

EXAMVISION



Instruction For Use
Total Pure/Intense LED

Model overview

This instruction for use is valid for ExamVision light system headlamp models:

- 20789 Total Pure LED (5000 K) GTIN: (01) 05744000230016
- 20790 Total Intense LED (6500 K) GTIN: (01) 05744000230023

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Introduction

Total LED is a headlamp in the ExamVision light system.

ExamVision headlamps are passive LED lamp units to be mounted onto ExamVision loupes, and to be powered by an ExamVision light system control unit.

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 headlamps 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.

Total LED comes in two variants: Pure and Intense. They should only be used with ExamVision Light system control units and with original ExamVision lamp cables.

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

Total LED has no defined Essential Performance. Temporary degradation of performance can occur due to electromagnetic disturbances. If this occurs turn the lamp unit off and on again.

Getting Started

Mounting the framepart to the loupe



Use two screws (included) to attach the framepart to the loupes as shown above. Tip: remove the loupe nosepad for easier access.

Recommended tool (not included): Philips PH00 screwdriver

Attaching Total LED to the loupe



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.

Follow your ExamVision Control Unit IFU to activate your Total LED.

Aligning the light spot

Up/Down adjustment



Side to side adjustment



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.

Using the curing filter

To activate:

Flip curing filter down



To deactivate:

Flip curing filter up



Cleaning and disinfection

Your headlamp 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 disinfection¹ wipe, 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.*

¹ Ammonium chloride <1% product similar to "Bossklein – Alcohol free surface disinfection wipes"

Cautions

This LED device has a very powerful light. Do not look directly into the light, and do not point it into the eyes of other people.

To obtain an optimal 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, as 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.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Total Lamp, including cables specified by the manufacturer. Otherwise, degradation of performance of this equipment could result.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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 20789 Total Pure LED (5000 K) 20790 Total Intense LED (6500 K)
	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.

20789 Total Pure LED (5000 K) and 20790 Total Intense LED (6500 K) is covered by a 3-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 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 with frame part	18 g
Available Control unit	PowerGo
Connection type	USB-C
Spot size at WD 40 cm	70 mm uniform light spot
Light colour	Total Pure: 5000 K Total Intense: 6500 K
Maximum light intensity at 25 cm	Total Pure: 21,900 Lux Total Intense: 51,500 Lux
Maximum light intensity at 35 cm	Total Pure: 11,300 Lux Total Intense: 25,400 Lux
Colour rendering index	Total Pure: >90 CRI Total Intense: >70 CRI
Maximum continuous input rating	3 VDC 450 mA
LED Chip Total Pure LED LED Chip Total Intense LED	Samsung LH351D 5000K Osram GW CSSRM3.PM 6500K
Warranty	3 years
Operation temperature range	0 °C - 25 °C
Storage temperature range	-20 °C - 60 °C
Humidity range	0 %rh - 60 %rh
Atmospheric pressure range	70 kPa – 106 kPa
Features	Over-current protection, Over-voltage protection



Accessories & Spare parts

Description	Catalogue no.
Lamp Cable 1.3m USB-C 45/USB-C 45	20872
Total Lamp Curing filter	20871
Connect v3 Frame part	20795
Connect v3 Coaxial Extending	20870

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 Data

Phenomenon	Test method	Emission class and group/ Immunity test level
Conducted RF emissions	CISPR 11	N/A
Radiated RF emissions	CISPR 11	<p>Class A Group 1</p> <p>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.</p>
Harmonic current emissions	IEC 61000-3-2	N/A
Voltage fluctuations and flicker	IEC 61000-3-3	N/A

Phenomenon	Test method	Emission class and group/ Immunity test level
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
		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/bur st immunity	IEC 61000-4-4	N/A
Surge immunity	IEC 61000-4-5	N/A

Phenomenon	Test method	Emission class and group/ Immunity test level
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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