

BT-410

Head-worn light

Operator Manual



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Section 1

Safety

1.1 Instructions for the Safe Operation and Use of the BT-410 .

- Before administering BT-410, read all section of this manual carefully.
- Observe all precautions to ensure the safety of the patient and those near the instrument.
- Do not attempt to service the BT-410. Only qualified service personnel should attempt any needed internal servicing.

WARNING: Identifies conditions or practices that might present danger or possible injury to the patient and/or user.

CAUTION: An instruction that, if not followed, can result in a condition that could damage the light.

NOTE: Background information provided to clarify a particular step or procedure.

1.2 Warnings

WARNING: Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.

WARNING: Incorrect use of the light, or the use of parts and accessories that are not manufactured or supplied by Bistos Corporation can damage the light, and may cause injury to the user.

WARNING: Do not use the light in the presence of gases that support combustion (for example, oxygen, nitrous oxide, or other anesthetic agents).

1.3 Cautions

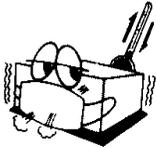
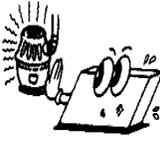
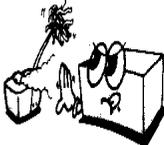
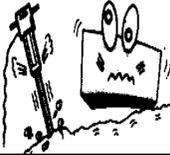
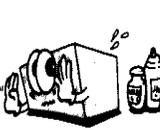
CAUTION: The relevant law restricts this device to sale by or on the order of a physician.

CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location..

CAUTION:
 -The equipment conforms to Class A according to IEC/EN 60601-1(Safety of Electric Medical Equipment)
 - This equipment conforms to Level B according to IEC/EN 60601-1-2 (Electromagnetic Compatibility Requirements)

General Precaution on Environment

- Do not keep or operate the equipment under the environment listed below.

	Avoid placing in an area exposed to moisture. Do not touch the equipment with wet hand.		Avoid exposure to direct sunlight
	Avoid placing in an area where there is a high variation of temperature. Operating temperature ranges from 10°C to 40°C. Operating humidity ranges from 20% to 90%.		Avoid in the vicinity of Electric heater
	Avoid placing in an area where there is an excessive humidity rise or ventilation problem.		Avoid placing in an area where there is an excessive shock or vibration.
	Avoid placing in an area where chemicals are stored or where there is in danger of gas leakage.		Avoid dust and especially metal material into the equipment.
	Do not disjoint or disassemble the equipment. BISTOS Co., Ltd. does not take responsibility of it.		The equipment shouldn't be connect to the power while used. May cause it may cause damage to equipment

1.4 Definitions and Symbols

Symbol	Description	Requirements
	Stand-by	IEC TR 60878
	This symbol identifies a safety note. Ensure you understand the functions of these controls before using it. Function controls are described in the operator's manual.	IEC TR 60878
	Polarity of d.c. power connector	IEC TR 60878

Section 2

Introduction

2.1 General

This chapter provides a general description of the BT-410 monitor including:

- Brief Device Description
- Product Features
- Model Configurations

2.2 Brief Device Description

This Head-worn light is used for medical examination by fixing it on the head and illuminating with condensed light to the injured part. This unit doesn't intend to contact directly to the patient's body and can be used for all medical field except ophthalmology. All material is made of the light plastic, and is consist of mainbody and headband. The main body is composed of a light source (LED), main frame, and battery pack. Optional accessories are consist of an astral lamp for shadowless effect, and loupe (magnifying glass). The battery uses a lithium-ion rechargeable one, and using time is about 4 hours. Full recharge takes about 4 hours. LED's optical power will be a little decreased even though you use the unit normally according to recommended using time. The expectedly possible using time is for approximately 50,000 hours.

2.3 Intended Use

The BT- 410 Head-worn light allows doctors to examine with a clear eye onto the affected part by wearing it onto the head.

2.4 Product Features

- Battery pack can be separated, so separate recharging is possible.
- You can check necessary recharging time with LED indicator of recharging status.
- Irradiating to up & down and left & right side is possible by pivot joint.
- Operation is very simple, so the unit is easy to use .

2.5 Product Configuration

BT-410 system consists of the following elements. Open the packaging contains the following accessories, please check. Also check for any damage to your

console and accessories, please check.
If you wish to purchase, please contact our office.

Part	Name	Part	Name
	Main body		Loupe (Optional)
	Charger		Astral Lamp (Optional)
	User Manual		Battery Pack (Optional)
	Main body (Optional)		

Table 1.1. BT-410 Configuration

Section 3 Assembly and Operation

3.1 The overall panel

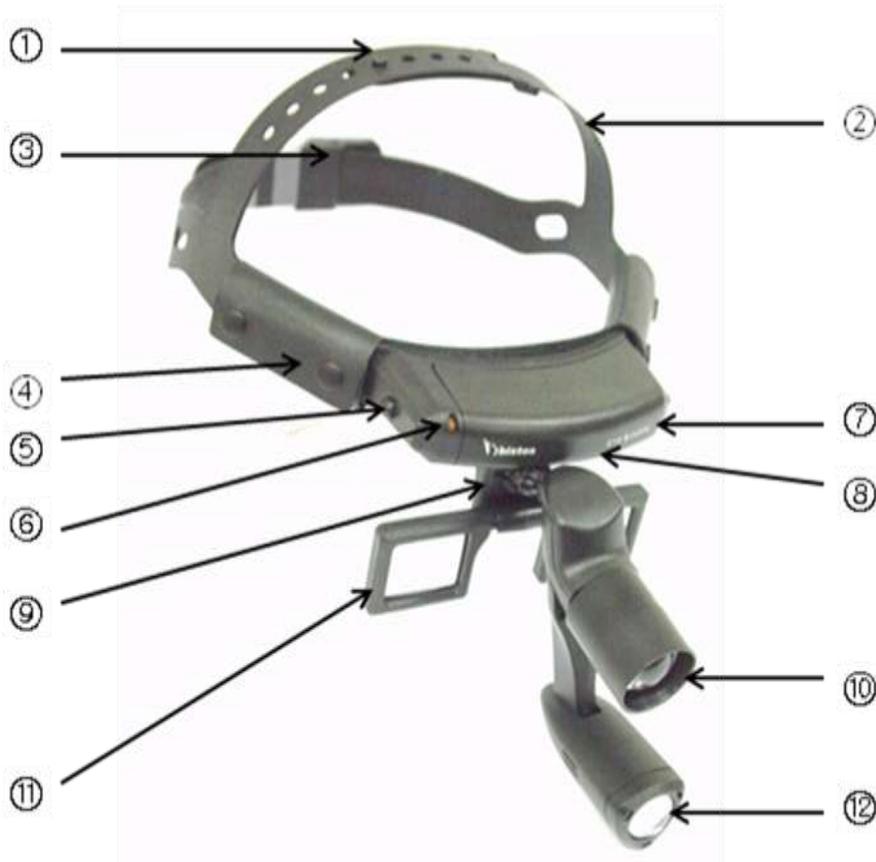


Fig. 1.1 The overall panel

- | | |
|-----------------------------------|--------------------------|
| ① Headband height adjustable part | ② Headband part |
| ③ Headband size adjustable part | ④ Protect band |
| ⑤ Power On/Off Button | ⑥ LED indicator |
| ⑦ Main Frame Part | ⑧ Battery Pack |
| ⑨ Pivot joint | ⑩ Source of Light Part |
| ⑪ Loupe (Optional) | ⑫ Astral Lamp (Optional) |

3.2 Loupe (Optional) Assembly

BT-410 turn in front of our parts are assembled in the loupe.
In order to assemble the picture below.



Fig. 1.2 Loupe (Optional) Assembly

3.3 Astral Lamp (Optional) Assembly

BT-410 is located at the bottom of the astral lamp and pay off the lens cap from the bottom up by assembly.

In order to assemble the picture below.



Fig. 1.3 Astral Lamp(Optional) Assembly

Section 4

Use Method

4.1 Adjustable headband

The height and size adjustable headband part call the user's head to adjust the Head-worn light is worn

4.2 Turn on the power Method

Once the power switch button pressed remains locked in. When he turned on the light from the light source occurs..
LED charging status indicator into orange charging status indicator and then illuminated with charger must recharge.

WARNING: Power is turned on, please do not charge. LED light might be faulty due to high power from charging.

4.3 Adjust distance of focusing light(only for standard)

250 ~ 300 mm focal length for the light to examine the treatment and examination.

CAUTION: The light of a head-worn light directly to the patient's eyes should avoid. It might cause temporary vision impairment.

4.4 Turn off the power Method

The power switch once more to keep from pressing the button will turn off the lights.

CAUTION: You must turn off the head-worn light for battery consumption and lifetime of a light source (LED). That may not reduce the equipment's life

4.5 Adjust intensity of light(only for "Optional Main body")

User can adjust intensity of light using the dial at the bottom side of the "Source of Light Part" by rotating the dial CW or CCW. The range of intensity is from 15,000lx to 30,000lx at 25cm working distance.

Dial for adjusting intensity of light



4.6 Charging Method

There are two ways of battery operations such as separation of battery pack and its un-separation (However, the equipment must be powered off to charge the battery, un-separated.) Please refer to the below, as shown simply in order of how to separate the battery.



Fig. 2.1 Battery Pack assembled method



Fig. 2.2 Battery Pack separation method



Fig. 2.3 Battery charging method

4.7 Charger operation

Normal

100 ~ 240 Vac, 50 / 60 Hz outlet, connect the charger to the red light illuminates when charging fire red orange suspension changed, when the fire turns green fire.

Fault

In case of the below situations, recharging function might be defective.

- 1) There is no light or a light is flickering.
- 2) A red light still doesn't change to green while recharging
- 3) If a green light is not shown with a full recharge status or if light colors changes from green color to red or orange.

NOTIFICATION: Lithium-Ion rechargeable battery doesn't need to be charged every day. Charging everyday might decrease the product life. Thus, please charge the unit when LED indicator shows orange color.

CAUTION: Lithium-Ion rechargeable battery might be discharged when the unit remains turned on for a long time. Please turn off a light source (LED) when you don't use it.

4.8 Optional Features

Loupe(Optional): Surgery or medical details by expanding the area used to be you. And when not in use loupe loupe, or a separation of 90 degrees by raising the visibility can be secured.



<Standard>



<Optional Main body>

Fig. 2.4 Loupe image

Astral Lamp(Optional): During surgery or imaging to reduce shadows caused partial use when you want to be.

Section 5

Maintenance and Cleanliness

5.1 *Checking the Light Intensity*

It is recommended that the intensity of the light be checked before each use, and at least every six months.

Have a qualified technician test the intensity level and readjust the intensity potentiometers to achieve the desired output, if required.

CAUTION: Only qualified personnel should perform service and repair, than the light should be readjusted.

5.2 *Cleaning*

WARNING: Before cleaning, remove the battery Pack.

Remove dust from the exterior of the light with a soft brush or soft cloth with tepid water. Please remove the dust and dirt on the cable, wipe the unit with a cloth, soaked in lukewarm water (40°C / 104°F). Kindly also wipe it with a clinical alcohol about once a week.

CAUTION: Observe the following precautions;

- Do not use caustic or abrasive cleaners.
- Do not clean with alcohol, acetone, or other solvents.
- Never immerse the light or its components parts

5.3 *Battery Disposal and Handling*

Be cautious when disposing of Lithium-ion Battery pack.

Adhere to all applicable laws regarding recycling. Avoid storing battery above 60°C (140°F). If clothing or skin comes in contact with material from inside the battery, immediately wash with plenty of clean water.

When you replace Battery pack, contact us for our technical support.

Section 6

Specifications

BT-410 Head-worn light Specifications:

Main body

Dimensions: (L) 303 mm × (H) 165.00 mm × (D) 195.00 mm

Illumination

Standard : 30,000 lx (at 25 cm working distance) / 50,000lx (with astral lamp)

Optional Main body : 15,000lx ~ 30,000 lx (at 25 cm working distance)

Color Temperature : 6,000 Kelvin

Lighting (LED) Life time : 50,000 hours

Headband Size : 534 ~ 638 mm

Weight : 119 g

Battery Pack

Using the time : 4 hours

Rechargeable times : 800 times

Capacity : 3.7 V, 2,200 mAh

Type : Lithium-ion rechargeable battery (included protection circuit)

Weight : 69 g

Options

Optional Main body

Loupe : 3.5 x

Astral Lamp

Battery Pack

Safety

EN60601-1, EN60601-1-2-compliant application

Protection against electric shock Type : Internally Powered Equipment

Operation mode by Category : Continuous operation

Power

Internal Power	Battery :	Lithium-ion rechargeable battery 3.7V, 2,200mAh
Charger	Input :	AC 100 ~ 240 Vac, 50 / 60 Hz, 0.8 A
	Output :	DC 4.2 V, 750 mA
	Charging time :	4 hours
Power Consumption :		3.15 VA

Environmental

Operating Temperature:	10°C to 40°C (50°F to 104°F)
Storage Temperature:	-20°C to 60°C (-4°F to 140°F)
Relative Humidity:	20% to 90% non-condensing
Altitude:	0 -3048m (0 -10,000 ft)
Atmosphere pressure :	70 kPa to 106 kPa

Product Guarantee

Product Name		Head-worn light
Model Name		BT-410
Approval No.		
Approval Date		
Serial No.		
Warranty Period		2 Years
Date of Purchase		
Customer	Hospital: Address: Name: Telephone:	
Sales Agency		
Manufacture		Bistos Co., Ltd

- ※ Thank you for purchasing BT-410.
- ※ This product is manufactured and passed through strict quality control and inspection.
- ※ Compensation standard concerning repair, replacement, refund of the product complies with “**Consumer’s protection law**” noticed by Economic Planning Dept.

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