



New Operating Theatre Light Launched

The Galaxy Ultra 30 Mobile is the brand new mobile surgical light from Brandon Medical. Our award-winning range of Galaxy Ultra lighting has spawned numerous successful models in the past and this mobile version looks set to continue the trend.

The most striking aspect of the Galaxy Ultra 30 Mobile is its reach. The unique spring-arm has been designed specifically to give the light extended reach over an operating table, allowing a surgeon to literally operate from underneath the lamp head. This lamp provides the same ULTRA-high quality light as a ceiling mounted surgical light featuring shadowless performance, focus control, colour filtering and a UCV-friendly design.

This long arm is complemented by a smaller base. This smaller 'footprint' reduces the trip-hazard encountered with traditional mobile lights (which often need large bases for stability) and also allows for easy positioning by using low-inertia, anti-static, double-caster wheels.

The base is also home to an optional battery back-up system which can provide up to 3 hours run-time in the event of power loss. The batteries are equipped with a 'quick-charge' facility for fast battery charging.

Other new and useful features include an ergonomic handle with integral cable tidy, making the light easy to push around and reducing trip hazards in the operating theatre. A sterilisable handle cover is also provided.

Nigel Davill, Technical Director of Brandon Medical, was responsible for overseeing the development of this light - "...this is the most technologically advanced mobile operating light on the market today. We have really taken into account what surgeons told us was wrong with traditional mobile light design and kept this in mind throughout the entire development process."



"...this is the most technologically advanced mobile operating light on the market today."

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YEARS OF
EXCELLENCE



New Products Galore in 2005

Brandon Medical have accelerated the pace of change during 2004, and we aren't letting up in 2005. 2004 was the most successful 12 months in our 50 year history and we have expanded our product catalogue considerably. Along with the new Galaxy Ultra Operating Light (see front cover) we also have a brand new range of Coolview® Examination Lights, an expanded range of Bed / Ward lighting and a new range of ancillary operating theatre equipment including UPS power systems and theatre pendants.



Coolview®

We hope that many of you are already aware of our new Coolview® range, which has now expanded to include the CVXM (see picture) and new FX versions of the C50, C35 and C20 models. Each of these models is available in ceiling, wall, mobile or rail models and can be mounted on either spring-balanced or multi-flex arms. These lights can all be fitted with a Daylight Colour Filter for optimal colour recognition. We offer so many different options within the Coolview® range that there are now over 100 models to choose from! If this isn't enough for you, we even offer to custom manufacture some of our products to your specific requirements.

Bed / Ward Lighting

Amadea is the latest addition to our range of bed head and ward lighting. Examination lights are classed as medical devices under the Medical Device Directive and we believe that Amadea is the first product of this type to include a fully functional examination light. Amadea is certified to IEC60601 for this reason.

Amadea can function as an examination light, patient reading light, general room light and night light all in one! The luminaire contains

individual lighting units to support all these functions. Each function is supported with all the necessary photometric data to allow computer aided light planning so we can design lighting schemes for every medical environment.

DALI (Digital Addressable Lighting Interface) versions of Amadea are also available which allow lighting scenes and switching to be pre-programmed. DALI can be used to set different levels of light for night time, patient examination or when a patient gets out of bed with each scenario being set by switches of sensors. Video Cameras & Flat Screen Displays New for 2005 is an improved camera system with 18x optical zoom for mounting on Galaxy Ultra operating lights. We have also added a range of medical grade (IEC60601) flat screen monitors that are all suitable for mounting to our operating theatre lights.

Control Panels

Brandon Medical have been building operating theatre control panels for 30 years but recent changes to our manufacturing methods and technology have allowed us to make substantial reductions to cost and order times. With our new investment, we believe we can beat any one on price, service and delivery.



UPS

Our new range of BXI Uninterruptible Power Supplies is designed to support IT equipment in healthcare buildings and to protect from power loss. Modular systems can be configured to provide hours of run-time and are designed to allow easy battery exchange and low maintenance.

All these developments come on top of the ongoing success and improvements of our Galaxy Ultra, Astralite and Optica ranges. If you would like information about any of our products please feel free to either visit our website www.brandon-medical.com, or contact us direct.

We believe as a company that we need to constantly change and update our products to keep up with both the latest technology and customer demands. We already have a list of top-secret developments for release in 2005 - watch this space for further information!

New Brochure Range

Many of you will have received a copy of our new Coolview brochure last year and this year we are planning several new brochure releases. We are currently

designing new Galaxy Ultra Mobile, Control Panel and Bedhead brochures - as well as a couple of top-secret highly classified new products!



What is a Medical Device?

And why do Medical Lights qualify?

Many companies have been slow to react to the Medical Devices Directive, despite it being implemented over 10 years ago. There is still insufficient industry understanding and acknowledgement of the Directive and its implications, with several people arguing that certain lights (especially examination lights) do not fit the 'Medical Device' profile as outlined below. As such, these lights are not always manufactured to the European Union performance and safety standards as set out in the Directive.

As the UK's leading medical lighting specialists, we have manufactured and tested our products to the guidelines set out in the Medical Device Directive for many years.

EU Directives have the task of harmonizing national legislation and regulations across all member states. Each country chooses how best to incorporate these Directives into their own legal system and then apply appropriate laws.

There are several Directives which are of particular relevance to the Medical Equipment industry. This article will focus on arguably the most important of these - the EC Medical Devices Directive 93/42/EEC.

Medical Devices Directive

This Directive was enacted to provide a harmonized regulatory environment for all Medical Devices sold within the EU. All products which fall within the scope of the Directive must meet certain essential safety and administrative requirements and are CE marked to show they comply.

The Directive defines a Medical Device as: "any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, or alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process, control of conception
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."

Operating theatre, surgical, examination and reading lights which are also used for examinations all fall under this definition and are covered by the Directive.

This above definition of Medical Devices is expanded to cover 4 different risk classes of Device. All Brandon Medical products fall under Class I (Low Risk Devices). Further information on this classification can be found in Annex IX of the Directive.

Naturally, this leads us to another question - what is an operating theatre, surgical or examination light? Standard definitions are given in EN60601 as follows:

Operating Theatre Lamp System

- Combination of lamps for local illumination of the body
- Used for diagnosis or treatment
- Minimum light output of 40,000 Lux
- Light fail-safe owing to the combination of 2 or more lamps

Minor Surgical Light

- For local illumination of the body
- Used for diagnosis or treatment
- Min 40,000 Lux
- Not light fail-safe



Nigel Davill is the advisor to the British Standards Institute on Surgical Lamps and represents BSI on the International Standards Committee. As Technical Director of Brandon Medical, Nigel is responsible for ensuring compliance with forthcoming regulatory standards.

Examination Light

- For local illumination of the body
- Used for diagnosis
- Not light fail-safe

CE Marking

The CE Mark forms an integral part of the Medical Devices Directive.

While in theory article 100a of the Treaty of Rome should ensure that the legislation governing EC Markings is the same across the whole of the EU, the reality is that different member states have interpreted the Directive differently. This means that different CE marking standards need to be met in different countries.

Due to the Medical Devices Directive, every Medical Device sold within the EU has to carry this CE Mark, and the appropriate laws for each country have to be checked and adhered to.

A CE Certificate lists all the relevant international standards which a product has been manufactured to. In the case of lights, the most important standards to look for are EN60598 (Lamps) and EN60601 (Medical Electrical Equipment).

EN60589 - Lamps

This is the Basic Standard governing safety requirements applicable to lamps. Part 1 (General Safety Requirements) and Part 2-25 (Lamps for Rooms Used for Medical Purposes and for Hospitals) apply to Brandon Medical lights. In Part 2-25 a 'Medical Room' is defined as hospitals, doctors' surgeries, nursing homes or clinics etc. in which patients are treated, examined or cared for.

EN60601 - Medical Electrical Equipment

EN60601 is the Basic Standard governing the design and safety requirements applicable to electrical medical equipment. Part 1 (General Requirements, Safety Requirements, EMC Compatibility) and Part 2-41 (Safety of Operating Theatre, Treatment and Examination Lamps) apply to Brandon Medical lights.



Brandon Medical in the Premier League!

Aston Villa FC have just joined a highly elite European league by becoming the latest top club to purchase Brandon Medical lighting. They are joining the likes of Manchester United and Benfica, who have been using our lights to treat their players for many years.

Our Sales Team were particularly surprised by the details of the order - it isn't often we get a specified delivery date of "before our big game against Man U"! Unfortunately, not even our new examination light could help Aston Villa out in this match - they lost 1-0.

The light itself was a Coolview® XM model, Brandon Medical's brand new examination light. This light is perfect for a physiotherapy or examination room due to its extended reach - allowing it to reach all around a patient couch.

Our Managing Director Graeme Hall commented "it is flattering to be chosen by another top European club, especially when you consider how much money they have and how much their players are worth. That they chose Brandon, out of all the other lights on the market, really means something!"



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Fax Back

Contact Name _____

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Do you have any development or refurbishment plans for (please tick box): 2005 2006

What products / services might you require?

- | | |
|---|---|
| <input type="checkbox"/> Galaxy Ultra operating theatre lamps | <input type="checkbox"/> Bed head lighting |
| <input type="checkbox"/> Examination lamps | <input type="checkbox"/> Minor surgery lamps |
| <input type="checkbox"/> Mobile OT lamps | <input type="checkbox"/> Operating theatre lamps (BCMX range) |
| <input type="checkbox"/> Operating theatre camera systems | <input type="checkbox"/> Operating theatre control panels |
| <input type="checkbox"/> Emergency power units | <input type="checkbox"/> Servicing - all makes of operating theatre lamps |

Please fax back to Brandon Medical Company Ltd. on 0113 272 8844 - or call us on 0113 277 7393