

EXAMVISION



Instruction For Use
PowerGo Control Unit

Model Overview

This instruction for use is valid for ExamVision light system control unit model:

□ 20791 PowerGo GTIN: (01) 05744000230009

Content

Model Overview.....	2
Content	2
Introduction	3
Getting Started	4
Operating PowerGo	5
Battery Level Status	5
Charging Level Status	5
Service Charging.....	6
Cleaning and Disinfection	6
Cautions	7
Safety Notice.....	7
Symbol explanation	8
Warranty.....	10
Technical Description.....	11

Introduction

PowerGo is a control unit in the ExamVision light system.

ExamVision control units are internally battery powered LED drivers for ExamVision light system headlamps.

The ExamVision light system is intended to be used as an illuminating aid that enhances the working conditions for the operator by illuminating the working area, while performing medical procedures.

ExamVision control units are to be used by health care professionals only such as dentists, hygienists, doctors, surgeons, and students of these fields, in healthcare facilities and are not intended to come into contact with patients.

PowerGo is designed with a rotatable belt clip and a single combined power/control button large enough to be operated with the forearm or the palm of the hand.

PowerGo is intended for use in two different use scenarios:

1. Normal use scenario, connected to an ExamVision light system headlamp.
2. Charging scenario, connected to a separate power source.

PowerGo has one custom USB-C port used for both the normal use scenario (power output) and the charging scenario (power input).

To achieve the optimum result from your new light system, please follow the instructions carefully. If in doubt, please ask your local ExamVision dealer for assistance.

PowerGo has no essential performance. Temporary degradation of performance can occur due to electromagnetic disturbances. If this event occurs turn the PowerGo off and on again.

Getting Started



Attach lamp unit 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 PowerGo.

For more information about your headlamp please follow the IFU for your ExamVision light system headlamp.

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.

Battery Level Status



100 % - 20 %
Continuously green



19 % - 0 %
Light flashes green

Charging Level Status



0 % - 99 %
Slow pulsing green¹



100 %
Continuously green

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"*

¹ Depending on charger output, charger cable and battery level, power is prioritized to the battery, and it may take some time before the indication light starts pulsing.

Service Charging

If the PowerGo unit isn't used for longer periods, the PowerGo unit must be stored according to the technical description and the battery should be service charged every 3 months.

Perform the charging process stated in "Operating PowerGo" and let the unit charge to a minimum of 20 %.

Cleaning and Disinfection

PowerGo should be cleaned and disinfected before and after each use.

1. Clean the surface of the product 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 alcohol-free disinfection² wipes.

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.*

² Ammonium chloride <1% product like "Bossklein – Alcohol free surface disinfection wipes"

Cautions

To obtain the best possible lifetime of your product, always handle the device with care.

Do not expose the product to hot, cold, or moist conditions that exceed those specified in the technical description, this can damage the product.

Do not attempt to repair or modify your ExamVision product yourself. Do not short-circuit your ExamVision product.

Should the device become damaged or not work properly, you should not use the device and contact your ExamVision dealer for help.











Your ExamVision light system headlamp and control unit are not designed to be immersed in water. Clean off any splashes immediately to avoid damaging your unit. See “Cleaning and Disinfection” for correct cleaning and disinfection procedure.









Safety Notice

ExamVision strongly encourage health care professionals to comply 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.

Symbol explanation

	Manufacturer: ExamVision ApS. Industrivej 11, 8305 Samsø Denmark. www.examvision.com
	Catalogue number: 20791 PowerGo
	Non-sterile
	Do not use if package is damaged
	Fragile, Handle with care
	Keep away from sunlight
	Keep dry
	Read the instructions for use before using the product: https://examvision.com/support/
	Caution
	Medical device

	Unique device identifier GS1: GTIN + Serial No.
	For indoor use only
	MR Unsafe
	WEEE - DIRECTIVE 2012/19/EU Disposal product as electronic waste
	CE Mark
	Storage temperature range
	Humidity range
	Atmospheric pressure range

Warranty

All ExamVision products come with a comprehensive warranty as standard.

PowerGo - Unit is covered by a 3-year manufacturer warranty.
PowerGo – Internal 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, or cleaning 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 for manufacturing defects for one year.

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

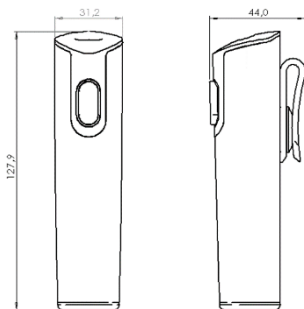
For more information about ExamVision Warranty please see Examvision.com/warranty.

Technical Description

Technical specification

Material	Aluminium
Weight	155 g
Compatible Headlamps	Total Pure LED (5000 K) Total Intense LED (6500 K)
Connection type	USB-C
Light Intensity Settings	Low, Medium & High
Operating time	Min. 6 hours at high intensity
Charging time	3 – 4 hours
Input rating	5 VDC 2.0-2.5 A
Maximum output rating	3 VDC 0-2 A
Battery Type	21700 Lithium-ion rechargeable battery
Battery Capacity	4.9 - 5.0 Ah
Battery Voltage	3.6 VDC
Discharge Cut-off Voltage	3.2 VDC
Warranty	PowerGo Unit 3 years PowerGo Battery 1 year
Operation temperature range	0 °C-25 °C
Storage temperature range	-20°C - 60°C >3 month -20°C- 45°C 12 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
Product information	Over-current protection Over-voltage protection



Accessories & Spare parts

Description	Catalogue no.
PowerGo Pocket Stabilizer	21004

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 Usability

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

IECEE CB Scheme

- Certificate for medical Equipment

Technical Data

Phenomenon	Test method	Emission class and group/ Immunity test level
Conducted 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.

Phenomenon	Test method	Emission class and group/ Immunity test level
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 61000-3-2	N/A
Voltage fluctuations and 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

<p>Immunity to proximity fields from RF wireless communication equipment</p>	<p>IEC 61000-4-3</p>	<p>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) 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)</p>
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Phenomenon	Test method	Emission class and group/ Immunity test level
Electrical fast transient/burst immunity	IEC 61000-4-4	±2 kV (100 kHz)
Surge immunity	IEC 61000-4-5	±1 kV
Immunity to conducted disturbances induced by RF fields	IEC 61000-4-6	0.15-80 MHz, 3 V (6 V ISM bands), 80 % AM 1 kHz
Power frequency magnetic field immunity	IEC 61000-4-8	N/A
Voltage dips, short interruptions and voltage variations immunity	IEC 61000-4-11	0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles 0 % UT; 250/300 cycle
Electrical transient conduction along supply lines	ISO 7637-2	N/A
Proximity magnetic fields	IEC 61000-4-39	N/A



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