

# Buyers' guide

## Operating theatre lighting

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CEP buyers' guides are intended to provide prospective purchasers of healthcare products on the UK market with general guidance on the technical, operational, and economic considerations to be taken into account in selecting the most appropriate product where a range of similar products exists. They do not include product-specific information, which is published separately via market reviews (which contain product specifications only) or evaluation reports (which contain additional technical and / or user evaluation data). Readers are encouraged to check CEP's web site for updates.

## Background

Effective and successful performance within the operating theatre is enhanced by having lighting which does not cause visual, operational and environmental difficulties such as glare, shadowing or visual stress. The operating theatre environment requires a combination of satisfactory ambient lighting and effective direct and indirect task lighting. The ability to adjust these lighting levels and change their characteristics will enable theatre staff to be more effective. Incorrect or poor lighting can impact on the patient, through poor performance and impaired effectiveness which may cause lengthened procedures through uncertainty or even errors. The wellbeing of the surgeon, the anaesthetist and surgical team may also be adversely affected, whilst the quality and safety of the working environment will be impaired by poor ambient lighting.

This buyers' guide has been developed after consultations with The Royal College of Surgeons of England who indicated that the issue of lighting within operating theatres was an area of concern. Surgical lighting is vitally important within the operating theatre to allow those working to have a clear vision of the surgical site and working area, and able to rely on the performance of the lighting equipment. In a survey of surgeon's preferences for changes to the operating theatre, lighting was commented on as one of the most important [1]. Lighting drift (movement of the pool of light away from the work area), and adjustment difficulties were cited as some of the most common complaints.

One study reports that 25% of surgical time is spent adjusting lights, although much of this time is in response to changing requirements as the operation develops [2]. It is estimated that 1 minute of operating time costs £15 [3]. This would mean that for an operation that lasts 60 minutes the time spent adjusting lights could cost the NHS £225. This presents the opportunity for significant efficiency gains through improvements in lighting adjustment timescales.

Many theatres traditionally used for open surgery are now also being employed for keyhole, laparoscopic, endoscopic or minimally invasive surgery (MIS) [4, 5]. Due to these new multifunctional requirements for various specific types of surgery, the

lighting within these theatres does not always provide an appropriate working environment for the surgical team [6].

## Scope

The buyers' guide will highlight the various characteristics and considerations that purchasers of theatre lighting should consider. Understanding of this information will inform purchasers when consulting with lighting manufacturers and suppliers.

The range of lights used within the operating theatre environment is extensive. This buyers' guide includes details of lights intended for use as the primary source of surgical lighting in the operating room. Examination lights, ambient lights, surgeons' head lights and fibre optic lamps are not included.

## Lighting selection

An important decision to be made when investing in theatre lights is whether each operating theatre will need identical lighting equipment or whether the lighting will need to be specific to surgical disciplines. If all lights are the same, this simplifies the selection process and will often reduce the installation and maintenance costs. Training and product familiarity will also improve efficiency. Uniform equipment across a number of theatres will also allow staff flexibility in moving between different operating theatres. However, deciding upon one manufacturer and one model may prove difficult, due to functional variations between individual surgeons and between surgical methods. A compromise can be made, whereby one manufacturer is chosen and a number of different models or modules selected according to individual requirements.

The lighting requirements between surgical specialities may be seen to be so diverse that the individual requirements for each speciality must be taken into account when selecting theatre lighting. Whilst this will ensure that suitable and effective lighting is available for a particular specialism, it will limit its use for a broader spectrum of applications. It is worth noting that installation and maintenance costs can often be higher due to the bespoke nature of each operating room, and a wider variety of training will be required to ensure staff are familiar with the full range of equipment in use across each operating theatre.

The variations in technical and design specifications across the range of manufacturer products, makes the selection of one specific model extremely difficult. Often, clinical preference will influence the features of lights required, based on the positive characteristics or limitations of existing lights. Manufacturers use technical measurements to convey illumination and other features; however, objective interpretation of these criteria by clinicians and procurement teams are often difficult.

In addition to theatre lighting, many companies also provide a package of equipment which can be used within the operating theatre. However, it is important that the specification and quality of individual pieces of equipment are fully detailed so that informed choices can be made. In some cases the final selection of equipment will be made by people with limited knowledge of the working environment and who possess only a basic understanding of the technical aspects of the lights. Therefore, to facilitate the correct choice, information from many sources must be gathered in order that the specified criteria for the final product meets the needs and requirements of those responsible for using and maintaining the equipment. Decisions are often made through gathering information from visiting trade exhibitions, experience and by consulting with colleagues from other hospitals. This buyers' guide, by highlighting key technical, operational and ergonomics considerations, can contribute to this purchasing decision to ensure the most appropriate lighting is selected.

Healthcare professionals involved in the decision making process include:

- **surgeons** – requirements for lighting can be categorised into more general features which will be applicable to all surgical procedures, and those features which are specific to individual clinical disciplines
- **nurses** – can offer a wide range of opinions on the purchasing of theatre lights as users *ie* those who adjust, set and manoeuvre lights and potentially those who, as the budget holder, will control, or have influence over, departmental budgets
- **biomedical engineers** – can be involved in the interpretation and evaluation of the quality of the design features of lighting equipment. It is important that the electrical, suspension and mounting of these systems are accurately assessed in order that they meet the requirements of those who use them and the environment in which they are situated
- **operating theatre committee** – capital investments, such as theatre lighting, will usually be made by a senior management board. The group will consider those factors included within the business case (including user preference) in order to reach a conclusion on light selection and associated costs
- **architects and lighting engineers** – the installation of any new lighting system will involve major revisions to the theatre structure and fabric of the building. The lights will also need to operate in conjunction with other equipment. Therefore, it is important that specialists are consulted in order that the lighting equipment can be safely integrated into the environment and used effectively. Lighting experts will also be able to assist in the coordination of the differing requirements of the general room lighting and any specific task lighting.

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There are three key areas in which decisions and priorities should be made when determining a suitable operating theatre light. These are:

- **adjustability** - the design of the lighting unit and how it can adapt to meet individual requirements
- **brightness** - the amount of light delivered by a source in order to illuminate a specific surgical area
- **control** - selection of a good design and an appropriate light source will help the system integrate into the operating theatre environment. However, flexibility and adjustability in the lighting system (amount of light or spread of light for example) will accommodate a wider range of tasks and activities.

Each of these elements will have an influence on the purchasing decisions for operating theatre lighting. The design of the unit, lighting specification and theatre environment are described in the *Technical* and *Operational considerations* chapters of this guide.

## Medical environment

Lighting in the hospital environment will vary from the very simple bedside lamps to operating theatre lighting units. The quality of operating theatre lighting is defined by a combination of the light's illumination, shadow control and colour rendition and temperature. The light beam characteristics, pattern and colour, and its luminance, are of major importance, particularly in areas of prolonged visual concentration. Glare from over lighting a surface may be just as impeding as under-lit conditions. In addition the environment in which the light is situated will also impact on its performance, and especially the levels of glare that may be generated. A balance between luminance and glare is vital in order to clearly identify different shapes, sizes and texture of three dimensional structures. The various lighting technologies that are used provide different levels of rendition of colour which will also influence the appearance of biological tissue.

The design standard EN 12464 provides guidance on the different types of lighting levels available within the medical environment [7]. In order to gain an appreciation as to the levels of lighting found within the hospital environment a summary of lighting levels and colour rendition are provided in table 1.

**Table 1. Recommended levels of medical lighting (adapted from EN 12464 [7])**

Hospital environment	Lighting specification	Illuminance (lux) <sup>1</sup>	Colour rendition (Ra) <sup>1</sup>
<b>Reception</b> Waiting rooms/ Day rooms	Relaxing	200	80
<b>Corridors</b> Day Night	Transportation areas	200 50	80 80
<b>Offices (clinical)</b> General Examination	Multipurpose use	300 1000	80 90
<b>Examination rooms</b> General Examination	Visual inspections	500 1000	90 90
<b>Patient rooms &amp; wards</b> General Reading Simple examinations Examinations/treatment Night/observation Bathrooms and toilets	Multi task	100 300 300 1000 5 200	80 80 80 90 80 80

<sup>1</sup> See table 2 for explanation of technical terms

Hospital environment	Lighting specification	Illuminance (lux) <sup>1</sup>	Colour rendition (Ra) <sup>1</sup>
<b>Intensive care</b>	Low level lighting		
General		400	90
Simple examinations		400	90
Examination/treatment		1000	90
Night watch		20	90
<b>Surgery &amp; out patients</b>	Specialised		
Pre-op/recovery		500	90
Operating theatre		1000	90
Operating cavity		40,000-160,000	90

<sup>1</sup> See table 2 for explanation of technical terms

## Design standards

A number of studies have indicated specifications which should be adhered to when selecting theatre lighting [8]; however, there is no detailed consensus as to criteria such as number of light heads, location and requirements for specific procedures [9]. The British Standard (BS) and International Electrotechnical Commission (IEC) standard 60601-2-41:2000 [10] sets out more specific requirements for the safety and performance of surgical lights. This standard establishes guidelines for the characteristics of a surgical and examination light, to secure safety for the patient, as well as to lower the risk of harm to a reasonable level when the light is used according to the manufacturer's instructions.

A description of the technical terms used when defining the design of the lamp head is given in table 2. The requirements outlined within BS 60601-2-41:2000 are identified in table 3.



**Table 2. Definitions of technical terminology**

Term	Description
lux (lx)	Unit for the amount of light at a given point. Measured using a luxmeter at that point. One lux equals one lumen per square metre.
Central illuminance ( $E_c$ )*	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. 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. An absence of cast shadow or coloured shadow is described as perfect shadow dilution.
Light field diameter ( $d_{10}$ )*	Diameter of light field around the light field centre, ending where the illuminance reaches 10% of $E_c$ The average of four different cross sections through the light field centre.
$d_{50}$	Diameter of light field around the light field centre, ending where the illuminance reaches 50% of $E_c$ . The average of four different cross sections through the light field centre.
Colour rendition index ( $R_a$ )*	The effect the light source has on the appearance of coloured objects (tissue for example). A measure is an average measure of the colour spectrum of the light and is made up from the R1 to R8 measurements of each visible colour. R9 is of particular importance as it represents the red colour saturation, important for distinguishing tissue colours.
Colour temperature (K)	Perceived coolness or warmth of light. Measured in kelvin.
Fail safe	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 illuminance (lux measurement), but not less than 40 000 lux. Within 40 seconds the light should be completely restored to the original output.

\* must be clearly marked near the lamp holder and on the lamps

The design standard also specifies the minimum technical specifications to which lights conforming to the standard must apply; these are presented in table 3.

**Table 3. Technical specification for surgical lights\***

Requirements	Surgical luminaire	
	Minor (treatment)	Major and system
Equipment classification	Class I, or Class II with connector to PA <sup>a</sup>	Class I, or Class II with connector to PA <sup>a</sup>
Fail safe	No	Yes
Anaesthesia (intended purpose)	Local/general	Local/general
Intended location	Operating room	Operating room

Requirements	Surgical luminaire	
	Minor (treatment)	Major and system
Sterile handle (standard)	Yes	Yes
Central illuminance ( $E_c$ )	40,000 -160,000 lx	40,000 -160,000 lx
Light field diameter ( $d_{10}$ )	Test value required <sup>b</sup>	Test value required <sup>b</sup>
Light distribution	Test value required <sup>c</sup>	Test value required <sup>c</sup>
Shadow dilution	Test value required <sup>d</sup>	Test value required <sup>d</sup>
Colour temperature ( $T_c$ )	3000 – 6700 kelvin	3000 – 6700 kelvin
Colour rendering index ( $R_a$ )	85 – 100	85 – 100
Maximum value for total irradiance $E_e$	Test value required <sup>e</sup>	Test value required <sup>e</sup>

<sup>a</sup> PA means potential equalisation conductor

<sup>b</sup> Light field diameter ( $d_{10}$ ) where the illuminance reaches 10% of Central illuminance  $E_c$

<sup>c</sup> Diameter  $d_{50}$  where the illuminance reaches 50% of central illuminance  $E_c$

<sup>d</sup> Percentage of the remaining illuminance when the beam is obstructed by one or two masks, with or without tube

<sup>e</sup> Information on the total irradiance  $E_e$  for the given central illuminance  $E_c$

\* table adapted from BS 60601-2-41:2000 [10]

## Lighting specifications

There are a range of technical specifications which are important to be aware of when making purchasing decisions. These are detailed in the following sections of this guide.

### Lamp technology

There are typically three basic types of lamp used within an operating theatre environment; these are incandescent, gas discharge and Light Emitting Diodes (LED). Incandescent and gas discharge lamps have traditionally been the main lamp type, utilising halogen, tungsten, xenon and quartz. However, other types of lighting are now emerging onto the market in several forms, particularly LEDs.

Incandescent lamps operate in a similar manner to traditional domestic light 'bulbs', a filament burns within a chamber filled with an inert gas. Variations can be made to the proportions and types of gases within the chamber and the filament to vary the characteristics of the light produced. It is important that these lamps have heat filters fitted to prevent burning to the patient. Gas discharge lamps are similar in operation to neon signs. The lamp does not contain a filament; rather an electric current is passed through a gas, which produces the light. LEDs are a recent technology to be incorporated into operating theatre lights. These lamps are small semiconductors which emit light when an electrical current is passed through them. LED units contain multiple lamps, which can either be all white, or a combination of white and

multicoloured lamps. Using a combination of colours allows the surgeon to adjust the lamps to produce the desired colour output.

## Lamp replacement

Unlike gas discharge and LEDs, incandescent lamps will fail with no prior warning; this makes it necessary to have a replacement lamp available immediately to allow the light to remain in use.

The use of multiple lamps within the light heads can reduce the impact of lamp failure. Although it is important that, if multiple light heads are used, the specification of each light head is such that in the event of the primary light head failure, the remaining lights provide an adequate light output and one that meets the levels recommended within the standards.

It is an important design feature which must offer a seamless transition of light in the event of lamp failure. Many theatre lights are designed with a reserve lamp which is automatically switched into use when the primary lamp fails. Just as it is important that the multiple light heads can continue to offer the required light in the event of lamp failure, so too the replacement lamp must provide as consistent a light as the lamp it is replacing. This fact is even more important if the replacement lamp is of a different technology eg halogen lamp replacing a gas discharge lamp.

Although LEDs and gas discharge lamps do not suffer from immediate burn out, the light does deteriorate over time. Regular inspections are required to ensure that the lamp is still producing the desired light quality. Although only three lamp types have been highlighted, many variations exist within each technology. The advantages and disadvantages of the three basic lamp types are summarised in table 4.

**Table 4. Summary of lamp differences**

Lamp type	Method of operation	End of life	Advantages/disadvantages
Incandescent	Gas filled chamber & burning filament	Burn out-no warning	✓ Excellent colour rendition ✗ Large amount of heat produced
Gas discharge	Electrical current passes through gas	Dims over time	✓ More light emitted than incandescent ✗ More expensive than incandescent
LED	Semiconductor	Dims over time	✓ Do not generate heat ✓ Fine adjustments to light ✗ Small range of light emissions

## Colour rendering ( $R_a$ & $R_9$ )

The colour rendering index (CRI) is denoted by the term  $R_a$ . This is a measure of the quality of light; natural daylight has a CRI value of 100. The closer an operating theatre light CRI value is to 100, the better its ability to render true colours to the human eye. The CRI value is calculated using a test devised by the International Commission on Illumination (CIE) [11] and involves illuminating eight standardised colour samples and measuring their colour relative to the reference source. The average change in those eight colour samples is reported as  $R_a$  or CRI.

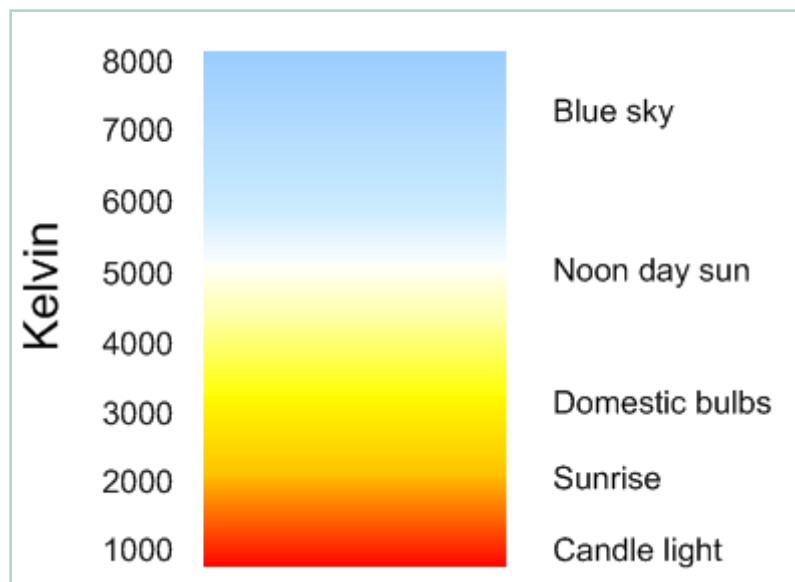
Unfortunately, the CRI does not include deep red within the calculation, an important aspect when viewing human tissue. Therefore, in addition to the eight colour samples used to calculate the CRI value, it is also important to appreciate how well the light renders a saturated deep red colour ( $R_9$ ). Values above 90 allow the surgeon to recognise details better in the area of the wound and to distinguish between tissue colours and arterial/venous blood. There needs to be sufficient light, but not enough to impair the visual performance or increase visual fatigue during longer procedures. Although the British standard states that operating theatre lights should be between 85 and 100, most lights have a value of approximately 95. Measurements should be taken when the lights are at their equilibrium operating temperature in a room at 21°C, as colour rendering can change with temperature.

Some LED designs will not produce adequate colour rendition to be useful as an operating light and it is essential that users take note of the colour rendition of LED lights, particularly the  $R_9$  value as some products may only contain 3% of the red content of natural daylight compared with the 90% plus which can be found in a good quality product.

## Colour temperature ( $T_c$ )

As an object is heated, the emission spectrum alters. Warmer colours (yellow-red) appear at lower temperatures of 1000 to 3000 kelvin, whereas at higher temperatures, of 5000 kelvin and above, cooler colours (green-blue) are seen, (figure 1). Some LEDs permit the ability to adjust colour temperature, which allows a surgical team to manipulate the light characteristics and hence facilitate tissue differentiation, based on factors such as the type and depth of the surgery, blood flow and a surgeon's preference. The correct combination of temperature and rendition enables the surgeon to distinguish between tissue discolouration.

Figure 1. Colour temperature guide



## Central illuminance ( $E_c$ )

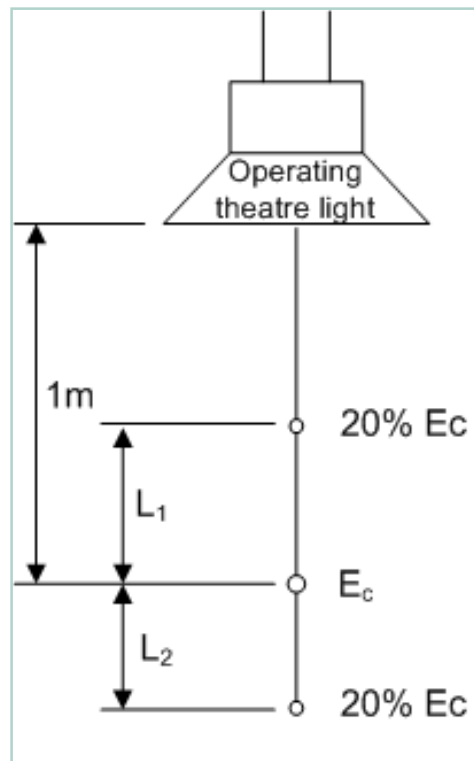
Central illuminance is the value at a distance of one metre from the light emitting surface, in the light field centre which is the point in the light field (lighted area), where illuminance reaches a maximum value. It is the reference point for most measurements, see figure 2, and is measured in lumens per square metre, a unit also known as lux. As with measuring colour rendition, measurements of illuminance should be made with the lamps at their equilibrium operating temperature in a room at 21°C. This is of particular importance when measuring LED lamps, as they will initially be very bright, but illuminance will be reduced as they warm up.

Measurements should be taken when the light is set at its smallest field size and with the colour set to the optimum colour rendition ( $R_a$ ) setting. For good performance it is important that the light is capable of achieving both a high illuminance and good colour rendition simultaneously.

## Depth of illumination

Often manufacturers will also indicate the depth of illumination; this is the distance under the light emitting area where the illumination reaches 20% of the central illuminance (which is the illuminance at a distance of one metre from the lamp). Two figures are cited, L1 above the central illuminance, and L2 below it. Both are expressed in millimetres, and are shown in figure 2.

Figure 2. Depth of illumination\*

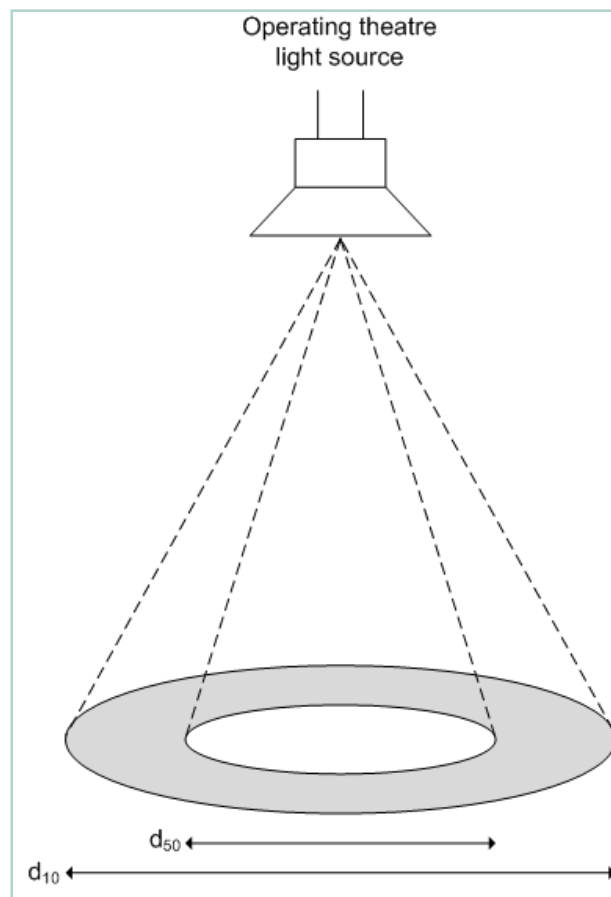


\* diagram reproduced from BS 60601-2-41:2000 [10]

## Light field diameter ( $d_{10}$ and $d_{50}$ )

It is important that, in a theatre where a range of surgical procedures are to be performed, the lighting technology has the ability to adjust to a wide range of light fields. Figure 3 identifies the light field values  $d_{10}$  and  $d_{50}$  as specified within IEC 60601-2-41 standard. These values indicate the diameter where the illuminance reaches 10% and 50% of the central illuminance respectively. It is important that any measurements given for field diameter refer to the standard otherwise they do not have any reference basis and are meaningless. There will be two sets of field diameter measurements for lights that have adjustable field size; one with the lights set to the smallest field size, and another with them set to the largest field size.

Figure 3. Light field diameter



The uniformity ratio between the  $d_{10}$  and  $d_{50}$  measurements can provide an indication as to the drop off of light away from the centre of the field. It is expressed as a simple ratio indicating the relative amount of light at the two measured points. A ratio of 1 will indicate that both areas have the same amount of light which suggests a more uniform performance.

## Considerations of lighting design

The lighting technical specifications outlined in the design standards impacts on the operation of the lights, both in terms of the light source, but also the design of the lighting unit and the interaction of the lights with features of the theatre environment.

Operating theatre lights are specified as class 1 products within the medical device classification system. This indicates that they are not being used directly on the human body, therefore do not have to be sterile. However, the lights should still comply with a number of regulations. Several of the details of BS EN 60601-2-41 have been indicated within the technical chapter of this guide, however, due to additional equipment included on many of the lighting units available, there a number of other standards which may be appropriate for operating theatre lighting. These are shown in table 5. Lighting must also comply with any relevant legislation for the market in which it is to be sold.

**Table 5: Associated European standards for theatre lighting**

International standard	Title
EN 60601-1	General requirements for safety
EN 60601-1-2	Electromagnetic compatibility - requirements and tests
EN 60601-2-41	Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
En 60601-1-8	Alarm systems
EN 60601-2-50	Photo therapy

The key operational considerations which should be addressed when determining the most appropriate light are presented below.

## Design variations

In addition to the differences in light source, there are many variations in the design of the equipment. Operating theatre lights are designed in single and multiple light heads which can be fixed in different ways within the operating theatre, for instance wall, ceiling, track mounted or in a floor standing version with a mobile base. Major operating lights should always be supplied as a “main” and “satellite” pair, as their use in combination is the major tool in reducing shadow from the surgical team.

Single lamps, used in isolation may not provide the required light output desired for a surgical procedure however, when used in conjunction with other light heads, offer the flexibility to adapt to a wide range of procedures. Therefore, when interpreting technical specifications, it is important to examine the light head configurations in addition to the individual output from each lamp. It is also important to examine other



features of the light, for example heat production. Heat production from individual lamps may be within acceptable limits however, if several lamps and satellites are used, the accumulated effect may exceed the desired level.

The systems can be provided in modular form and attached to a suspension arm for flexibility or pendant form which can also be moved in a variety of positions. These often make demands on the built environment for stability and security. Additional satellite lamps can be attached to some models. Floor standing models can have integrated transformers or batteries. Surgical lights can be controlled manually and some may have dimmer switches but other methods of control are central/wall panels or controls. Many lighting systems now allow for other equipment such as cameras or monitors to be mounted on the arms or integrated into the light heads [12, 13]. All medical lights should have a non glass or ceramic 'anti-shatter screen' between the lamp and the patient. This prevents fluids from being splashed onto a hot lamp and protects the patient from showers of hot glass if the lamp bursts. Lamp head surface temperatures of lights should avoid the possibility of burns on halogen lights.

## **Radiant energy**

Heat is produced from the light source in the form of infra-red which is felt by any person in the field of radiation. This can provide an uncomfortable working environment not only for the surgeon, but the whole surgical team as well as the patient. It may also hamper the operation by causing the wound tissue to dry out, especially during longer procedures. There is also the possibility of burns to staff, as well as patients, when the light source is directed in one place for a long period of time [12, 14, 15]. Radiant energy defines the radiation being directed onto the patient, including the visible light energy which is the largest component. Heat from the light can also affect other equipment including laminar airflow (ultra clean ventilation), and thermal buoyancy. The shape of some lamp heads or systems can affect the flow when moved. Some light sources, such as halogen lighting, are inefficient because of the amount of energy consumed which leads to heat. LED lights offer significant benefits in this respect, since they do not produce heat at the light source [12]. The life of the light source is also important, with LED lamps offering a service life far greater than incandescent light sources. This can impact greatly on the cost of the light over its service life.

To minimise damaging heat effects, surgical lights are designed to dissipate the heat at the light source away into the operating room. This is performed in a number of ways including the use of filters or lenses that pass visible light but not heat. Reflectors within the light head also reflect visible wavelengths of light toward the surgical site and transmit heat away from it. Heat may also be transferred by conduction, convection, radiation, or a combination of these. Reducing heat, particularly in the area of the surgeon's head, provides a more comfortable environment with the potential to improve surgical team performance and theatre efficiency, which would also improve patient outcomes. However, it is important that

all these technologies are maintained in good working order and in sound condition and that regular checks are made to ensure safe operation, as the consequences of failure to the patients can be severe [14].

## **Infection control**

It is important that lighting equipment, especially handles can be sterilised. Alternatively, disposable light handle covers should be available. Whilst a study of orthopaedic procedures failed to find any significant risk of bacterial inflection from light handles, the study did highlight that the light was adjusted between three and nine times during a procedure [16]. The ease of cleaning the lighting systems, including the sealed lights, should be investigated. Safe working practices as prescribed by the manufacturer should be validated against reasonable use and alarms and safety feedback (including service and maintenance information) should be checked.

The design of operating theatre lights should minimise cracks, crevices and visible fixings so as to provide clean, clear easy surfaces for cleaning. Surfaces for the build up of dust and debris should be minimised. The design should also take into account an easy, effective and safe cleaning regime without the requirement for aggressive chemicals, whilst providing sterile controls for movement and control of the light functions.

## **Audio visual equipment**

Many surgical lights are designed to be an integrated component of the whole operating theatre environment. It is not within the scope of this buyers' guide to provide details of cameras and other audio visual (AV) equipment however, some manufacturers offer video cameras mounted directly in the light head or on surrounding equipment. When considering integration of AV equipment, the quality and interaction of other theatre equipment must be taken into account during the procurement process. This is particularly important when considering the power source for additional equipment.

## **Cabling, power source and fail safe**

Trip hazards should be eliminated as far as possible by using ceiling or wall mounted lights, mobile lights should include cable stowage. Cabling of AV accessories such as cameras and monitors should be integrated into the operating theatre light arms and not attached externally where they are an infection control hazard and a trip hazard. There are requirements to ensure that operating lights are 'equi-potential' bonded. This ensures that the light is earthed to the same clean earth potential as other equipment in the room.

There is an increasing practice to mount equipment on operating theatre light accessory arms. The standards referred to in table 5 do not provide explicit

information as to permitted configurations. However, it may be good clinical practice not to allow mains powered or un-isolated devices to be mounted on the end of the operating theatre light accessory arm, as this defeats the good practice of using low voltage isolated lights in the operating field.

Major operating lights should always be installed with separate and parallel power supply systems to ensure that one lamp lead will continue to function in the event of the failure of any one component. Robust system designs should be fault tolerant of the first fault. It is never acceptable to run both lighting heads from a single power supply. All operating theatre lighting should always be supplied with an independent and dedicated three hour emergency power supply to ensure safe continuation of procedures in the event of a power failure.

BS EN 6061-241:2000 states that the light must include a backup possibility in case of interruption of the power supply. Light should be restored within 5 seconds with at least 50% of the previous illuminance, but not less than 40,000 lux. Within 40 seconds the light should be completely restored to the original value. It is important therefore, that the electrical infrastructure of the theatre has adequate electrical back up supplies to provide the requirements set out in the electrical regulations.

## **Warranty and maintenance**

It is important that practices and procedures are put in place to ensure safe operating of medical equipment. It is recommended that operating lights have 6 monthly safety inspections on all elements of the device. If the theatre light uses a battery back up system, this must also be checked. A three hour battery back-up is the UK minimum standard, systems should be checked as part of the service to make sure it is functioning correctly. A full discharge test should be performed to establish that the lights can still operate for at least three hours from a full charge (as specified in IEC 60364-7-710).

The IEC document also mentions what needs to be notified to the user - for example, the voltage and power consumption should be marked on or near the lamp holder as well as on the light head.

## **Ergonomics of light design**

### **Introduction**

Operating theatre lighting is a system which is very worthy of ergonomics scrutiny. Not only does it involve complex technology which needs to be operated and optimised but it also seeks to enhance, or at least limit the restrictions to, the human body at work. The operating theatre is a demanding workplace which requires high levels of vigilance for long periods of time, often in compromised physical positions or whilst applying force. The demands upon the user are great. Technology, such as

lighting, is used to assist the staff in ensuring the conditions are as beneficial as possible. However, often benefits are matched by associated drawbacks – for instance more light which helps vision of the work is normally accompanied by heat, which can cause attrition in the body. These factors need to be carefully balanced to ensure that the best performance is delivered.

Theatre lighting is a complex issue both from a technical, performance and systems perspective. Aspects of human vision account for significant amounts of scientific publications in human factors, whilst there is still healthy debate over precise mechanisms and optima for visual performance. Additionally, the increase in the age of the workforce (and population at large) has placed new emphasis on age related deterioration of sight as employers try to adapt to the needs of more elderly workers.

The unifying means of evaluating visual performance, and lighting as a function of that, is through user evaluation. Through investigation of the relationship between the user, the tasks they undertake and the environment in which they are conducted, it is possible to quantify the performance of lighting both empirically and subjectively. It is significant that once lighting systems are installed, their performance will be judged by the users not on a set of measurable criteria, but on their “adequacy”, which will be a function of the user’s preferences.

Failure to ensure that these preferences are met can lead to costly consequences – including reduced performance derived from visual strain, increased error rate from poor acuity or unsupported vigilance levels, reductions in safety from inferior lighting through inability to adjust the lights or additional capital expenditure if the lights are deemed unusable.

Whilst lighting performance can be described by the technical criteria associated with the equipment’s design, its effectiveness will be measured by the users. Accordingly, purchase of lighting on the basis of specification alone is an unreliable and possibly highly flawed approach. Inclusion of informed users early in the procurement process will help ensure that the final purchases made are fit for purpose and offer best value when all criteria are aggregated. These criteria need to be greater than just price and technical values.

It is also true that new and emergent technology offer potential benefits but also significant difficulties. Assessing the benefits of untested technology will be high in uncertainty and hence unappealing to risk-averse procurement professionals. Accordingly, step changes in performance may be severely hampered despite offering the potential for much greater rewards. Without the ability to experience system performance in situ, users are unlikely to be able to determine the likely benefits for themselves and so will demand systems that they know and trust.

This problem is evident in lighting procurement as entirely new lighting technologies become available. Users are familiar with incandescent lighting and newer systems, such as LEDs, are unknown, unexplored or lacking in first-hand experience. Consequently, even if procurers do engage with the users in the specification process they are unlikely to receive requests for such technologies. It is also harder to make the case for increased purchase costs if the real-world performance is unsubstantiated.

These factors combine to reinforce the need for greater user involvement, not only in the purchasing process but also in maintaining a high level of current knowledge such that they are informed contributors. Since these users are ultimately the individuals who will determine whether the system is satisfactory or not, largely on the basis of subjective performance, the relatively small cost involved in such involvement can be offset by the potential financial consequences of poor fit between the user and the equipment.

This section of the guide considers the ergonomics aspects of the specification of theatre lighting and is intended to illustrate the value in undertaking a user-centred approach and highlight key considerations that can be used to inform the procurement process.

## **Background**

It is the case that the human eye is best adapted for vision in natural light. However, many complex activities are now undertaken in controlled environments which require artificial lighting to be used. Consequently, much effort has been made to try to generate lighting systems which can emulate (or some claim improve upon) natural lighting. It is questionable whether these have been successful because of biological capabilities of humans rather than inferiority of technology.

The human eye works primarily on contrast to identify objects and to give them context. When contrast is lost, visual performance and hence human performance begins to fail. Contrast can be provided by colour or the amount of light being received by the eye having been reflected from visual targets. Lighting is therefore only part of the visual equation.

Specialist lighting, such as used to illuminate operation activities, is also used against a wider environment of ambient lighting which will play a part in the contrast levels available. Whilst the ambient lighting is not part of this guide, it cannot be completely removed from the performance of the lighting system. For instance, in very dim ambient conditions (which may reduce distractions for the surgeon) theatre staff may find glare from the operating lights an issue, whilst the surgeon will find that adapting from visual tasks at the site of the operation to those involving the surrounding area will take an appreciable amount of time.

Ideally natural lighting would be available for both ambient and task lighting, perhaps with 'enhanced' natural task lighting available. Stakeholders have reported a preference for natural lighting both for performance and wellbeing and have cited experience of theatres with windows which are highly regarded [17]. Unfortunately, such theatres are scarce and artificially generated "natural" light is not truly effective. Because of this, all lighting systems start out from a position of compromise and limitation and assessment should be undertaken from this perspective.

Other performance factors have also been shown to be directly associated with the effectiveness of theatre lighting [18]. These include:

- eye fatigue and headaches which are partly caused by bright lights and glare
- skin, surgical antiseptic preparations, bloody tissue and shiny instruments can all contribute to glare which leads to eye fatigue
- by decreasing the intensity of surgical lighting, good visualisation may still be obtained and glare reduced
- drying the surgical site before operating decreases glare from the skin and antiseptic solution
- goggles or glasses coated with an antiglare film may decrease eye fatigue
- brushed steel surgical instruments can be used instead of polished steel to reduce glare.

Essentially, in attempting to provide the greatest amount of illumination in order to compensate for the lack of natural light, a range of limitations are brought into effect. Additional technologies are then invoked to minimise these effects (such as water cooling for example) which increase the complexity of the system and the problems for the user. These issues can be explored through consideration of the nature of human vision and lighting.

General dissatisfaction with theatre lighting is reported with the following issues highlighted in an evaluation of the safety of operating theatres [13]:

- almost three quarters of surgeons have difficulties using their theatre lights as the arms of the ceiling stands collide or get entangled
- a third of surgeons find that one handed adjustment is not always possible
- two thirds of surgeons report that the operating field is not properly illuminated
- nearly half of all surgeons who can identify possible hazards from lighting for themselves or for patients have already experienced such a hazard more than once

- most of the hazards are due to insufficient illumination of the operation site, especially during dangerous situations – for example when unexpected bleeding occurs
- surgeons banging their heads against the lights resulting in black-outs, concussions or lacerations, is another frequently reported hazard.

## Human vision and lighting

The human visual system has a number of key functional capabilities which are used in undertaking visual tasks. These can be summarised as [19]:

- acuity – the ability to perceive detail of objects either moving or stationary (static or dynamic)
- contrast sensitivity – the ability to distinguish between an object and its background
- colour perception – the ability to distinguish between the standard colour set
- visual field – the ability to see the world as a continuous field, with peripheral vision of nearly 180 degrees
- accommodation – the ability to focus on objects at different distances
- adaptation – the ability to see when changing from high illumination to low illumination or vice versa.

The quality of lighting in the user's environment can impact on each of these processes and so has the capacity to impair visual performance in numerous ways, some of which may be less apparent when considering the technical specification of lighting.

For instance, both contrast sensitivity and acuity improve progressively as the illuminance is raised from low to high levels. The eye not only sees contrast and detail better in good light; moving objects can be seen with more certainty and so necessary action can be anticipated in good time. A given object is not only seen more quickly, but significant information is picked up more quickly from a complicated seeing task when the light is good than when it is poor [20].

The level of illumination required for detailed tasks has been suggested as lying between 1000 lux and 5000 lux, with a possible maximum of 9000 lux for older users in excess of 60 years of age [21]. Beyond this value, there may be little benefit to be gained from increasing levels of illumination [22-24]. Accordingly, very high levels of illumination from theatre lighting may not reveal additional detail to users, although it may help in compensating for other limitations in the theatre environment, such as shadowing or blocking of light.



Since surgeons are a group of workers who may be still active in theatre until the age of 65 years or more, it is advisable to take into account the needs of these more elderly users where they are more demanding than for younger colleagues. Accordingly, specification for theatre lights should be inclusive in this respect and require equipment that can meet the needs of the most vulnerable user.

## **Expert evaluation of key specification variables**

Expert advice was sought on key light specifications. The following sections identify the critical elements of each variable from the user's perspective. The intention is to inform the reader of the guide such that the values quoted by manufacturers can be placed in context and hence the overall benefit of the specification can be determined.

### **Type of light source**

The primary consideration from a user's point of view is the characteristics of the radiation produced by the lamp. The three categories needed to be considered are *spectral*, *spatial* and *temporal*.

#### *Spectral*

Ideally, any operating theatre light should only emit radiation within the visible portion of the electro-magnetic (e-m) spectrum, and the factors to consider within this range are considered below (rendition, temperature and luminance). Any radiation emitted outside of the visible portion of the e-m spectrum may bring with it disbenefits – in particular the primary issue for theatre lighting is the presence of infra-red radiation. The absorption of infra-red radiation will be felt as heat and this is highly undesirable in the theatre environment where surgeons and other staff may be working in close proximity to the radiation source for long periods of time without changes to their posture. In terms of specific technologies, traditional incandescent lamps produce a large amount of infra red, whereas neither gas discharge lamps nor light emitting diodes (LEDs) produce heat to the same extent. The heat from incandescent sources can be managed by technical means, but this might not be fully effective and may attract additional costs, either at source or in terms of consumables, maintenance or repair.

Infra-red absorption (and the subsequent generation of heat in the tissues) by the surgeon or other member of the theatre team may lead to reduced performance, poor vigilance, the need for increased breaks or stoppages, physical discomfort and possible physical damage. Secondary effects such as sweating will require management and may bring attendant issues of hygiene or management, and associated physiological demands such as dehydration will also play an increasing role. Ultimately, error rates in tasks may increase with the requirement for corrective actions, increased surgery times or even liability issues.



In summary, the less heat generated the better; either from infra-red radiation or from the technology which generates or manages the light source.

## *Temporal*

Incandescent lamps produce light by heating a filament and once working, there are no changes in illuminance over time. A gas discharge lamp however, will have a characteristic waveform and the flicker frequency will depend upon the mains frequency and the type of ballasts used. Generally, however, the flicker frequency of the lamps should be 100Hz or higher, which should not impact on the occupants of the theatre, unless there is some interaction with another time-varying light source. Ideally an audit of the theatre should be undertaken to identify possible conflicts with other light sources in this regard, as well as compatibility throughout the other key variables. Physical compatibility should also be fully evaluated.

The main problems arise with gas discharge lamps as they age, when lower-frequency flicker may become apparent. A solution is to simply replace the lamp. However, this may be at intervals below that which is anticipated due to complete failure, which will elevate the on-costs associated with this lighting type. Maintenance or theatre staff will also need to be educated in identifying when the light has reached a point of inferior performance even if still functioning, otherwise the light could remain in use when it is hazardous. Gas discharge lamps are expensive to replace and this should be factored in when considering this technology in light of the reduced periods between replacement. Procurers may wish to ask suppliers as to both the theoretical and the practical life of these lamps rather than merely work from the quoted lifecycle. If an LED is driven by a DC source, then flicker should not be a problem to the user from this type of lamp.

## *Spatial*

The spatial distribution (the 'spread' of the light) is dealt with in the section below headed "Depth of illumination and field diameter".

## **Colour Rendering Index ( $R_a$ )**

The performance of the medical team will be affected by how well they can differentiate between different colours, for example in correctly identifying venous and arterial blood or tissue suffused with such blood. The crucial factor here for the user is the ability of the light to reveal such differences to them.

The Colour Rendering Index ( $R_a$ ) is a measure which provides an indication of how close the light from a lamp comes to reproducing daylight (skylight) which is taken to be the standard, and is given a value of 100. In this sense, the higher the  $R_a$  value, the better the lamp.

However, in evaluating human performance, the assumption is made here that daylight is the ideal for differentiating between different colours and this may not always be the case. In the same way that a blue sky can be darkened by looking through a yellow filter, increasing the contrast between the sky and white clouds to make the clouds more apparent, appropriate variation in the spectral content of a light source can make specific features more obvious. This principle is used in an ophthalmoscope, in which a 'red-free' filter can be introduced to alter the appearance of the fundus.

Accordingly, it could be considered advantageous to have the ability to vary the spectral content of the light produced by the lamps, such that the optimum lighting can be selected in situ. This facility may reduce the need for multiple lights or even lights of considerable light output since the level of illumination is often increased in order to try to increase the contrast. Lower overall lighting levels, if they can be achieved whilst maintaining contrast, will result in less glare, less fatigue and less conflict between the ambient lighting activities and those undertaken in conjunction with the main theatre lights.

## **Deep red colour rendition ( $R_9$ )**

The value of  $R_a$  is produced by comparing the radiation emitted by a lamp with daylight at eight discrete wavelengths. The longer wavelengths, which humans sense as red, are particularly important for illuminating tissue, and so  $R_9$  is provided in the specifications in addition to that of  $R_a$ . The higher the value, the better the rendition of the saturated red colours in comparison to daylight. These values may be subject to the same limitations as for the  $R_a$  variable, so the capability to progressively include or exclude red enhancement would be useful.

## **Colour temperature**

The colour temperature (in kelvin) refers to the temperature to which a black body would have to be heated for it to provide the colour appearance of that lamp. The lower the colour temperature, the more "yellow" and "warm" a white light will appear; the higher the colour temperature the bluer and "cooler" it will appear.

Caution may need to be exercised when evaluating the cited temperature for some lighting technologies. If a black body is heated to a given colour it may continue to emit radiation at below that colour temperature as well, such that a white hot body emits radiation corresponding to all visible light wavelengths. This might be analogous to the light generated by incandescent light sources. Other technologies, however, such as LED's may not produce the full array of radiation implied by the colour temperature cited and consequently users may be unable to differentiate colours so effectively.

## Central illuminance

This unit relates to the amount of energy in the radiation, without reference to its spectral composition. As a general rule, everything else being equal, the more light the better. High light levels are required for surgery to produce optimum visual performance. However, it must be borne in mind that levels which are too high can produce damage, in particular to the eye. These levels are likely to be very high, however.

## Depth of illumination and field diameter

These are measures which relate to the spatial distribution of the illumination in all three directions from a point one metre below the lamp centre. The user requirements of the spatial distribution are likely to be highly dependent upon the particular procedures to be performed, but in essence it is likely that “bigger is better”. For most tasks it is recommended that the maximum illumination is provided at the point of maximum interest, and this recommendation holds for surgery. The relevance of these measures is in relationship to how much imprecision is allowable/acceptable in the positioning of the lamps. In general, the larger these numbers the greater tolerance there will be.

This variable is associated with the physical layout of the operating workstation and, to some degree, variables such as the anthropometry of the surgeon. A tall surgeon may require the lights to be further from the table in order to be able to achieve the head clearance required for satisfactory access. A shorter surgeon will require the lights to be lower. Both, however, are likely to require similar lighting performance so the lighting technology must adapt such that it can provide a similar quality of vision at either height (and at heights in between). This flexibility is highly desirable when theatres are used by different surgeons or where adjustments to the operating table height may occur during the procedure.

## Data collection

Because of the subjective nature of the evaluation of performance of lighting equipment and the development of new technologies in the area, user opinion is valuable in informing the purchasing process. In order to explore the user opinion, discussion groups were held with a selection of stakeholders. These included:

- surgeons
- Operating Department Practitioners (ODP)
- theatre nurses/perioperative practitioners
- procurement professionals
- manufacturers.

## Surgeons

Three discussion sessions were held with surgeons, one with an orthopaedic surgeon whilst undertaking orthopaedic knee surgery in theatre, one with a group of general surgeons and one with a group of urologists.

## Orthopaedic surgery

This surgery was conducted with a two light array featuring a main light unit and a satellite unit. The lights were conventional incandescent models with small LED enhancement and camera facility. The main observations are shown in table 6.

**Table 6. Orthopaedic surgery comments**

Group Orthopaedic Surgery
The performance of the main lighting array was satisfactory.
The ambient lighting was problematic since theatre staff could not readily identify the correct equipment required for surgery – sometimes using light from the main array to identify typed or imprinted information.
The surgeon did not feel qualified to talk about lighting technologies and had not explored the features of the light.
The lights were left unadjusted and in their original position for the duration of the operation after initial setting up.
Cleaning and hygiene were mentioned as potential problems.

## General surgery

A group of mixed experience surgeons were consulted with a semi structured discussion to highlight areas of concern and satisfaction. The key findings are shown in table 7.

**Table 7. General surgery comments**

Group General Surgery
Surgeons may have limited technical knowledge of lighting but are aware of poor lighting when they experienced it. Clarity of vision is lost and the eyes become uncomfortable. Surgeons admit that they get familiar with lighting in their current theatre and it takes time to get used to a new theatre. There is some resistance to change.
Generally surgeons are satisfied with theatre lighting. It is normally set up for them before the operations starts. Some prefer to then adjust them while others may just use them as they are set up.
Surgeons usually require light on a particular spot and may have to adjust the lighting (moving, defusing or focusing). They may adjust the light themselves or, more commonly, ask theatre staff to do this.
Lights are large, heavy and bulky to move. Some have a lot of flexibility and control but it sometimes takes one or two others to help move them. The surgeon may have to swing the lighting arm above their head which is awkward. An ODP may help but it is better to do it oneself to get the positioning right. Other equipment may be in the way of the lights so this has to be moved before the lights can be moved.
Ambient lighting generally tends not to be a problem for the surgeon and with laparoscopic surgery you need to have the lights down.

Group General Surgery
Surgeons may ask for a headlight (battery operated) or other task lighting which may take a few minutes to arrive; lights may also be attached to instruments.
Lighting is most problematic for areas of the body which are difficult to access – cavities, for example. Task lighting best addresses this since main lighting is always ineffective.
The surgeons tend to be most experienced with tungsten lights.
There is very little awareness of technology (in particular LED lights) or the benefits that new technologies may offer, such as colour enhancement or cool operation.
Glare is not a major problem in conventional surgery. However, glare is a significant issue with laparoscopic work when the theatre lights are turned off.
Surgeons are interested in the procurement of new lighting but it is hard to try a new installation properly. It would be useful to have demonstrations of good lighting.
None of the surgeons present had played a role in the procurement of lighting.

## *Urology*

The urologists were presented with a similar set of issues and responded with very similar opinions. Their main comments are shown in table 8.

**Table 8. Urology surgery comments**

Group Urology Surgery
Effective lighting is crucial for high precision surgery.
A headlamp is always needed for pelvic surgery close to the area of operation (the wound) but surgeons strive for the best operative lighting.
Any windows in the theatre are blacked out to facilitate screen-based surgery. However, this is detrimental to overall lighting.
The lighting systems are too heavy. There is a sterile handle in the middle so leverage cannot be enhanced by touching other parts of the lights. The lights can be swivelled but not always tilted. Reaching up while underneath them is awkward and the surgeon does not have the strength from that position. They may have to stop working whilst theatre staff assist in positioning lights, but even then it can be difficult.
The structure is also awkward, with lights on two arms from a single structure. They can clash when moving them around. Additional equipment mounted in the array can also cause conflicts.
There is interest in new technology but no awareness of its nature or capabilities.
Lighting demonstrations are essential but should be in the theatre environment in order to properly evaluate them.
None of the surgeons had been involved in the procurement process.

## *Operating Department Practitioners*

ODPs from a midlands hospital provided their perspective which broadly aligned with the surgeons. Their comments are shown in table 9.

**Table 9. Operating Department Practitioner comments**

Group
Operating Department Practitioners
Good lighting in the surgery is important and on a scale of one to ten they would rate current provision eight or nine.
Old surgery lights can be a problem. They may flicker and are taped up. Bits may fall off them. Maintenance is the main problem.
Lights are very heavy and compromised by only being able to touch the central handles.
Tall surgeons may hit their head on the lights when they are properly positioned for illumination.
Glare can be a problem when you look away from the lights to select equipment or refer to notes – you ‘see green’.
Typically, 4 adjustments may be made within an operation up to a maximum of around 10, so difficulty in adjusting can cause delays in surgery.
If a surgeon is irritated by the lights, it affects the working environment for all the theatre staff.
The most important factor in lighting is ease of moving and set up.
Ideally, ODPs would like to see the design of a new lighting system with very smooth surfaces than can be cleaned more easily and effectively.

## *Theatre nurses/perioperative practitioners*

A further group representing both theatre nurses and ODPs were consulted. These were more senior theatre staff, often theatre managers and their views were more strategic as seen in Table 10.

**Table 10. Theatre nurse and perioperative practitioner comments**

Group
Theatre nurses/perioperative practitioners
Surgeons tended to hold strong views but may not actually know what they want or what may be most suitable or effective.
Lights need to be trialled in the correct location.
Some lighting systems lack good depth of field and focusing.
Excessive heat from lighting may dry out tissue especially in neurosurgery.
One of their primary needs is the ability to change defective light sources with minimum down time. Historically, changes were made by theatre staff but these resources are now ordered in. Light sources are often not kept on the premises due to the costs involved and there may be a delay in getting replacements, which may take up to a week.
Lights can drift in their location during an operation and are difficult and heavy to set. Many practitioners are female and struggle to reach and then manoeuvre the lights because of the height in theatre and the smaller stature of the female form. The female staff also have less strength to lever lights into position.
Pendants can interfere and block each other. This is particularly the case if there is a third arm for a camera (plus additional array equipment).
Cameras integrated into lights are problematic and bring little benefit (if they are actually used at all). If cameras are needed they should be fixed.
The risk of contamination remains high due to difficulty in moving lights, parts and components falling from lights, inadequate provision of handles (or the use of handle covers) and cleaning effectiveness.
It is noted that the preferred lights have a more yellow tint rather than bright white. Excess brightness is disadvantageous, whilst depth of field and spread are of value.
Practitioners feel strongly that they should be closely involved in procurement, including

Group
<b>Theatre nurses/perioperative practitioners</b>
demonstrations and technical briefings with staff that use lights already. Trials can be readily organised if they are included in the process. They need to liaise with estates before procurement.
The important criteria from a strategic perspective are: low running costs, low maintenance, longer life, length of warranty, ease of use.
Practitioners feel strongly about the absence of natural light and believe that the wellbeing of staff is compromised by its absence. Whilst they get used to working in artificial lighting, 'piped' natural light and other adaptations should be considered.
Much lighting equipment in current use is up to 20 years old with poor diffusers which make them yellow. They lack the broad spectrum of light needed. Cases of long term working in deficient lighting (missing, defective, flickering etc.) are common.
The balance of ambient to surgical lighting is important eg to read the lettering on a prosthesis.
Task lighting is important but not normally considered.
Remote controls for lighting would greatly ease the problems with positioning.
Reflections on instruments and ancillary equipment can be problematic so the lighting should be bought in conjunction with the specification of these other items.
Some capital purchases are poorly specified since corrections can be made after delivery from a maintenance or improvement budget.

## *Procurement professionals*

Two groups of procurement professionals were consulted, representing Private Finance Initiative (PFI) and non-PFI institutions.

The PFI Hospital was of new construction and had recently gone through the process of specifying for theatre lighting. The observations from this process are shown in table 11.

**Table 11. PFI procurement comments**

Group
<b>PFI procurement</b>
The main issues with new lighting installations are physical and include problems with arms, cameras, pendants and light fixings.
The focus of the procurement should be on the evaluation process; identifying the suppliers, setting the evaluation criteria before asking for prices etc. A model can then be created which can be appropriately weighted, eg. 15% for sustainability, 10% for maintenance etc. An overall score could then be derived based on everyone's views.
Adapted lighting may not conform to CE marking - this needs to be taken into consideration.
Maintenance is a significant cost and getting lights fixed is also a real issue. These should be heavily factored in the selection process.
Light handles and other 'consumable' accessories need to be purchased in addition to lights. This can add significantly to the cost, but this can be identified through discussions with current users or loan demonstrations.
Near miss reports and perceived risks will be recorded and used as evidence to replace lights. These systems need to be understood at the time of specification for procurement since they may affect the longevity of the service life.
Representatives of the surgical teams sign off the specification.



Group PFI procurement
The specification to the estates contractor might be quite rudimentary and depend on the contractor's skill and experience to deliver suitable lighting.
Discrepancies in effectiveness could be managed after installation (subject to meeting the specification) which may be addressed under a separate budget.
Integrated theatres place new demands on lighting systems as additional equipment is added (eg touch screens); this can be missed from, or change the nature of, the specification. The specification needs to be holistic as well as forward scoping to accommodate changes, enhancements and improvements.
Future proofing is essential in providing best value for the NHS.
The built environment is impactful given the mass of the lighting equipment; modifications to the built environment to support lighting arrays are very costly. Compatibility with current architecture is an important consideration or writing in the modification costs to the specification.
Light handles are an issue – they need to be able to withstand an autoclave but since they are critical to an operation then during the periods when they are missing from the lights numerous additional handle sets will be needed. These can be very costly.

The non-PFI hospital appeared to work to a different set of criteria since they had recently moved the responsibility for lighting from estates to medical equipment purchasing. This hospital felt there were benefits from utilising other purchasing systems, as can be seen in table 12.

**Table 12. Non-PFI procurement comments**

Group Non PFI procurement
Recent migration of lighting from estates to medical equipment purchasing means a lack of technical knowledge.
Because of this (and other constraints) it makes NHS Supply Chain framework agreements attractive but this limits specification development.
Theatres will specify their needs; each is risk assessed and equipment is ordered.
Historically (through estates), surgeons and ODPs have been involved in the procurement process with an anaesthetist communicating with the surgeons.
The procurement process may take a year to complete during which time the technologies may change.
Early exclusion of some products is possible due to the lack of an early evaluation phase in the procurement process.
Users are involved but this might be late into the specification development.
Other staff from different theatres may add texture to evaluation from different experiences.

It is of interest that the PFI hospital provided a basic specification to the main building contractor who then fulfilled this by selecting the most appropriate lighting systems in their view. The non-PFI hospital was attracted to utilising NHS Supply Chain for the provision of lights, again to a restricted specification, for reasons of convenience and efficiency. Both routes placed additional distance between the end users and the equipment providers which could lead to a poor level of satisfaction. Additionally,



there would be some lack of clarity about the range of technologies available, their potential benefits for the users and the consequential financial implications if the supplier of the lights was removed from their ongoing use and maintenance.

## *Manufacturers*

One lighting manufacturer was consulted for an industry perspective. Their comments are summarised in table 13.

**Table 13. Manufacturer comments**

Group Manufacturers
European companies dominate the market sector so they understand the application well.
Despite offering extensive portfolios of lighting equipment, the vast majority of purchases are based on four or five standard products.
Demonstrations and loans are the key ways for them to be able to allow users to see the benefits that their technologies may offer, but these are not always available.
The technologies are poorly understood by buyers, which makes delivering meaningful performance data and comparative benchmarking difficult.

## **Questionnaire development**

A further data collection sweep was undertaken utilising an online, web-based, questionnaire intended to gather a restricted amount of data from a larger number of participants. The data was intended to clarify how users define “good” and “bad” lighting such that these characteristics could be built into the procurement specification.

A total of 21 organisations were contacted and asked to participate by circulating the link to the questionnaire to their members. These organisations are shown in table 14.

**Table 14. Organisations approached to disseminate the user questionnaire**

Group Perioperative practitioners
College of Operating Department Practitioners
Association for Perioperative Practice
Nursing Times
British Medical Association
Royal College of Nursing
Surgeons
Royal College of Surgeons - England
Royal College of Anaesthetists
Royal College of Surgeons - Edinburgh
Association of Surgeons of GB & Ireland

Additional specialists
UEMS Section of Surgery & European Board of Surgery
Society of Academic & Research Surgery
Vascular Society of GB & Ireland
British Association of Endocrine and Thyroid Surgeons
British Association of Day Surgery
Association of Surgeons in Primary Care
Association of Upper Gastrointestinal Surgeons
Association of Coloproctology of Great Britain and Ireland
Association for Cancer Surgery and the Association of Breast Surgery
British Association of Urological Surgeons
British Association of Plastic, Reconstructive and Aesthetic Surgeons
British Association of Aesthetic Plastic Surgeons

Of these 21 organisations, four groups volunteered to assist in the dissemination of the questionnaire and placed links or information on their websites, forums and mailing lists. These are shown in table 15. These groups represented an estimated total membership in excess of 30,000 individuals.

**Table 15. Organisations agreeing to disseminate the user questionnaire**

Group
Perioperative practitioners
Association for Perioperative Practice
Royal College of Nursing
Surgeons
Royal College of Surgeons - England
Additional specialists
British Association of Aesthetic Plastic Surgeons

Despite the wide exposure there was only a single response. Whilst this does not illicit any meaningful data from the questions, it does provide insight into the prioritisation of this issue about workers within the healthcare sector.

It is normal to find in questionnaire surveys that responses are dominated by those with a criticism to make or who are motivated by poor performance or quality. In this instance it would suggest that despite many individuals and groups identifying theatre lighting as problematic or worthy of investigation, virtually no one felt so strongly as to express those opinions.

This did reflect the views voiced at the discussion groups whereby individuals were generally content with the performance of their current lighting, were unaware of new technology alternatives and only identified greater participation in the procurement process as a major obstacle to satisfaction.

## Anthropometry

In order to provide guidance as to appropriate dimensions and adjustability of lighting systems, anthropometric data was collated for the smallest (5th percentile female) and largest (95th percentile male) user. The population chosen was identified as UK adults aged 18 to 65 years to represent the typical workforce. However, healthcare attracts a wide diversity of staff and these parameters may need to be extended to include particularly short or tall individuals or groups. This data is presented in table 16 (overhead reach) and table 17 (overall stature)

**Table 16. Physical capabilities of users: overhead reach**

Female		Male	
5 <sup>th</sup> Percentile	95 <sup>th</sup> Percentile	5 <sup>th</sup> Percentile	95 <sup>th</sup> Percentile
1848 mm	2105 mm	1998 mm	2303 mm

**Table 17. Physical capabilities of users: stature**

Female		Male	
5 <sup>th</sup> Percentile	95 <sup>th</sup> Percentile	5 <sup>th</sup> Percentile	95 <sup>th</sup> Percentile
1515 mm	1727 mm	1642 mm	1870 mm

## Usability of the lighting controls

More complex lighting systems need to be controlled by an interface which may be readily understood and utilised by any of the operating theatre staff. It may require prompt and accurate activation so should be intuitive and logical. If the system includes a remote control, which has been indicated as desirable by some users, then the controls on the remote control should copy those on the main lighting system.

Examination of prospective systems can be undertaken using established principles of usability, as highlighted in table 18 below. Evaluation of particular systems in light of these considerations will illustrate those that have better considered the end user and hence are more likely to be accepted by those users and who will make less errors in using the system.

**Table 18. The control system principles**

Principle	Description	Application
Visibility of the system status	The system should always keep users informed about what is going on, through appropriate feedback within reasonable time.	An LCD light to show the system is working correctly or a command has been entered.

Principle	Description	Application
Match between the system and the real world	The system should speak the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms. Follow real-world conventions, making information appear in a natural and logical order.	Use of pictograms or icons to show control functions, avoid jargon or technical terms.
Consistency, standards and stereotypes	Users should not have to wonder whether different words, situations, or actions mean the same thing. Follow platform conventions.	Up arrow to increase values, down to lower. Use of de facto standard e.g. lock symbol, red for off or stop, green for on.
Aesthetic and minimalist design	Dialogues should not contain information which is irrelevant or rarely needed. Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.	Some control systems have complex layouts and labelling which will impair the efficiency of the user. The device should have a dedicated layout for patients with restricted options and accessible language.
Help and documentation	Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation.	Provide a simple, booklet prompt card or label located on the device to give explanatory information about its use.
Perceivable information	The design must communicate necessary information effectively to the user, regardless of ambient conditions or the user's sensory abilities.	Written text should be no smaller than a 14 point, and readable in both low and bright ambient lighting conditions. Contrast between text and background should be high.
Low physical effort	The design must be usable efficiently and comfortably and with minimum fatigue.	Provide a design such that the user can press and operate all buttons comfortably with one hand, even if suffering from restricted dexterity.
Tolerance for error	The design must minimise hazards and the adverse consequences of accidental or unintended actions.	Ensure that the control system requires confirmation of commands to avoid unwanted errors.
Permit easy reversal of actions	This feature relieves anxiety, since the user knows that errors can be undone; it thus encourages exploration of unfamiliar options. The units of reversibility may be a single action, a data entry, or a complete group of actions.	Link related controls such as increase and decrease with adjoining buttons so that operators can easily reverse an adjustment action.

Principle	Description	Application
Conformity with user expectations	The control should be intuitive to use for new users and for more experienced users accessing new controls or commands.	The system control should be tested with inexperienced users to see if they operate the equipment quickly and easily without practice as might be required in a real context.

Novelty just for the sake of it or solely for the purpose of representing a manufacturer's brand, may compromise these good practice ideals. For this reason convention should be welcomed, particularly if surgeons and theatre staff are likely to be moving between different equipment on a routine basis. If this is not possible then selecting equipment with a unified interface design (for instance, identical models, or models from the same manufacturer) will restrict errors and increase usability.

In addition to the design principles there are also a range of broad considerations regarding the specific design elements of the control system. Whilst these are normally assessed by expert appraisal, it is possible to review the design of specific products with regard to their likely usability. Alternatively, suppliers can be asked to provide evidence as to their consideration of these matters so as to provide separate means of assessment. The main issues are outlined in table 19.

**Table 19. Main issues regarding design elements of the control system**

Design element	Application
<b>Design the control system to be intuitive</b>	<ul style="list-style-type: none"> <li>• Important functions should be mapped to dedicated buttons. Users often struggle with controls that require a switch between 'modes' to access features.</li> <li>• Buttons should be clearly distinguished from each other. Group related buttons using size, texture, shape and colour to make buttons stand out.</li> <li>• Avoid using logos and ambiguous icons on buttons. These are often too subtle and require a text label or some explanation to communicate their purpose.</li> </ul>
<b>Ensure the control system is accessible for the target users</b>	<ul style="list-style-type: none"> <li>• Ensure buttons are a good size and well spaced to allow easy access.</li> <li>• Users with large fingers, long finger nails or dexterity impairment often hit the wrong button.</li> <li>• Co-locate buttons that are often used in combinations. For example putting directional arrows together.</li> <li>• Make sure the control system works well for both right-handed and left handed users.</li> </ul>
<b>Ensure the control system is responsive in operation</b>	<ul style="list-style-type: none"> <li>• Consider providing a light or audible response to indicate when a button has been pressed – users often repeatedly press buttons in the absence of good visual and tactile feedback.</li> <li>• Design buttons so they provide firm feedback when pressed.</li> </ul>

Design element	Application
<b>Ensure the functions of the control system are recognisable</b>	<ul style="list-style-type: none"><li>• Use recognisable symbols and shapes – to an international standard where possible or by user testing where not.</li><li>• Identify the most important and frequently used buttons on the control system, and make these easy to find even when the user is not looking directly at the system.</li></ul>

## Maintenance and hygiene issues

Maintenance and hygiene were identified as issues by all of the users consulted, primarily through ensuring that the equipment is not rendered inoperative through mechanical breakdown or wear and tear. The provision of, and easy access to, consumables and regular spares was cited as an obstacle to effective use.

Users believe they had the capability to undertake some routine maintenance (eg changing light sources) but that this requirement was being outsourced to the detriment of equipment provision. This may be a way of improving the continuity of equipment but may not be appropriate for more recent technologies, which may also be too expensive to keep stocks of spare parts locally (discharge lighting, for example).

There is clearly an issue about identification of the effective service life of light sources, as opposed to the functional life. LEDs and discharge lighting both deteriorate in performance before suffering complete failure and this needs to be recognised by maintenance staff such that lights are not used in an ineffective state.

Other issues raised included the ease of maintaining good hygiene standards though the selection of well designed equipment and the security of components and finishes. One participant remarked that they did not adjust lighting as dust tended to fall onto the patient, indicating a close relationship between hygiene and usability. As lights get older they may suffer deterioration in finish and the security of the fastenings. These should be checked as part of the maintenance programme, since there are cases where flakes of paint or small fasteners have fallen from the light onto the patient. Type and quality of finish, as well as the design of fasteners on the lighting system, may help to alleviate this problem at the specification stage.

## Recommendations

- When specifying lighting it should be remembered that the primary recipient of the light (the surgeon) may not be the primary user in the traditional sense; other staff may be the ones to interact with the lighting system and they need to be able to do so readily. Their characteristics should be represented in the specification and they should also be involved in evaluation.

- The light provided for the surgeon may be improved by using lamps of a higher luminance, but there may be a downside in terms of glare and veiling contrast for the other team members. If the theatre is to work as a team, all the team member's performance must be optimised which may require compromise in the surgical lighting or improvements in ambient lighting to match excellent surgical lights.
- New technologies need to be disseminated and demonstrated much wider such that users and purchasers can effectively evaluate and compare the benefits with traditional lighting systems.
- Greater access to in-situ demonstrations is desirable, with the demonstrations taking place in the theatre in which the equipment is to be used to highlight potential system conflicts with other apparatus and the environment.
- The importance of the mechanical performance of the system in terms of the support structures, mountings, clearances and adjustability which should be elevated in priority against illumination or electrical specification since this generated the most complaints.
- The prevention of failure and the ease of repair appear more critical than outright performance.
- The specification for the fitting and use of camera technology in light systems seems unpopular and ineffective. Separate cameras are preferred.
- A greater range of consultation across a diverse range of users will elicit more usability and highlight potential conflicts before they become costly mistakes. Resources invested in this manner before purchase will prove worthwhile.
- The on-costs associated with specific lighting products should be detailed and clear.
- The installation, mounting and design of the lighting equipment should ensure that all members of the theatre team can readily reach and adjust the lights. This should be validated through demonstration and usability trials. If this can't be assured then a remote control adjustment system should be provided.
- Lighting is a compromise not only for a given user over time and activity but across users at any given moment. The specification should recognise this and not favour one user group over another.
- Task lighting is integral to the performance of the team and should be widely and easily available.
- Task lighting may also be needed for supporting theatre staff preparing equipment
- Ambient lighting plays a role in the contrast, and hence impacts on the theatre lights' effectiveness. Lighting should be seen as a system and commissioned on that basis.



## **Additional information**

In many cases the choice of theatre lighting will be part of a comprehensive review of the theatre environment and will not occur in isolation. In addition to the categories specified earlier, the light sources chosen must be considered in relation to many factors such as the ambient and task lighting, other theatre equipment and the environment factors.

### *Ambient theatre lighting*

Eye fatigue and eye disturbances have been the subject of several studies into the long term use of operating theatre lighting [25, 26]. Eye tiredness, heaviness, burning and redness are some of the symptoms experienced by those working in the theatre. One particular focus has been the transition between the bright light at the surgical site and the lower lighting around the operating room.

Whilst the operating theatre's ambient lighting is not within the scope of this report, this is an important factor to consider when deciding upon specific surgical lighting. Two methods of lighting are used in an operating theatre; general (lighting the whole room) and task (specific task lighting). It is important that a balance is made to ensure comfortable visibility in the operating theatre as the persons' eye moves to view different points in the room. The balance ratio of task lighting to general room lighting (known as the brightness ratio) can impact on human performance, through eye fatigue, visual stress or error generation [15]. Eye strain can be avoided by maintaining the illuminance at the surgical site at no more than 10 times that of other areas of the room; areas immediately adjacent to the surgical site should have a ratio of at most 5:1 [27].

General surgical lighting may not be appropriate for all procedures. For example endoscopic surgery lighting may need to be adapted for specific operations. Also, if the operating theatre was designed for open surgery the lighting may be dimmed to view the monitors to prevent glare [28]. This may lead to safety implications when selecting surgical equipment or for staff movement as the rest of the team may require greater levels of ambient lighting in order to safely undertake tasks such as instrument preparation, moving equipment or for anaesthetic monitoring in particular [29].

### *Shadows or glare*

Shadows can be cast from the surgeon's head, shoulders or hand, whilst other team members or equipment around the surgical area may also obscure the light source. Glare can be found in several forms; direct (glare originating directly from the light source) and reflected (glare from other surfaces illuminated by the light) which may cause discomfort or eye fatigue [6] and each of which may impede performance in the theatre.



This can be managed in numerous ways, for instance reflections can be reduced by the use of brushed steel instruments in preference to polished steel [6, 30]. However, reduction of glare sources is preferential. The correct illuminance should be available with the minimum of shadowing or glare to illuminate the area and depth of the surgical site [13]. This is vital to enable the surgeon to have a clear view of the surgical area, to distinguish tissue colour, and have depth perception of cavities.

To reduce the effects of shadows, theatre lights usually incorporate one of three design features in order to minimise the effect of obstructions. The design may utilise a single lamp surrounded by reflectors or multiple lamps each positioned to help minimise shadowing. Alternatively, a combined solution may be used whereby multiple lamps are placed in an arrangement and reflectors direct the light. It should be noted that total elimination of shadow is undesirable, as some light shadowing will enhance depth perception.

## *Installation*

Theatre lights commonly weigh 100 – 150kg and hang directly above the patient and clinical team and as such present a danger if not correctly installed and maintained. NHS estates guidance suggests that all operating theatre lights be maintained under a maintenance contract with two planned visits per year. Equipment from most manufacturers performs best when correctly maintained and adjusted.

There must be a co-ordinated approach with other fixed equipment in the theatre when positioning of operating theatre lights. Clearance for the mounting, including the satellite lights, must be taken in to account and structural strengthening may have to be provided before installing the lighting unit.

## *Manoeuvrability*

The ability to easily and quickly manoeuvre or adjust the light system is required, especially since this is rarely done by the operator. This will include factors such as the weight and degree of rotation as well as the focus, size and illuminance levels provided by the light [13]. The light systems also need to remain in position and not drift during the procedures which may cause delays or distractions [1]. Special attention should also be given to risks of positioning, moving & handling the lights, the ability of the scrubbed operating team to perform this task with one gloved hand and the ability of non-scrubbed personnel to move them at arm's length to avoid contaminating the surgical field.

It is also important that users of the lights are fully trained in the positioning and adjustment of the lights. This is a service offered by the manufacturers of lighting units and should be used to optimise best performance. If users have a poor understanding of the principles of using lights, this can result in procedures being poorly lit by sophisticated operating theatre lights. Increasingly, the use of automatic

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position controls are being used to move lighting positions, however, even with these aids the vertical and horizontal range of movement needs to be considered.

The position of the light handles is also important in the control and positioning of the theatre lights.

## *Health and safety*

The operating theatre is a highly challenging occupational environment. Given the immediacy and importance of the activities conducted within it, it is possible to overlook the normal health and safety issues, such as slips and trips. Cabling and connections between hardware such as lighting needs to be managed and strategies for removing the cabling away from the floor area will help allow safer movement in and around the operating theatre.

The theatre environment is a prime target for electrical accidents with lowered body resistance and a high number of electrical equipment and conductors such as blood, urine, saline, and water. The combination of these elements presents a challenge to increase electrical safety.

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Some light sources have a lifespan of five to ten years. As they age the lamps dim and so are less efficient. The modular systems appear to be easier to update as different parts can be replaced rather than the whole system. Total ownership costs should be considered for the different types of lighting available, highlighting the key cost considerations associated with the lifetime costs. Efficiency gains and cost savings associated with appropriate choice of lighting should also be demonstrated.

## Purchasing procedures

The Trust Operational Purchasing Procedures Manual provides details of the procurement process [31].

European Union procurement rules apply to public bodies, including the NHS, for all contracts worth more than £90,319 (from January 1<sup>st</sup> 2008) [32] (appendix 1). The purpose of these rules is to open up the public procurement market and ensure the free movement of goods and services within the EU. In the majority of cases, a competition is required and decisions should be based on best value.

NHS Supply Chain ([www.supplychain.nhs.uk](http://www.supplychain.nhs.uk)), a ten year contract operated by DHL on behalf of the NHS Business Services Authority, offers OJEU compliant national contracts or framework agreements for a range of products, goods and services. Use of these agreements is not compulsory and NHS organisations may opt to follow local procedures.

The procurement of operating theatre lighting will involve many decisions regarding the specification of the product. Table 20 outlines several key specifications which should be considered during the decision making process. These summarise the technical and operation considerations presented within the guide.

**Table 20. Purchasing decisions**

Lighting design
One primary light head plus additional satellite(s)
Multi reflectors to ensure shadowless light
Homogenous luminous field with lowest possible amount of shadow
Heat filters (not required for LED lights)
The light head should be constructed as to provide optimum conditions for laminar air flow
Light field adjustment by sterilisable handle
Easily accessible control panels for adjustment of light intensity
Simple to clean and disinfect and maintain
Spare lamp for automatic fast switch over with visible indicator in case of lamp failure (if applicable)
Easily replaceable system components including lamps
Light output
Colour rendition index value, $R_a$ , of above 90
Colour rendition value $R_9$ of over 90
Colour temperature: 4300-4500K

Theatre lights can often be trialled in the hospital for a period of time before the final purchasing decision is made. This is a useful strategy, as with any new technology, some of the intended users may be resistant to change. This is also a good opportunity for staff to become familiar with new design features and technical advances which may not have been present in previous designs. A period of training and familiarisation should be provided in order to allow adequate time for staff to experiment with the light outside of the “live” environment.

## **Sustainable procurement**

The UK Government launched its current strategy for sustainable development, *Securing the Future* [33] in March 2005. The strategy describes four priorities in progressing sustainable development:

- sustainable production and consumption – working towards achieving more with less
- natural resource protection and environmental enhancement – protecting the natural resources and habitats upon which we depend
- sustainable communities – creating places where people want to live and work, now and in the future
- climate change and energy – confronting a significant global threat.

The strategy highlights the key role of public procurement in delivering sustainability.

## **LED technology**

The use of LED technology within the operating theatre environment is a relatively recent development. As with most new technologies the initial investment may be greater than for more traditional lights. However, over the life of the product, LEDs, do show reduced operating costs, lower maintenance and reduced waste [34].

## **End-of-life disposal**

Consideration should be given to the likely financial and environmental costs of disposal at the end of the product's life. Where appropriate, suppliers of equipment placed on the market after the 13<sup>th</sup> August 2005 should be able to demonstrate compliance with the UK Waste Electrical and Electronic Equipment (WEEE) regulations (2006) [35]. The WEEE regulations place responsibility for financing the cost of collection and disposal on the producer. Electrical and electronic equipment is exempt from the WEEE regulations where it is deemed to be contaminated at the point at which the equipment is scheduled for disposal by the final user. However, if it is subsequently decontaminated such that it no longer poses an infection risk, it is again covered by the WEEE regulations, and there may be potential to dispose of the unit through the normal WEEE recovery channels.

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British Association of Aesthetic Plastic Surgeons

Royal College of Nursing

Royal College of Surgeons of England

Manufacturers and suppliers of operating theatre lights

<b>MIS</b>	Minimally invasive surgery
<b>BS</b>	British standard
<b>IEC</b>	International electrotechnical commission
<b>LED</b>	Light emitting diode
<b>CRI</b>	Colour rendering index
<b>AV</b>	Audio visual
<b>WEEE</b>	Waste electrical and electronic equipment

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## Lease options

National frameworks are in place for operating leases to help the NHS procure leases more cost efficiently and effectively. Further details are available from the PASA website [36].

## EU procedures

The Public Sector Directive (2004/18/EC) has been transposed into UK law via the following statutory instruments:

- the Public Contracts Regulations SI 2006 No.5 (the regulations)
- the Utilities Contracts Regulations SI 2006 No. 6 (not relevant to this guide).

The regulations apply to contracts worth more than £90,319 (from January 1<sup>st</sup> 2008) [32] over their whole life, and specify the procedures to be followed for public sector contracting, including adherence to strict timetables, requirements for advertising, invitation to tender and the award of contract. Organisations undertaking a procurement exercise covered by the regulations must give all suppliers an equal opportunity to express an interest in tendering for the contract by placing a contract notice in the Official Journal of the European Union (OJEU).

At all stages of the procurement process, the purchaser must be demonstrably fair, as any decision made can be challenged by the unsuccessful suppliers.

## Establishing a procurement strategy

To achieve a successful outcome, decisions need to be made on:

- whether an existing contract/agreement can be used
- the need to consider sustainable development issues
- whether EU directives apply
- the type and form of contract
- sourcing potential suppliers
- duration of contract and opportunity to review/extend
- payment schedules
- how to minimise any risks with the chosen strategy, including supplier appraisal and evaluation/clarification of suppliers' bids.

## **Preparing a business case**

A business case should be drafted and approved before conducting any procurement exercise. Further guidance on preparing business cases is available from the Office of Government Commerce [37] and an illustrative example is provided in the *NHS PASA Operational Purchasing Procedures Manual*, Procedure 1-01 [38].

## **The EU tendering exercise**

EU procurements usually take between 4 and 6 months to complete. This needs to be taken into account in the planning stages. The length of the exercise depends on the chosen procedure (open or restricted). Further information is available from the Department of Health [39].

## **The procurement panel**

A multidisciplinary team should be selected to guide the purchase. Representatives from clinical, user, technical, estates and financial areas should be considered.

## **Identifying potential suppliers**

Criteria for supplier selection must be established. A pre-qualification questionnaire, seeking background information (eg on the skills and experience of the service engineers) may be employed as an initial screen to exclude unsuitable suppliers.

## **Evaluation criteria**

Performance specifications should be derived from local operational requirements, and agreed by the procurement panel. They will form the basis for assessing the adequacy of suppliers' technical specifications, provided in response to the technical specification questionnaire.

It is important to have agreed on the performance specifications of the product as they will be used in the adjudication against company specifications.

Requests for features which are supplier-specific are not permitted under the regulations. Very specific features which are not supported by operational requirements are also not allowed.

## **Award of contract**

Following award of the contract to the successful supplier; unsuccessful suppliers may need to be debriefed. This is at the supplier's request.

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Buyers must be aware of the 'Alcatel' procedure (see the *Trust Operational Purchasing Procedures Manual* [31], Procedure No.T-08, section 6 - *Mandatory Standstill Period*).

For more information on procurement please refer to the Department of Health Website [40].

## **Buyers' guide: Operating theatre lighting**

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## **About CEP**

The Centre for Evidence-based  
Purchasing (CEP) is part of the NHS  
Purchasing and Supply Agency. We  
underpin purchasing decisions by  
providing objective evidence to support  
the uptake of useful, safe and  
innovative products and related  
procedures in health and social care.

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available from our website.

[www.dh.gov.uk/cep](http://www.dh.gov.uk/cep)

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