EXAMVISION

# Instruction For Use

Total Pure/Intense LED

## Model overview

This Instruction for Use (IFU) 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

# Indhold

## 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 illuminate the magnified working area of ExamVision loupes, for Health Care Professionals while performing medical procedures.

ExamVision headlamps are to be used by Health Care Professionals only, such as dentists, hygienists, doctors, surgeons, and clinicians and are not intended to come into contact with patients.

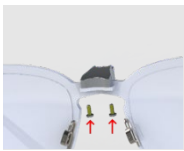
Total LED comes in two versions: Pure and Intense. They should only be used with ExamVision Light system control units and with original ExamVision lamp cables.

To achieve the optimum result from your new light system, please follow all instructions and videos 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 the lamp 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.

*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 Total lamp 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, 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.*

*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 short-circuit your ExamVision product.

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 section 5 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.

Do not attempt to repair or modify your ExamVision product yourself. Should the device become damaged or not work properly, contact your ExamVision dealer for assistance.

## 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.

## More info

### 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 Frame part | 20795 |

### Symbol explanation

| | |
|---|---|
|  | **Manufacturer**<br>ExamVision ApS, Industrivej 11<br>8305 Samsø Denmark<br>www.examvision.com |
|  | **Catalogue number**<br>20789 Total Pure LED (5000 K)<br>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) is covered by a 3-year manufacturer warranty.
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.

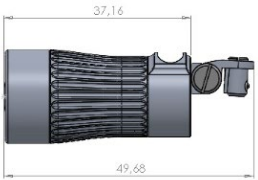
For more information about ExamVision Warranty please see Examvision.com/warranty.

## Technical Description

### Technical specification

| | |
|---|---|
| **Material** | Aluminium |
| **Compatible Control unit** | 20791 PowerGo |
| **Connection type** | USB-C |
| **Spot size at WD 40 cm** | 70 mm uniform light spot |
| **Weight with frame part** | 18 g |
| **Light colour** | Total Pure: 5000 K<br>Total Intense: 6500 K |
| **Maximum light intensity at 25 cm** | Total Pure: 21,900 Lux<br>Total Intense: 51,500 Lux |
| **Maximum light intensity at 35 cm** | Total Pure: 11,300 Lux<br>Total Intense: 25,400 Lux |
| **Colour rendering index** | Total Pure: >90 CRI<br>Total Intense: >70 CRI |
| **LED Chip Total Pure LED** | Samsung LH351D 5000K |

| | |
|---|---|
| **LED Chip Total Intense LED** | Osram GW CSSRM3.PM 6500K |
| **Maximum continuous input rating** | 3 VDC 450 mA |
| **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 |
| **Product information** | *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 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<br><br>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 |

| Phenomenon | Test method | Emission class and group/ Immunity test level |
|---|---|---|
| Electrostatic discharge immunity | IEC 61000-4-2 | ±8 kV Contact<br>±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)<br>450 MHz, 28 V/m, FM +/- 5 kHz dev., 1 kHz sine<br>710 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave)<br>745 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave)<br>780 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave)<br>810 MHz, 28 V/m, 18 Hz PM (50 % duty cycle square wave)<br>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)<br>1720 MHz, 28/ V/m, 217 Hz PM (50 % duty cycle square wave)<br>1845 MHz, 28 V/m, 217 Hz PM (50 % duty cycle square wave)<br>1970 MHz, 28 V/m, 217 Hz PM (50 % duty cycle square wave)<br>2450 MHz, 28 V/m, 217 Hz PM (50 % duty cycle square wave)<br>5240 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave)<br>5500 MHz, 9 V/m, 217 Hz PM (50 % duty cycle square wave)<br>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 |

| 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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