BT-410F and BT-410A
Head-worn light
Operation Manual

Keep this manual for future reference

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0 Safety information

Before using BT-410F and BT-410A, read this entire manual and be fully understood the following safety information to prevent injury of patient and user.
Observe all precautions to ensure the safety of the patient and those near the instrument.

0.1 Symbols used

The following symbols identify all instructions that are important to safety. Failure to follow these instructions can lead to injury or damage to the device. When used in conjunction with the following words, the symbols indicate:

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.

The following symbols are placed on product, label, packaging and this manual in order to stand for the information about:

	Stand-by
	Those symbols identify safety information. Warning and caution necessarily well-know when operating the device or control in order to avoid undesirable consequences.
	Indicates the manufacturer.
	Indicates the production date.
SN	Serial number
EC REP	Authorized representative in the European Community
	Refer to Operation Manual
	Indicates the temperature limitation for transport and storage.
	Humidity limitation for transport and storage.
	Keep dry. Transport package shall be kept away from rain.
	Fragile, handle with care
	Indicate correct upright position on the transport package.
	Indicate that the product contains the recyclable parts depending on whether there is a collection mechanism within the local community for those particular materials.
CE	The product conforms to European Medical Directive 93/42/EEC as amended by 2007/47/EC and meets applicable health, safety and environmental requirements.

0.1.1 Symbols on the power adapter

	Polarity of DC power connector / DC Adaptor
	This symbol indicates that the power adaptor is a class II device.

	This symbol indicates that the power adaptor is for indoor use only.
	This symbol indicates direct current.
	This symbol indicates alternating current.
	UL Listing means that UL has tested representative samples of a product and determined that the product meets specific, defined requirements.
	This symbol indicates to not dispose the device together with unsorted municipal waste (for EU only). The solid bar symbol indicates that mains adapter is put on the market after 13 August 2005.

0.2 Warnings and cautions

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.
- Incorrect use of the light or the use of parts and accessories, especially LED and Battery that were not supplied by Bistos Co., Ltd. can damage the light, and may cause injury to the user.
- Do not use in the out of range for humidity, temperature and atmospheric pressure environment than indicated in this manual.
- Do not use the light in the presence of gases that support combustion (for example, oxygen, nitrous oxide, or other anesthetic agents).

CAUTION

- The relevant law restricts this device to sale by or on the order of a physician.
- 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.
- Do not attempt to service the BT-410F and BT-410A. Only qualified service personnel should attempt any needed internal servicing.

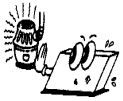
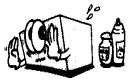
0.3 Battery warnings

WARNING

- Do not use the device during recharging the battery. Using the device during recharging the battery may cause injury to the user.
- Improper operation may cause the internal lithium ion battery to be hot, ignited or exploded, and it may lead to the decrease of the battery capacity. It is necessary to read the operation manual carefully and pay more attention to warning message.
- Do not open the housing of battery pack. Only the qualified service personnel authorized by the manufacturer can open the battery pack and replace the battery, and batteries of same model and specification should be replaced.
- Be careful when connecting the battery with polarity.
- Do not use the battery near fire or environmental temperature exceeds 60 ℃. Do not heat or splash the battery or throw it into fire or water.
- Do not destroy the battery. Do not pierce battery with a sharp object such as a needle. Do not hit with a hammer, step on or throw or drop the battery. Do not disassemble or modify the battery. The battery can heat, smoke, deformation or burning.
- When leakage or foul smell is found, stop using the battery immediately. If your skin or cloth comes into contact with leaked liquid, cleanse it with clean water at once. If the leaked liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and go to see a doctor immediately.
- Properly dispose of or recycle the depleted battery according to local regulations.

0.4 General precautions 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 Head worn light with wet hand.		Avoid exposure to direct sunlight
	Avoid placing in an area where high variation of temperature exists. Operating temperature ranges from 10 ~ 40℃. Operating humidity ranges from 5 ~ 85 %.		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 enters into the Head worn light.
	Do not disjoint or disassemble the Head worn light. Bistos Co., Ltd. does not have liability of it.		Power off when the Head worn light is not fully ready to operate. Otherwise, the Head worn light could be damaged.

1 Introduction

1.1 General

This chapter provides a general description of the BT-410F and BT-410A Head-worn light including:

- Brief Device Description
- Product Features
- Model Configurations

1.2 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 main-body and headband. The main body is composed of a light source (LED), main frame, and battery pack. Optional accessories are consisting of an astral lamp for shadow less effect, and loupe (magnifying glass). The battery is a lithium-ion rechargeable one, and operating 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 operating time. The expectedly possible operating time is for approximately 50,000 hours.

1.3 Intended use

The Head-worn light utilizes to provide supplemental light to improve visibility by illuminating during minor medical procedures such as examination.

The device designed to use by a medical professionals by wearing it onto the head.

1.4 Contraindication

The head-worn light is not intended to the any procedure for ophthalmology. Do not glare the light directly to the patient's eyes. It may cause temporary vision impairment.

1.5 Product features

- Battery pack can be separated. Please separate it from the main body during recharging.
- Check the battery capacity by LED indicator. When the battery is low, please recharging it immediately.
- Irradiating to up & down and left & right side is possible by pivot joint.
- Operation is very simple, so the unit is easy to use.

1.6 Product configuration

BT-410 series is supplied in two derivatives – BT-410A and BT-410F. BT-410A has Variable focus lens but BT-410F has Fixed focus lens. BT-410F and BT-410A system consists of the following function and elements.

Model	BT-410A	BT-410F
Control of Light Intensity	X	O
Control of Light Focus	O	X
Light Spot Size (at 300mm)	30~70mm	70mm
Astral Lamp (option)	O	X

Open the packaging contains the following accessories, please check. Also check for any damage to the console and accessories, please check.

1) BT-410A (Variable Focus Lens)

	Standard		Option		
Name	Main body	Charger	Astral Lamp	Additional battery pack	Loupe
Shape		 (output: 4.2V⎓ 1000mA)			

2) BT-410F (Fixed Focus Lens) : This model cannot attach the Astral lamp

	Standard		Option	
Name	Main body	Charger	Additional battery pack	Loupe
Shape		 (output: 4.2V⎓ 1000mA)		

2 Assembly and operation

2.1 Product outlook and description

Fig. 2.1 BT-410A outlook and description

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)

Fig. 2.2 BT-410F outlook and description

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)		

2.2 Loupe (optional) assembly

The loupe can be assembled to the joint of BT-410F and BT-410A. Assemble the loupe in the sequence shown below.

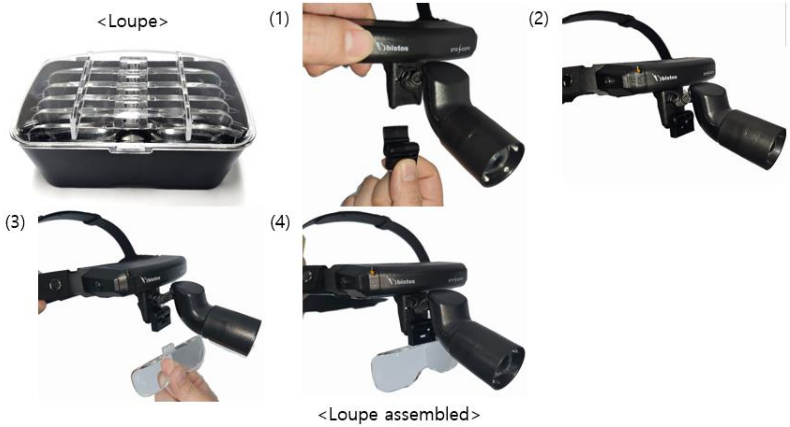


Fig. 2.3 Loupe Assembly

2.3 Astral lamp (optional / BT-410A only) assembly

The astral lamp can be assembled at the bottom of light source. Remove the lens cap from the light source and connect the astral lamp to the connector as shown below.

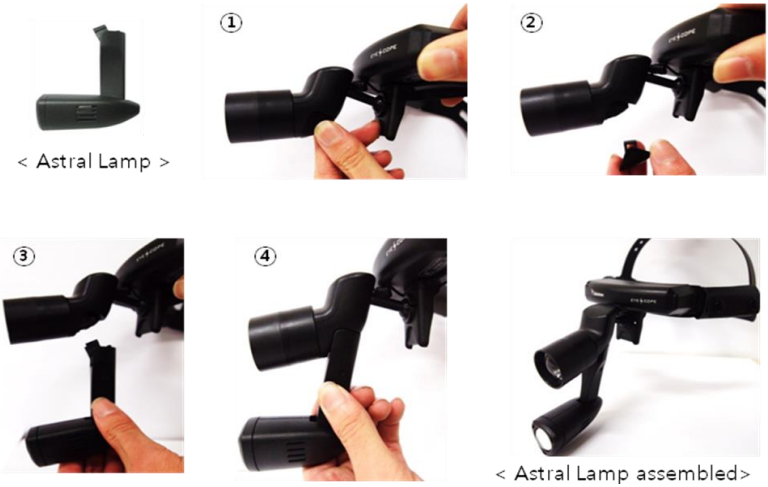


Fig. 2.4 Astral Lamp Assembly

3 Operations

3.1 Adjust the headband

Adjust the height and size of headband to fit the user's head.

3.2 Turn on the power

Press the power button to turn on the light. The power button is push lock type. It remains lock in when pushed. Press the button smoothly until it locked.

Battery charging status will be displayed by LED light. If the LED turns to orange light, please charging immediately for further use.

⚠ **WARNING**	• Do not charge the light while turned on. The high charging voltage may cause the device malfunction.

3.3 Focusing the light (BT-410A only)

You can adjust the focal length by rotating the "Source of Light Part". Adjust the focus for the best light quality before treatment and examination.

⚠ **CAUTION**	• Do not glare the light directly to the patient's eyes. It may cause temporary vision impairment.

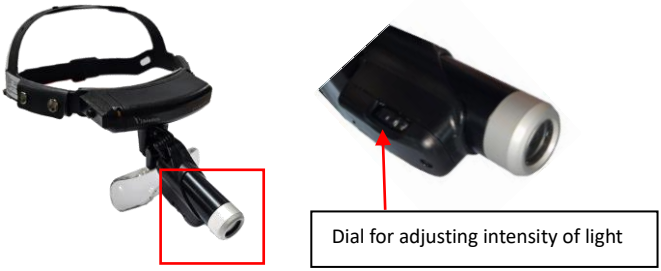
3.4 Turn off the power

Press the power button again to turn off the device.

⚠ **CAUTION**	• You must turn off the device to avoid running out of the battery and to save the lifetime of a light source (LED).

3.5 Adjust the intensity of light (BT-410F only)

User can adjust intensity of light rotating the dial at the side of the "Source of Light Part". The range of intensity is from 15,000lx to 30,000lx.



3.6 Charging the battery pack

There are two ways of battery charging. One is charging the battery pack as separated and the other is unseparated. When charging unseparated, be sure the device turned off. To separate or assemble the battery pack, refer below.

Fig. 3.1 Battery pack assembly method

Fig. 3.2 Battery pack separation method

Fig. 3.3 Two way of charging the battery pack

3.7 Charger

1) Normal state

When connect the charger to the power socket, the red light has comes on. When the charging has been finished, the light changes to green.

2) Fault state

In below case, the charger may be defected.

- There is no light or a flickering light.
- A red light still doesn't change to green.
- If a green light does not come on after sufficient time has been passed or if the light color changes from green to red or orange.

⚠	**CAUTION**	The battery pack may be discharged when the device remains turned on for a long time. Please turn off the device when do not use it.
	Note	It is not necessary to charge the lithium-ion battery pack every day. Charging every day may decrease the life time of battery pack. Thus, please charge the battery pack when the LED indicator turns to orange.

3.8 Optional operation

1) Loupe

This function can be used to enlarge the examination area. When not using the loupe, loupe can be separated or turn the loupe 90 degrees to secure the view.

Fig. 3.4 Loupe turned 90 degrees

2) Astral Lamp (BT-410A only)

This function can be used to reduce shadows during surgery or other cases.

4 Maintenance and cleaning

4.1 Checking the light intensity

It is recommended that the intensity of the light be checked before each use, and at least every six months. When required, please contact to your regional service agent or Bistos Co., Ltd.

⚠	**CAUTION**	Only qualified service personnel should perform service, repair or intensity adjustment.

4.2 Cleaning

⚠	**WARNING**	Before cleaning, remove the battery pack.

Remove dust from the exterior of the device with a soft brush or soft cloth wetted with tepid water. Remove the dust and dirt on the cable, wipe the unit with a cloth soaked in lukewarm water (40˚C / 104˚F). Also kindly wipe it with a clinical alcohol about once a week.

⚠	**CAUTION**	• Do not use caustic or abrasive cleaners. • Do not clean with alcohol, acetone, or other solvents. • Never immerse the device or its parts.

4.3 Battery disposal and handling

Be cautious when disposing of the battery pack. Adhere to all applicable laws regarding recycling Where you try to keep the battery, avoid storing battery above 60°C (140°F). If clothing or skin comes in

contact with material leaked from inside the battery, immediately wash with plenty of clean water. When you need to replace battery pack, please contact to your local distributor or Bistos Co., Ltd for technical support.

5 Troubleshooting

Problems	Possible cause	Corrective action
Headlight does not turn on.	Battery is discharged or is defective.	Recharge the battery pack. If the device does not turned on after charging, contact to the service center
Brightness decreases during use.	Temperature of LED may have increased due to blockage of airflow.	Turn off the headlight, check and remove any obstructions from the headlight module and vent hole.
Brightness is diminished and/or the spot appears fuzzy.	Headlight lens may be contaminated.	Clean the lens according to this manual.
Fully charged battery operates for less than 2 hours.	Battery may be losing its capacity.	Contact to the service center to replace battery pack.

※ *If you have not resolved the problem with device or you have further questions, please contact Bistos customer center.*

6 Specifications

The BT-410F and BT-410A head-worn light is classified as follows in accordance with EN/IEC 60601-1

Category Name	Specification
Type of electric shock protection	Internally powered equipment
Operating mode	Continuous mode

Main body	
Dimensions	303(L) X 165(H) X 195(D) mm
Illumination	15,000 ~ 30,000 lx
	Maximum illumination with Astral lamp: 50,000 lx (Applicable model: BT-410A)
LED lift time	50,000 hours
Headband size	534 ~ 638 mm
Weight	119 g
Loupe lens magnification *(at 20 cm working distance)	1.0x / 1.5x / 2.0x / 2.5x / 3.5x
* When using Loupe, the recommended working distance is 20 cm.	

Battery pack	
Type	Lithium-ion rechargeable battery
Capacity	3.7V, 2,600mAh
Continuous operating time	4 hours
Life span	800 charge-discharge cycles
Weight	69 g

Battery charger	
Input	AC 100 ~ 240 Vac, 50/60 Hz
Output	DC 4.2V, 1000 mA
Charging time	4 hours (100%)

Environment		
Operating	Temperature	10°C to 40°C (50°F to 104°F)
	Humidity	5 ~ 85% non-condensing
	Atmospheric pressure	70 -106kPa
Transport and storage	Temperature	- 20°C to 60°C (–4°F to 140°F)
	Humidity	0% to 95% non-condensing
	Atmospheric pressure	70 -106kPa

7 Manufacturer's declaration on EMC

BT-410F and BT-410A needs special precautions regarding EMC (Electromagnetic compatibility) and needs to be used according to the EMC information provided in this manual. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect the head-worn light BT-410F and BT-410A and should be kept at least 1 m away from the equipment.

7.1 Electromagnetic emissions

The head-worn light BT-410F and BT-410A is intended for use in the electromagnetic environment specified below. The customer or the user of BT-410F and BT-410A should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	BT-410F and BT-410A is no intentional or controlled RF emission for it's intended performance. Therefore, its RF emissions are very low and are not likely cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class A	The BT-410F and BT-410A is suitable for use in all establishments including domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emission IEC61000-3-2	Class A	
Voltage fulctuations /flicker emissions IEC61000-3-3	Complies	

WARNING

- The BT-410F and BT-410A should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- 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 the BT-410F and BT-410A, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of adapter other than those specified or provided by the manufacturer of this equipment could results in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

7.2 Electromagnetic immunity

BT-410F and BT-410A is intended for use in the electromagnetic environment specified below. The customer or the user of BT-410F and BT-410A should assure that it is used in such an environment.			
Immunity test	Test level	Compliance level	Electromagnetic environment -guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±8 kV Contact ±2 kV, ±4 kV,	±8 kV Contact ±2 kV, ±4 kV,	Floors should be wood, concrete or ceramic tile. If floors are covered by synthetic material, the

	±8 kV, ±15 kV Air	±8 kV, ±15 kV Air	relative humidity should be at least 30 %.
Electrical Fast Transient/Burst IEC61000-4-4	±2 kV AC, 100 kHz PRR	±2 kV AC, 100 kHz PRR	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±0.5 kV, ±1 kV L1 to L2 (DM)	±0.5kV, ±1kV L1 to L2 (DM)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT for 0.5 cycle At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, 315˚ 0% UT for 1 cycle At 0˚, 180˚ 50 Hz : 70 % UT for 25 cycles At 0˚, 180˚ 50 Hz : 0 % UT for 250 cycles At 0˚, 180˚	0 % UT for 0.5 cycle At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, 315˚ 0% UT for 1 cycle At 0˚, 180˚ 50 Hz : 70 % UT for 25 cycles At 0˚, 180˚ 50 Hz : 0 % UT for 250 cycles At 0˚, 180˚	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the BT-410F and BT-410A be powered from uninterruptable power source, battery.
Power frequency (50Hz) magnetic field IEC61000-4-8	30 A/m, 50Hz	30 A/m, 50Hz	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the electric breast pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz ~ 800 MHz $d = 2.3\sqrt{P}$ 800 MHz ~ 2.7 MHz where P is the maximum output power rating of the transmitter (W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m).
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM	3 V/m 80 MHz to 2.7 GHz 80% AM	

			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol:  (IEC 60417, Ref. no. 5140: "Non-ionizing electromagnetic radiation")
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people			

Product Warranty

Product Name	Head-worn light
Model Name	BT-410F and BT-410A
Serial No.	
Warranty Period	1 Years
Date of Purchase	
Customer	Hospital name: Address: Contact Name: Telephone:
Sales Agency	
Manufactured by	Bistos Co., Ltd.

※ Thank you for purchasing BT-410F and BT-410A

※ This product is manufactured and passed through strict quality control and inspection.

※ Compensation standard concerning repair, replacement, refund of the product complies with "**Framework Act on Consumers**" noticed by Fair Trade Commission of Republic of Korea.

Service Telephone and Fax. Numbers

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