

**ETKIN TIBBI CİHAZLAR
LED SURGICAL LIGHT
PERGAMON+ SERIES
USER MANUAL**



You should definitely read the User Manual before using your device.

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This device meets the eligibility criteria in accordance with T.C. Ministry of Health 2017/745 Medical Device Regulation (MDR).

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INTRODUCTION

ETKIN TIBBİ CİHAZLAR, who implements Total Quality Management at every stage and base their understanding of quality on the principle of customer satisfaction ;

- System / Device / Material / Software
- Packaging / Transportation / Delivery
- Marketing / Sales
- Acceptance Tests
- Installation / Facility / Test
- Operation / Maintenance / Reparation
- Book / Document
- Training
- Payment / Invoice etc., is waiting for you to call customer problem/request notification line to report problems/requests on these issues.

CUSTOMER PROBLEM/REQUEST NOTIFICATION LINE

+90 232 464 0020

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1. PRECAUTIONS & ATTENTIONS

1.1. Safety Informations

Read this guide for patience and user safety before using the operating light head, serious injuries may be caused in cases where misuse and safety precautions are not followed.

General Safety Precautions

- The manufacturer/seller cannot be held responsible for any damages or damages that may occur if the products are out of the intended use specified in this user manual or in case of misuse.
- Staffs who are responsible for the use and maintenance of Etkin Tibbi Cihazlar branded Surgical Lights, are responsible for knowing and applying the contents of this user manual.
- This user manual should be kept within the easy reach of the user staff.
- If the purchased products are not fully installed, do not use the device, otherwise the manufacturer/seller company will not be responsible for the adverse outcome that may arise.
- Device installation, maintenance and repairs should only be performed by Etkin Tibbi Cihazlar staff or authorized companies/persons.
- The device must not be interfered in any way by unauthorized companies/persons. Installation, maintenance and repairs by unauthorized companies/persons may pose a danger to the user. In situations that require intervention to the device, support should be obtained from authorized companies/persons or authorized technical service.
- Light heads and arms should be protected against the possibility of collusion during operation or when adjusted to the desired position. Otherwise both patient/user and light system may be adversely affected, also the fragile parts inside the light heads may fall on the patient and cause damage to the patient and user.
- If the “light activated” drugs/solutions etc. were to be used in the patient’s body during the operation, the experts or manufacturer/seller should be consulted. .



- Distance sensors and anti-shadow sensors emit Class I laser. Looking directly at the sensor from close distance can damage the eyes.
- Looking directly at the lights coming out of the light head may cause eye discomfort.

**General Electrical and
Electromagnetic Safety
Precautions**

- Etkin Tıbbi Cihazlar branded surgical lights are not systems compatible with magnetic resonance (MRI), can not be installed and operated in rooms that produce strong magnetic fields. Otherwise both patient and user health could be seriously imperiled.
- If there is no backup battery supply in the operating room, after electricity cut off and re-coming in lights, the lights will not work, the light will be off position when the electricity is available. The light head must be opened from the control panel before it can be used again.
- Electric must be connected through the own fuse of the lights. No other devices should be connected to the fuse. Otherwise, the light heads will be affected in case of failure in other devices.
- 220 V AC electricity that to be used for light installation is recommended to be taken from the line that is reserved for the operating theatre and isolated from the electricity (isolation transformer etc.). The 220 V AC socket to be used must be grounded. It is the responsibility of institution/clinic for the building's ground line to operate and be maintained.
- Light heads must be connected to the electricity through the fuse in accordance with the values on the label.
- 220 V AC power cord of mobile operating lights must be plugged into a grounded outlet. It is the institution/clinic responsibility for the grounding line to work.
- Supply cables to the device (halogen free) should be capable of removing toxic gas. Cables suitable for the current that will pass through must be used. Cables used must be completed, connection and isolation should be provided with appropriate apparatus when additional.
- No improper connector should be attached to the connectors of the device. Under no circumstances the cable terminals should be short-circuited on the device.
- When there is an electricity on the device, maintenance, repair or cleaning should not be done.
- If the device with battery unit, the batteries should be left fully charged when not in use.
- If the device with battery unit, gives "charge battery" warning when its battery is about to run out. The battery unit must be charged after this warning.
- Even light heads with battery are not used, the battery charge status should be checked once a week and should be 100% charged again after being discharged once a week.

**General Mechanic
Safety Precautions**

- Take into consideration to avoid collision with an object that you need to adjust the light usage preference position.
- Damaged control panel, light head or any part of the device should never be used, support must be obtained from authorized companies/persons or authorized technical service.
- No any material/apparatus should be placed on the light head or arms and/or should not be covered. In such a case, it will not be possible for the light to remain stable in the desired position or it may cause the light to fall into the area where surgery is performed or the light to not focus in the desired place.

**General
Cleaning and
Sterilization
Processes**


- Sterilizable on the light head, must be sterilized with steam sterilizer (autoclave). It should never be sterilized Is should never be sterilized in any dry air sterilizers (incubator) or with Ethylene Oxide (ETO). For detailed information of this subject, please see the topic titled “Sterilization of Sterilizable Handle”.
- Acid, chlorine (not containing hydrogenperoxide parasetic acid combination) and alcohol-containing abrasive disinfectant materials should not be used while cleaning the light head and other parts of the device. Otherwise it will make damaging on the light heads and other parts. For detailed information of this subject, please see the topic titled “Cleaning of Surgical Light Heads and Arms”.
- It should never be scraped with a metal object during cleaning the light head and other parts of the light, otherwise it will cause scracthing of the lenses and paint. For detailed information of this subject, please see the topic titled “Cleaning of Surgical Light Heads and Arms”.
- When cleaning the front side of the light head, the light head must be parallel to the floor, leds ,nside of the light headsshould face down. For detailed information of this subject, please see the topic titled “Cleaning of Surgical Light Heads and Arms”.
- Cleaning of the light heads and other apparatus of the device, please see the topic titled “Cleaning of Surgical Light Heads and Arms”. Cleaning should not be done when there is electricity on the device.

**Safety
Precautions for
Transportation**

- Mobile surgical lights should not be used on sloping and uneven surfaces to avoid the loss of balance or toppling during the transportation. During use of the device, at least 2 lockable wheels must be locked. In order to carry the light head safely, the light arm shown in Figure 1 should be brought to the closed position, (1) device must be moved carefully by holding the handle (2). The arms system of the mobile light heads must be closed during transportation. User can get harmed if mobilization is not done in this way.




Figure 1 Closing The Arm System

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1.2.Warning Regarding Useage Errors

- The light intensity should be adjusted to the midlevel when starting the surgical operation. If necessary, the light intensity can be increased or decreased from the “LUX” indicator on the control panel. Setting the light intensity higher than needed will cause eyestrain on the user as the operation time is extended. In order to prevent eyestrain, if the light intensity of the light head is turned off at a value above % 80, when the light heads turned on it will open at %80 light intensity.
- Incase of using more than one light head by turning tot he same point, the illumination intensity in the illuminated area can exceed 160.000 Lux, this situation is not suitable for eye health.
- If the light head used is a model with colour temperature adjustable, colour temperature values can be increased or decreased gradually on the device. When the light head is turned on from the control panel, it should be used at midlevel colour temperature values at first. Colour temperature can be adjusted to cooler or warmer light colour if needed. Excessive glare can be seen at cold light levels.
- In order to attach the sterilizable handle, it is placed on the handle by pressing the trigger latch on the handle and pushed upwards. Sterilizable handles with camera infrastructure that are not properly fixed may fall into the operating field, for this reason, after the handle is placed in its place, it should be pulled down to make sure that it is fully seated. For the attachment and detachment of the sterilizable handle, please see the topic titled “Attaching and detaching of the Sterilizable Handle”.
- When it is desired to detach the sterilizable handle, it must be removed by pressing the trigger latch on the handle and pulling it down. Attempting to detach the handle without pressing the trigger latch will may cause damage to the handle. For detaching of sterilizable handle, please see the topic titled “Attaching and detaching of the Sterilizable Handle”.
- If the positioning of the light heads will be made in a sterile field, sterilizable handle must be used. Person in the sterile field should not position from non-sterile handles, otherwise sterility may deteriorate in operation; these are not sterile.

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2. DESCRIPTIONS, ABRIDGMENT, ATENTION & SYMBOLS


2.1.Descriptions

Light Head	Each light head is a light source.
Light	The whole system by combining one or more light heads and other connection equipments.
LED (Light Emitting Diode)	Light-producing electronic part.
LED Module	The structer created by bringing together LED clusters.
Light Power (Light Intensity)	The light power generated by each light head at a distance of 1 (one) meter.
Kelvin Adjustment (Colour Temperature)	The feature of adjusting the colour temperature (tone) of the light
Narrow-Wide Spot	Unless otherwise stated, the narrow spot (min. spot) narrow spot where the diameter of the illumination are in 1 (one) meter is the smallest (min. spot), in the widest case, a wide spot (max. spot) is formed.
Color Rendering Index(CRI)	Colour rendering index. This value measures the spread of the light over fourteen (14) different shades with spectrodiometer and values. To be close to 100 as possible of the value means that all different colours are distinguished sharply from each other.
Sterilizable Handle	It is located in the mid of the light head and allows the head to be moved by sterile users. The handles should be sterilized in their first use, before and after each operation, in cases where their sterility is impaired.
Central Axis (Main Carrier Arm)	Main carrier arm that holds the sipring arms. It has two types, mobility and limited mobility. Dynamic central axis 360° (camera infrastructure / camera models are optional) can rotate on the horixantal axis, the rotation angle of limited moving central axis can be limited optionally, generally 330°.
Spring Arms	Spring Arms is movable arm structure that enables the light heads to move up to 45° and down to 50°.
Boom/Flange	Boom is the carier tube that provides the connection between ceiling and the central axis. Flange is the fixing part of the boom on the ceiling.
Mobile Unit	It is the movable unit which the spring arm is attached, with wheels, batteries (depending on model), power card, fuses and indicators.



















Sheet 1. Descriptions

2.2.Abridgment

AC	: Alternative Current
GND	: Ground
LCD	: Liquid Crystal Display
LED	: Light Emitting Diode
TFT	: Thin Film Transistor
OPS	: Optional

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2.3.Attention & Symbols

	Refer to the User Instructions		Medical Device
	European Conformity Mark		Manufacturer
	Serial Number		Catalogue Number
	Caution/Attention		Model Number
	Recycling Instructions		MR unsafe
	Carry It Carefully.		Fragile, handle with care
IP54	Insulation structure protected against air, water, dust and dirt.		Protect from heat and radioactive sources
	Class I Laser Sensor Application		Keep dry
	Humidity limitation		Temperature limit
	Protective Grounding		

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3.INFORMATION ABOUT THE DEVICE

3.1.Purpose of Usage and Usage Areas

Surgical lights are medical devices to be used to illuminate the area to be operated on the patient in operating or examination rooms. Etkin Tibbi Cihazlar branded surgical lights designed and manufactured to provide medical illumination in the operating theater and examination rooms or to ensure that the surgical operations can be carried out smoothly and in a healthy way.

Surgical lights consists of device combinations which are light head, carrier arms of light heads, battery attached according to the purpose of use and camera infrastructure that can be added according to the product feature, camera, monitor, recorder etc...

Etkin Tibbi Cihazlar branded surgical lights are the “Lighting Armatures Used In Surgical Lights” which is mentioned in the clause 201.3.107 of the TS EN 60601-2-41 standard. Hereunder, it has been defined as “ Lighting armature surrounding the patient that is intended to support treatment, and diagnosis and to be used in operating rooms, where illumination is interrupted where it may caused a dangerous situation”. Products are used in operating rooms. These devices are designed to be used in minor and major surgeries, considering the type of surgical operations.

It is Protection Class I within the scope of TS EN 60601-1 Electrical Medical Equipment Standard.

It is a class I - other Active Medical Device scope of the T.C. Ministry of Health 2017/745 Medical Device Regulation (MDR).

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3.2.Pergamon+ Series Led Surgical Operation Lights Technical Specifications

Product General Name	LED Surgical Light
Brand of Product	Etkin Tıbbi Cihazlar
Illumination System	Surgical operation light. In each light head there are Leds place in modules.
Light Source Type	LED lighting elements are used in the light head
Lighr Head Material	Aluminium
Diameter of Light Head	65 cm.
Light Power (Lighting Intensity)	Each light head has a maximum power of 160.000Lux or 130.000Lux at a distance of 1 meter, depending on the light head model.
Kelvin Adjustment (Colour Temperature)	Colour temperature is fixed or adjustable according to the light head type. Light head with adjustable colour temperature feature can adjust colour temperature in 3 or 5 steps.
Light Head Light Intensity Level Setting	Light intensity on the light head can be adjusted in 10 steps.
Spot Diameter	Spot diameter can be adjusted from the handle and/or the control panel.
Positioning	Spring arms have steel spring brake systems.
Auxiliary Mechanism for Positioning	Positioning can be done from the handle to which the sterile handle is inserted in the light head center and from non-sterile light head grips. Since there is a steel spring brake sytem on the spring arms, positioning can be dne easily.
Control Center	Controls of the light heads are controlled from the control panel and if it is included in the light head system, they are controlled from the wall control panel
LED Life	>60.000 hours
Other Technical Informations	The shape of the light head designed to eliminate the shadows that may fall on the operation area and designed to adapt to laminar flow system. The light heads are manufactured to have dust and water resistant in IP54 standard.

Sheet 2. Pergamon+ Series Led Surgical Operation Lights Technical Specifications

*The values given were measured in a laboratory environment. It may vary according to the ambient conditions.

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3.3. Definition Product Technical Specifications

3.3.1. Adjustable Luminous Intensity Feature

The light intensity of Etkkin Tibbi Cihazlar branded surgical lights can be adjusted gradually in 10 levels according to need during the surgical operation. During the first stage, if the light intensity of the light head uses at every high level, it may cause rapid eyestrain at the beginning of the operation. It has to take into consideration that the light head should be opened at a medium level when first used. The light intensity can be adjusted to higher or lower levels depending on the need. When the light head is turned off while operation above 80%, the adjusted light intensity of the light head will default to 80% when the light head is turned on again.

Opt: In Pergamon+ model surgical lights (models which do not consist autofocus feature), the intensity of light can be adjusted separately from the control panel, using a sterilizable handle. With this feature, the spot width is electronically adjusted with a short-term rotation movement of the sterilizable handle to the right or left. Light intensity adjustment is increased/decreased by keeping the sterilizable handle turned left/right.

*For making the light intensity checks, please see the topic titled ‘Introduction of Light Head Control Panels’.

3.3.2. Endo Mode Feature

Endo mode feature has been developed since low light intensity is required in endoscopic surgeries. The reason is the image taken by the endoscopic camera used in endoscopic surgeries under intense light is not in the desired clarity. Therefore, **Endo mode** whose intensity can be adjusted, has been developed apart from the illumination intensity of the light head. **Endo mode** is not reflected on the operation area, the light head should be positioned facing upwards. In cases where the light intensity is high, brightness may be seen in the image of the endoscopy camera. Cause of that, the light intensity should be reduced until the desired clarity image is captured. In that way, optimum light intensity is selected for the image.

*For the control of the Endo Mode feature, please see the topic titled “Introduction of Light Head Control Panels”.

3.3.3. External Endo Feature (Optional)

It is the endo mode feature on the light heads between flange cover and the central axis.

*For the control of external endo mode feature, please see the topic titled “Introduction of Light Head Control Panels”.

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3.3.4. Colour Temperature Feature (Kelvin Adjustable Feature) (Optional)

For models with colour temperature adjustment, Kelvin value can be adjusted between 3.500-5.000 kelvin. To be adjusted colour temperature provides a comfortable operation for the surgical team, during the operation, the tissues can be seen in their natural colours. A light compatible with the skin colour is obtained preferring a lower colour temperature for transdermal operations. White tissues (such as brain, bones etc...) and surgeries in deep areas can be seen and distinguished in their natural colours by preferring higher colour temperature. Colour temperature adjustable in different values prevents the surgeon from getting tired.

*For colour temperature adjustment control, please see the topic titled “Introduction of Light Head Control Panels”.

*For models without colour temperature adjustment, colour temperature adjustment can not be made, work at one colour temperature value.

*Setting/changing the setting range of colour temperature values made by Etkin Tıbbi Cihazlar Sanayi ve Ticaret A.Ş.

3.3.5. Adjustable Light Spot Feature

A better view is obtained during the operation by adjusting the light spot according to the size of the operation area. Surgical operations should be done by selecting “wide spot” for operations in a wide area, “narrow spot” for operations in a narrow area.

The spot diameter adjustment on the light heads can be adjusted with the control panel and the right-left movement of the sterilizable handles.

Opt: The spot width is electronically changed with a short-term rotation movement of the sterilizable handle to the right or left. Light intensity adjustment is increased/decreased by keeping the sterilizable handle turned left/right.

*For the control of the spot diameter adjustment, please see the topic titled ‘Introduction of Light Head Control Panels’.

3.3.6. Run in Synchronism of Light Heads Feature (Optional)

In double head and triple head light heads; this feature allows any parameter changes made from the control panel of a light head to be made automatically in other light heads. Thus, there is no need to adjust the technical parameters in others. Light heads work synchronously with each other.

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Synchronous operation function in models without wall control panel, control of each light head takes place synchronously. Only opening and closing of the light heads does not occur synchronously, each light head must be opened and closed separately. The light intensity, colour temperature value, light focus diameter, endo mode feature etc., set on a light head functions are automatically adjusted due to the synchronization feature in the other light heads.

*Control of the light heads which are with wall control panel and that are synchronously operated, unless the light heads are individually selected from the control panel and processed, the light intensity, the colour temperature value, light focus diameter, endo mode feature etc. functions set on one light head are set synchronously in other light heads.

When the “Endo” button on the control panel is pressed once, the light head changes to the endo mode. When the “Endo” button is pressed once more while the light head is in endo mode, “External Endo Mode” is activated. Synchronization will work as ON/OFF when the “Endo” button is pressed until a double beep sounds.

3.3.7. Auto Focus (Optional)

From LED modules with lamp heads, lights coming from different angles are overlapped, providing uniform color and desired light power illumination. In the movement of the patient bed or operating head; because of distance of the lamp head to the patient bed will change, there will be a shift in the lights coming from the lamp head and one after the other. In order to prevent this, the focal diameter has been taken under control with the sensors.

In models with auto focus, press the NARROW / WIDE button for 3 seconds to activate auto focus. When the auto focus is activated, the "WIDE" led on the upper left of the control panel will blink. To deactivate auto focus, the NARROW / WIDE button should be pressed for 3 seconds again.

This feature will be off when the lamp heads are turned on by the control panel. It should be activated by using the control panel when it is want to be used.

In models with no automatic spot adjustment, (models without distance sensing sensor) , in order to provide homogeneous illumination in the illuminated area, focusing should be done using a sterilizable handle according to the distance of the lamp head to the patient bed. In this model lamp heads, the spot adjustment is made from the control panel it cannot be made from the handle.

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3.3.8. Anti-shadow Sensor (Optional)

It is the feature that allows the LEDs to light on again when the obstacle between the LED and illumination area is gone, to minimize the heat effect on the personnel and prevent the shadow on the target which may occur when the LEDs come same level with body. While health professionals work under the light head.

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4.CONTROL PANEL INTRODUCTION

Control of the light heads are made from the control panel on the heads. On-off, light intensity adjustment, colour temperature adjustment, endo mode on-off, external endo mode on-off, light focus diameter adjustment, camera controls etc... feature adjustments can be done from the light control panels.

While the light head control panel, such as TFT displays, offers to the user the ease of control by touching and also offers as robustness as control panels with mechanical buttons. The top features of TFT displays and control cards with mechanical buttons are taken as an example on it's design.

*Control panels should not be exposed to daylight.

*If optional control panel is added to the product and necessary connections are provided, all transactions made from the control panels below, can also be made from the wall control panel.

In Etkin Tıbbi Cihazlar branded surgical lights, different control panels are used according to their technical specifications. These control panels and their descriptions are mentioned below;

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4.1.Control Panel

Opening and closing the light heads, light intensity, colour temperature, light focus diameter, endo mode, external endo mode and synchronization are controlled from this panel.

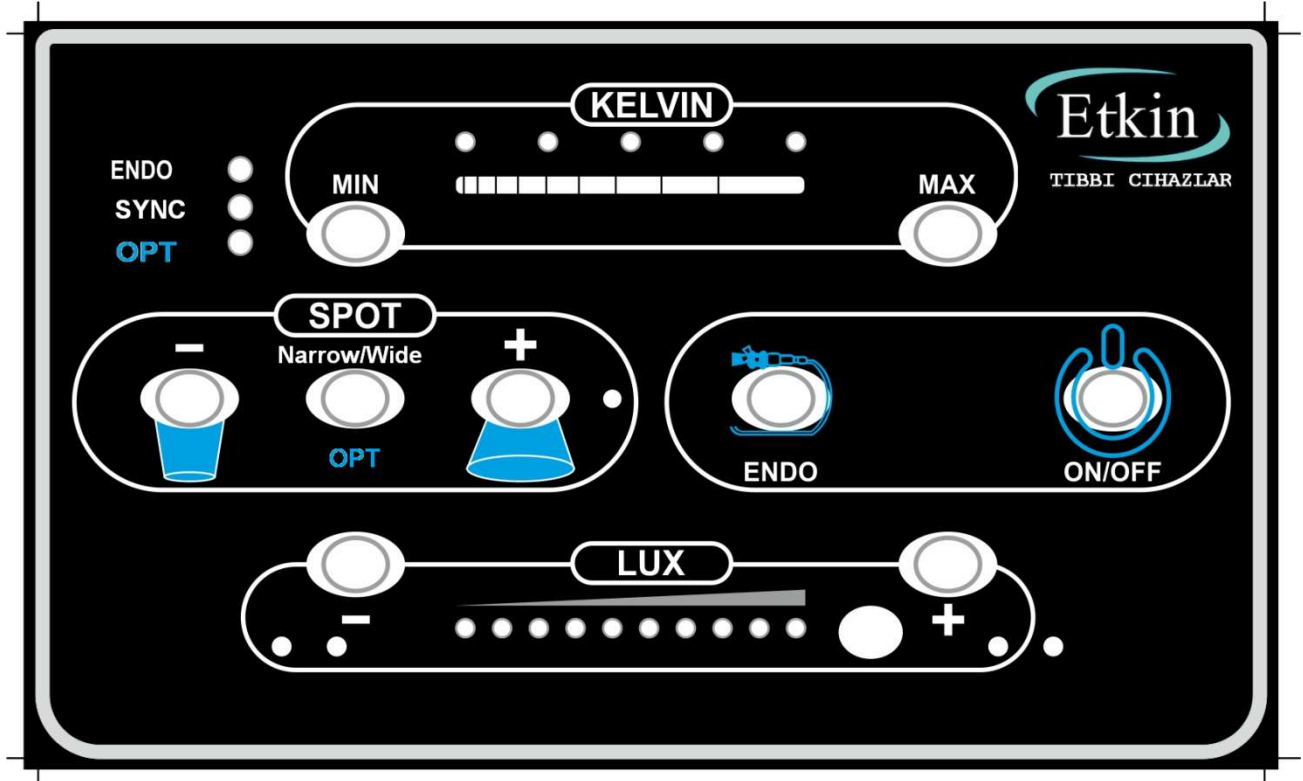


Figure 2 Control Panel

- Two blue LEDs on the right and left side of the LUX adjustment scale of the control panel are on, indicating that electricity is coming to the control panel. Even when the light head is closed, the blue LEDs will light up whenever the control panel is powered.
- In order to make the light head controls, the panel is turned on using the ON/OFF button on the control panel.
- From the Kelvin indicator, the adjusted stage of the colour temperature value is monitored. The colour temperature value is decreased with KELVIN MIN button, the colour temperature value is increased with KELVIN MAX button. With this control panel, colour temperature values are adjusted in five (5) steps in light heads. Light heads with fixed colour temperature feature, operate at a single colour temperature value and colour temperature can not be adjusted. In the light heads operating in one colour temperature, the Kelvin led will light up in the mid of the Kelvin indicator.

- From the LUX displayed, the adjusted stage of the light intensity is monitored. LUX (-) button decreases the light intensity of the light head, LUX (+) button increases the light intensity of the light head. Light intensity setting and level are adjusted between 25% and 100% by default.
- Switch to endo mode from ENDO button. When the endo mode is active, the ENDO led in the upper left part of the control panel should be lit. When the 'ENDO' led is lit (if there is no External Endo Mode), touching the ENDO button again, the light head will exit the endo mode.
- If External Endo Mode has been added to the light head system, the ENDO button must be pressed two (2) times to enable this feature from the control panel. After this operation, it will be seen that the external endo mode is working between the flange cover and central axis. This mode will be exited by pressing the Endo button again while the light head is in the External Endo Mode.
- Light focus diameter adjustment of the light head is provided by turning on and off the leds on the LED modules in groups. In the SPOT indicator, from the SPOT (-) button, by reducing the light focus diameter, a narrow spot is formed and from the SPOT (+) button, by enlarging the light focus diameter, a wide spot is formed. By pressing the NARROW/WIDE button on the SPOT indicator, the smallest or largest light focal diameter is adjusted. The "WIDE" led on the top left will be lit when opened in a wide spot via NARROW/WIDE button.
- In models with automatic focus, the "SPOT" button must be pressed for 3 seconds in order to activate the automatic focus. When the auto focus is active, the 'OPT' led on the upper left of the control panel will blink. To deactivate auto focus, "OPT" button in the "SPOT" part should be pressed for 3 seconds again. Meanwhile, the "OPT" led will turn off.
- When the "ENDO" button on the control panel is pressed until a double beep sounds, the synchronization will work as ON/OFF. If the light heads have synchronization feature and synchronous mode is activated, the "SYNCHRON" led in upper part of the control panel will be lit. To exit asynchronous mode, "ENDO" button should be kept pressed until double beep sounds.

4.2. Control Panel with Camera (Optional)

Opening and closing the light heads, light intensity, colour temperature, light focus diameter, endo mode, external endo mode, synchronization, activation of the anti-shadow sensor and the controls of the camera are controlled from this panel. Control panels with camera can control both the light functions of the light head and the functions of the camera.

All light head controls that can be done with this panel are the same as the controls performed on the “Control Panel”.

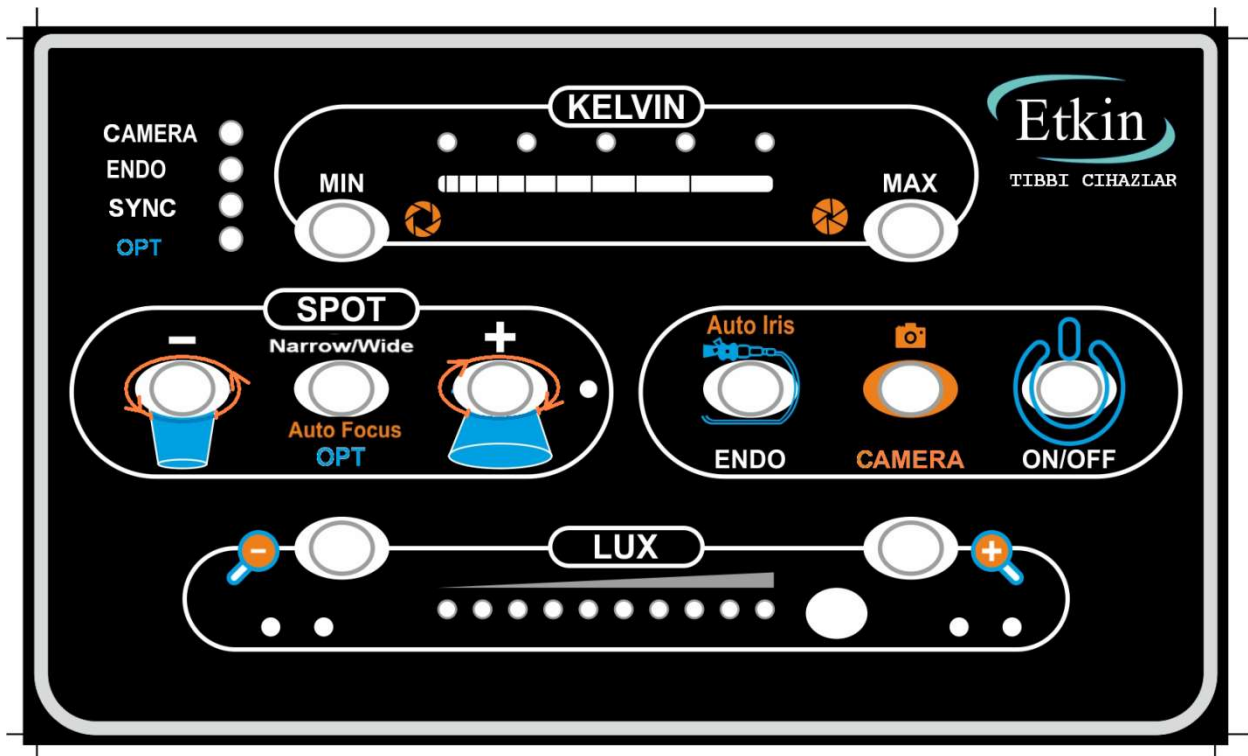


Figure 3 Control Panel with Camera

*All controls below can be done when the light head in “CAMERA” mode.

- In order to check the functions of the camera from the above panel, the panel is turned on first by pressing the ON/OFF button on the control panel.
- In order to activate the camera functions, the “CAMERA” button on the control panel should be touched. Touching the CAMERA button will activate the icons on the control panel. At the same time, the “CAMERA” led on the top left of the control panel should be on. When switching to camera mode, 2 (two) blue LEDs on the right and left of the LUX adjustment scale will turn orange.

- Switching the control panel from camera control to light head control is done by touching the “CAMERA” button again. In this case, the orange colors on the panel will turn blue and the light head light parameters can be controlled. After this transition, the “CAMERA” led on the upper left of the control panel will not light up and orange colours on the control panel will turn blue.
- The camera can be turned on and off using the ON/OFF button while the control panel is in “CAMERA” mode.
- When the light head is desired to be turned off while in the “CAMERA” mode, it is necessary to exit the “CAMERA” mode first. The camera must be turned off before the light head can be turned off. The light head can not be turned off from the control panel when the “CAMERA” mode is on.
- ‘ENDO’ button is used for auto iris activation, when the light head is in ‘CAMERA’ mode. Iris: the brightness of the spot taken, affects the quality of the received image. Iris is reduced and a clear image is formed.
- Auto focus is activated when the auto focus button is touched. When this button is touched again, focus adjustment is made manually.

Focus: The lenses on the camera are moved to occur a clear image according to the distance between the camera and the point where the image is taken.

- ‘KELVIN MIN’ and ‘KELVIN MAX’ buttons are used for manual iris adjustment. In order for these buttons to be activate, auto iris must be disabled.
- ‘SPOT (+)’ ve ‘SPOT (-)’ buttons are used to turn the camera 360° unlimitedly around itself. In this way, the image is displayed properly on the screen without the need for light head movement. The motor will move as long as the ‘SPOT (+)’ ve ‘SPOT (-)’ buttons are pressed, when 180° turn is completed, the movement is terminated, when pressed again, 180° motion is provided once again.
- ‘LUX (+)’ ve ‘LUX (-)’ buttons are used for zoom adjustment.
- To fix and unfix the camera, please see the topic titled ‘How to Assembled and Disassembled the Camera?’ on this manual.

Optional: For the use antishadow sensor, The CAMERA button on the control panel shown in Figure 3 must be pressed for 3 seconds (until the beep sound stops). At this time, the “SYNC” led will turn on. Caused of the head detection sensors on the lamp head are activated, the LEDs above the health professional's head will automatically extinguish. When the same button is pressed for 3 seconds (until the beep sound stops), the “SYNC” led will turn off, the shadow sensors will be disabled.

4.3. LCD Control Panel

When the light heads with LCD control panel are energized, the screen in figure 4 will appear on the panel. In the meantime, the light head is off and one of the screens in Figure 5, 6 or 7 will appear when the ON / OFF button on the screen is touched. The functions of the light head are controlled through these screens.



Figure 4 Light Head Satartup Screen

- Turkish or English language options can be selected from the LCD control panel in Figure 6.
- Adjustments on LCD control panels are made using sliding and touch buttons.

4.3.1. LCD Control Panel I (Opt.)

Turning on and off the light heads, light intensity, color temperature and endo mode adjustments are controlled from this panel.

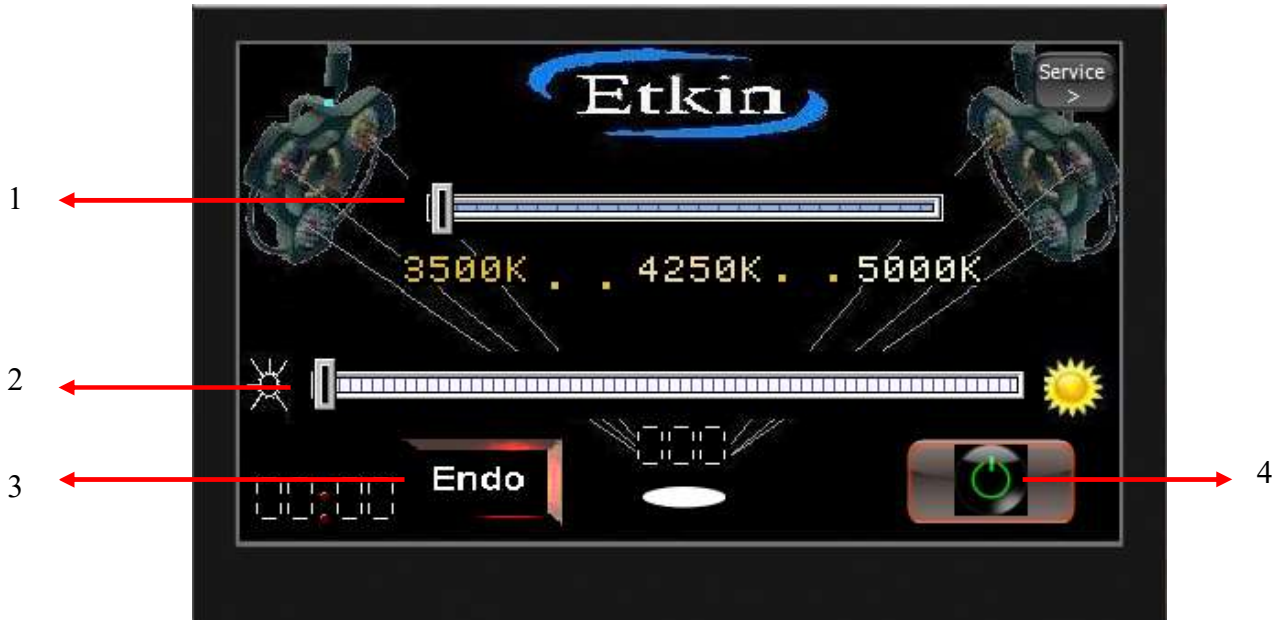


Figure 5 LCD Control Panel I

- Adjustment bars numbered 1 and 2 on the panel are used by dragging. The adjustment bar indicated by the number 1 is used to adjust the light head color temperature in 3 or 5 steps. While the value of kelvin is increased by dragging to the right from this adjustment bar, the value of kelvin is decreased by dragging to the left.
- The light intensity is adjusted using the adjustment bar indicated by the number 2. While the light intensity is increased by dragging to the right from this adjustment bar, the light intensity is decreased by dragging towards the left.
- The light head is switched to Endo Mode by pressing the "ENDO" button number 3 on the control panel. In this mode, the light intensity is increased or decreased by dragging right and left over the adjustment bar indicated by number 2. To exit the Endo Mode, press the "ENDO" button again.
- By using the button number 4, the open light head is closed. In the meantime, the screen will be as in Figure 4.
- In the light heads with this LCD screen, the spot setting is made by turning the sterilizable handle located in the center of the light head to the right and left

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4.3.2. LCD Control Panel II (Opt.)

Turning on and off the light heads, light intensity, color temperature, light focus diameter, endo mode adjustments, controlling anti-shadow sensors, camera adjustments are controlled from this screen.

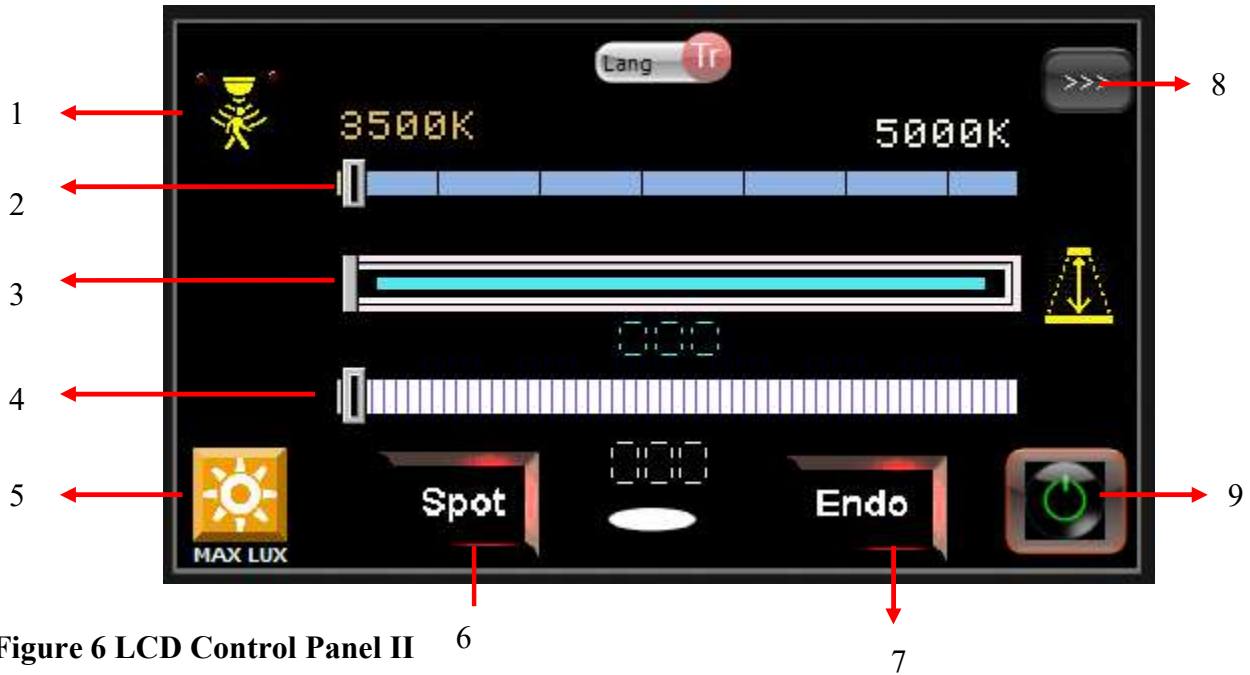


Figure 6 LCD Control Panel II

- With the number 1 button, anti-shadow sensors that prevent the increase in the temperature of the doctor's head are turned on and off. The anti-shadow sensor icon will appear yellow when this sensor is turned off, and green when it is on. If any object comes in front of the sensors 30 cm away, the corresponding leds on the light head will turn off. When the object in front of the sensors moves away, the LEDs will turn on again.
- The adjustment bar indicated by the number 2 is used to adjust the light head color temperature in 3 or 5 steps. From this adjustment bar, the value of kelvin is increased by dragging to the right, the value of kelvin is decreased by dragging to the left.
- With the button number 3, the focus is adjusted. With this adjustment, if the light head is positioned above or below a distance of 1 meter, a homogeneous and non-diffuse illuminated zone is obtained.

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- With the adjustment bar numbered 4, the light intensity is adjusted in 100 steps. By dragging from this adjustment bar to the right, the light intensity is increased, and by dragging to the left, the light intensity is decreased.
- With the button number 5, the minimum and maximum light intensities can be adjusted. The light head will appear green when operating at maximum light power, and yellow when operating at minimum light power.
- With the button numbered 6, the light spot diameter of the light head can be adjusted in 3 steps.
- With the number 7 ENDO button, the light head is switched to endo mode. While in Endo mode, the light intensity is increased and decreased by dragging right and left over the adjustment bar indicated by number 4. To exit the Endo Mode, press the "ENDO" button again.
- With the button number 8, you can switch to the camera screen for models with camera and to the service screen for models without a camera.
- By using the button number 9, the open lamp head is closed. In the meantime, the screen becomes as in Figure 4.

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4.3.3. LCD Control Panel III (Opt.)

With the following LCD screen, only features 1 and 5 among the commands indicated in Figure 7 cannot be used. Other controls are the same as using the panel shown in figure 7.



Figure 7 LCD Control Panel III

4.3.4. LCD Camera Control Panel (Opt.)

The camera control screen is the screen where the camera features are controlled. Switching to the camera control screen is made by using the button number 8 in Figure 6 in models with cameras.

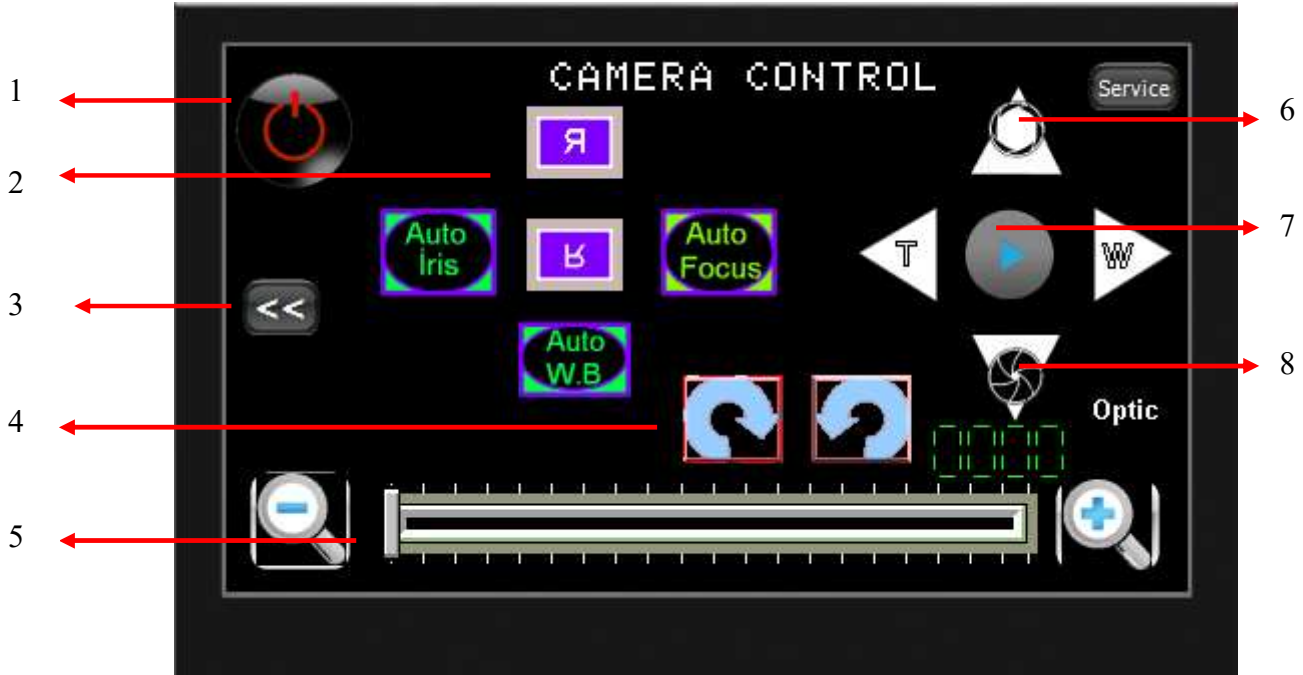


Figure 8 Camera Control Panel

- The number 1 button is used to turn the camera on and off. When the camera is on, the button is shown in green.
- The number 2 "R" buttons are used to create image effects.
- By using the button number 3, the screen where the light head functions are controlled is switched.
- Number 4 buttons are used to rotate the camera around 360° without limit. In this way, the image is displayed properly on the screen without the need for light head movement. As long as these buttons are pressed, the motor will move, When the 180°s turn is completed, the movement is terminated, when pressed again, 180°s movement is achieved once again.
- Zoom settings of the camera are made with the sliding adjustment bar numbered 5.
- With the buttons 6 and 8, manual iris adjustment is made. These buttons should be used after pressing the Auto Iris button and turning the iris adjustment into manual mode (Green Auto Iris button will be white).

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- Tapping the auto focus button activates auto focus. When this button is touched again, (Green Auto Focus button will be white color) focus adjustment is done manually. Manual focus adjustment is made using the "T and W" buttons. These buttons should be used after passing the manual adjustment position by pressing the Auto Focus button.
- Button 7 is used to freeze the camera image. When this button is pressed again, the image will become fluent.

4.4.Twin Side Control Panel (Ducop®) (Optional)

Controls of the light heads are made unilaterally from the control panels above. With the double-sided control panel, light parameters can be controlled on both sides in the sterile area. This feature allows the light head control panel to be used by the other side instead of the operator facing side during operation. On the other hand, it is possible to use a desired side in camera mode in camera models.

For use of the double-sided control panel, please see the topic titled “Control Panel and Control Panel with Camera (Optional)”.

To turn on and to turn off the light heads, light intensity, colour temperature, light focus diameter, endo mode, external endo mode, synchronization and the controls of the camera are controlled by this panel.



Figure 9 Twin Side Control Panel Ducop®

4.5. Wall Control Panel (Optional)

Due to wall control panel, each light head can be controlled separately or all together. Due to light head selection, operations of the control panel on each light head, can be made separately from the wall panel. By selecting all light heads, it is possible to set synchronously all light heads simultaneously, instead of adjusting for each light head. Although, wall control panel is wireless and touch-operated by default, on demand it can be supplied wired or different.

To control the light head and camera functions on the wall control panel, the wall control panel should be turned on by using ON/OFF button on the panel.

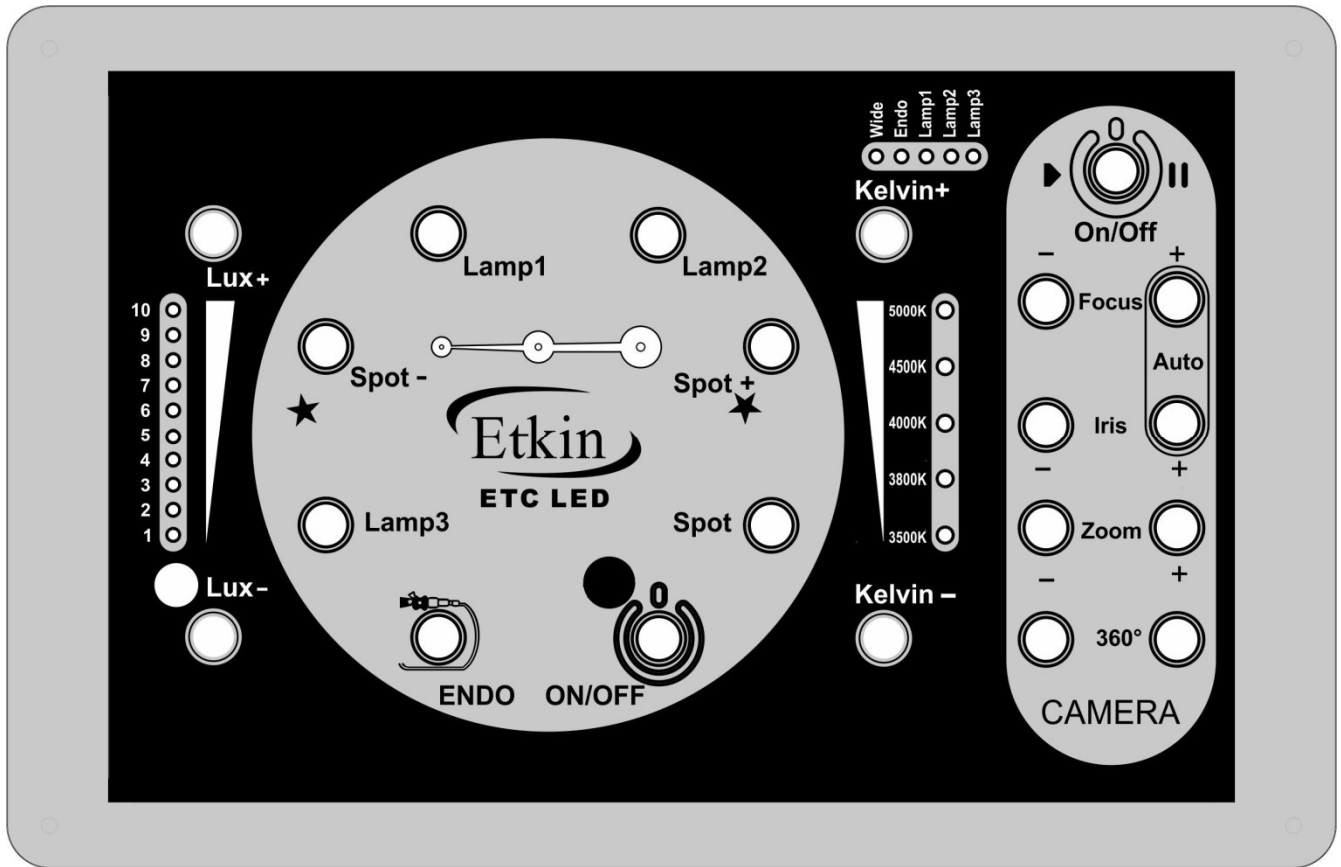


Figure 10 Wall Control Panel

Each light head can be controlled separately or together with wall control panel. When Lamp 1 is intended to be turned on, the Lamp 1 button should be pressed and the Lamp 1 led should be observed on the upper right, when Lamp 2 is intended to be turned on, the Lamp 2 button should be pressed and the Lamp 2 led should be observed, when Lamp 3 is intended to be turned on, the Lamp 3 button

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should be pressed and the Lamp 3 led should be observed on the upper right. In that way, the control of 3(three) light heads can also be done from the wall control panel.

If light heads are opened from their own control panels; for synchronization of the light heads on the wall control panel, incase of Lamp1, Lamp2 veya Lamp3 buttons are pressed, synchronization between light heads and wall control panel is provided. Then, the LED of the relevant light head must be on from the wall control panel.

Which leds of the light heads are lit on the wall control panel, when the colour temperature value, light intensity, transition to endo mode, spot diameter adsutment and camera adsutment are pressed, those lilght heads apply the commands given. Light heads, whoase LED is not lit, do not detec commands given, they will not detect commands.

To remove any or both light heads from commands or synchronization mode from the control panel, must be pressed the button of the relevant light head (Lamp1, Lamp2, Lamp3) and should be observed that the led on the wall control panel turnes off.

To turn off the desired light head, press the button of the relevant light head from the wall control panel for 3(three) seconds. In the mean time, 2(two) beeps are heard and the related light head is closed.

Controls of the light heads with camera can be done from the wall control panel. On the task of each key is mentioned on the wall control panel, in camera section.

When the camera is turned on for the first time, the iris and focus adjustment functions are in self adjusting.

- When the 'Focus (+)' button is pressed for 3(three) seconds, a warning tone sounds for the first time, this sound means that manual focus adjustment is enabled. While in manual focus, if 'Focus (+)' button is pressed, then double warning sound will be heard. This indicates that the camera has been put into auto focus mode for focus. (Focus: The lenses on the camera are moved so that a clear image can be formed according to the distance between the camera and the point where the image is taken.)
- When 'Iris (+)' button is pressed for 3(three) seconds, a warning tone sounds for the first time, this indicates that the iris function of the camera is set to manual iris adsutment. In taht case, 'Iris (+)' and 'Iris (-)' buttons can be used for manuel iris adjustment (Iris: Brightness of the spot taken; affects the quality of the image taken. To reduce the iris, a clear image should be provided.)

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- The '360 (+)' and '360 (-)' degree buttons are used to rotate the camera unlimited 360° around itself. In this way, the image is displayed properly on the screen without need for light head movement. The motor will move as long as the '360 (+)' and '360 (-)' buttons are pressed, when 180° turn is completed, the movement is terminated, when pressed again, 180° motion is provided once again.

4.6. Image Acquisition in ETC Wi-Fi Systems

This system is designed for wireless transmission of Full HD video. It enables the transfer of the camera in the same room to the monitor without the need for any cable in the arm structure of the light head. Thus, 360 ° unlimited rotation capability is gained in the light head arms.

In this system; The encoder device is used to transfer the image from the camera wirelessly, the decoder device is used to take the signal sent from the encoder and convert it to HDMI interface and transfer it to the monitor with HDMI cable.

The following warnings should be observed for the correct operation of this system:

- The light and the monitor must be in the same room. The antennas of the DECODER device, which is mounted next to the monitor, are positioned so that they can directly see the antennas on the light head control panels. Otherwise, the image may freeze as the signal will weaken. (Figure 11)



Decoder Correct Positioning



Decoder Incorrect Positioning

Figure 11 Decoder Antenna Installation

- Decoder HDMI output must be connected to the monitor.
- HDMI should be selected as source input for monitor.
- By applying power to the decoder, the power led on the decoder should be turned on.
- "NO SIGNAL" should appear on the Monitor screen.
- After the light head is turned on, luxury, kelvin and spot settings should be made according to preference.
- By pressing the camera button on the control panel, the camera mode must be switched. In the meantime, it should be seen that the camera led at the top left and the orange leds at the bottom of the BERAS control panel are lit.
- The camera must be turned on by pressing the On / Off button (the first press of the On / Off button turns the camera on, the second time the camera turns off).

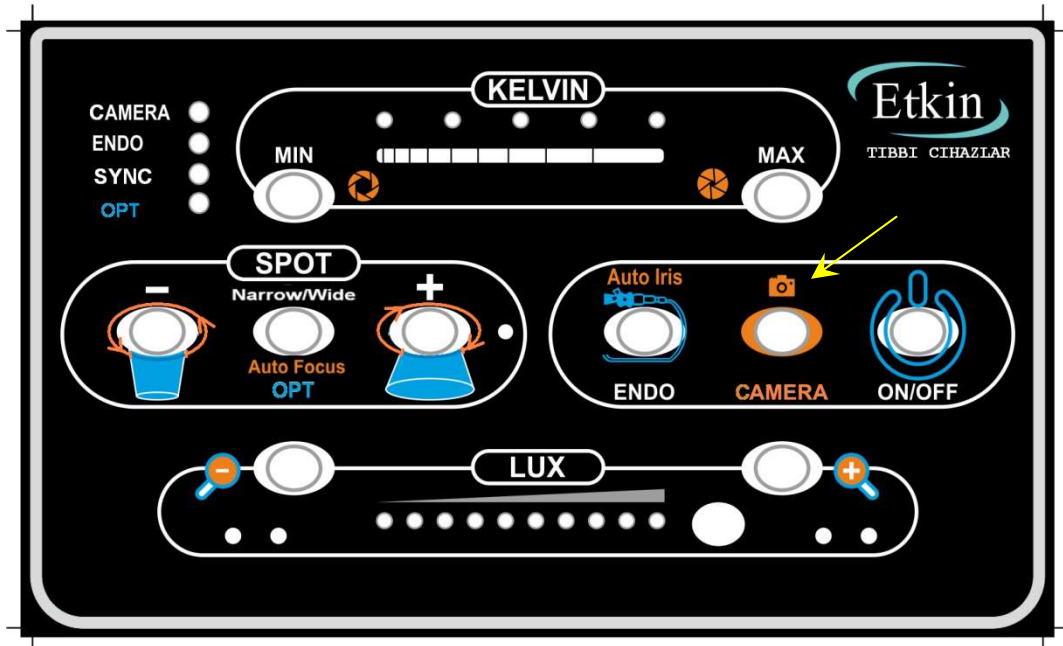


Figure 12 Camera Button

- The VIDEO led on the encoder should light up within about 1 minute after the camera is turned on. This led means that the connection between the encoder connected to the monitor and the light head is provided. If the camera is attached to the light head, the image will be taken.

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- After the image acquisition process from the camera is completed, the camera must be turned off by pressing the On / Off button again while the control panel is in camera mode (while the orange leds are on).

NOTE: When the image acquisition is completed, when the control panel is in camera mode (while the orange leds are on), the camera must first be turned off by using the ON / OFF button. Then, by pressing the CAMERA button, the lamp mode should be switched to (orange LEDs will turn blue at the bottom) and the light head should be turned off. If this sequence is not followed; The control panel must be switched to camera mode and the camera must be turned on and then turned off using the ON / OFF buttons.

To view the Camera Image on a mobile phone, tablet or computer;

- A Static IP must be given to computers or phones. (Eg. 192.168.8.20). Support can be obtained from IT Department for this process.
- A media player program must be installed to view the video recording.

(For example, the display is provided through the VLC program, for other media players, the "program's help" file should be looked at and this work should be done within the knowledge of the IT Department.)

For computer use, the following screen is opened by pressing CTRL + N while the VLC program is running.

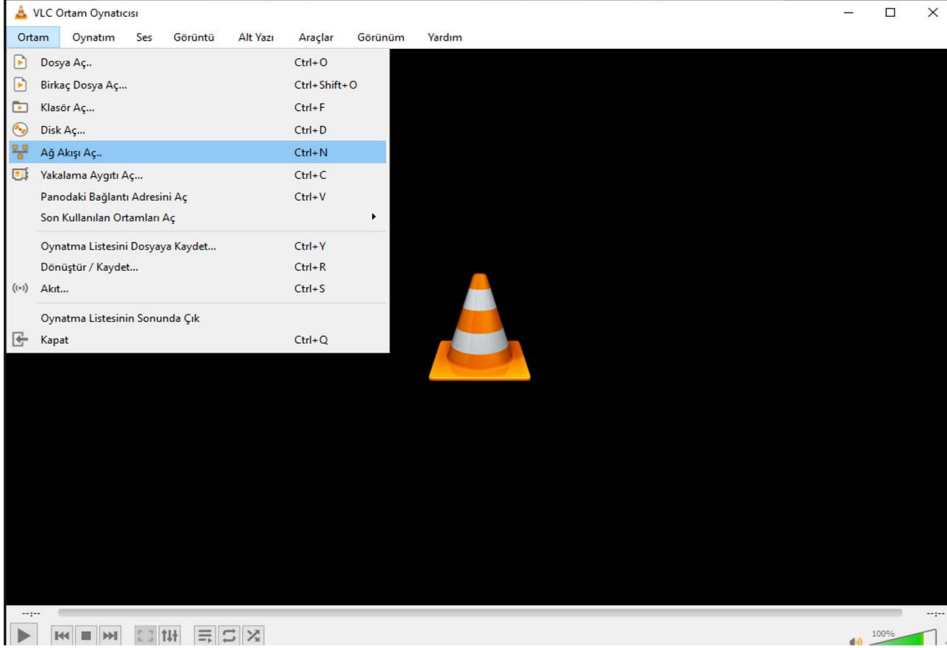


Figure 13 VLC Program Setting

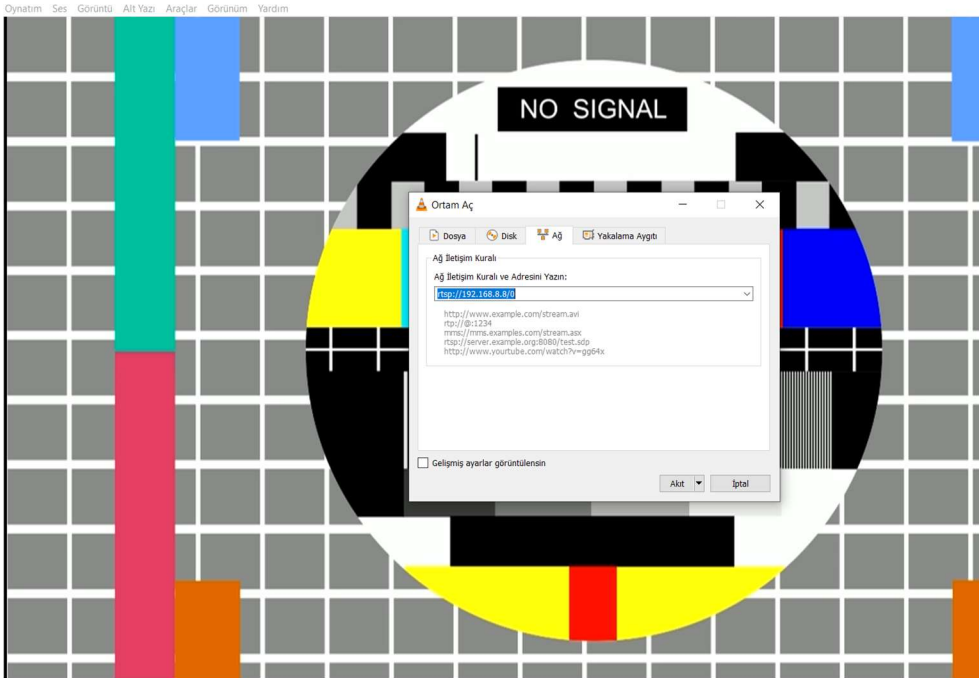


Figure 14 VLC Program Setting 2

In the window that opens, after typing 192.168.8.8/0 and pressing the OK button, the camera view is taken.

5.DEVICE ADDITIONAL FEATURES (Opt.)

5.1.Camera Infrastructure & Camera

In order to mount a 'Camera' to the surgical operation light, the necessary camera infrastructure must be made by the manufacturer. The cameras that can be mounted can be HD, Full HD or Ultra HD cameras. The operation field is visualized by attaching a camera to the operating light with camera infrastructure.

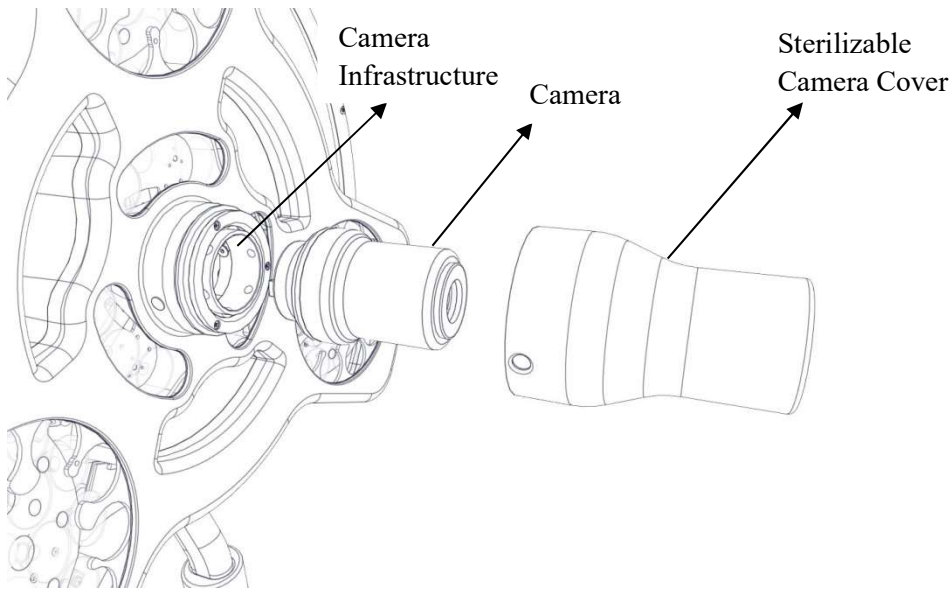


Figure 15 Camera Infrastructure & Camera

The camera can be mounted in the center of the operating light head with camera infrastructure or on a separate arm if desired. If necessary equipment is provided, images taken through the camera can be transferred to devices such as monitor, TV, etc., can be recorded if needed. It is the responsibility of the hospital that the monitors to be used in the operating room are medical compatible. Our image transfer format is 1920X1080 / 25P.

In the operation lights with camera, camera setting sare made with the head control panel and / or wall control panel. Controls of both the camera and the light head can be done with the control panel and / or wall control panel used. The cameras used can also be adjusted for iris, focus and optical-digital zoom. The camera can rotate 360⁰ unlimited around its own axis. The cameras are easily attached and removed from the light head using one hand, without the need for any hand tools. While using the camera, the camera cover in the image above should be used and it should be sterilized before and after each use.

5.1.1. How to Mount and Dissassemble the Camera?

- Camera latch shown in Figure below, should be pushed towards the body of light head, in direction 1 indicated by red arrows. Place the camera in the camera socket on the front of the light head and release the camera latch pushed to the light head body. When the camera is rotated slowly around its axis, a "click" sound will be heard if the camera is correctly placed in the mount. The camera latch will return automatically when the camera is correctly seated in its mount.
- It should be ensured that the camera is pulled down and checked whether it is dislodged.

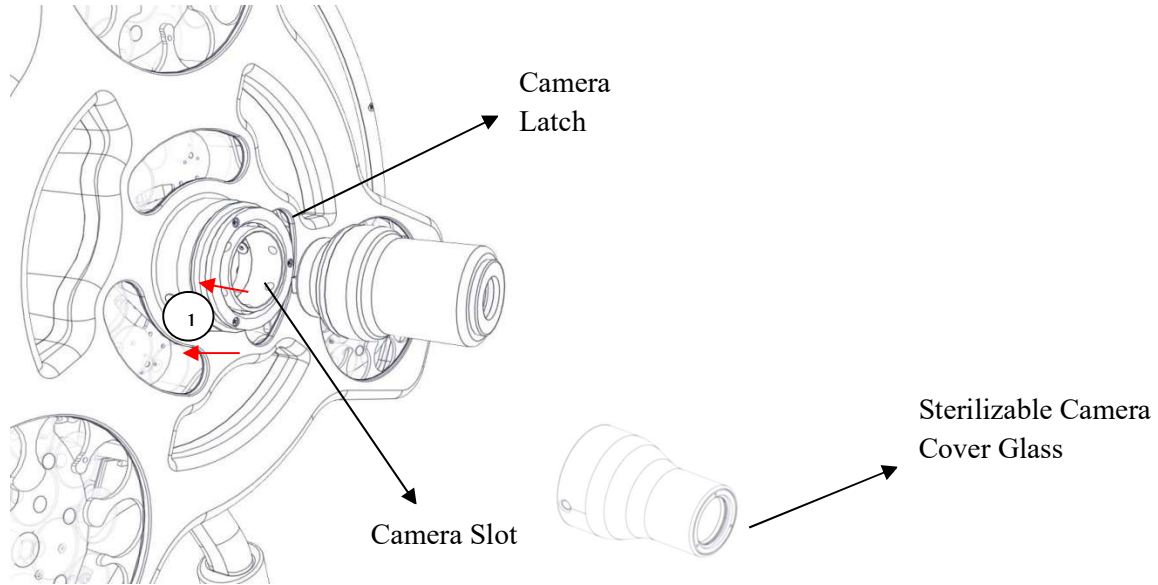
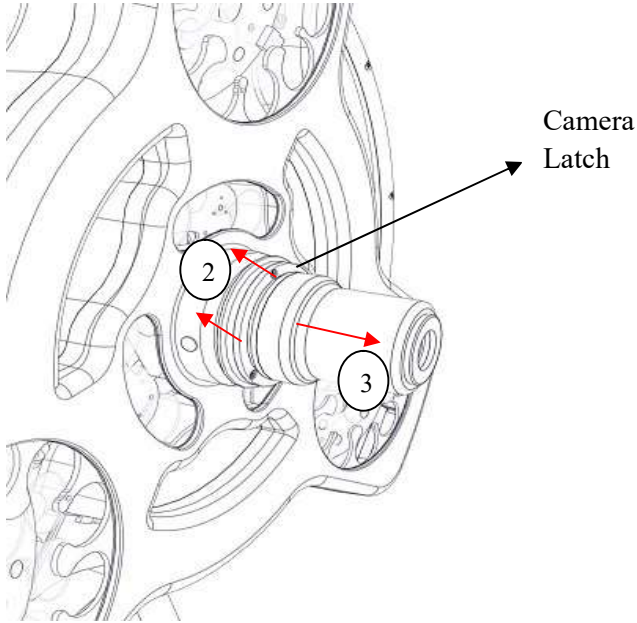


Figure 16 Camera Mount

- When the camera is wanted to be taken out, the camera latch shown with red arrows in Figure 16 should be pushed in the direction indicated by 2 and the camera should be pulled to the opposite direction indicated by 3.



Against the risk of falling when removing the camera; One hand pushing the camera latch in direction 2 while the other hand holding the camera in 3 direction can be safely removed in the opposite direction.

Figure 17 Camera Dissassemble

5.1.2. Spot Adjustment from the Handle on the Light Heads with Camera Infrastructure

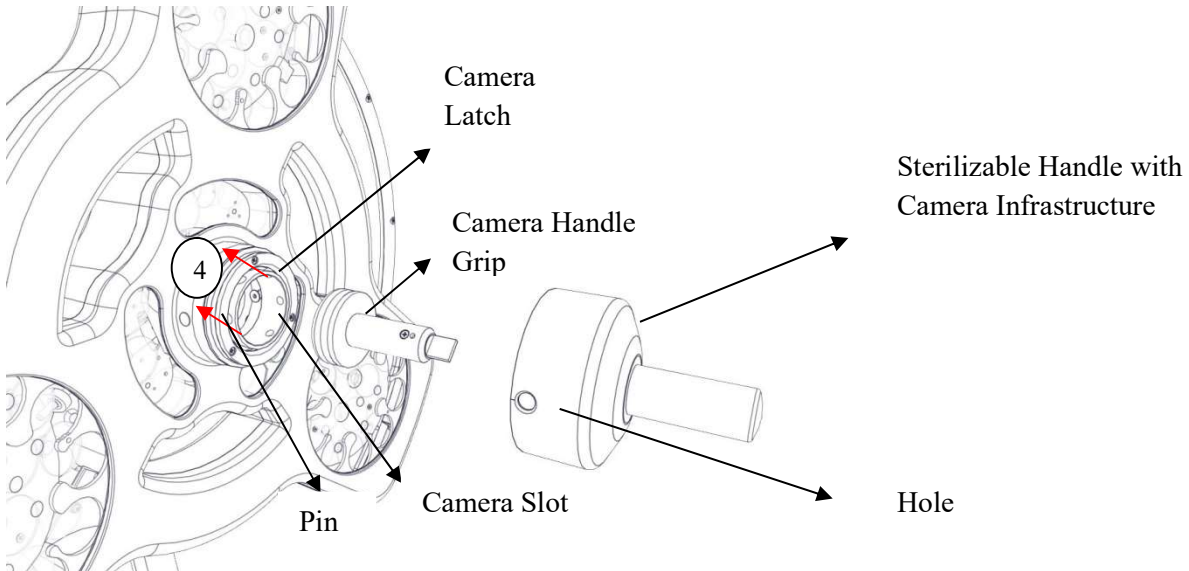


Figure 18 Light Head with Camera Infrastructure

In the light heads with camera infrastructure, the camera handle grip must be attached instead of the camera when the camera is not in use. During use, a handle with a sterilizable camera infrastructure is attached to the handle. Positioning of the light head can be achieved by using a sterilizable handle with

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camera infrastructure. At the same time, the spot diameter can be adjusted with the right and left movement of the sterilizable handle with camera infrastructure.

- The camera latch shown in Figure 18 should be pushed towards the light head body in the 4 direction indicated by red arrows. Place the camera handle grip in the camera socket on the front of the light head and release the camera latch pushed to the light head body. When the camera handle grip is rotated slowly around its axis, a "click" sound will be heard if the camera handle grip is correctly placed in the mount. The camera latch will automatically return to its original position when the camera handle grip is correctly seated in its slot.
- It should be ensured that the camera handle grip is pulled down and checked whether it is dislodged.
- After the camera handle grip is attached, sterilizable handle with camera infrastructure is attached to the handle grip. In order for the handle to fit in its place, it should be ensured that the pins and holes shown in Figure 18 are interlocked. For this, the sterilizable handle with camera infrastructure should be rotated around its own axis and a "click" sound should be heard.



The glass on the front face of the sterilizable camera cover shown in Figure 16 is not resistant to hard and sharp impacts and may cause fragmented fractures. For this reason, it does not get hit and the strength of the glass should be checked after each sterilization. Damaged or deformed camera covers should not be used.



The adapter used during the operation of the camera on the operating light heads of the Etkin Tıbbi Cihazlar brand or on the carrier arm alone must be connected to the 220 V AC grounded line isolated from the mains in the operation room.



The camera will automatically turn off in case of power cuts or short-term power cuts in the operation room. Camera needs to be turned on again using the control panel.



The camera ought to be used with a sterilizable camera cover. The body of the luminaire in which the camera is used is connected to the ground line of the building. Protection of the metal camera body against electrical leakage is provided in this way.



Before removing the camera; The camera must be turned off using the camera ON / OFF button on the control panel.

5.1.3. Inserting and Removing the Sterilizable Camera Cover

- After the camera is installed, a sterilizable camera cover should be placed on the camera. For this, it should be ensured that the sterilizable camera cover is placed on the camera and rotated around its own axis and inserted into the pin slot on the camera bottom cover flange.
- After hearing the sound of pins engaging, the connection should be checked by pulling down the sterilizable camera cover.
- When a sterile camera cover is wanted to be removed, the camera cover must be pulled down by pressing the pins.



The pins in the camera holder that enter the holes of the sterilizable handle with camera infrastructure are not sterile. If the camera handle is to be removed during the operation; sterility will be impaired if this part is touched by sterile users.



Sterilizable handles with camera infrastructure that are not properly fixed may fall into the operating field, for this reason, after the handle is placed in its place, it should be pulled down to make sure that it is fully seated.



The glass on the front face of the sterilizable camera cover is not resistant to hard and sharp impacts and may cause fragmented fractures. For this reason, it does not get hit and the strength of the glass should be checked after each sterilization. Damaged or deformed camera covers should not be used.

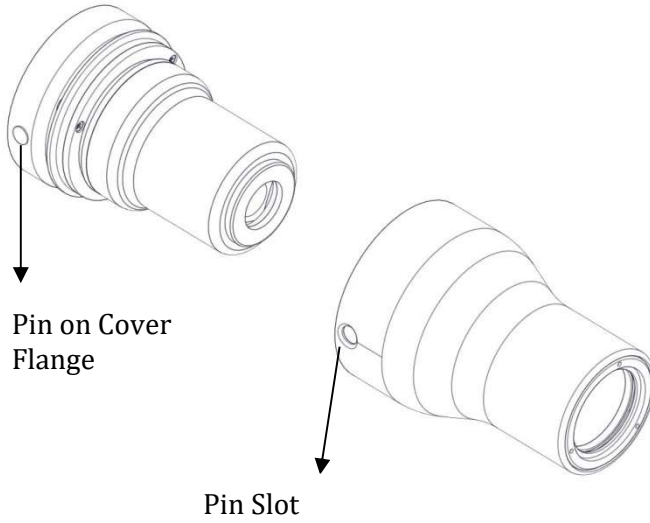


Figure 19 Installing and Removing the Sterilizable Camera Cover

5.2. Monitor, TV, etc. Imaging Devices

Images taken from cameras mounted to Etkin Tıbbi Cihazlar brand surgery light heads can be viewed on monitors, TVs or conference rooms. (It is the responsibility of the hospital that the monitors to be used in the operation room are suitable for medical conditions).



The power inputs of the monitors to be hung on the arm system to which the light heads are connected must be 24 V DC. The cable carrying 24V DC should be passed through the arm where the monitor is hung. 220 V AC cable should never be passed through the arm to which the monitor is connected.

5.3. Image-Audio Transfer & Recording

By connecting the surgical operating light heads and the necessary equipment, the image and sound in the operating environment can be recorded, If needed, it can be transferred to another place other than the place where the operation is performed. (Legal permissions required for image / sound recording and transmission must be obtained by the hospital.)

5.4.Ensuring the Continuity of the Adjusted Light Intensity With Sensors

Special sensors are used so that the luminaire can remain stable at the set value within the minimum and maximum light intensity range. The adjusted light intensity may change over time, influenced by external factors such as temperature and humidity. Special sensors are used to prevent this. In this way, a comfortable working environment is provided without changing the adjusted light intensity.

6.PERGAMON+ SERIES OPERATING LIGHT INSTALLATION FIGURES

Mounting types vary according to the usage of operating light heads. These mounting types are 3 types as shown in the figures below, ceiling mounted, wall mounted and mobile.

The high mobility of the carrier arm, produced in accordance with international standards, allows the light head to be given any desired position easily. There is no hydraulic, pneumatic or similar piston system inside the spring arm and a steel spring system is used. Thanks to the movement of the spring arm at high angles, the heads of the operating light head can easily move in different axes. Thus, it can be lowered even to positions facing the table from the opposite side. The light head stops in the position it was released with the hardness adjustable brake system.

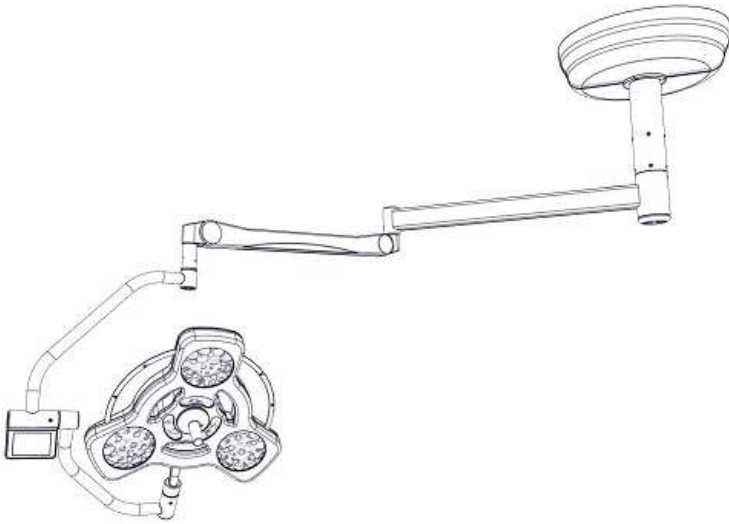


Figure 20 Single Head Ceiling Surgical Light

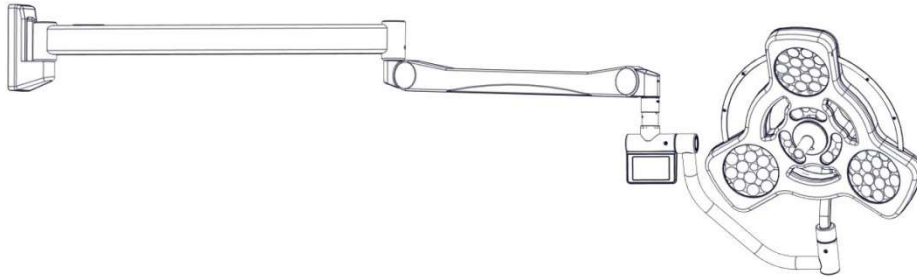


Figure 21 Wall-Mounted Surgical Light

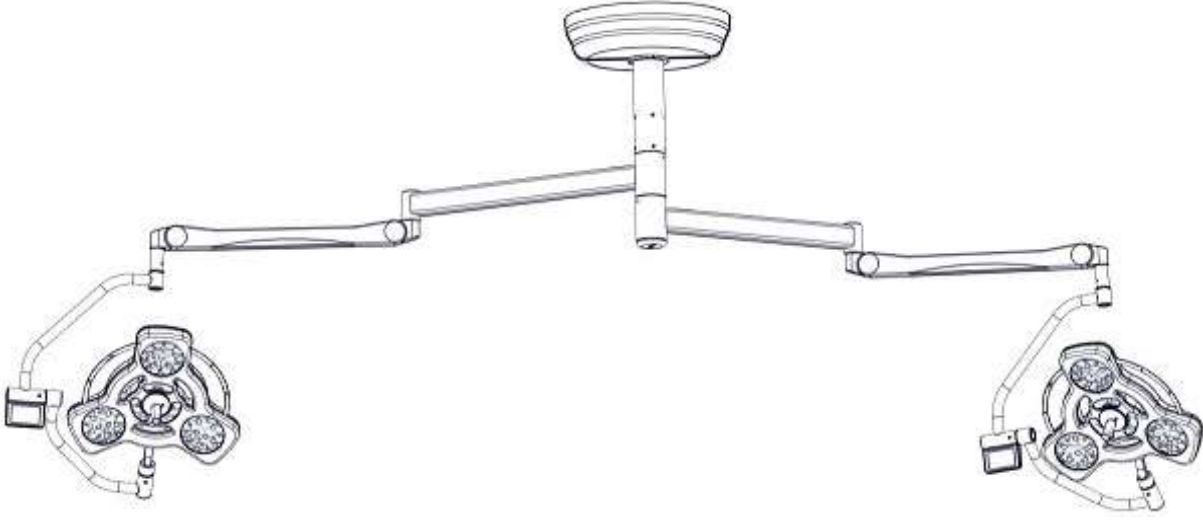


Figure 22 Double Head Ceiling Surgical Light



Figure 23 Double Head Ceiling Surgical Light with Camera Infrastructure

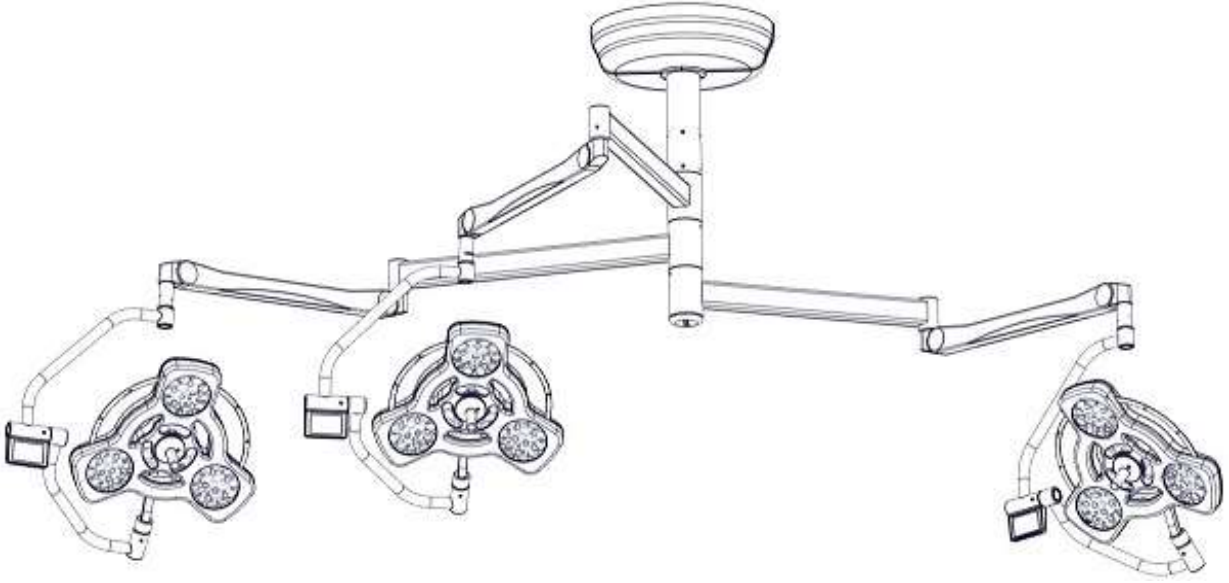


Figure 24 Triple Head Ceiling Surgical Light

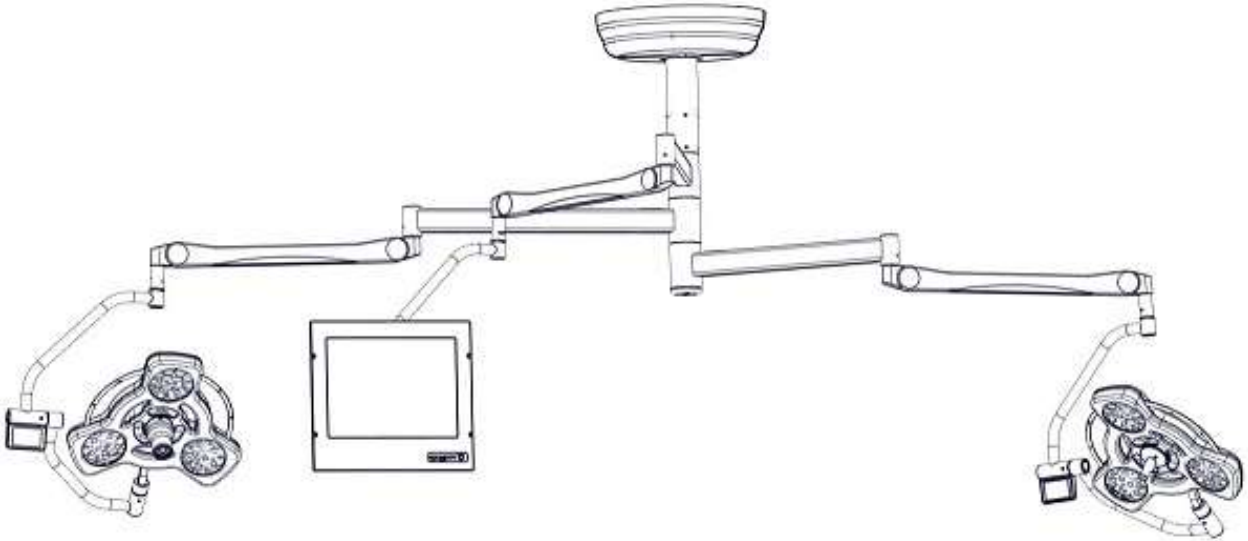


Figure 25 Triple Head Ceiling Surgical Light with Camera Infrastructure & Monitor

7. MOBILE SURGICAL LIGHT

- Mobile surgical lights are 2 types which are with and without battery. Mobile surgical light can be moved easily by moving between the rooms where operation is made with 4 wheels, at least 2 of which are lockable.
- Mobile surgical light with battery is designed with battery to keep the operation in case of power outages.
- Mobile surgical lights without battery work with 220 V AC voltage. It will work depending on the power system of the operating room in case of power outages.

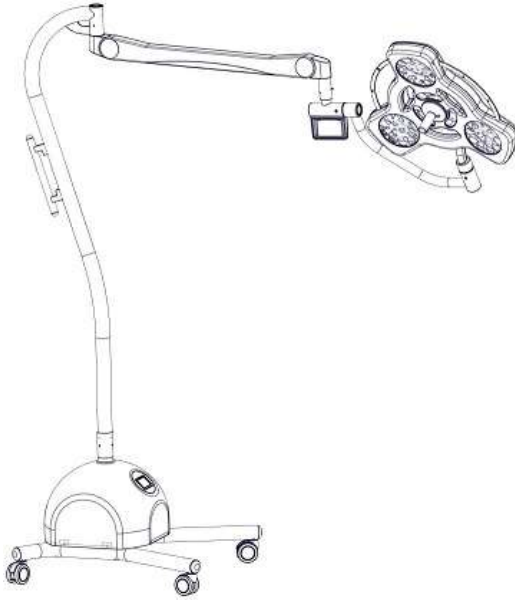


Figure 26 Mobile Surgical Light

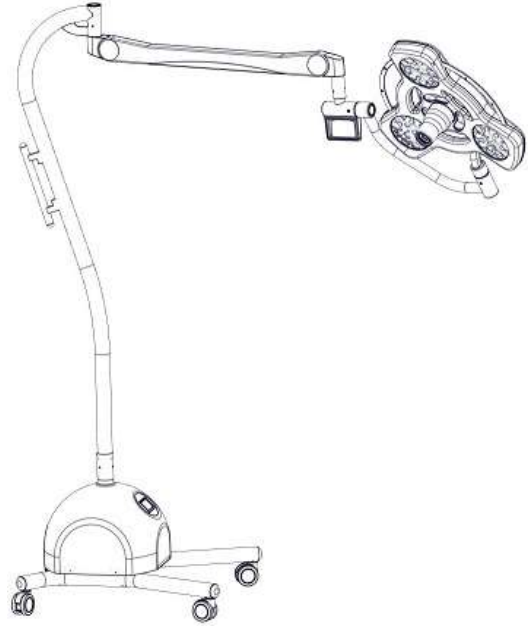


Figure 27 Mobile Surgical Light with Camera Infrastructure

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7.1.Battery Information (Opt.)

When the battery powered device is started, the screen will appear on the backup power unit as in Figure 28.



Figure 28 Battery LCD Display

- Battery charge status,
- Whether the device is running on the network or on the battery,
- The battery level of the device can be seen as% (percentage). When the battery level drops below 20% (twenty percent), a warning sound is heard, in this case, the backup power unit needs to be charged.

Via LCD screen;

It is monitored from 'Main' indicators that the device is operating from the network, and from the 'Batt' indicators that the device is operating from the battery. When the 'Main' indicator on the screen lights up, the system is fed through the network. The fact that the battery indicator is lit indicates that the lighting will continue by automatically activating the battery when the mains are cut. The battery is activated / deactivated by the fuse switch on the back of the backup power unit.

If your device is with battery, there will be 3 keys at the back of the battery as shown in Figure 29



Figure 29 Back of Backup Power Unit of Mobile Light with Battery

- In order for the light head to operate and the backup power unit to be charged, the 220V AC ON / OFF switch at the back of the backup power unit must be turned on.
- In order for the device to operate on the battery, the Battery On / Off switches at the back of the battery block must be turned on. When the 220 V ON / OFF switch is open, the light head is fed through the network. If the battery is not fully charged, it will be charged over the network. When the battery On / Off switch is on, the battery will automatically switch on in case of power outages and the light head will continue to illuminate without interruption.


- There is an SDI OUT outlet on the back of the backup power unit in mobile models with cameras. Signal transfer from SDI OUT output to the monitor to be connected should be done using RG 6 75 ohm cable.



In case of power outages that may occur during operation, the Battery On / Off switch must always be turned on during the light head use so that the battery can immediately start up and fulfill its functions, unless there is a malfunction in the battery. If the system with backup power unit will not be used for any surgical procedure, the backup power unit must be left fully charged and the battery ON / OFF switch must be in the OFF position. The battery reaches full charge when it is connected to the mains for 6 hours while the light head is off. In order for the battery to charge, the Battery ON / OFF button must be turned on. At the end of 6 hours, the charging process is completed when the phrase "Charging" on the screen goes to the phrase "Charge Status". When the charging process is completed, the 220 V ON / OFF switch should be turned off or the device should be unplugged from the electrical socket.



When the device is not used, the battery should be kept fully charged.

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- Information can be transferred to the hospital information system from the data tip specified below in the backup power unit.

Data tip;

- uses RS485 physical interface.
- should be set to speeds of 38400 bps.

- The backup power unit can transmit information from the data tip to the outdoor units in case of 4 different alarms:
 - 1) When the mains voltage is cut off
 - 2) When the mains voltage comes back on
 - 3) When the battery level drops below 20%
 - 4) When the batteries overheat

7.2.Mobile Surgical Light without Battery

When the mobile surgical light without battery is operated, the mains voltage will appear on the screen on the battery case as in Figure 30.



Figure30 Mobile Unit LCD Screen Display

- Mobile surgical lights without battery do not have battery system. In order for the light head to work, the device cable must be plugged into the electrical outlet.



Figure 31 Back of Backup Power Unit of Mobile Light without Battery

- In order to turn on the mobile surgical light without battery, ON / OFF switch on the back of the mobile unit shown in Figure 31 must be turned on and the light head plug must be plugged into the electrical outlet. After the light has been started, the functions can be checked on the control panel.
- There is an SDI OUT outlet on the back of the backup power unit in mobile models with cameras. Signal transfer from SDI OUT output to the monitor to be connected should be done using RG 6 75 ohm cable.

7.3. Transporting of the Mobile Light Head

In order for the mobile light to be transported safely, the spring arm to which the light head is attached must be bent and the light head must be positioned parallel to the pipe coming out of the battery backup power unit as follows. It should not be transported / used on sloping and uneven surfaces in order to prevent loss of balance or toppling during transportation, transportation should be done by holding the handle on the pipe coming out of the battery backup power unit. The arm system of mobile light heads must be closed during transportation.



Figure 32 Closing the Arm System

8. STERILIZABLE HANDLES

Sterilizable handles are used for positioning the light head by placing it on the handle in the center of the light head or camera infrastructure.

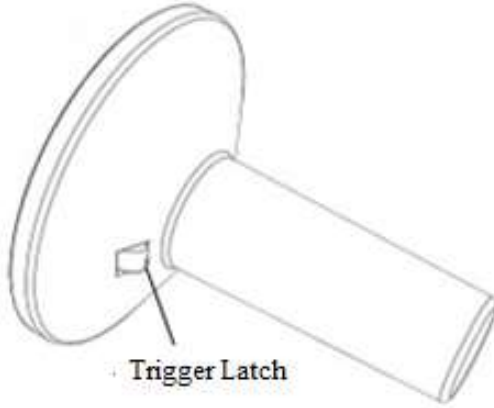


Figure 33 Sterilizable Handle

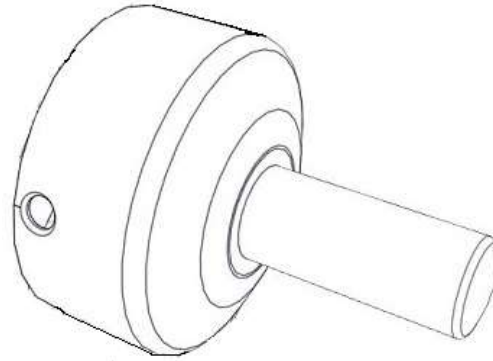


Figure 34 Sterilizable Handle with Sterile Camera Infrastructure

8.1. Mounting and Removing the Sterilizable Handle

The grip on which the sterilizable handle will be mounted is located on the lower surface of the light head as shown in figures 35 and 36. A sterilizable handle is placed on this grip.



The locking mechanism on the sterilizable handle should be controlled manually before being mounted to the light head, must be installed in the light head after checking. Handles with deformed locking mechanism should never be used.

In order to attach the sterilizable handle, it is placed on the handle in the figure 35 and 36 by pressing the trigger latch shown in figure 33 and pushed upwards. A warning sound should be heard from the trigger latch in order to understand that the sterilizable handle is properly in place. The sterilizable handle should be pulled down and be sure that it is fully seated.

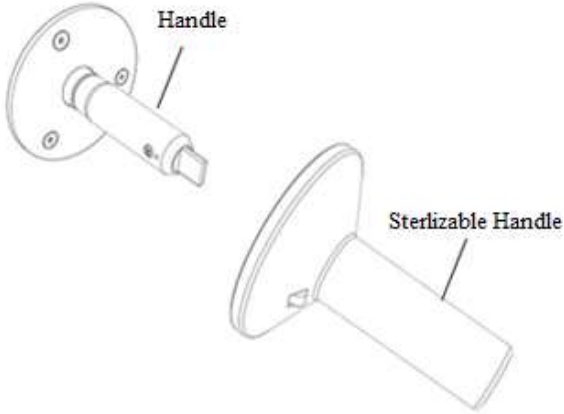


Figure 35 Passing Over the Sterilizable Handle to the Light Head Grip

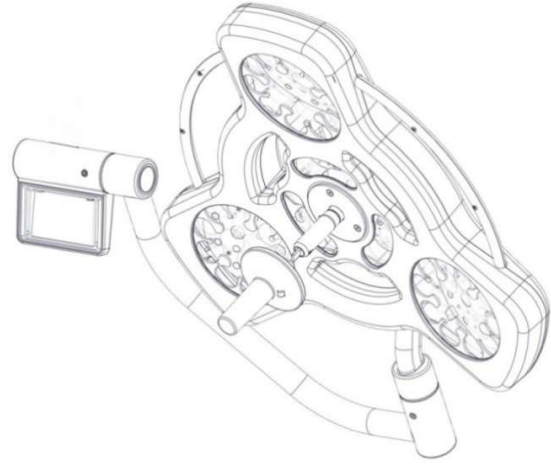


Figure 36 Mounting the Sterilizable Handle to the Light Head



Sterilizable handles with camera infrastructure that are not properly fixed may fall into the operating field, for this reason, after the handle is placed in its place, it should be pulled down to make sure that it is fully seated.

In order to remove the sterilizable handle, it is pulled down by pressing the trigger latch on the handle. Trying to remove the handle without pressing the trigger latch may cause damage to the handle.

8.2. Sterilization of the Sterilizable Light Head Handles

Sterilizable light head handles must be sterilized in the first use, before and after each surgery.



The operation should not be started without the handle fix to the operation light head. The handle to be mounted must be sterilized under the conditions specified in this user manual.



Handles delivered in light head packaging are not sterile.



Sterilizable light head handles should never be sterilized in dry air sterilizers (oven) or with Ethylene Oxide (ETO). Sterilizing the handles under inappropriate conditions causes the material not to be sterilized and the material deformation by shortening its life.



Sterilizable light head handles are suitable for sterilization in steam sterilizer (autoclave) at 134 ° C. Sterilizable light head handles can be sterilized and used repeatedly as long as the plastic is not deformed. Deformed handles should never be used.



Before the light head handles are sterilized in the steam sterilizer (autoclave), they must be subjected to a manual washing process in order to remove the residual waste. It should not be subjected to sterilization process before this washing process is carried out.



Sterilizable light head handles should not be subjected to mechanical load (no other material should be placed on it and it should not be left in contact with another material) while being sterilized in a steam sterilizer (autoclave).

8.3.Mounting and Removing Sterilizable Handle with Camera Infrastructure

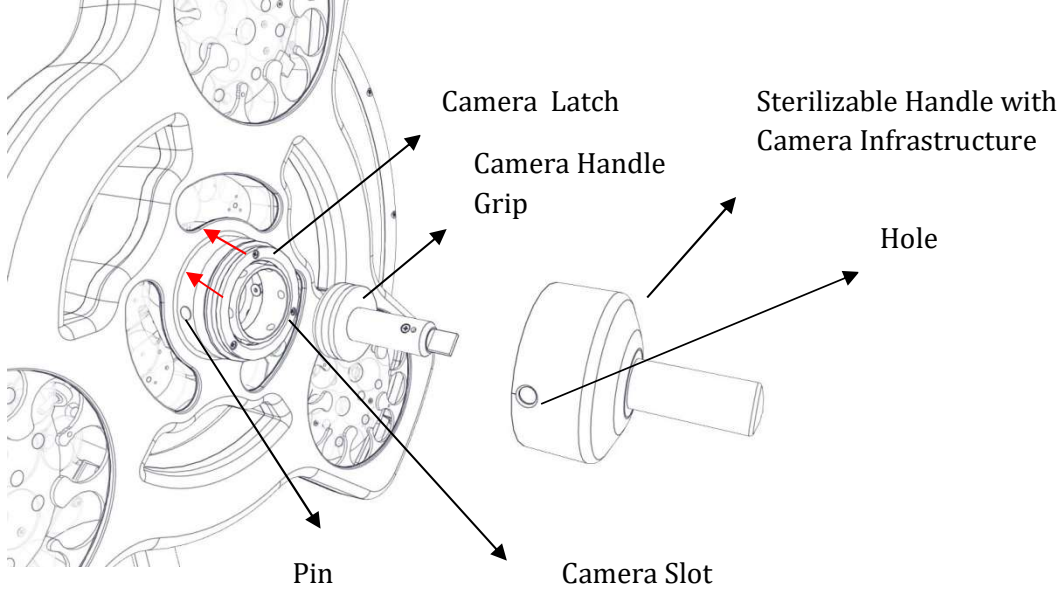


Figure 37 Sterilizable Handle with Camera Infrastructure

Sterilizable handles with camera infrastructure is used in surgical light heads with camera infrastructure. As shown in Figure 37 while installing a sterilizable handle with camera infrastructure; It should be ensured that the spring pins on the camera handle and the holes on the handle are intertwined by turning to the right or left. Rotation must be done until the ‘click’ locking sound is heard. After the locking sound is heard, it should be ensured that the sterilizable handle with camera infrastructure is pulled downwards and is fully seated.



In order to connect the sterilizable handle with camera infrastructure to the light head, it should be checked that the 2 holes on the handle are clean and not deformed. If these holes are deformed, the handles should not be used.



The pins in the camera grip that enter the holes of the sterilizable handle with camera infrastructure are not sterile. If the camera handle is to be removed during the operation; sterility will be impaired if this part is touched by sterile users.



Sterilizable handles with camera infrastructure that are not properly fixed may fall into the operating field, for this reason, after the handle is placed in its place, it should be pulled down to make sure that it is fully seated.

In order to remove the sterilizable handle with camera infrastructure, the pin must be pressed into the locking holes of the handle and pulled down.

8.4. Sterilization of the Sterilizable Light Head Handle with Camera Infrastructure

Sterilizable light head handles must be sterilized in the first use, before and after each surgery.



The operation should not be started without the handle with camera infrastructure fix to the operation light head. The handle to be mounted must be sterilized under the conditions specified in this user manual.



Handles delivered in light head packaging are not sterile.



Sterilizable light head handles with camera infrastructure should never be sterilized in dry air sterilizers (oven) or with Ethylene Oxide (ETO). Sterilizing the handles under inappropriate conditions causes the material not to be sterilized and the material deformation by shortening its life.



Sterilizable light head handles with camera infrastructure are suitable for sterilization in steam sterilizer (autoclave) at 134 °C. Sterilizable light head handles with camera infrastructure can be sterilized and used repeatedly as long as the plastic is not deformed. Deformed handles should never be used.



Before the camera handles are sterilized in the steam sterilizer (autoclave), they must be subjected to a manual washing process in order to remove the residual waste. It should not be subjected to sterilization process before this washing process is carried out.



Sterilizable camera handles should not be subjected to mechanical load (no other material should be placed on it and it should not be left in contact with another material) while being sterilized in a steam sterilizer (autoclave).



The pins in the camera grip that enter the holes of the sterilizable handle are not sterile. If the camera handle is to be removed during the operation; sterility will be impaired if this part is touched by sterile users.

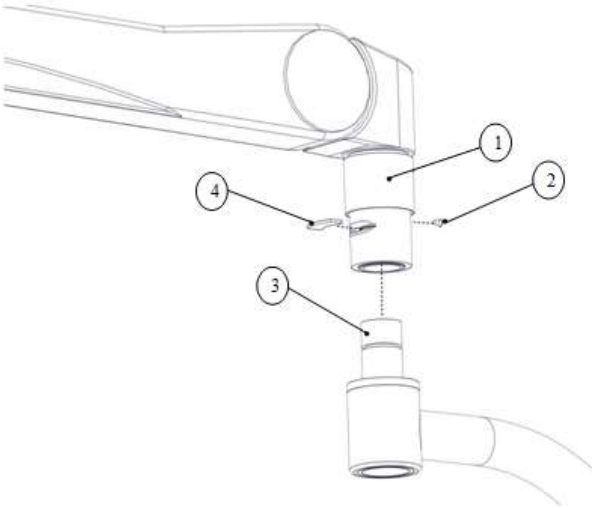
9.INSTALLATION OF THE LIGHT HEADS

9.1. Installation Instruction of ETC LED Light Head

The installation of the operating light head and other connection equipment under the brand name of Etkin Tıbbi Cihazlar should only be carried out by the people / companies who have received the necessary training and are authorized by the Etkin Tıbbi Cihazlar company. The installation staffs should have personal protective equipment during installation and perform operations with appropriate mounting equipment.



If the assembly personnel interfere with the product without having the above mentioned features, it may cause serious injuries.



**Figure 38 Light Head Assembly
Demonstration**

As shown in Figure 38, the screw (2) on the sleeve (1) at the end of the spring arm is removed by using philips screwdriver, the sleeve is pushed upwards. The security segment (4) is removed. The pivot of light head (3) is placed into the spring arm. The security ring is mounted into its place. The sleeve is pushed downwards and positioned to align the screw hole and fixed with screw by using screwdriver. The rotation of the head on the arm should be controlled easily on the horizontal axis.

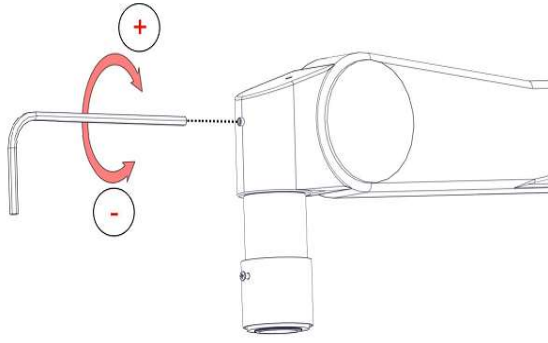


Figure 39 Vertical Limit Setting

The vertical limit of the spring arm is in limited position during installation, the vertical limit needs to be adjusted after mounting the light head. As shown on Figure 39, Allen key (size metric 5) is insert into adjustment hole, to adjust the spring arm vertical limit on upward direction, it is rotated + direction, paying attention to the objects that the spring arms may hit on the right or left side. To adjust the spring arm vertical limit on downward direction, the allen key is rotated - direction.

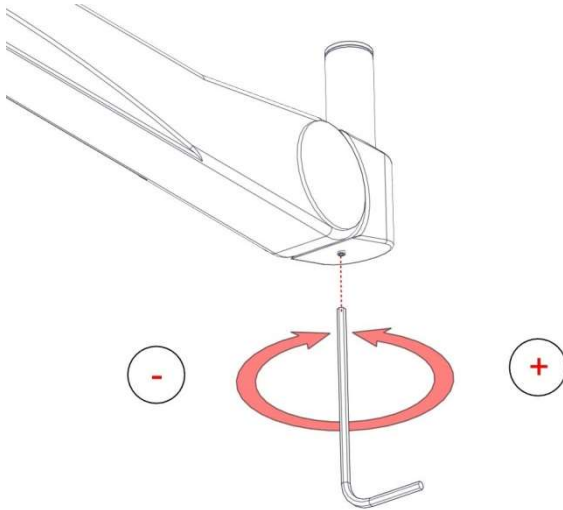
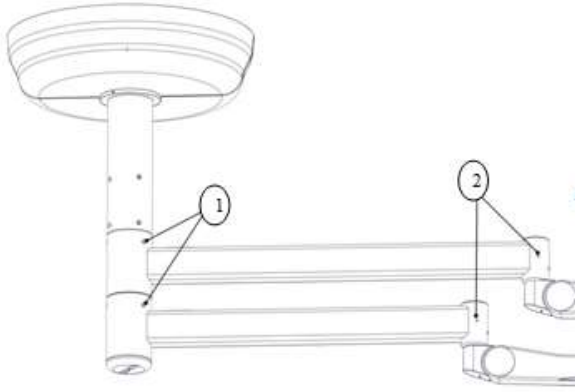


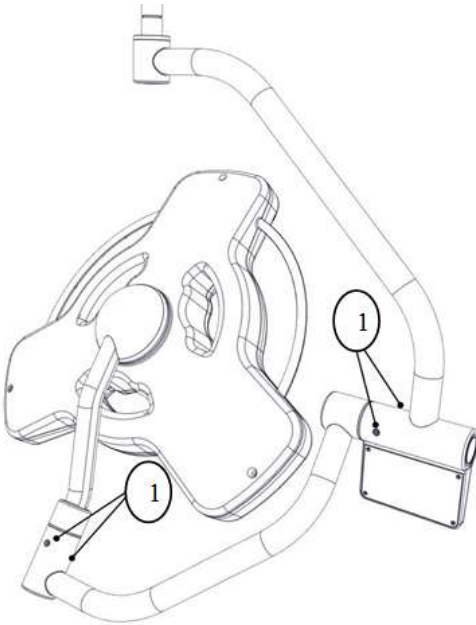
Figure 40 Spring Tension Adjustment

According to the weight of the light head, spring tension adjustment is required after the light head is mounted. To adjust the spring tension, allen key (size metric 5) is inserted into the covered adjustment aperture as shown on Figure 40. If the spring arm moves to the downwards direction, the allen key is rotated to + direction. if the spring arm moves to upward direction, the allenkey is rotated to - direction. After the appropriate tension adjustment is made according to the weight of the light head, the light head is left in the appropriate position and the process is completed.



The hardness of the central axis right, left turn and spring arm right and left turn are adjusted by tightening the brake screws numbered 1 and 2 shown in Figure 41 with a flat screwdriver.

Figure 41 Central Axis Brake Adjustment



Light head short arm and long arm brake adjustment; performed by tightening the bolts numbered 1 shown in left figure, with metric 5 hex.

**Figure 42 Light Head Short Arm, Long Arm
Brake Adjustment**

10. POSITIONING OF THE LIGHT HEADS, CONSIDERATIONS IN USE AND INSTALLATION TYPES

10.1. Positioning of Etkin Tibbi Cihazlar Brand Surgical Lights

Positioning the light head is made with non-sterile arms of the light head or sterilizable handles at the center of the light heads. Depending on the type of operation performed, one or more light heads are directed to the operation area. It is recommended to position the light heads not parallel to the patient bed but at an angle on the sides of the patient bed as shown in Figure 43. Angled light head will reduce its interaction with the laminar flow system. The light head arms should be positioned while the "Etkin Tibbi Cihazlar" logo in the sections 1 and 2 shown in below Figure, is in a straight and readable position.

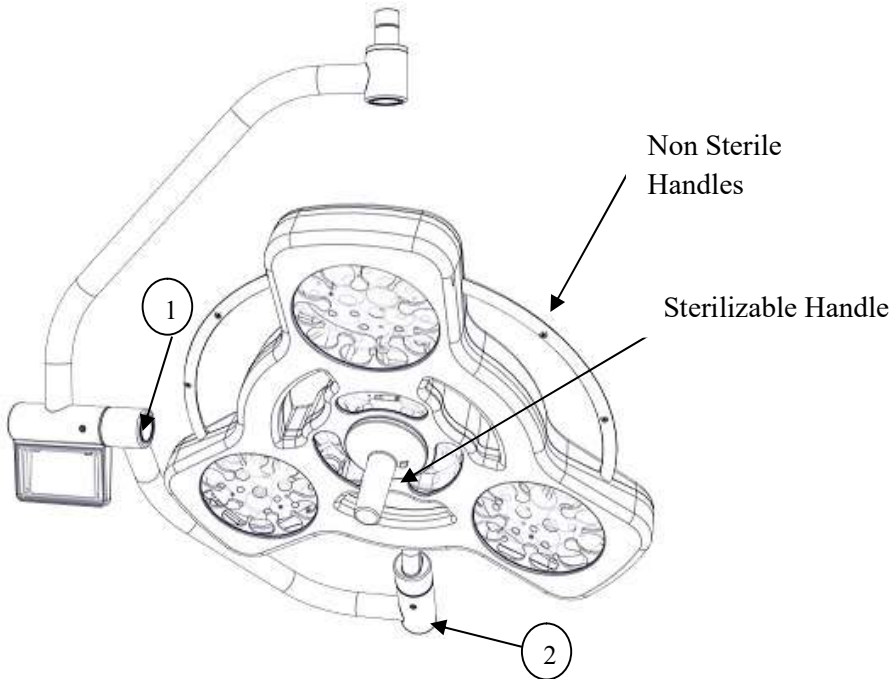


Figure 43 Positioning the Light Head

10.2. Things to Consider When Using Surgical Lights

- It is recommended to use double or triple heads operating lights in order not to interrupt the operation in case of malfunction in the operation light heads.

- When more than one lighting head illuminates the same spot; the light intensity in the illuminated area will exceed the maximum light intensity. Excessive light intensity will cause eye fatigue during the operation and increase in the radiant energy value measured in the illuminated area. When the same area is illuminated with the double or three light heads, it is recommended to work by taking the light intensity level setting in each head to the middle point.
- No material / apparatus should be placed on light heads and arms, and / or should not be covered or covered. In such a case, the light will not be able to remain fixed in the desired position, and may cause the light to fall into the surgical operation area or the light to be unable to focus in the desired place.
- Light heads and arms must be protected against the possibility of collision during operation or when adjusting to the desired position. No hitting / collision with hard objects should be made to the fragile parts of the light heads. Otherwise, both the patient / user and the light head system may be adversely affected and the fragile parts in the light head may fall on the patient, causing harm to the patient or user.

Check the working condition of the light head before each use;

- Light head itself, light head control panels and other connection equipment should be checked before each use.
- Make sure that there are no damages and sags on the light heads and arm systems.
- It should be checked that electricity is coming to the light head control panels.
- Care must be taken that the sterilized handle is properly fixed to the center of the light head.

10.3. Mounting Types

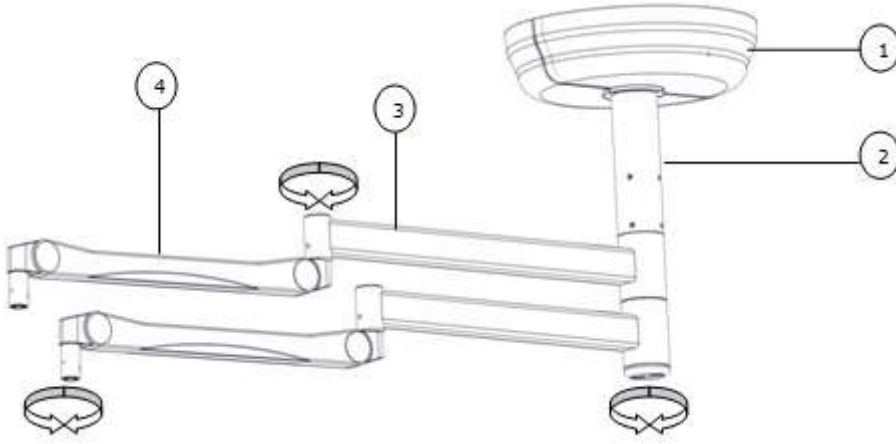


Figure 44 Light Head System Ceiling Mount

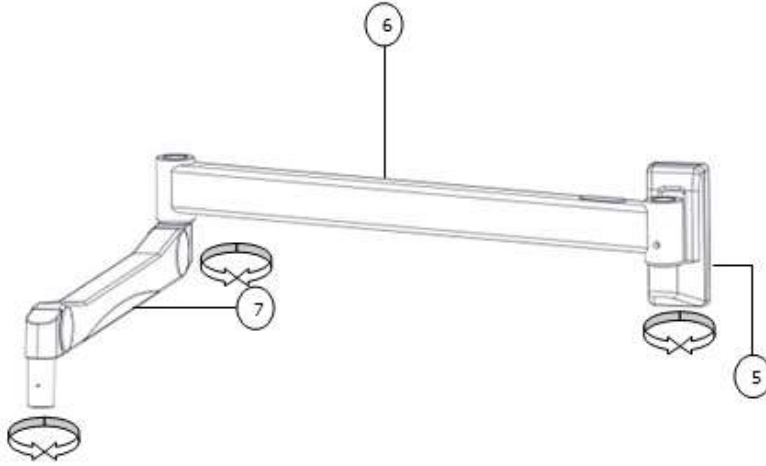


Figure 45 Light Head System Wall Mount

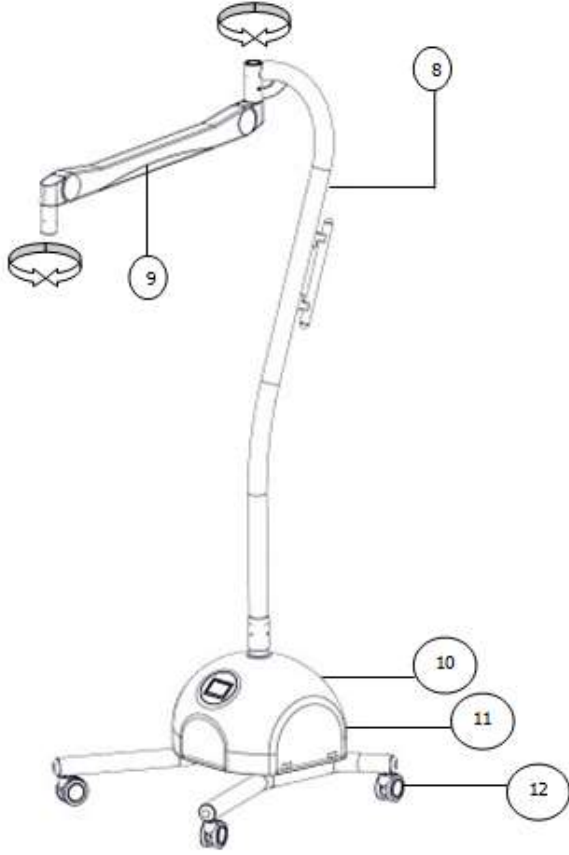


Figure 46 Mobile Surgical Light

* While using the lamp, avoid the movement that may hit or force the axial parts that are limited.

Ceiling	Wall Mount	Mobile
Flanşge Cover (1)	Wall Mount Bearing (5)	Swan Tube (8)
Boom (2)	Central axis (6)	Spring Arm (9)
Central axis (3)	Spring Arm (7)	Backup Power Unit (Opt.) (10)
Spring Arm (4)		Mobile base (11)
		Castors (12)

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11. MAINTENANCE, REPAIR, TROUBLESHOOTING AND CLEANING INFORMATION

11.1. Maintenance

The service life of the device will extend if the necessary maintenance is done to the light head parts. The maintenance and repair operations of the device should be carried out by the authorized persons / companies, authorized by the Etkin Tıbbi Cihazlar Company, and who have received the necessary training.

During the warranty period of the device, maintenance and calibration procedures must be made free of charge by the seller company once a year. Following the end of the warranty period, maintenance and calibration procedures should be done twice a year.

11.1.1. User Maintenance

User maintenance is the maintenance activity performed by the staff using the device and the care level with limited capacity in the hospital. The first stage of this maintenance activity is called "preventive maintenance". It is the most important link in the maintenance chain. It is applied daily by the person or operator using the device.

Preventive maintenance is a systematic maintenance service to keep the device in working order.

With a conscious application;

- Possible malfunctions can be avoided,
- The service life and efficiency of the device increases,
- Increased device life provides economy.

Preventive maintenance includes the following operations.

- V - Visual Inspection,
- P - Palpation,
- T – Tightening,
- C - Cleaning,
- A - Adjustment

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Visual Inspection

The most important process of preventive maintenance is visual inspection. With this examination, unusual appearances of the device are detected. By carefully examining all visible parts of the device, broken, cracked, scratched parts, dirty, rusty, incomplete elements are detected. Discoloration, blistering, dents or melting insulators suggest a malfunction.

Palpation

Movable, snap, clamp or screw parts are controlled by hand. In addition, abnormal manual warming is again considered a sign of malfunction.

Tightening

Some screws and latches may loosen during prolonged use or transportation. These situations should be identified, tightened and corrected or reported to authorized personnel.

Cleaning

Protecting electronic material from all kinds of dirt, rust and dust is an important maintenance phase.

Adjustment

The moving arms of the light head may lose their tightness over time and may not stay in the position where it is located. In this case, the necessary adjustment should be made using the set points..

11.1.2. Daily/Weekly Maintenance

Main Body

The presence of any physical damage on the main body, the condition of the fasteners such as screws, latches, and plugs are visually checked. In case of any problems, measures are taken to prevent harm to users and patients. Authorized technical service is informed to eliminate the detected problem.

Carrier Arm

The presence of any physical damage on the carrier arm, the condition of the fasteners such as screws and plugs etc... are checked visually. Weight balancing and movement axes are controlled by applications made in appropriate directions. In case of any problems, measures are taken to prevent harm to users and patients. Authorized technical service is informed to eliminate the detected problem.

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Electronic Control Panel

It is visually checked whether there is any physical damage to the control panel on the carrier arm. By operating the system, the operation of the electronic control panel is observed. In case of any problems, measures are taken to prevent harm to users and patients. Authorized technical service is informed to eliminate the detected problem.

Electrical Connections

Visually checked for any physical damage to accessible electrical cables and connections. General cleaning is done with disinfectant materials. In case of any problems, measures are taken to prevent harm to users and patients. Authorized technical service is informed to eliminate the detected problem.

Labels

Visually checked the accuracy, legibility, cleanliness and presence of any physical damage of the location of the labels on the entire product. In case of any problems, measures are taken to prevent harm to users and patients.

Auxiliary Equipment


Visually checked the presence of any physical damage to fixed and portable auxiliary equipment. In case of any problems, measures are taken to prevent harm to users and patients. Authorized technical service is informed to eliminate the detected problem.

Light Head Maintenance Settings

During maintenance, the joint brakes of the light head and arms are adjusted, and the existing problems are corrected. If the adjustment screws on the joint are loosened, the brake adjustment is made by tightening it clockwise with the help of an allen key.

11.2. Repair and Troubleshooting


The repairs, fault situations and actions to be taken in such cases that may occur with the device and can be fixed by the user are given below. For failures not covered in this manual, contact the seller / authorized company. The serial number of the defective head must also be reported when a failure notice is made to the seller / authorized company.

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Light Head System Failure Table

Step	Failure Cause	Check-Out Procedure
1	There is no electricity to the device.	The fuse in the electrical panel of the device must be checked.
2	The spring arm of the light head does not stay in place.	If there is a movement in the vertical axis, up and down, the spring tension should be adjusted with metric 5 hex key. If there is a movement to the right and / or left in the horizontal axis, the brake screws on the side of the spring arm on the central axis must be tightened with a flat screwdriver.
3	The light head does not stay where it was dropped.	The brake Set Screw must be tightened with metric 5 allen key.
4	Central Axis arms do not stay in place.	Brake screws on the carrier arm must be tightened with a flat screwdriver.
5	When the ON / OFF button is pressed on the wall control panel, no LED is lit.	The 12 V DC electricity coming to the wall control panel must be controlled.
6	The commands given from the wall control panel do not work.	Which light head we want to activate from the wall control panel, the LED of the relevant light head should be activated by selecting the desired light head from the Lamp1, Lamp2 and Lamp3 buttons on the panel. If the commands given still do not work, the relevant light head should be de-energized and re-energized after 15 seconds.
7	The LED in the middle of the control panel is constantly lit.	Bu LED herhangi bir tuşun sürekli basılı olduğunu gösterir. It should be checked that the glass on the keys is not cracked or stained.
8	Anti-Shadow sensors are not working.	The glass in front of the anti-shadow sensor may become dirty, scratched and dull. It should be checked and cleaned if there is any contamination on the glass.
9	Anti-Shadow sensors are not working.	The CAMERA button on the control panel must be pressed for 2 (two) seconds (until the warning sound stops). When the warning sound is stopped, the led at the top of 5 (five) leds on the upper left of the control panel will light up.
10	Anti-Shadow sensors malfunction.	Anti-shadow sensors are positioned in contact with PMMA material on the front surface. The position of the anti-shado sensors should be visually checked. There should be no scratches, dirt and matting on the surface in front of the sensors.

Sheet 4. Bug Lookup Table

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Backup Power Unit Fault Table

Error Code	Error Indicator	Description of the Error	What to Do
E1	Battery Overheated Warning	The battery is overheated, in which case the battery charge will be automatically cut off. The warning sound will be heard for 30 seconds.	As a precautionary measure, the mobile power supply should be disconnected from electricity and the two ON / OFF switches on the back of the mobile power supply should be turned off, The seller company or authorized technical service should be informed.
E2	Sensor Error	Checks the functionality of the sensors used when the device is first turned on. If communication cannot be established with the sensors, this alarm will appear.	If an alarm occurs, ask for support from the manufacturer and technical service.
E3	Battery Full Warning (Battery Status)	Means that the battery is fully charged.	The mobile power supply should be unplugged in order to use the battery efficiently, to save energy and to prevent possible errors.
E4	Charge Alert (Charge Battery)	Battery charge level has dropped below 10%. The warning sound will be heard for 20 seconds.	Charge the battery.
E5	Communication Error: All LEDs on the control panel flash at 1 second intervals.	There is a communication problem between the control board and the control panel.	The power of the light head should be cut off from the main fuse and it should be energized again after waiting for 15 seconds. If the problem continues, please contact the authorized company.

Sheet 5. Mobile Light Head Troubleshooting Table

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11.3. Cleaning

11.3.1. Cleaning Surgical Light Heads and Arms

- The operating light head and accessories and other equipment connected to the light head should be disinfected with appropriate disinfection materials before and after each surgery.
- In the cleaning of light head system can be disinfected with metal compatible detergent disinfectant cleaners that do not contain acid, chlorine (also containing hydrogen peroxide paracetic acid combination) and alcohol. In order not to damage the anti-bacterial and anti-static paint used on the light head and arms, it should be cleaned with the above-mentioned disinfectant materials. It is appropriate to use a soft lint-free cloth for cleaning the device; Otherwise, it may cause a decrease in light intensity and quality. If antibacterial paint is damaged, persons / companies authorized by Etkin Tibbi Cihazlar should be informed.
- Cleaning materials containing acid, chlorine and alcohol should never be used on the glass surfaces of the light head.
- The cleaning of the light head system should never be done by scraping it with any object, otherwise, it may cause scratching of lenses and paint.
- For good cleaning, the LEDs light head should be cleaned in the downward position. The cleaning of the glasses on the front surface of the operating light head can be cleaned with a soft and lint-free cloth.
- The cleaning of the operating light head should not be done by direct contact with water.
- In order for the shadow sensors working under PMMA material to make accurate measurements, the transparency on the surface must not be disturbed. Therefore, the transparent PMMA material on the front of the light head should never be cleaned with acid, chlorine and alcohol-containing cleaning materials.

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12. RECYCLING INSTRUCTIONS



Sheet 47 Recycling Symbol

Do not dispose of this device or its parts together with unsorted household waste. Improper disposal can harm the environment and human health. Separate collection and recycling of waste equipment over time helps to protect natural resources and human health. Please seek assistance from the licensed recycling and collection systems in your region / country for disposal / disposal of this device / parts or contact the seller / manufacturer.

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13. WARRANTY CONDITIONS

The following written statements are valid unless stated otherwise in the contract or similar documents.

1. The warranty period starts from the date the product is first received by the User-Customer and is 1 (one) year unless otherwise specified.
 2. The product is under the warranty of our company with all its parts.
 3. In case the product fails within the warranty period, the time spent in repair is added to the warranty period. The repair period of the product is up to thirty (30) business days. This period starts from the date of notification of the product malfunction to the service station or in the absence of a service station, to the seller, dealer agent, representative office, importer or manufacturer of the product.
 4. During the warranty period, if the product fails due to material and workmanship or assembly errors, it will be repaired without any charge under the name of labor cost, replacement part price or any other name.
 5. If the product is repaired free of charge;
 - I. Failure again within the warranty period,
 - II. Exceeding the maximum time required for repair,
 - III. Determining that the repair is not possible with a report by the authorized service station, seller, manufacturer or importer,
- In cases; The cost of the consumer goods will be refunded, the price discount at the rate of defects or if possible, the replacement of the goods with the value of the goods without defects will be provided.
6. Malfunctions caused by the use of the product contrary to the matters contained in the user manual are not covered by the warranty.
 7. If it is understood that the product is defective, the consumer;
 - I. Withdrawing from the contract by stating that it is ready to return the sold product,
 - II. Retaining the sold product and asking for a discount from the sales price at the rate of defects,
 - III. If it does not require an excessive cost, to request free repair of the sold, at the expense of the seller,

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IV. If there is possibility, to request the replacement of the sold product with a duplicate without defects, can use one of its optional rights. This demand, preferred by the consumer, will be fulfilled

8. Consumers can make their complaints and objections to Consumer Courts and Consumer Arbitration Committees.

9. Consumers will notify in writing of the disagreements between the maintenance, repair and service stations, which is the manufacturer and authorized service station that the company address below.

ETKIN TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

1358 sk. No:9/A Alsancak İZMİR, TURKEY

Tel: +90 232 464 0020

Fax:+90 232 464 1493

10. Customer must keep,

I. The original warranty document on which the name / title and address of the seller and the place and date of purchase, the product type and serial numbers are clearly and legibly written and without any changes or

II. A copy of the original and unaltered purchase receipt, given by the seller / distributor of the product, containing the same information.

11. The responsibility of issuing the warranty certificate and giving it to the consumer belongs to the seller, dealer, agency or representative offices from which the consumer purchases the goods.

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14. MATTERS TO BE CONSIDERED DURING TRANSPORT, STORAGE AND SHIPPING

- 14.1.** The device must be transported in its original packaging. This packaging is made of specially manufactured packaging material that is resistant to impact and drops and has been tested for durability.
- 14.2.** During transportation, tools that facilitate transportation should be used.
- 14.3.** More than 4 (four) boxes should not be stacked on top of each other.
- 14.4.** The device has been tested in special dust, water and humidity chambers. However, it should not be exposed to long-term dust and wet environment during storage.
- 14.5.** Storage ambient conditions are between -5 degrees and +40 degrees. Therefore, ambient conditions during transportation should be within these temperature ranges.
- 14.6.** In case of problems that may occur as a result of not fulfilling the above-mentioned conditions, support must be obtained from the seller / authorized company.

CAUTION!

Installation, Disassembly, Repair and Maintenance operations must be carried out by the authorized service.

Otherwise, the device will be out of warranty.

ETKIN TIBBİ CİHAZLAR SANAYİ VE TİCARET A.Ş.

Tel: +90 232 464 0020

Fax:+90 232 464 1493

Head Office Address: 1358 Sokak No:9/A

Alsancak/Konak IZMIR TURKEY

**Manufacturing Address: İAOSB 10052 Sokak No:10, 35620 Çiğli/İzmir
TURKEY**

Mail: etkintibbi@etkintibbi.com

Web Sitesi: www.etkintibbi.com

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Delivery Statement for the User:

I have read and understood the user manual. I am knowledgeable about safety instructions. In order to avoid hazards, I have been adequately trained in preventive measures and will use the machine in accordance with these operating instructions.

Brand, Etkin Tıbbi Cihazlar, modele and Serial Number, I received the usage and maintenance manual of the same product with this model.

Vendee

Name-Surname:

Company:

Position:

Date & Signature:

Vendor

Name-Surname:

Company:

Position:

Date & Signature:

CAUTION!

Installation, Disassembly operations must be carried out by the authorized service.

Otherwise, the device will be out of warranty.

Complaints and Appeals:

Consumers can make their complaints and objections to Consumer Courts and Consumer Arbitration Committees.

ETKIN TIBBI CIHAZLAR SANAYİ VE TİCARET A.Ş.

Head Office Address: 1358 Sokak No:9/A

Alsancak/Konak IZMIR TURKEY

Manufacturing Address: İAOSB 10052 Sokak No:10, 35620 Çiğli/İzmir
TURKEY

Tel: +90 232 464 0020

Fax: +90 232 464 1493

mail: etkintibbi@etkintibbi.com

Note: The Delivery Declaration Form for the User of this manual will be signed in two copies and one copy will be archived by the customer and one copy by the vendor company.