



User's Manual

COGENTIX MEDICAL
Battery Powered Light Source

BLS-1000

NOTE: Federal (USA) law restricts this device to sale by, or on the order of, a physician or other appropriately licensed medical professional.

www.cogentixmedical.com

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How to Use This Manual

This User's Manual contains an overview of the **BLS-1000** Battery Powered Light Source, installation instructions, operation procedures, and information about the **BLS-1000** features and settings.

- If you are a **first time user**, read this manual in its entirety to familiarize yourself with the **BLS-1000**, and to learn about preparation and proper use of the unit.
- If you are an **experienced user**, select the chapter and/or sections that pertain to **BLS-1000** features and functions you wish to utilize.

Organization of this Manual

Following is a list of the chapters included in this User's Manual. Each chapter's title is listed at the top of all pages after the title page, so that you can quickly access the information you need.

Chapter 1, Symbols and Terms – Defines the symbols on the Light Source unit. Also included is a brief summary of terms commonly used in the manual.

Chapter 2, Important Information – Provides a summary of critical Warning and Caution statements, outlines important safety precautions to be observed when using the instrument, and provides preparation instructions.

Chapter 3, Equipment and Features – Introduces the **BLS-1000** features and controls of the unit. Also provides a list of Cogentix Medical catalog numbers for equipment and accessories associated with the unit.

Chapter 4, BLS-1000 Operation – Describes operating procedures of the Light Source, and recommends a thorough inspection of the unit prior to use.

Chapter 5, Reprocessing – Contains important instructions on the proper cleaning and disinfection of the Light Source unit. Strict adherence to the instructions provided in this chapter will ensure the unit's longevity and optimal performance during each procedure.

Chapter 6, Care and Storage – Recommends basic and essential practices for medical staff to follow when using the Light Source; and describes how to care for and maintain the unit. If the unit will not be used for an extended period of time, this chapter provides information on safe, secure storage.

Chapter 7, Troubleshooting – Describes possible problems that may be encountered and suggests corrective actions.

Chapter 8, Warranty and Service – Contains the terms of the Cogentix Medical warranty on the Light Source unit, and restrictions that apply. Also provides user actions that may void the warranty if taken. This chapter includes shipping instructions in case the **BLS-1000** must be returned to Cogentix Medical for repair.

How To Use This Manual

Appendix A, Specifications – Contains the technical specifications for the **BLS-1000** Battery Powered Light Source.

Additional Information

The information in this User's Manual is subject to change without notice. If you have any questions regarding any of the material contained in this manual, or wish to confirm that this is the most comprehensive information available for this product, please contact your local distributor or Cogentix Medical Customer Service Department at 866-258-2182 (toll free in U.S.) or (+1) 952-426-6189 (international).

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1 Symbols and Terms

Symbols



Power OFF



Power ON



Alerts the user to the presence of important operating, maintenance, and service instructions. Refer to the User's Manuals for warnings and safety precautions associated with equipment used in the procedure.



Serial number of the unit



Equipment bearing this mark has been designed, tested, and certified as essentially compliant with all applicable European Union (EU) regulations and recommendations.



Consult Instructions for Use



The presence of this symbol on the product or packaging indicates that the device is RoHS compliant.

Terms

The "**BLS-1000**," "**Unit**," "**Equipment**," "**Instrument**" and/or "**Light Source**" all refer to the Cogentix Medical **BLS-1000** Battery Powered Light Source.

2 Important Information

Intended Use

The equipment and the information in this manual are intended for physicians, medical staff and other licensed practitioners. This unit is intended to be used as an LED light source for endoscopic procedures, and is compatible only with Cogentix Medical fiberoptic endoscopes.

Do not use this equipment for any other purpose.

User Qualifications

This equipment should only be used in a medical facility by or under the supervision of a physician trained in endoscopy.

Reprocessing

The **BLS-1000** Battery Powered Light Source should be thoroughly cleaned after each use in a clinical procedure; it should also be disinfected when exposed to direct contamination. See Chapter 5, **Reprocessing**, for information on reprocessing equipment and procedures.

Maintenance and Repair

The **BLS-1000** Battery Powered Light Source contains **no** user-serviceable parts. **Never** attempt to modify or repair it. Doing so may cause equipment damage. The unit may only be serviced or repaired at an authorized Cogentix Medical facility.

Signal Words



Alerts the user to situations which, if not avoided, could jeopardize personal safety.



Alerts the user to situations which, if not avoided, could result in equipment damage.



NOTE: Indicates additional helpful information.

Important Safety Precautions

The following precautions should always be exercised with the use of all electro-medical equipment to ensure safety for all involved parties: user(s), patient(s), etc.

WARNING

FAILURE TO FOLLOW INSTRUCTIONS AND PROPER HANDLING OF LITHIUM-ION BATTERIES POSES A RISK OF FIRE OR EXPLOSION.

WARNING

DO NOT exceed 30 minutes of continuous usage to avoid extreme temperatures on the body of the **BLS-1000**. Allow a minimum 10 minute cool-down period between uses.

CAUTION

DO NOT attempt to disassemble any part of the **BLS-1000** Light Source other than to replace the battery; there are no user-serviceable parts in or on this unit.

Refer to all relevant manuals for proper use of endoscopic equipment and optional battery powered light sources.

Preparation/Installation

WARNING

The **Cogentix Medical Battery Charger** (07-3048) must not be used in the immediate patient contact area of 6 feet (1.83 meters). Place the Battery Charger in a location where it **cannot** come in contact with the patient or physician during a medical procedure.

The **BLS-1000** and the **Battery Charger** should **NEVER** be installed or used in the presence of flammable or explosive gases or chemicals.

DO NOT attempt to recharge lithium disposable (non-rechargeable) type batteries. Doing so may cause a risk of fire or explosion.

Observe proper polarity (+ / – direction) when inserting batteries into the **BLS-1000** or the Charger.

CAUTION

The **BLS-1000** Light Source or the battery charging equipment should **NEVER** be used in areas where the unit could be exposed to environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc., which could adversely affect the equipment. **DO NOT** alter, disassemble or expose the Cogentix Medical Battery Charger to high temperatures or water.

This equipment should **NEVER** be subjected to extreme vibration.

When using an isolation transformer for any ancillary equipment, ensure the power requirements of the devices do not exceed the capacity of the isolation transformer. For further information, contact your local Cogentix Medical distributor or Customer Service.

Never drop this equipment or subject it to **severe impact** as it could compromise the functionality and/or safety of the unit. Should this equipment be mishandled or dropped, do not use it. Return it to an authorized Cogentix Medical service facility for inspection and repair.

Only Lithium-Ion rechargeable batteries supplied by Cogentix Medical should be used in conjunction with the Battery Charger.

WARNING

All devices connecting to the **BLS-1000** must be Classified Medical Equipment. If additional equipment is connected to the **BLS-1000** the operator must determine that all equipment complies with the appropriate end-product safety standard (such as IEC 60950-1 or IEC 60065) and Standards for Medical Electrical Equipment (UL 60601-1 or IEC 60601-1).

Prior To Use

Confirm that this equipment **functions properly** and check the operation of the switch, lamp, etc.

Confirm that other **devices** used in conjunction with equipment **function properly** and that these other devices will not adversely affect the operation or safety of this equipment. If any component of the endoscopic system is not functioning properly, the procedure should not be performed.

During Use

WARNING

The light emitted by the **BLS-1000** Battery Powered Light Source is extremely intense and can cause permanent eye damage if viewed directly with the unprotected eye. **Do not look directly at the light** exiting the endoscope or into the light emitting area on the light source while the unit is turned on.

Continually monitor this equipment and the patient for any signs of irregularities.

If the operation of any of the components of the endoscopic system fails during the procedure, and the visualization of the procedure is lost or compromised, make sure the bending section of the endoscope is in the neutral position, and slowly withdraw the endoscope.

This equipment should only be used according to the instructions and operating conditions described in this manual. Failure to do so could result in compromised safety, equipment malfunction or instrument damage.

Be careful to minimize continuous usage in environments where the operating temperature approaches the highest recommended limit of 38°C.

Important Information

CAUTION

Always wear appropriate personal protective gear when using this unit and other endoscopic equipment, such as a gown, gloves, and face and eye shields.

After Use

Refer to the operating instructions supplied with all the components of the endoscopic system to establish the correct order in which components should be turned off.

To prolong the life of the lamp and electronic components, and to avoid extreme temperatures on the body of the light source, turn the power switch to the "off" position and allow the light source to cool for at least ten minutes after each use. Do not exceed 30 minutes of continuous use.

3 Equipment and Features

The Cogentix Medical **BLS-1000** offers excellent performance for endoscopic viewing using a battery powered light source. Designed with portability in mind, its compact size, ease of attachment to endoscope, versatility, and quality of light emission make the **BLS-1000** a superior endoscopic accessory. This Light Source can be used with Cogentix Medical flexible endoscopes.

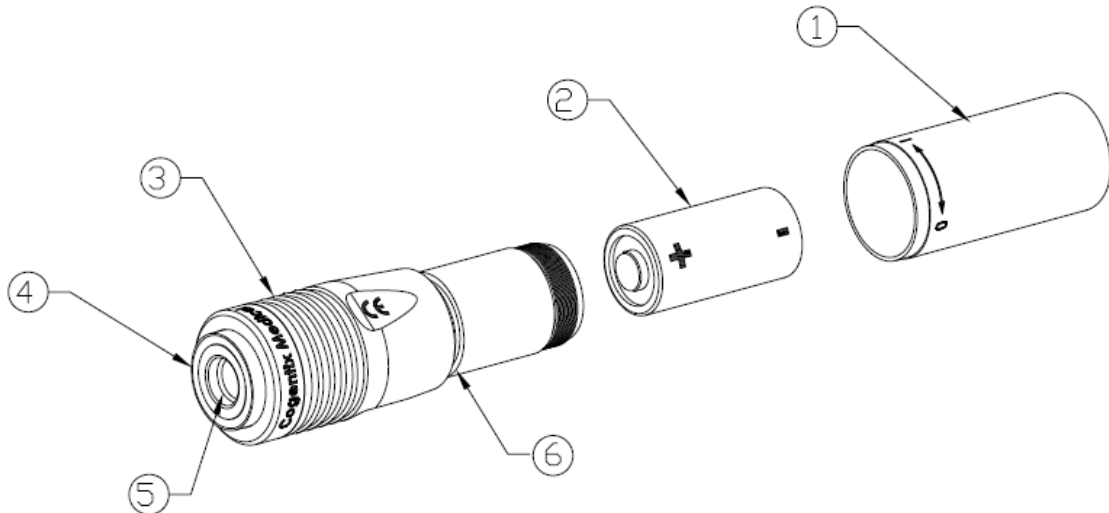
BLS-1000 Standard Set

When the **BLS-1000** is shipped to you from Cogentix Medical, immediately inspect your shipment upon receipt. Confirm that all items ordered (listed below) were shipped, and check them for damage. If any item is missing or damaged, do not use the equipment. Contact Cogentix Medical Customer Service to obtain a replacement part.

BLS-1000 STANDARD SET	
CATALOG NO.	DESCRIPTION
07-3053*	BLS-1000 Battery Powered Light Source Set Includes Batteries and Battery Charger
	BLS-1000 User's Manual (this document)
REPLACEMENT ITEMS	
07-3050	BLS-1000 Battery Powered Light Source
07-3048*	Cogentix Medical Lithium-Ion Battery Charger
07-3049	BLS-1000 Rechargeable Batteries (2)

***Contact the distributor or manufacturer for region-specific configuration**

BLS-1000 Diagram



Components:

1. Casing / Rotary Switch
2. Battery
3. Cooling Fins
4. Face Seal
5. Light Port
6. O-Ring

BLS-1000 Compatibility

ENDOSCOPES

The **BLS-1000** is designed to be used ONLY with the following Cogentix Medical endoscopes:

- **CST-4000/4000i** Cystoscope/Hysteroscope
- **ENT-4000/4500** Nasopharyngo-Laryngoscope
- **BRS-4000** Bronchoscope

BATTERIES



FAILURE TO FOLLOW INSTRUCTIONS AND PROPER HANDLING OF LITHIUM-ION BATTERIES POSES A RISK OF FIRE OR EXPLOSION.

The **BLS-1000** is designed to be used only with the following approved batteries:

- Cogentix Medical 3.7 Volt Lithium-Ion Rechargeable Battery, Catalog # 07-3049
- 3.0 Volt Lithium Disposable Battery type CR123 or CR123A.



When using disposable Lithium batteries, only use batteries which comply with the Underwriters Laboratory Recognized Component mark certification.



NOTE: When using a 3.0 Volt Lithium Disposable battery, the light output of the **BLS-1000** may be slightly reduced. Use the Cogentix Medical 3.7 Volt Li-Ion Rechargeable batteries for optimal operating time and illumination between battery replacements/ recharging.

4 BLS-1000 Operation

Installing/Changing a Battery in the BLS-1000

WARNING

DO NOT ATTEMPT TO RECHARGE DISPOSABLE LITHIUM BATTERIES. Charging of disposable batteries may cause a risk of explosion, fire or damage to equipment. Only use Cogentix Medical Lithium-Ion Rechargeable Batteries (Catalog # 07-3049) in the Cogentix Medical Charger (Catalog # 07-3048).

The **Cogentix Medical Battery Charger** (07-3048) should **not** be installed in an immediate patient contact area of 6 feet (1.83 meters). Only use the Battery Charger in a location where patient or physician contact is not possible during an endoscopic procedure. Please refer to the Battery Charger *Instructions for Use* to ensure proper installation and use of the equipment.

CAUTION

Use only approved Lithium-Ion 3.7V Rechargeable or Lithium 3.0V Disposable batteries with the **BLS-1000**. Ensure proper installation to avoid damage or improper function of unit.

Open the **BLS-1000** by gently unthreading the back Casing counterclockwise. Place the battery into the Battery Slot positive (+) end first. Holding the lamp away from eyes, thread the back Casing onto the unit clockwise until secure. If lamp illuminates after securing the Casing, rotate slightly into the 'off' position to avoid using battery power until necessary.

Connecting the BLS-1000 to a Cogentix Medical Endoscope

Before connecting to the endoscope, confirm battery power and light emission are functioning. Place illuminating end of the **BLS-1000** onto the Light Post of the endoscope. Holding the **BLS-1000** by the fins, thread clockwise until unit is securely attached. Verify unit is secure before transport or use of the endoscope.

On/Off Control on the BLS-1000



NOTE: If using the **BLS-1000** on a Cogentix Medical Endoscope utilizing the EndoSheath[®] Protective Barrier, take care to avoid contamination by improperly handling the light source during an endoscopic procedure. Please refer to the EndoSheath[®] *Instructions for Use* for detailed information on the use of that system.

BLS-1000 Operation

Gently rotate the back Casing into the ON position.

If attached to an endoscope, turn the unit ON before inserting the endoscope's insertion tube into the patient. View through eyepiece to ensure light output.

To power off the unit, gently rotate into the OFF position until light emission stops.

When powering off after a procedure, **do not handle unit with contaminated gloves.**



NOTE: Before storing the **BLS-1000** during non-use or for brief downtimes, make certain lamp is turned **OFF** to avoid draining battery power.

If illumination of the lamp begins to noticeably fade, the battery power is almost exhausted. If fading occurs during an endoscopic evaluation, make certain a new/recharged battery is installed in the unit before performing another procedure.



NOTE: The Lithium-Ion Rechargeable Batteries may be recharged many times before needing replacement (typically 300 times or more). However, with repeated use, the batteries will begin to lose the ability to hold a full charge and may have a shortened operating time. If the batteries exhibit shortened operating times, replace them with new Cogentix Medical Lithium-Ion Rechargeable Batteries (catalog #07-3049).

Removing the BLS-1000 from a Cogentix Medical Endoscope

Verify unit is in the OFF position. Holding the **BLS-1000** by the fins, turn counterclockwise until unit disengages from the endoscope.

5 Reprocessing

Cleaning and Disinfection of the BLS-1000

WARNING

Always verify back Casing is secure before cleaning/disinfecting the **BLS-1000** Light Source. Failure to do so may result in damage to equipment.

CAUTION

Failure to properly clean the unit may render disinfection ineffective.

Cleaning the Light Source

CAUTION

Do not use cleaning/disinfecting agents that are not suitable for use with plastics, for example, ammonia, acetone, or salty acids (HCl).

Do not allow cleaning agents or liquids to enter the Light Source unit.

The Light Source should only be cleaned with cleaning agents designed for external cleaning of electrical equipment, and should only be used according to the manufacturer's instructions.

1. Gently pat down and wipe the equipment with a soft material (gauze 4x4) to remove any gross debris.
2. Gently wash all external surfaces with 70% ethyl or isopropyl alcohol or an instrument-grade cleaning solution designed for electrical equipment.
3. Rinse the unit with lukewarm water.
4. Dry all external surfaces of the Light Source.

Disinfecting the Light Source

The Light Source should only be disinfected with agents designed for disinfection of endoscopic equipment, such as glutaraldehyde solutions, and should only be used according to the manufacturer's instructions.

CAUTION

Some methods of disinfection may be harmful to the Light Source and exposure could result in extensive damage. Please contact Cogentix Medical Customer Service to verify compatibility of a cleaning method not listed in this manual.

1. Clean the Light Source, following the cleaning protocol given in this chapter.

Reprocessing

2. Allow the Light Source to remain immersed in the disinfectant for the period of time recommended by the disinfectant manufacturer, but no longer than one (1) hour.
3. Rinse the unit thoroughly following disinfection.
4. Carefully wipe the Light Source with 70% ethyl or isopropyl alcohol and wipe all outside surfaces of endoscope with soft material (gauze 4x4) until completely dry.
5. Ensure the Light Source is free of solution residue.

Sterilizing the Light Source

CAUTION

The **BLS-1000** Light Source **cannot** be autoclaved, EtO sterilized or steam-sterilized.

The **BLS-1000** Light Source **cannot be sterilized** using traditional methods. For more information, contact your local distributor or Cogentix Medical Customer Service.

6 Care and Storage

Routine Care and Maintenance

Routine care and maintenance can identify potential problems before they occur, ensuring the **BLS-1000** has a reliable and long operating life.



Do not use the **BLS-1000** if the unit is not functioning properly. Continued use of a unit not functioning properly may impair long-term operability.



NOTE: Ensuring that all users of the **BLS-1000** are properly trained on operating procedures can help prevent mishandling and accidental damage to the unit.

Preventative maintenance involving the use of the unit is not necessary. There are no user-serviceable parts in the **BLS-1000**. As a general rule, following these simple practices will maintain the Light Source unit in good condition:

- Always confirm switch and light on the **BLS-1000** are working properly.
- Verify working condition immediately following transportation or routine cleaning/disinfection.
- Ensure **BLS-1000** is installed according to the procedures detailed in this manual and all users are following safety precautions.
- Ensure all users and medical staff are following Cleaning/Disinfection procedures outlined in this manual.

Cogentix Medical does not recommend that users allow outside facilities to perform repairs or service. Repair by any party not authorized by Cogentix Medical will void the warranty.

Storage

The **BLS-1000** Light Source, the Battery Charger and the Batteries should NEVER be stored in areas where they could be exposed to liquids or environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc., which could adversely affect the equipment.

This equipment should NEVER be stored in the presence of flammable or explosive gases, or chemicals.

Battery Charger Pack, power cords, accessories, etc., should be cleaned and neatly stored.

This equipment should be maintained in a clean condition during storage so that it is ready for subsequent use.

Disposal

The equipment should be returned to Cogentix Medical for disposal. Contact your local Cogentix Medical representative or service facility.



DO NOT dispose of the Lithium-Ion batteries in an improper manner. Burning or crushing of batteries can potentially cause fire or explosion.

7 Troubleshooting

Problem	Corrective Action
Light does not emit from the port	<p>Verify unit is in ON position Verify new/recharged battery is installed Verify no obstructions to the light emission area</p> <p>Once these steps are confirmed, if light still does not emit, lamp may not be functional. Contact your local distributor or Cogentix Medical Customer Service.</p>
Light Source won't attach to endoscope	<p>Verify there is no damage to Light Post on endoscope Verify there is no damage to Light Source threading Verify no obstructions to the light emission area are present</p> <p>Verify light source is compatible with endoscope connection type</p> <p>Once these conditions are confirmed to be in order, if Light Source still will not connect, contact your local distributor or Cogentix Medical Customer Service.</p>
Light Source operates for a shortened period of time	<p>Batteries not fully charged; need to recharge</p> <p>Batteries not able to hold a full charge due to age; replace the batteries (charger screen will show "Null" if the battery can no longer be recharged)</p>
Batteries not charging	<p>Check proper placement of batteries in charger (correct polarity); if one battery is installed incorrectly and two batteries are in the charger, neither battery will charge.</p> <p>Refer to the following Battery Charger LCD Status Indicator to interpret the displayed message on the Lithium Ion Battery Charger:</p> <ul style="list-style-type: none"> ❑ Batteries Charging: Pointer on dial/voltage meter moves ❑ Batteries Fully Charged: 'Full' message displays ❑ Batteries Installed Incorrectly: 'Err' message displays ❑ Battery No Longer Holds Charge: 'Null' message displays <p>Note: If a fully charged battery is placed in the charger, the voltage meter dial will point to 4.2V, it may take a few minutes for the mAh reading to change to "Full."</p>

8 Warranty and Service

Warranty Information



NOTE: Alterations or repairs done by persons not authorized by Cogentix Medical will void this warranty.

Cogentix Medical is not liable for any damages to the **BLS-1000** Battery Powered Light Source resulting from misuse, negligence, or improper cleaning or storage. The warranty defined herein shall apply only to the original buyer. In no event shall Cogentix Medical be liable for anticipated profits, consequential damages or loss of time incurred by the buyer with the purchase or use of this equipment.

NOTE: Cogentix Medical sells many of its products through regional distributors. Before sending equipment to Cogentix Medical, contact your regional distributor for repair/return procedures.

Cogentix Medical warrants that the **BLS-1000** Battery Powered Light Source and its accessories will be free from defects in materials and workmanship **for a period of one year from the date of the invoice.** Replacement parts are warranted **for a period of ninety (90) days from the date of the invoice.**

All non-warranty repairs will be warranted to be free from defects in materials and workmanship **for a period of ninety (90) days from the date of the invoice.**

Upon receipt of a **BLS-1000** Battery Powered Light Source for repair, Cogentix Medical will evaluate the instrument and make the final decision as to the warranty status.

The above warranties are in lieu of all other warranties, either expressed or implied, including warranties of fitness or merchantability.

Cogentix Medical Service Information

BLS-1000 Battery Powered Light Sources are serviced at authorized Cogentix Medical facilities only. Use the following procedure to expedite returned goods for repair or replacement:

1. Telephone your regional distributor, or Cogentix Medical Customer Service Monday through Friday from 8:00 AM to 7:00 PM EST.

USA customers call **866-258-2182** (toll free in U.S.)

International customers call **(+1) 952-426-6189** for Cogentix Medical Customer Service or call your regional distributor.

Fax 866 255-4522 (toll free in U.S.)

Fax (+1) 952 426-6199 (international)

Email: customercare@cobentixmedical.com

2. Provide a detailed description of the problem.
3. If troubleshooting cannot solve the problem, a Returned Goods Authorization (RGA) number will be issued.
4. Complete an Incident Report Form and send it to Cogentix Medical along with the returned goods.

Shipping to Cogentix Medical or Distributor

WARNING

If the **BLS-1000** Battery Powered Light Source has been used in a clinical setting, disinfect the unit before shipping as described in Chapter 5, **Reprocessing**. Shipping contaminated equipment could present an acute infection-control risk for those handling the endoscope, both during shipping and at Cogentix Medical.

If the **BLS-1000** Battery Powered Light Source has been used in a clinical setting but cannot be disinfected before shipping, **place a red biohazard label** on the shipping container to indicate that the contents are contaminated, in accordance with OSHA standards 29 CFR 1910.1030.

Observe the following precautions before shipping the Light Source:

Ship the **BLS-1000** unit in a secure container. Place the container inside a corrugated box with protective shipping material to prevent damage during shipment.

Regardless of warranty status, all shipping charges to and from an authorized Cogentix Medical facility are the responsibility of the customer.



NOTE: The customer will be contacted and advised of the estimated repair costs. Repairs will not begin on any equipment until authorization or a purchase order has been issued indicating approval of the charges.

Appendix

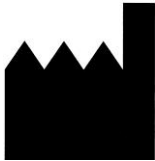
Specifications BLS-1000

Item	Specification
Lamp Type	LED (Light Emitting Diode)
Lamp Power Rating	3 Watts
Lamp Life	50,000 hours (approximate)
Brightness Control	None. On/Off
Operating Voltage	3.0 – 3.7 Volt
Battery Type	<input type="checkbox"/> Lithium-Ion Rechargeable 3.7 Volt <input type="checkbox"/> Lithium Disposable 3.0 Volt type CR123/CR123A
Regulatory Approvals	CE Marked
Mode of Operation	Continuous up to 30 minutes maximum (with 10 minute cool-down between usage)
Operating Temperature	10° C to 38° C
Degree of Protection Against Ingress of Liquids	Fully Immersible
Degree of Explosion Proofing	Not suitable for use in the presence of flammable anesthetics mixture with air or with oxygen or with nitrous oxide.
Unit Dimensions	88mm Length / 25 mm Max Width
Unit Weight	93g

Table A - 1: Specifications

Cogentix

Medical



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