

## Introduction

The ExamVision Light System consists of an ExamVision control unit and an ExamVision headlamp. In this configuration, PowerGo is the control unit, and Total is the headlamp.

PowerGo is an internally battery-powered LED driver for compatible ExamVision headlamps.

Total is a passive LED headlamp, available in the variants Pure and Intense, intended to be mounted on compatible ExamVision loupes and shall only be used with compatible ExamVision Light System control units and original ExamVision lamp cables.

The ExamVision Light System is intended to illuminate the magnified working area during medical procedures and support the visual working conditions of the operator.

The system is intended for use by healthcare professionals in healthcare facilities.

The system is not intended to come into contact with patients.

PowerGo is intended for two operating scenarios:

1. Normal use, connected to a compatible ExamVision headlamp.
2. Charging, connected to a separate external power source.

Note: PowerGo has one custom USB-C port used for normal use and charging.

The ExamVision Light System has no Essential Performance. Temporary degradation of performance may occur due to electromagnetic disturbances. If this occurs, turn the system off and on again.

The user shall read and follow all instructions provided with the ExamVision Light System before use.



1. USB-C port & cable USB-C
2. Power button
3. LED indicator
4. Belt clip
5. Pocket stabiliser mount

6. Curing filter
7. USB-C port & cable USB-C
8. Total lamp unit
9. Framepart

## Getting Started

### Mounting the Framepart to the Loupe



Use two screws (included) to attach the framepart to the loupes.

**Recommended tool (not included):** Philips PH00 screwdriver

**Tip:** remove the loupe nosepad for easier access.

### Attaching Lamp Unit to the Loupe and Control Unit



Attach the lamp firmly to the framepart



Connect the USB-C connector to the lamp unit



Fix the cable on the right or left temple



Connect the USB-C connector to the control unit

### Operating PowerGo

Power on



Press the power button once.

Changing light intensity



One click increases the light intensity, and additional single clicks will cycle the unit through low, medium & high intensity settings.

Power off



Press and hold for two seconds.

### Aligning the Light Spot



Up/down adjustment

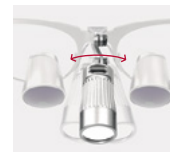


Side to side adjustment

### Aligning the Light Spot With the Coaxial Extender<sup>1</sup>



Up/down adjustment



Side to side adjustment

<sup>1</sup> Only applicable for 21103 Total Pure v2 w. coaxial extender and 21104 Total Intense v2 w. coaxial extender.

## Getting Started

### Mounting of Pocket Stabiliser

Option 1



Mounting of pocket stabiliser with belt clip

Option 2



Mounting of pocket stabiliser without belt clip

### Mounting the Curing Filter on Total LED



Slide the curing filter ring gently onto the lamp unit with the screw facing upwards



Tighten the pinol screw to fix the curing filter in place using the hex key (included)



If the filter parts are separated, slide the curing filter into the curing filter ring



Ensure curing filter is attached securely and cannot be pulled off before use



Flip curing filter down to activate



Flip curing filter up to deactivate

### Battery Level Status<sup>2</sup>



100 % - 20 %  
Continuously green



19 % - 0 %  
Light flashes green



100 % - 20 %  
Slow pulsing green<sup>4</sup>



100 %  
Continuously green

### Charging Level Status<sup>3</sup>

#### CAUTION

- USB-C Power supply connected to PowerGo must be certified to the IEC standards IEC 60950/ IEC 62368-1 or IEC 60601-1
- USB-C Power supply connected to PowerGo must be rated 5VDC, 2.0-2.5A

<sup>2</sup> PowerGo must be connected to Total Lamp and be turned on to show battery status.

<sup>3</sup> For extended periods of disuse, the PowerGo unit must be charged at a minimum of 3 month intervals and stored at a minimum charge of 20% (before it starts flashing).

<sup>4</sup> If the battery is drained to a minimum, it may take some time before the indication light starts pulsing.

## Cleaning and Disinfection

Your products should be cleaned and disinfected before and after each use.

1. Clean the product surface with a clean, soft, dampened cloth.
  - a. Ensure any physical residues (e.g. blood/tissue) are removed from the surface.
  - b. Ensure all connections are free of dust.
2. Wipe the surface of the product with an alcohol-free disinfection wipe<sup>4</sup>, taking care not to allow fluid into the USB-C port.

### **CAUTION**

- To ensure correct disinfection, follow the specific instructions on the disinfection product.
- Do NOT use alcohol-based products, ultrasonic cleaners, autoclave, UV disinfections methods or other chemical disinfection, this will damage the product.
- Excessive liquids in the USB port can damage the product.

## Safety Notice

ExamVision strongly encourage health professionals to stay in compliance with current regulations and notify any unintended incidents to your local dealer or directly to the manufacturer ExamVision.

We continuously strive to incorporate usage experience into corrective action for the benefit of health professional users of the product.

<sup>4</sup> Ammonium chloride <1% product like "Bossklein – Alcohol free surface disinfection wipes"

## Cautions

The light source emits high-intensity light. Do not stare into the beam or direct the beam into the eyes of another person.

Handle the ExamVision Light System with care to obtain the best possible product lifetime.

Do not expose the product to hot, cold, or moist conditions outside the limits specified in the technical description, as this may damage the product.

Do not short-circuit the product.

Do not leave the PowerGo in its charger for over 24 hours.

Do not charge in locations exposed to direct sunlight.

Do not attempt to repair or modify the product.

If the product becomes damaged or does not function properly, contact the local ExamVision dealer for assistance.

The ExamVision Light System is not intended to be immersed in water. Remove splashes immediately to avoid damage. See the section on cleaning and disinfection for the correct procedure.

Portable RF communications equipment, including peripherals such as antenna cables and external antennas, shall not be used closer than 30 cm (12 inches) to any part of the ExamVision Light System, including specified cables. Otherwise, degradation of performance may occur.

Use of accessories, cables, or other components other than those specified or provided by the manufacturer may result in increased electromagnetic emissions, decreased electromagnetic immunity, or improper operation.

Use of the ExamVision Light System adjacent to or stacked with other equipment shall be avoided, as this may result in improper operation. If such use is necessary, the equipment shall be observed to verify normal operation.







## More Information

### Spare Part List














Description	ExamVision Catalogue No.
Lamp Cable 1,3m USB-C 45/USB-C 45	20872
Total Lamp Curing Filter	20871
Connect v3 Framepart Service Pack	40047
Accessory Bag, Cable and Collar Clip	40008
Connect v3 Extending Kit*	20870

\* Only to be factory mounted

### Symbol Explanation

 <p><b>Manufacturer</b> ExamVision A/S. Industrivej 11, 8305 Samsø. Denmark. <a href="http://www.examvision.com">www.examvision.com</a></p>	 <p>Do not use if package is damaged</p>
 <p><b>Catalogue number</b> 21100 PowerGo v2 21101 Total Pure v2 21102 Total Intense v2</p>	 <p>Fragile, handle with care</p>
 <p>Non-sterile</p>	 <p>Keep away from sunlight</p>

### Symbol Explanation

 <p>Keep dry</p>	 <p>WEEE - DIRECTIVE 2012/19/EU Disposal product as electronic waste</p>
 <p>Read the instructions for use before using the product: <a href="http://examvision.com/support/">examvision.com/support/</a></p>	 <p>CE mark</p>
 <p>Caution</p>	 <p>Storage temperature range</p>
 <p>Medical device</p>	 <p>Humidity range</p>
 <p>Unique device identifier GS1: GTIN + Serial No.</p>	 <p>Atmospheric pressure range</p>
 <p>For indoor use only</p>	 <p>InMetro</p>
 <p>MR unsafe</p>	

## More Information

### Warranty

All ExamVision products come with a comprehensive warranty as standard.

21101 Total Pure v2 is covered by a 3-year manufacturer warranty.

21102 Total Intense v2 is covered by a 3-year manufacturer warranty.

21100 PowerGo v2 - Unit is covered by a 3-year manufacturer warranty.

21100 PowerGo v2 - Battery is covered by a 1-year manufacturer warranty.

This warranty covers all manufacturing defects which might manifest within the warranty term.

Please note, our warranty does not cover defects caused by normal wear or tear, misuse, neglect, accidental damage, modification, shipping in non-original packaging, or faults due to improper fitting, maintenance, service, cleaning or disinfection procedures.

This warranty is also void if the product is not used according to the Instruction for use.

### Additional Information:

Detachable cables and curing filters are considered replaceable parts that can be expected to wear.

Replaceable parts are covered by a 1-year manufacturer warranty.

In the event of malfunction, please return the device to your ExamVision dealer for repair.

For more information about ExamVision Warranty please see [www.examvision.com/warranty](http://www.examvision.com/warranty).



## Technical Description

### Technical Specification

Material	Aluminium
Weights	Lamp unit: 33 g (incl. Framepart and cable) PowerGo: 155 g
Connection type	USB-C
Spot size at WD 40 cm	63 mm uniform light spot
Light intensity settings	Low   Medium   High
Operating time	Total Pure: 16h   12.5h   9h Total Intense: 16h   12.5h   9h
Charging time	3.5 - 5 hours (depending on environmental conditions)
Light colour	Total Pure: 5000 K Total Intense: 6500 K
Maximum light intensity at 25 cm	Total Pure: 43,000 Lux Total Intense: 51,500 Lux
Maximum light intensity at 35 cm	Total Pure: 21,500 Lux Total Intense: 25,400 Lux
Colour rendering index	Total Pure: >90 CRI Total Intense: >70 CRI
Battery type	21700 Lithium-ion rechargeable battery
Battery capacity	5.0 Ah
Battery voltage	3.6 VDC
Discharge cut-off voltage	3.2 VDC
Maximum continuous input rating	3 VDC 450 mA
Warranty	Total Lamp unit: 3 years PowerGo unit: 3 years PowerGo battery: 1 year
Operation temperature range	0 °C - 25 °C

## Technical Description

### Technical Specification

Storage Temperature Range	-20 °C - 60 °C > 3 month -20°C - 25°C
Humidity Range	0 % ≤RH≤ 60 %
Atmospheric Pressure Range	70 kPa – 106 kPa
Features	Flicker Free Light Rotatable belt clip Easy-to-operate Power button Over-current protection Over-voltage protection



### Technical Information

The manufacturer declares that this product is compliant with the following regulations, standards, and certifications:

#### MDR EU 2017/745

- European medical device regulation

#### IEC 60601-1:2005 + A1:2012 + A2:2020

- Medical electrical equipment - Part 1: General requirements for basic safety and essential - performance

#### IEC 60601-1-2:2014 + A1:2020

- Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

#### IEC 60601-1-6:2010 + A1:2013 + A2:2020

- Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

#### IEC 62471:2006

- Photobiological safety of lamps and lamp systems

#### IECEE CB Scheme

- Certificate for medical equipment

## Technical Description

### Technical Data

Phenomenon	Test Method	Emission Class and Group/ Immunity Test Level
Conducted RF emissions	CISPR 11	N/A
Radiated RF emissions	CISPR 11	Class A Group 1 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 radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic current emissions	IEC 61000-4-4	N/A
Voltage fluctuations & flicker	IEC 61000-3-3	N/A
Electrostatic discharge immunity	IEC 61000-4-2	±8 kV Contact ±2, ±4, ±8, ±15 Air
Radiated RF electromagnetic field immunity	IEC 61000-4-3	80 MHz – 2.7 GHz, 10 V/m, 80% AM 1 kHz
Immunity to proximity fields from RF wireless communication equipment	IEC 61000-4-3	385 MHz, 27 V/m, 18 Hz PM (50 % duty cycle square wave) 450 MHz, 28 V/m, FM +/- 5 kHz dev., 1 kHz sine 710 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave) 745 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave) 780 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave) 810 MHz, 28 V/m, 18 Hz PM (50 % duty cycle square wave) 870 MHz, 28 V/m, 18 Hz PM (50 % duty cycle square wave)

Phenomenon	Test Method	Emission Class and Group/ Immunity Test Level
Immunity to proximity fields from RF wireless communication equipment	IEC 61000-4-3	930 MHz, 28 V/m, 18 Hz PM (50 % duty cycle square wave) 1720 MHz, 28 V/m, 217 Hz PM (50 % duty cycle square wave) 1845 MHz, 28 V/m, 217 Hz PM (50 % duty cycle square wave) 1970 MHz, 28 V/m, 217 Hz PM (50 % duty cycle square wave) 2450 MHz, 28 V/m, 217 Hz PM (50 % duty cycle square wave) 5240 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave) 5500 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave) 5785 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave)
Electrical fast transient/burst immunity	IEC 61000-4-4	N/A
Surge immunity	IEC 61000-4-5	N/A
Immunity to conducted disturbances induced by RF fields	IEC 61000-4-6	N/A
Power frequency magnetic field immunity	IEC 61000-4-8	N/A
Voltage dips, short interruptions and voltage variations immunity	IEC 61000-4-11	N/A
Electrical transient conduction along supply lines	ISO 7637-2	N/A
Proximity magnetic fields	IEC 61000-4-39	N/A



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