Equipment Package: Lamps and Lights

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Equipment Packet Contents:

This packet contains information about the operation, maintenance, and repair of laboratory lamps and lights.

Part I: External From the Packet:

1. **An Introduction to Operating Room Lights:** PowerPoint

Part II: Included in this Packet:

1. Operation and Use of Lamps and Lights

Featured in this Section:

Malkin, Robert. “Theatre Lamps and Other Lights.” *Medical Instrumentation in the Developing World*. Engineering World Health, 2006.

WHO. “Operating Light.” From the publication: “WHO Technical Specifications for 61 Medical Devices. *WHO*. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Wikipedia. “Surgical Lighting.” *Wikipedia.* Retrieved from: https://en.wikipedia.org/wiki/Surgical_lighting

Brief Introduction to Lamps

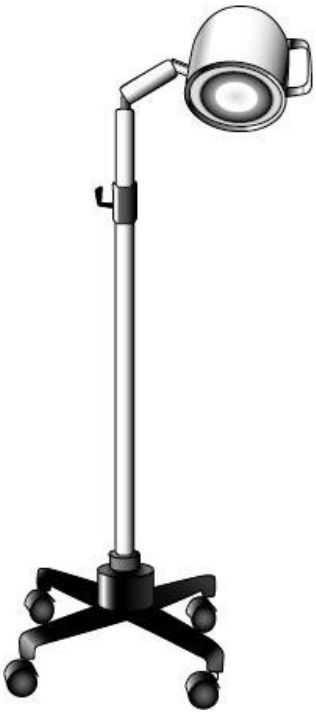
Chapter 4.10 Lamps

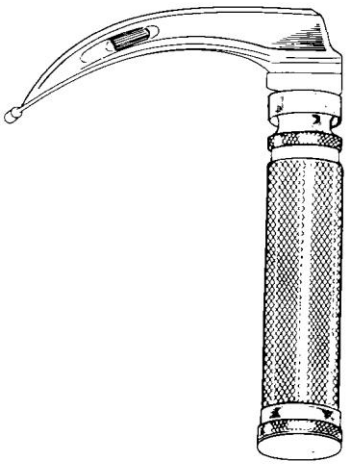
Function

There are many kinds of sources of light used in medicine. This chapter deals with large lights for operating theatres or delivery suites, ultraviolet or infrared phototherapy units, ophthalmic slit lamps, handheld and head worn lamps for ENT clinics, dental curing lights and domestic torches. However, the principles here will help in the user care of any kind of light source. Endoscopes are dealt with separately in chapter 4.7.

How it works

Each type of lamp will have a power source with switch and a bulb. Some will also have controls for the brightness or focus of the light, while others will also have lenses to direct the light where required. Some lights operate off mains electricity, while others use batteries instead. Some lights have both, using the batteries for back-up power in case of mains supply failure. Electric bulbs and batteries have limited life and will need regular checking. Bulbs can last from hundreds of hours operation to thousands of hours. Some equipment, e.g. UV phototherapy units, will indicate when bulbs need replacing. Turning bulbs on and off frequently can reduce the bulb life. A stock of spares should be kept of all the correct voltages and wattages (ratings) of parts.





Surgical lighting

A **surgical light** – also referred to as an operating light or surgical lighthead – is to assist medical personnel during a surgical procedure by illuminating a local area or cavity of the patient. A combination of several surgical lights is often referred to as a "surgical light system".

History

Technology development For lighting a surgical operation in the middle of 1850s, the room itself was built towards the south-east with windows in the ceiling to benefit from the natural sunlight as much as possible. The greatest problem with this was that the possibility to perform a procedure relied on the time of the day and weather conditions, but also the problem of the doctor, nurse or medical equipment easily blocking the illuminated area. A development of this was the use of mirrors on the four corners of the ceiling to reflect the sunlight towards the operating table but the problems where only slightly reduced.

Optical condenser in an indirect light was also tried to reduce the heating but without success. When the electric lights made their entrance into the operating room in the 1880s it also quickly showed problems. At this early stage of electricity the ability to control the light emitted was very low. The light created was still moving and diffuse with great heat radiation.

With the introduction of light-emitting diodes as light sources, the problem of heat radiation is removed, while energy requirement is reduced.

Terminology and measurements

• **Lux (lx)**

Unit for the amount of visible light measured by a luxmeter at a certain point.

• **Central illuminance (Ec)**

Illuminance (lx) at 1m distance from the light emitting surface in the light field centre.

• **Light field centre**

Point in the light field (lighted area) where illuminance reaches maximum lux intensity. It is the reference point for most measurements.

• **Depth of illumination**

The distance under the light emitting area where the illumination reaches 20% of the central illuminance

• **Shadow dilution**

The lights ability to minimise the effect of obstructions.

• **Light field diameter (D10)**

Diameter of light field around the light field centre, ending where the illuminance reaches 10% of Ec. The average of four different cross sections through the light field centre.

• **D50**

Diameter of light field around the light field centre, ending where the illuminance reaches 50% of Ec. The average of four different cross sections through the light field centre

Norms and requirements for surgical light

The International Electrotechnical Commission (IEC) has created the document *IEC 60601-2-41 – Particular requirements for the safety of surgical luminaries and luminaries for diagnosis, 2000* to establish norms and guidelines for the characteristics of a surgical and examination light to secure safety for the patient as well as lower the risk to a reasonable level when the light is used according to the user manual. Some of the standards for surgical lightheads are the following.

Homogenous light The light should offer a good illumination on a flat, narrow or deep surface in a cavity, despite obstacles such as surgeons' heads or hands.

Lux The central illuminance can not exceed 160 000 lux and should not be lower than 40 000 lux

Light field diameter The D50 should not exceed 50% of d10 diameter

Colour rendition For the purpose of distinguishing true tissue colour in a cavity, the colour rendering index (Ra) should be between 85 and 100.

Backup possibility In case of interruption of the power supply, the light should be restored within 5 seconds with at least 50% of the previous lux intensity, but not less than 40 000 lux. Within 40 seconds the light should be completely restored to the original amount of lux.

Announcement The IEC document also mentions what needs to be notified to the user. For example, should the voltage and power consumption be marked on or near the lampholder as well as on the lighthead. In the instructions for use the following info should be announced.

- Cleaning and decontamination of the surgical light
- Safety aspects of optical filter (purpose and warning to prevent removal)
- Central illuminance
- Light field diameter
- Depth of illumination
- Shadow dilution
- Correlated colour and colour rendering index
- Total irradiance
- Cleaning, disinfecting
- Handling of the lighthead in case of failure
- How the user should respect the national rules for hygiene and disinfecting

References

1. Extrait de la revue Techniques Hospitalières noo 400 Janvier/1979 "L'éclairage en salle d'opération" by M. Hainault p. 47

2. IEC International 60601 – Particular requirements for the safety of surgical luminaries and luminaries for diagnosis – Part 2-42.

Article Sources and Contributors

Surgical lighting *Source*: http://en.wikipedia.org/w/index.php?oldid=434703128 *Contributors*: A5b, Chris the speller, Fabrictramp, Kjkolb, MarmotteNZ, Mild Bill Hiccup, Paalappoo, Respirator, RockfangSemi, Thorseth, Wperdue, 9 anonymous edits

License

2.16 Theatre Lamps and Other Lights

2.16.1 Clinical Use and Principles of Operation

All lights in all parts of the hospital operate on the same principals. However, the operating theatre has the most variety of lights.

Operating rooms in the developing world have several separate lighting sources. The first is the general room lighting found in the ceiling. This is used during the set up of the rooms, cleaning and as background lighting for the staff who are not working in the sterile field.

The second source of light is the overhead operating room lights. These can be large reflectors with one or more bulbs in them, mounted on a counter balanced arm that can be positioned over the site of the operation. These units have a sterile positioning handle that is often adjusted over the period of the operation. Many of the problems associated with these lights are mechanical in that they do not stay in the position selected and the counter weights have to be adjusted. A secondary problem is that one or more of the lights will burn out giving dark spots in the surgical field. These lights have control boxes on or in the wall where the intensity control is found along with the on off controls. This control box usually contains an SCR control board, or transformer that powers the lights at some voltage under 115 volts.

A typical OR in Africa showing two principal lighting sources: The overhead light and the window. Against the far wall is an X-ray viewing light source.

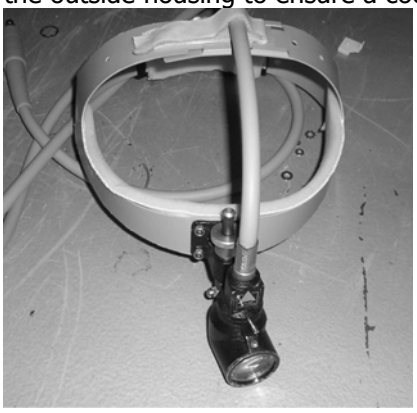
In some rooms there may be a portable operating room light. These are large reflector lights that roll from room to room. They simply plug in to a 115 pr 220 volt outlet and are positioned as needed by the surgeons.

The third source of light is the "personal head light" that a surgeon will wear. This is a lens that focuses light transmitted to it by a fiber optic cable from a remote light source. This light source may have a multitude of bulbs in it that can be switched into use via a knob on the top of the

Malkin, Robert. "Theatre Lamps and Other Lights." Medical Instrumentation in the Developing World. Engineering World Health, 2006.

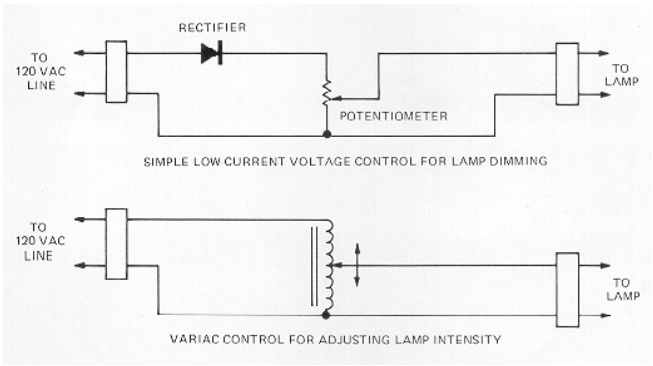
unit, or by moving the fiber optic cable from one side to another and turning on that light. These units are often the personal property of the surgeon.

Some lights will utilize cooler light systems by filtering out infrared portions of the light. The different mirrors and reflective surfaces on the inside of the light will allow for maximum light transfer to the operating area. Also, the lights may have a plastic coating and thermal guard on the outside housing to ensure a cooler surface when adjusting the light.



A surgeon's headlamp

For overhead lights, the distance from the lower edge of the light to the operating table should be approximately one meter. Initial positioning is accomplished by using the rail on the lamp housing to move it into place. The surgeon has the option of adjusting the light using the center hand grip, which is provided with a replaceable, sterilized sleeve.



Older theatre lamps used simple circuits, such as those shown here to vary the intensity of the light. Similar circuits are used for 220 volts.

Most operating lamps work directly from the outlet power through a switch. However, some lights may provide dimming circuits. Older dimmers found in the developing world often work with a rectifier or a variable transformer (variac) gradually varying the voltage applied to the lamp and therefore the intensity of the light delivered. Some dimmers operate using solid-state electronics (SCR's). These are rarely seen in the developing world and are typically impossible to repair.

Some operating room lights use fluorescent bulbs. Fluorescent bulbs generally operate through a transformer and use a starting circuit (sometimes called a ballast). In some cases, the bulb is heated before the starter is engaged. The heat causes both a change in the internal tube pressure and an increased electronic flow between the electrodes. A high voltage (25,000 V) spike from the starter establishes an arc in the atmosphere between the electrodes. After the initial spike, the bulb will operate at a low current and temperature,

2.16.2 Common Problems

Take special precautions when working with medical lights. The highest intensity lights can cause blindness if you look directly into the light. For the same reason, the light should not be used if the cover glass or filter system is damage or destroyed. In placing the light to begin work, your eyes should be greater than two feet or approximately sixty centimeters away from the source.

The lamps can be xenon, quartz-halogen, mercury-vapor or metal halide. These bulb types are not interchangeable because of the voltage supplying the bulb, the connector for the bulb and the heat generated by the bulb. The bulbs have a life expectancy of about 250 hours and need to be monitored for replacement. When replacing bulbs care must be taken to avoid touching the reflector part of the bulb as that can affect the brightness at the surgical site. Also, avoid touching the bulb itself. Your fingerprints can cause excessive heating of the glass, dramatically shortening the life of the bulb. If the glass of the bulb has been touched, clean the fingerprints off with alcohol.

It can be very difficult to find replacement light bulbs in the developing world and impossible to ship replacements into the county. While it may be possible to wire a replacement socket for a more readily available bulb, the engineer must be sure to consider size, voltage, temperature and materials. It maybe more prudent to start with a readily available bulb and socket and design a completely new fixture.

2.16.3 Suggested Minimal Testing

There is no calibration needed for operating room lights. If the light turns on, changes intensity (if equipped) and stays in place after adjustment, it is ready to use.

Malkin, Robert. "Theatre Lamps and Other Lights." Medical Instrumentation in the Developing World. Engineering World Health, 2006.

2. Diagrams and Schematics of Lamps and Lights

Featured in this Section:

Skeet, Muriel and David Fear. "Shadowless Theatre Lamps." *Care and Safe Use of Medical Equipment*. VSO Books, 1995, p. 118-125.

WHO. "Operating Light." From the publication: "WHO Technical Specifications for 61 Medical Devices. *WHO*. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

WHO. "Examination Light." From the publication: "WHO Technical Specifications for 61 Medical Devices. *WHO*. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Wikimedia Commons. "Incandescent light bulb (with labels)." Posted November 8, 2009. Retrieved from: https://commons.wikimedia.org/wiki/File:Incandescent_light_bulb_(no_labels).svg

Wikipedia. "Light-emitting diode." Wikipedia. Retrieved from: https://en.wikipedia.org/wiki/Light-emitting_diode

Figure 1: Mobile Theatre Lamp

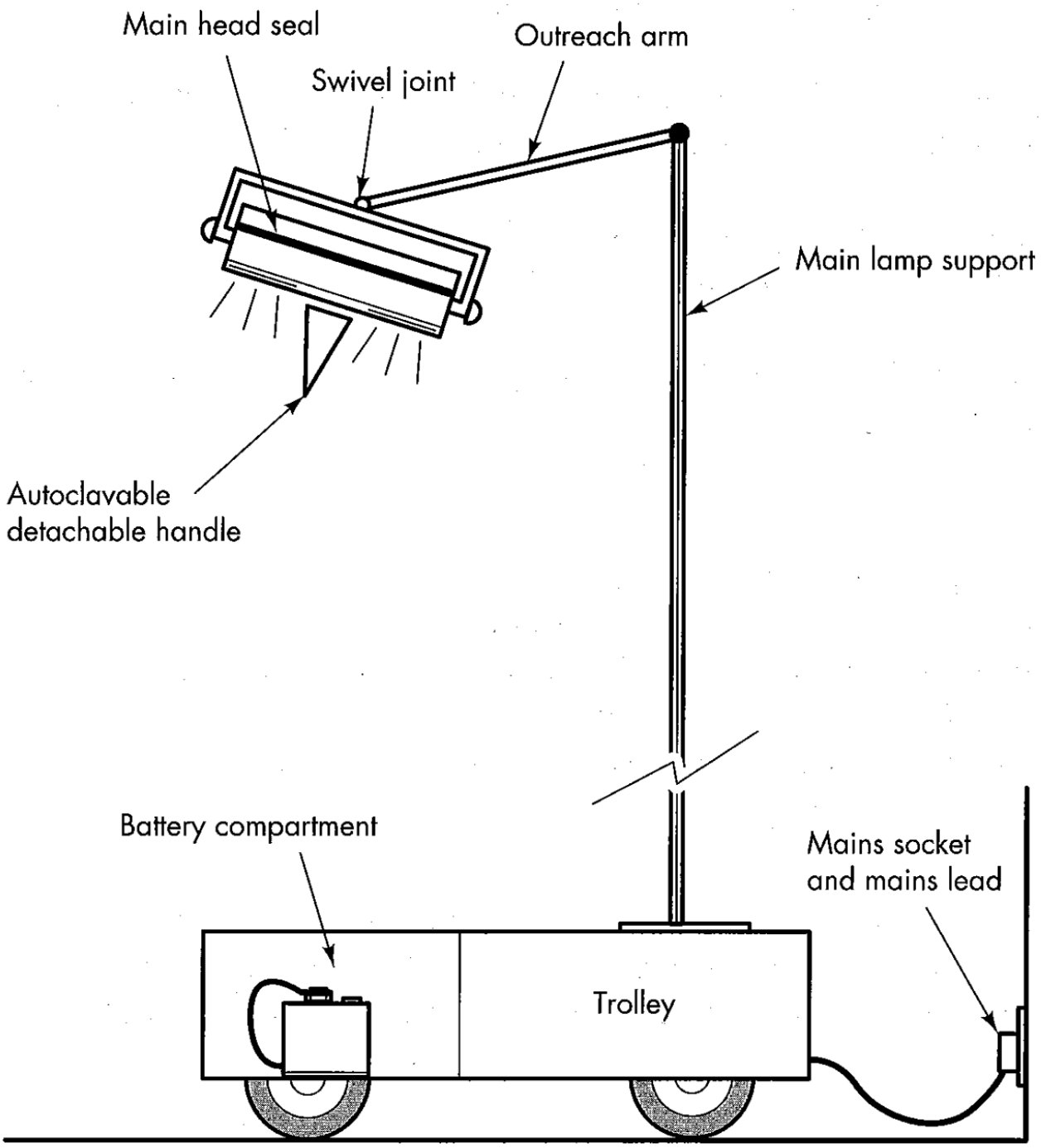


Figure 39: Mobile theatre lamp

Skeet, Muriel and David Fear. "Shadowless Theatre Lamps." Care and Safe Use of Medical Equipment. VSO Books, 1995, p. 118-125.

Figure 2: Fixed Theatre Lamp

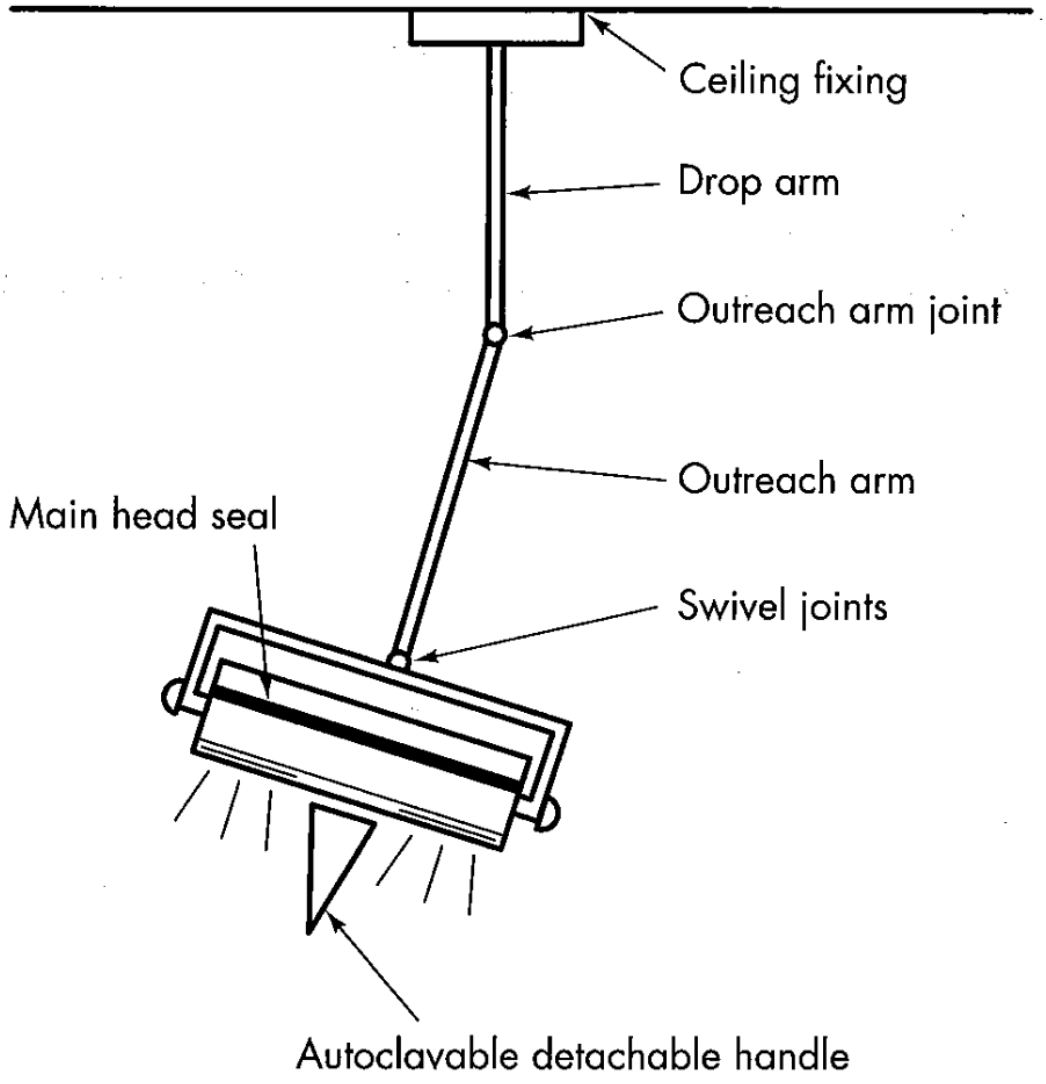
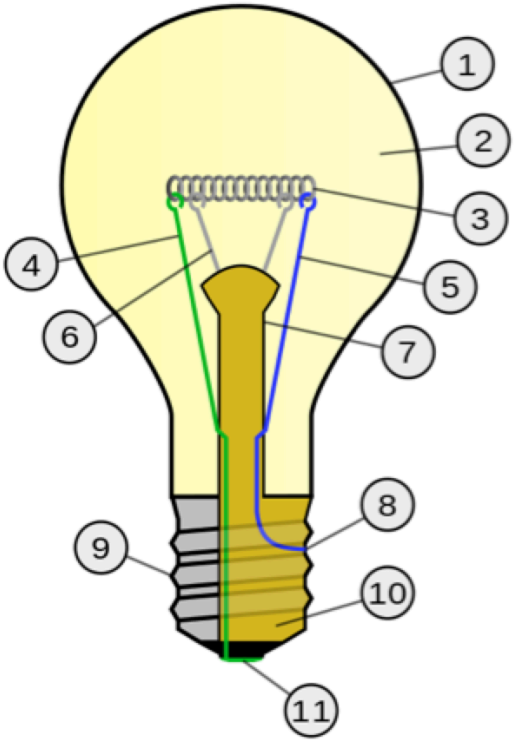


Figure 38: Fixed theatre lamp

Skeet, Muriel and David Fear. "Shadowless Theatre Lamps." Care and Safe Use of Medical Equipment. VSO Books, 1995, p. 118-125.

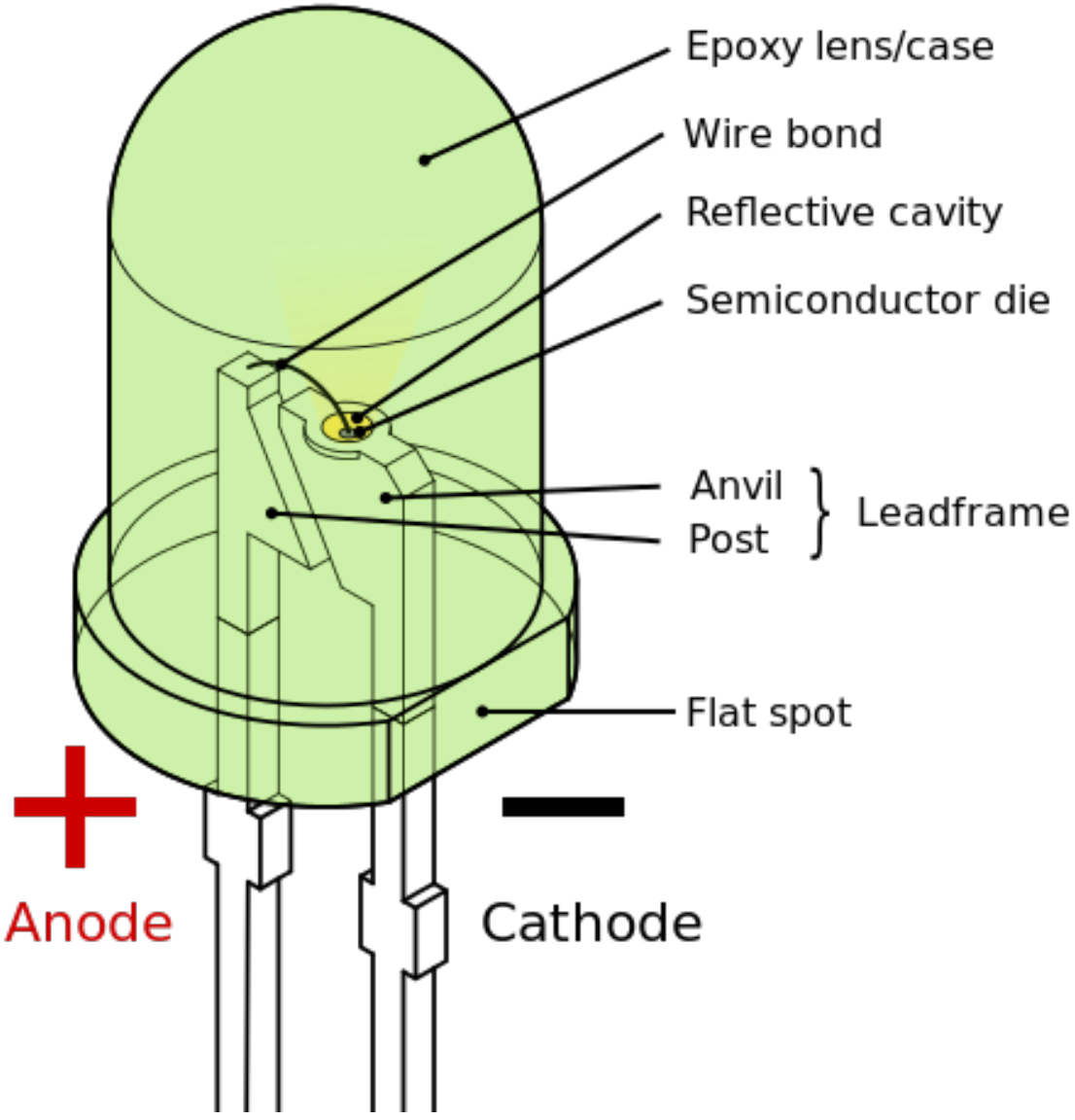
Figure 3: Parts of an Incandescent Bulb



1. Outline Glass Bulb
2. Low Pressure Inert Gas
3. Tungsten filament
4. Contact Wire
5. Contact Wire
6. Support Wires
7. Stem
8. Contact Wire
9. Cap (Sleeve)
10. Insulation
11. Electrical Contact

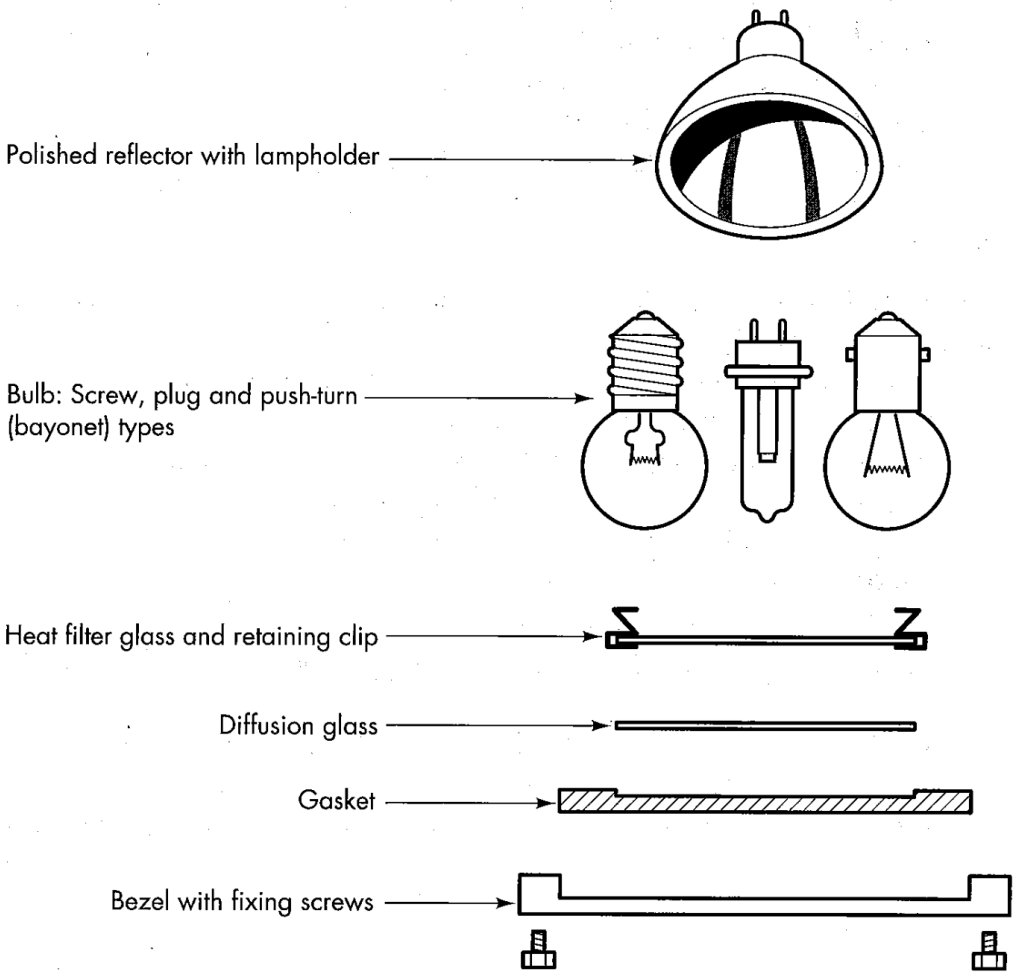
Wikipedia Commons. "Incandescent light bulb (with labels)." Posted November 8, 2009. Retrieved from: https://commons.wikimedia.org/wiki/File:Incandescent_light_bulb_(no_labels).svg

Figure 4: Parts of an LED (Light-Emitting Diode)



Wikipedia. "Light-emitting diode." Wikipedia. Retrieved from: https://en.wikipedia.org/wiki/Light-emitting_diode

Figure 5: Bulb Replacement



Skeet, Muriel and David Fear. "Shadowless Theatre Lamps." Care and Safe Use of Medical Equipment. VSO Books, 1995, p. 118-125.

Figure 6: WHO Specification: Operating Light

MEDICAL DEVICE SPECIFICATION *(Including information on the following where relevant/appropriate, but not limited to)*		
i	Version No.	1
ii	Date of initial version	6/13/12
iii	Date of last modification	7/4/14
iv	Date of publication	
v	Completed / submitted by	WHO working group
NAME, CATEGORY AND CODING		
1	*WHO Category / Code*	(under development)
2	Generic name	Operating light
3	Specific type or variation (optional)	fixed
4	GMDN name	Operating light
5	GMDN code	12282
6	GMDN category	04 Electro mechanical medical devices
7	UMDNS name	Lights, Surgical
8	UMDNS code	12-282
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Lamp/light for medical use; Lamp, operating-room; Lamp, surgical; Lamp, surgical, incandescent; Light, surgical, ceiling-mounted; Light, surgical, connector; Light, surgical, instrument; Operation light; Operating shadowless light; OR light; Surgical lamp
11	Alternative code/s (optional)	MS 34634; S 39345; S 32248; S 39385; S 32244; S 32243; S 32238; S 36539; S 34635; S 32216; S 32326
12	Keywords (optional)	operating theater, operating room, overhead, theatre, theater, lamp
13	GMDN/UMDNS definition (optional)	A device designed to provide a specialized source of light for illumination of a site of medical intervention. It provides a high intensity, high colour rendering field of light that minimizes shadows and the emission of heat. It typically consists of an individual light head with more than one light source which may include halogen bulbs or light-emitting diodes (LEDs), reflectors, mirrors and a mechanism to adjust the focus. This device is usually mounted to the ceiling or wall of an operating room (OR) and the mount may be included. It can be part of an OR light system comprising more than one light head.
PURPOSE OF USE		
14	Clinical or other purpose	Designed to provide a specialized source of light for illumination of a site of medical intervention.
15	Level of use (if relevant)	district hospital, provincial hospital, specialized hospital
16	Clinical department/ward(if relevant)	operating room, orthopaedics, emergency room
17	Overview of functional requirements	Provides clear and cool light to operating area. Minimizes shadows and distortion of colour. Mounted on wall or ceiling of operating theatre. Single head must be easily moved by operator to direct light to required area.
TECHNICAL CHARACTERISTICS		
18	Detailed requirements	Colour temperature to be between 3,000 and 5,000 K. Maximum illumination level at 1m distance to be at least 150,000 lux. Minimum bulb life required 1,000 hours (incandescent type) or 20,000 hrs (LED type). Field diameter required >=20cm (at 1 meter distance from the light source), field depth required>= 50cm. Focal length required>= 65 cm. Heat to light ratio to be ≤ 6 mW/m2.lx. Vertical height adjustment greater than 0.8 m range and rotational radius greater than 1.5 m. Brightness control to allow full adjustment from zero to maximum illumination. Illumination backup to be provided through, e.g. multiple bulb use or spare bulb auto-activation, if a bulb fails (safety system of an additional bulb in each head with automatic switch in case of first bulb failure) Bulb lamp tension no greater than 24V. 24) For xenon lamp infrared filtration of at least 90% of the emitted power. 25) Color Rendering index of the illumination at least 92%. 26) Manual mobilization of each lamp through removable autoclave sterilizable handler.
19	Displayed parameters	

WHO. "Operating Light." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

20	User adjustable settings	
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components(if relevant)	*Case is to be hard and splashproof. *Exposed surface characteristics: a) free of sharp edges and washable; b) resistant to corrosion, water, detergent soap, 70% ethylic alcohol solution with or without nitrite and to the hypochlorite of sodium. *Handle for movement must be easy to grasp and clean. *Light must remain steady on position once moved. *Layout and heat production must not interfere with laminar air flow system.
22	Mobility, portability(if relevant	*Allowed movements and ranges: a) arm vertical displacement of at least 75cm; b) horizontal independent rotation of each head of at least 340°; c) independent inclination of each head of at least 90º. Movement must be easily achieved by operator of height 1.5 m.
23	Raw Materials(if relevant)	
38	User care(if relevant)	Unit layout to enable easy cleaning and sterilization of all surfaces.
WARRANTY AND MAINTENANCE		
39	Warranty	
40	Maintenance tasks	
41	Type of service contract	
42	Spare parts availability post-warranty	
43	Software / Hardware upgrade availability	
DOCUMENTATION		
44	Documentation requirements	Advanced maintenance tasks required shall be documented User, technical and maintenance manuals to be supplied in ********** language. List to be provided of equipment and procedures required for local calibration and routine maintenance, List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. Contact details of manufacturer, supplier and local service agent to be provided
DECOMMISSIONING		
45	Estimated Life Span	10 years
SAFETY AND STANDARDS		
46	Risk Classification	Class A (GHTF Rule 4);Class II (USA); Class I (EU, Japan, Canada and Australia)
47	Regulatory Approval / Certification	Must be FDA, CE or UL approved product.
48	International standards	ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU) ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
49	Reginal / Local Standards	
50	Regulations	**US regulations** 21 CFR part 820 21 CFR section 878.4580 Light, surgical, ceiling-mounted **JP regulations** MHLW Ordinance No.169 12282000 Surgical light

Figure 7: WHO Specification: Examination Light

MEDICAL DEVICE SPECIFICATION *(Including information on the following where relevant/appropriate, but not limited to)*		
i	Version No.	1
ii	Date of initial version	6/13/12
iii	Date of last modification	6/18/14
iv	Date of publication	
v	Completed / submitted by	WHO working group
NAME, CATEGORY AND CODING		
1	*WHO Category / Code*	(under development)
2	Generic name	**Examination light**
3	Specific type or variation (optional)	Halogen light, LED light
4	GMDN name	Fixed examination/treatment light
5	GMDN code	12276
6	GMDN category	04 Electro mechanical medical devices
7	UMDNS name	Lights, Examination
8	UMDNS code	12-276
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Lamp/light for medical use; Examination light; Light, examination, ceiling-mounted; Light, examination
11	Alternative code/s (optional)	MS 34634; S 34636; S 15866; S 45460
12	Keywords (optional)	operating theatre, operating room, portable, physician offices
13	GMDN/UMDNS definition (optional)	A device that provides light to illuminate the site of examination and/or treatment of the patient. It typically consists of one or more light bulb(s), which reflect the light via reflectors or mirrors depending upon the construction and will often be mounted on a pantograph counterbalance assembly that is attached to the mobile mount. It is usually used during examination or treatment in locations that do not have the required lighting installed. This device is designed to be easily moved from one location to another.
PURPOSE OF USE		
14	Clinical or other purpose	Provides light to illuminate the site of examination and/or treatment of the patient
15	Level of use (if relevant)	Health centre, district hospital, provincial hospital, specialized hospital, general hospital
16	Clinical department/ward(if relevant)	External consult, physician offices
17	Overview of functional requirements	1. Clear and cool light to operating area, with minimal shadows and distortion of colour. 2. Mounted on mobile base. 3. Single head must be easily moved by operator to direct light to required area. 4. Integral rechargeable battery for operation without mains electricity. 5. Halogen light or LED light.
TECHNICAL CHARACTERISTICS		
18	Detailed requirements	A star base with at least four anti-static castors wheels. Height adjustable stand or articulated (or flexible) arm with step-less vertical displacement. At least radial and angular movements of the lamp. Led or halogen light source. Maximum intensity not less than 20 000 lux / 1 m (+/-10%). Illumination control. Color Temperature not less than 3200 °K. Lifetime of halogen bulbs not less than 1500 hours; if LED light is provided not less than 20.000 hours. Integrated ON/OFF switch button.
19	Displayed parameters	N/A
20	User adjustable settings	N/A
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components(if relevant)	mobile base, single head, integral rechargeable battery, halogen or LED light.
22	Mobility, portability(if relevant)	Mobile

WHO. "Examination Light." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

23	Raw Materials(if relevant)	N/A
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Electrical source requirements: Amperage: _____; Voltage: _____. 1. Internal, replaceable, rechargeable battery allows operation for at least (*****) hours in the event of power failure. 2. Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Compliance with _____ electrical standards and regulations
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	N/A
26	Sterilization process for accessories (if relevant)	N/A
27	Consumables / reagents (if relevant)	N/A
28	Spare parts (if relevant)	Two sets of spare fuses (if replaceable fuses used). Ten sets of replacement bulbs (if incandescent).
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	N/A
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	N/A
33	Labelling (if relevant)	N/A
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	N/A
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements(if relevant)	N/A
36	Requirements for commissioning (if relevant)	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
38	User care(if relevant)	Unit layout to enable easy cleaning and sterilization of all surfaces
WARRANTY AND MAINTENANCE		
39	Warranty	2 years warranty
40	Maintenance tasks	Preventive/periodic maintenance requirements to be listed.
41	Type of service contract	None
42	Spare parts availability post-warranty	N/A
43	Software / Hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	1. User, technical and maintenance manuals to be supplied in English language. 2. Certificate of calibration and inspection to be provided. 3. List to be provided of equipment and procedures required for local calibration and routine maintenance. 4. List to be provided of important spares and accessories, with their part numbers and cost. 5. Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		

45	Estimated Life Span	10 years
SAFETY AND STANDARDS		
46	Risk Classification	Class A (GHTF Rule 4); Class I (USA, EU, Japan, Canada and Australia)
47	Regulatory Approval / Certification	FDA approval (USA); CE mark (EU)
48	International standards	ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU) ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
49	Reginal / Local Standards	N/A
50	Regulations	**US regulations** 21 CFR part 820 21 CFR section 880.6320 device, medical examination, ac powered **EU regulations** Council Directive 93/42/EEC of 14 June 1993 concerning medical devices Directive 93/68/EEC (CE Marking) Directive 98/79/EC Directive 2001/104/EC Directive 2007/47/EC **Japan regulations** MHLW Ordinance No.16912276000 Examination light

WHO. "Examination Light." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

3. Lamps and Lights Preventative Maintenance

Featured in this Section:

Cooper, Justin and Alex Dahinten for EWH. “Operating Room Light Preventative Maintenance.” From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

Operating Room Light Preventative Maintenance

EQUIPMENT

OR Light Preventative Maintenance

***Preventative* Maintenance:**

- Checking mechanical functionality (grease, tightening, etc.),
  - Check supporting framework for mobility
  - If framework is high resistive to movement, grease resistive parts and/or loosen braking screws
  - If framework moves too easily (does not stay in place after adjustment), tighten braking screws
- Cleaning bulb housings
  - Clean the bulb housings periodically so lengthen bulb life and improve light quality
  - Do not touch IR filters with bare hands
  - Fingerprints left on bulbs/filters will cause overheating and could damage lamp
- Keep any bulbs that could be viable replacements available
  - Salvage functional light bulbs from non-functional OR lamps and keep for future use as replacements in other lamps
  - Keep any bulbs that are viable replacements for those in lamp to use as replacements when needed

Cooper, Justin and Alex Dahinten for EWH. "Operating Room Light Preventative Maintenance." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

Lamp Preventative Maintenance Table

User Care of Medical Equipment – First line maintenance for end users

User Care Checklist – Lamps

Daily	
Cleaning	✓ Wipe dust off exterior and cover equipment after checks
Visual checks	✓ Check all fittings and accessories are mounted correctly ✓ Check there are no cracks in glass / covers or liquid spillages
Function checks	✓ If in use that day, run a brief function check before clinic

Weekly	
Cleaning	✓ Unplug, clean outside with damp cloth and dry off ✓ Clean any filters, covers and battery compartment ✓ Remove dirt from wheels/any moving part
Visual checks	✓ Check all screws and parts are fitted tightly ✓ Check mains plug screws are tight ✓ Check mains cable has no bare wire and is not damaged
Function checks	✓ Check all switches operate correctly ✓ Remove or charge batteries if out of use

Every six months
Biomedical Technician check required

4. Troubleshooting and Repair of Lamps and Lights

Featured in this Section:

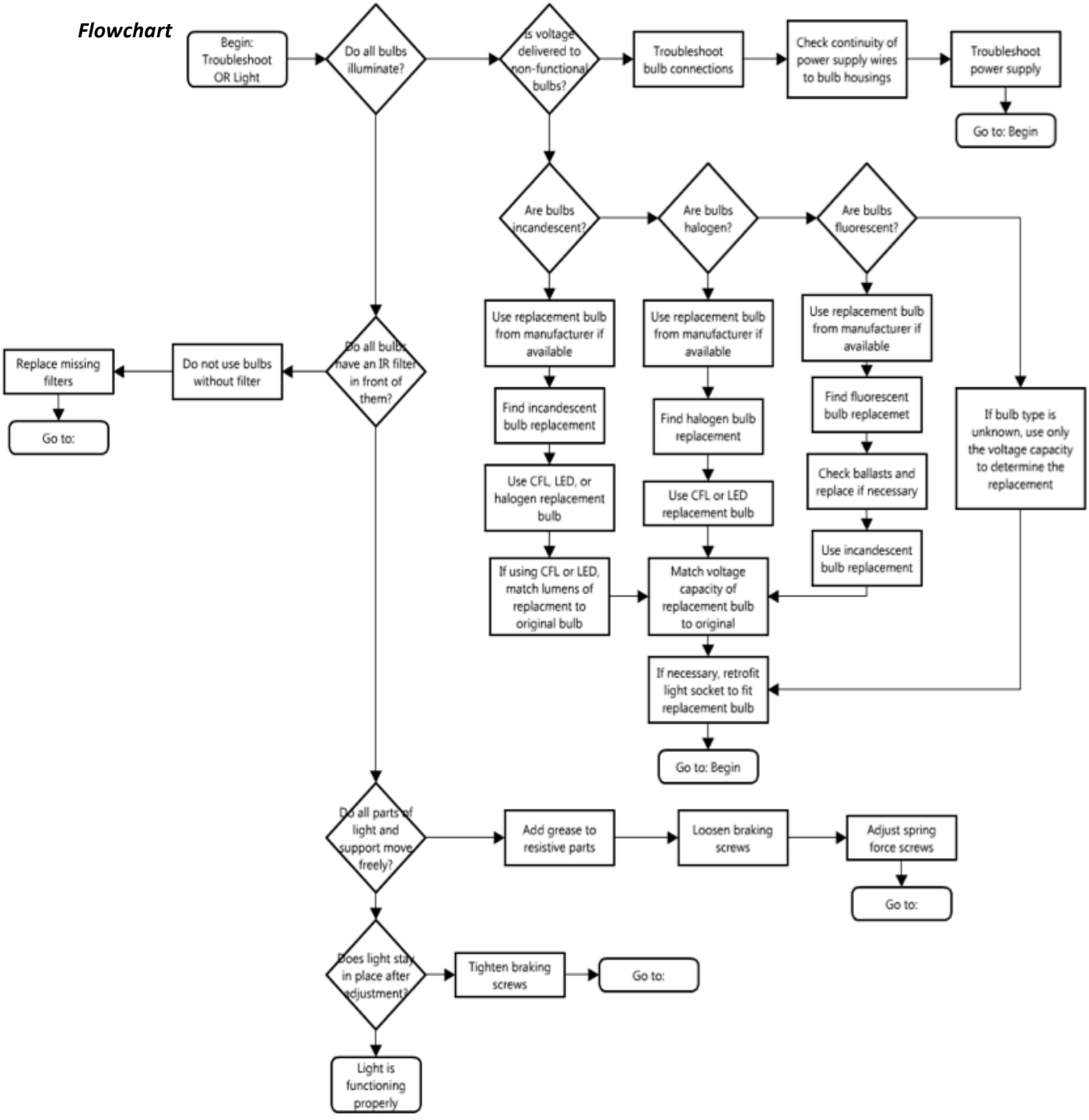
Cooper, Justin and Alex Dahinten for EWH. “Operating Room Light Troubleshooting Flowchart From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

Operating Room Light Troubleshooting Flowchart

OR LIGHT

Flowchart



Cooper, Justin and Alex Dahinten for EWH. "Operating Room Light Troubleshooting Flowchart." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

Description

#	Text box	Explanation or Comment
1	Begin: Troubleshoot OR Light	Start the diagnostic process for a work order on an OR Light.
2	Do all bulbs illuminate?	Provide the light with power and observe whether or not all of the bulbs produce light.
3	Is voltage delivered to non-functional bulbs?	If some of the bulbs do not illuminate, it could be due to issues with the bulb or the power supply. Use a multimeter to check that appropriate voltage is being delivered to the bulb housings. See BTA skills on Electrical Lighting/Indicators.
4	Troubleshoot bulb connections	If bulbs do not illuminate and are not receiving power, then there may be something wrong with the connections from the bulb housing to the bulb itself. Inspect the housing, clean any residue on connections and mend poor connections.
5	Check continuity of power supply wires to bulb housings	Ensure that the bulb housings are connected to the power supply. Use a multimeter to check the continuity of the wires running from the power supply to the bulbs.
6	Troubleshoot power supply	If the device is connected to power but does not turn on, there is a problem with the power supply. This could be a problem with the wiring or connections within the device. See BTA skills on Power Supply.
7	Are bulbs incandescent?	Incandescent light bulbs use a tungsten filament encased inside a glass housing.
8	Are bulbs halogen?	Halogen bulbs have a tungsten filament encased inside a quartz housing. The housing is much closer to the filament than in incandescent light bulbs.
9	Are bulbs fluorescent?	Fluorescent bulbs have a sealed glass tube filled with mercury and an inert gas.
10	If bulb type is unknown, use only the voltage capacity to determine the replacement	Reference BTA skills: Unit: Lighting/Indicators, Skill: Fixtures.
11	Use replacement bulb from manufacturer if available	Acquire the bulb designed for the OR lamp unit by the same manufacturer as the unit. Use this replacement bulb to replace any

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		broken bulbs in the lamp.
12	Find incandescent bulb replacement	Match the voltage capacity and wattage of replacement bulb to original.
13	Use CFL, LED, or halogen replacement bulb	If a CFL or LED bulb can be found that matches the voltage of the original incandescent bulb, then it may be used to replace the original bulb.
14	If using CFL or LED, match lumens of replacement to original bulb	If using a CFL or LED as a replacement, ensure that the lumens value of the replacement bulb matches that of the original.
15	Find halogen bulb replacement	Match the voltage capacity and wattage of replacement bulb to original.
16	Use CFL or LED replacement bulb	If a CFL or LED bulb can be found that matches the voltage of the original incandescent bulb, then it may be used to replace the original bulb.
17	Check ballasts and replace if necessary	Reference instruction document.
18	Find fluorescent bulb replacement	Match the voltage capacity and wattage of replacement bulb to original.
19	Check ballasts and replace if necessary	Reference instruction document.
20	Use incandescent bulb replacement	If an incandescent bulb can be found that matches the voltage of the original incandescent bulb, then it may be used to replace the original bulb.
21	Match voltage capacity of replacement bulb to original	If the bulb type of the original is unknown, then the voltage capacity alone may be used to find a replacement. Match this value of the replacement bulb to that of the original.
22	If necessary retrofit light socket to fit replacement bulb	Reference BTA skills: Unit: Lighting/Indicators, Skill: Fixtures.
23	Go to: Begin	Go back to step 1 to restart the troubleshooting process.
24	Do all bulb have an IR filter in front of them?	Check that all of the functional bulbs have infrared filters between the bulb and the operating field. This filter usually looks like a plastic sheet

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		sitting in front of the bulb in its housing.
25	Do not use bulbs without filter	DO NOT use the lamp if any illuminating bulbs do not have a filter. This filter is necessary to ensure the safety of patients.
26	Replace missing filters	Insert infrared filters wherever missing. These filters can be taken from bulb housings containing non-functional bulbs or from other OR lamp units. DO NOT handle filters with bare hands.
27	Go to:	
28	Do all parts of light and support move freely?	Manipulate the lamp to ensure that all moving parts can be easily adjusted.
29	Add grease to resistive parts	If any moving parts of the lamp resist adjustment, lubricate these parts using grease or oil.
30	Loosen braking screws	Locate the braking screws on the lamp unit. Loosen these screws to allow for more fluid movement.
31	Adjust spring force screws	Locate and adjust the tightness of spring force screws on the lamp unit to change the amount of tension in the lamp supports.
32	Go to:	
33	Does light stay in place after adjustment?	Ensure that the lamp stays in place after it has been adjusted. Try several manipulations of the lamp and let lamp stand in each for a few minutes. Observe any deviations from the original adjustment.
34	Tighten braking screws	If lamp moves after adjustment, tighten the braking screws to prevent this movement.
35	Go to:	
36	Light is functioning properly	

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Lamps Troubleshooting Table

Troubleshooting – Lamps

	Fault	Possible Cause	Solution
1.	No light or 'power on' visible	No power at mains socket	Check power switch is on. Replace fuse with correct rating of voltage and current if blown. Check mains power is present at socket using equipment known to be working. Contact electrician for rewiring if power not present.
		Dead battery	Charge or replace batteries
		Blown bulb	Replace bulb with correct voltage and wattage
		Battery leakage	Remove batteries (if accessible), clean battery terminals and replace with new battery
		Electrical cable fault	Try cable on another piece of equipment. Contact electrician for repair if required.
		Internal wiring fault	Refer to electrician
2.	Fuse / bulb keeps blowing	Fuse or bulb is wrong rating	Replace with correct rating
		Power supply or cable fault	Refer to electrician
3.	Light cannot be made bright enough	Dirt on lens or tube	Clean area with dry, clean cotton
		Poor power supply	Check power line or replace batteries
		Wrong bulb rating	Check bulb rating is correct
		Control malfunction	Refer to electrician
4.	Electrical shocks	Wiring fault	Refer to electrician

5. Resources for More Information about Lamps and Lights

Featured in this Section:

Skeet, Muriel and David Fear. “Shadowless Theatre Lamps.” *Care and Safe Use of Medical Equipment*. VSO Books, 1995, p. 118-125.

Cooper, Justin and Alex Dahinten for EWH. “Bililight Preventative Maintenance.” From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Cooper, Justin and Alex Dahinten for EWH. “Bililight Troubleshooting Flowchart.” From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Resources for More Information:

Internal Resources at library.ewh.org: For More Information about, please see these resources in the BMET Library!

1. Skeet, Muriel and David Fear. "Shadowless Theatre Lamps." *Care and Safe Use of Medical Equipment*. VSO Books, 1995, p. 118-125.

2. Cooper, Justin and Alex Dahinten for EWH. "Bililight Preventative Maintenance." From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

3. Cooper, Justin and Alex Dahinten for EWH. "Bililight Troubleshooting Flowchart." From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Lamps and Lights Bibliography:

Cooper, Justin and Alex Dahinten for EWH. “Operating Room Light Preventative Maintenance.” From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Cooper, Justin and Alex Dahinten for EWH. “Operating Room Light.” From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Malkin, Robert. “Theatre Lamps and Other Lights.” *Medical Instrumentation in the Developing World*. Engineering World Health, 2006.

Skeet, Muriel and David Fear. “Shadowless Theatre Lamps.” *Care and Safe Use of Medical Equipment*. VSO Books, 1995, p. 118-125.

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

WHO. “Operating Light.” From the publication: “WHO Technical Specifications for 61 Medical Devices. *WHO*. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

WHO. “Examination Light.” From the publication: “WHO Technical Specifications for 61 Medical Devices. *WHO*. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

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Wikipedia. “Light-emitting diode.” Wikipedia. Retrieved from: https://en.wikipedia.org/wiki/Light-emitting_diode

Wikipedia. “Surgical Lighting.” *Wikipedia.* Retrieved from: https://en.wikipedia.org/wiki/Surgical_lighting