ENGINEERING WORLD HEALTH

2016 DESIGN COMPETITION

Uninterruptible Surgical Lamp

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May, 2016

1 Problem Definition

There are many challenges faced by surgeons working within developing countries. Within the operating theatre, they must often perform surgery with an unreliable power supply and, consequently, non-functional equipment. As a result, equipment with an independent power supply is often used as a substitute. However, this substitute equipment is usually substandard in comparison to that which is used in well-resourced regions.

One area of concern is the current standard of surgical lamps being used within these regions. Due to the frequent power shortages occurring in some hospitals, the main source of illumination during surgery is often a simple plug-in lamp, flashlights or natural light [1]. These light sources are insufficient in many cases, they cannot provide the necessary level of detail or clarity necessary for surgeons to operate on patients with ease and precision.

Surgical lamps are designed to illuminate the site of focus during a surgical procedure and ensure small, low-contrast objects at different depths in incisions and body cavities can be clearly observed [2]. With their aid, open surgery operations to treat conditions such as obstetric complications and trauma can be more easily and accurately performed by surgeons [3]. An appropriately designed, reliable surgical lamp, which possesses a comparable level of illumination at a low cost, would resolve this concern surrounding the current standard of lighting within operating theatres in developing countries.

Our proposed surgical lamp design aims to:

- Mitigate the effects of unreliable power sources in developing countries, such as mains power.
- Be readily available at a low cost to underfunded hospitals internationally (it should at least have a lower initial and maintenance cost than commercial surgical lamps).
- Provide illumination capabilities similar to commercial surgical lamps.

The design is aimed to satisfy international standards performance requirements for surgical lamps at a reduced price via the use of technologies such as LEDs, lenses that reduce cast shadow [4], and storage elements to provide consistent power. Part of the design will be a stand to provide the surgical lamp with greater manoeuvrability, with a sterile handle which will allow the surgeon greater control of lighting direction during surgery. In accordance with international standards, sterilisation procedures will also be considered in the design [5] for use within operating theatres.

2 Impact in the Developing World

An estimated one-third to one-half of the world's population lacks basic surgical care [6][7]. Disease treatable by surgery remains one of the biggest killers of the world's poor, and these deaths are largely attributable to an absence of surgical services [8]. Basic surgical procedures are among the most cost effective of all health interventions in the developing world, and if made widely available, could prevent 1.5 million deaths per year [9].

Only a small percentage of patients requiring surgery are treated because of constraints, with obsolete infrastructure and lack of electricity being among them [6]. A standardized World Health Organization (WHO) tool was used at selected district-level hospitals to assess infrastructure, supplies, and procedures relating to essential surgical and anaesthetic capacity. Data from 132 facilities in 8 low- and middle-income countries revealed shortfalls in basic infrastructure, including water, electricity and oxygen. In 68% of the facilities, electricity was sometimes or never available [10].

WHO estimates that as much as 80% of medical equipment in some developing countries is donated or funded through foreign sources, but only 10-30% of the equipment is ever put to use [11]. Some reasons for this are that medical equipment is often incompatible with the country's electrical system, or difficult to repair or maintain given the country's limited resources and training [11][12].

It is worth noting however, that while these limitations exist, they do not seem to apply to larger hospitals in main cities where patients are able to pay for surgical services. A community-based survey conducted in the 1980s in Haiti for instance, suggested that the rates of caesarian sections in a large area of southern Haiti were close to zero, yet interestingly, among the affluent of the country, rates of caesarians did not vary much compared to those registered in the United States [8].

As such, we propose a design for a surgical lamp that will primarily benefit small community hospitals and local clinics. From anecdotal evidence of surgeons volunteering in the developing world, it is not uncommon for surgery in these types of clinics to be performed under hand-held battery-powered flashlights and pretzel-type optical headlamps [13]. A complete surgical lighting system can easily cost thousands of dollars, and even a standalone lamp, although cheaper, can be made redundant if technical problems arise and the device requires specialised replacement parts or maintenance from the manufacturer alone. With our design, we aim to deliver a standalone lamp that meets the minimum surgical requirements while being cheap to manufacture, easy to repair locally and has a back-up power supply that allows it to run interrupted in the absence of mains power.

3 Required Performance Specifications

Shown below is a table of the required performance specifications.

ID	Requirement	Reference
3.1	No unintentional changes in operational state will be permitted	[14]
3.2	The reflector must keep the surgical site clearly illuminated while maintaining a large depth of field	[15]
3.3	The central luminance of the surgical lamp shall be without obstruction of the light beam - a distance of 1000mm from the light-emitting area of the medical electric equipment in the light field	IEC 60601-2-41
3.4	The surgical light shall operate for extended periods without radiating excessive heat - this can be fulfilled with heat-protection filters	[16]
3.5	The region of the operating field shall give a lighting with a radially tapered distribution and with attenuation of the cast shadow	IEC 60601-2-41
3.6	Minimum diameter where the lamination reaches 50% of the central luminance shall be at least 50% of the light field diameter	IEC 60601-2-41
3.7	The luminous flux emitted by the device shall not vary more than 20% during use, and the colour temperature and rendering shall remain stable during use	IEC 60601-2-41
3.8	The material must be resistant to corrosion	[17]
3.9	The medical electrical equipment shall remain in the intended position after adjustment or positioning	IEC 60601-2-41
3.10	Temperatures for detachable handle and other rails moulded from plastic, rubber or wood likely to be touched shall not exceed 60 °C	IEC 60601-2-41
3.11	Temperatures for detachable handle and other rails of metal likely to be touched shall not exceed 51 °C	IEC 60601-2-41
3.12	The stand must support the light head and allow it to be oriented to a range of heights, horizontal locations and orientations	
3.13	The device shall be designed such that a process of thorough cleaning with a low level disinfectant or thorough cleaning alone is possible	
3.14	The battery used must be able to supply at least 12 V of electricity	
3.15	The battery can be charged via mains power	[17]
3.16	In the event of interruption to mains supply, automatic change shall occur to a backup power supply	IEC 60601-2-41
3.17	The devices should be easy to assemble	
3.18	The equipment should be easy to repair	[11][12]
3.19	The lamp should be constructed entirely from off-the shelf components using only cheap hand-operated or battery-powered tools	

4 Implementation of Prototype

The prototype consists of three main subassemblies: the lamp head, the stand, and the box. The lamp head consists of four sub-head units. These units are spaced evenly around a central joiner. Extending downwards from the joiner is a handle with which the lamp head can be moved or reoriented. The joiner is supported by a stand consisting of a vertical support and a main arm. The joiner mounts to the end of the main arm. The main arm is in turn mounted to the vertical support, which holds it above the height of a standard examination table. The vertical support is in turn mounted to a wheeled box which sits on the floor. The box contains all of the electrical components necessary to power the lights, including an uninterruptible power supply.

The lamp head consists of 24 commercially available LED units, each of which are enclosed in a silver plastic half-sphere dome with a flat surface at the site of light emission. Each unit consists of 6 individual LEDs, so a total of 144 individual LED bulbs are used. The large number of individual bulbs serves several purposes: 1) to increase the overall brightness of the lamp, 2) to aid in shadow dilution, and 3) to ensure a negligible effect on performance in the instance of one or more bulb failure during use.

The 24 LED units are divided across 4 light heads, each of which contains a cluster of bulbs arranged in a circular formation, with 5 forming a circle and one in the centre. The frame for each light head was created from a 3 mm thick PVC sheet cut into the shape of a pentagon, with slits made from the corners inwards to create 5 flaps that could be slightly bent. This makes the PVC sheet for each unit slightly concave, with the individual LED units pointing slightly inwards. The individual light beams to converge at the central illuminance location approximately one meter away, as per requirements. Holes were cut into the flaps in the PVC sheets to match the size of the LED units. Each unit was embedded into the plastic frame and held in place with silicone sealant.

The 4 light heads were positioned together in a cross-shape formation, and angled relative to each other such that they focus on the same central illuminance area. A design consisting of 4 light heads primarily assists in shadow dilution- a blocked light path from one light head in the presence of an obstruction will be countered by the light from the other three.

The stand structure is composed mostly of hollow aluminium tubes, and has three degrees of freedom which allow the lamp head to be positioned. The hollow aluminium tubes allow electrical wires to be passed within the stand from the head to the box.

The vertical support is composed of two circular section aluminium tubes each 25 mm in diameter, with a 1 mm wall thickness. Connecting the two tubes (and sitting within them) is a galvanised iron connector which allows the lower tube to remain fixed while the upper tube (which is connected to the lamp head) rotates about its long axis (yaw of the main arm). This moves the lamp head left or right.

Fitted over the top of the upper circular section tube (and riveted to it) is a bracket cut from a rectangular section aluminium tube (50 x 30 mm, with a 2 mm wall thickness). Two vertical flanges extend upwards as part of this bracket. Holes for the main pivot bolt have been drilled through the flanges. The main horizontal arm sits between these flanges. A bolt passes through the flanges and the main horizontal arm, allowing the angle of the arm to the horizontal to be adjusted (luffing of the main arm). This raises or lowers the lamp head.

A horizontal hinge located near the lamp head end of the horizontal arm allows the angle of the lamp head to be adjusted relative to that of the horizontal arm. This allows the light to be directed downwards even as the angle of the arm relative to the horizontal is altered. A spring extends across this hinge to prevent the lamp head from falling downwards under its own weight. The weight of the lamp head is offset by a counterweight on the opposite end of the main pivot bolt. A spring extends at a 45 degree angle from the counterweight to the side of the upper vertical tube, which allows the horizontal arm to remain in the position it is left, for a range of arm angles.

Extending downwards from the central joiner of the lamp head is a short length of square section aluminium tube. This serves as the handle, with which the user can alter the position and orientation of the lamp head. In future versions, this handle will be removable and able to be sterilised.

Figure 1: Surgical lamp

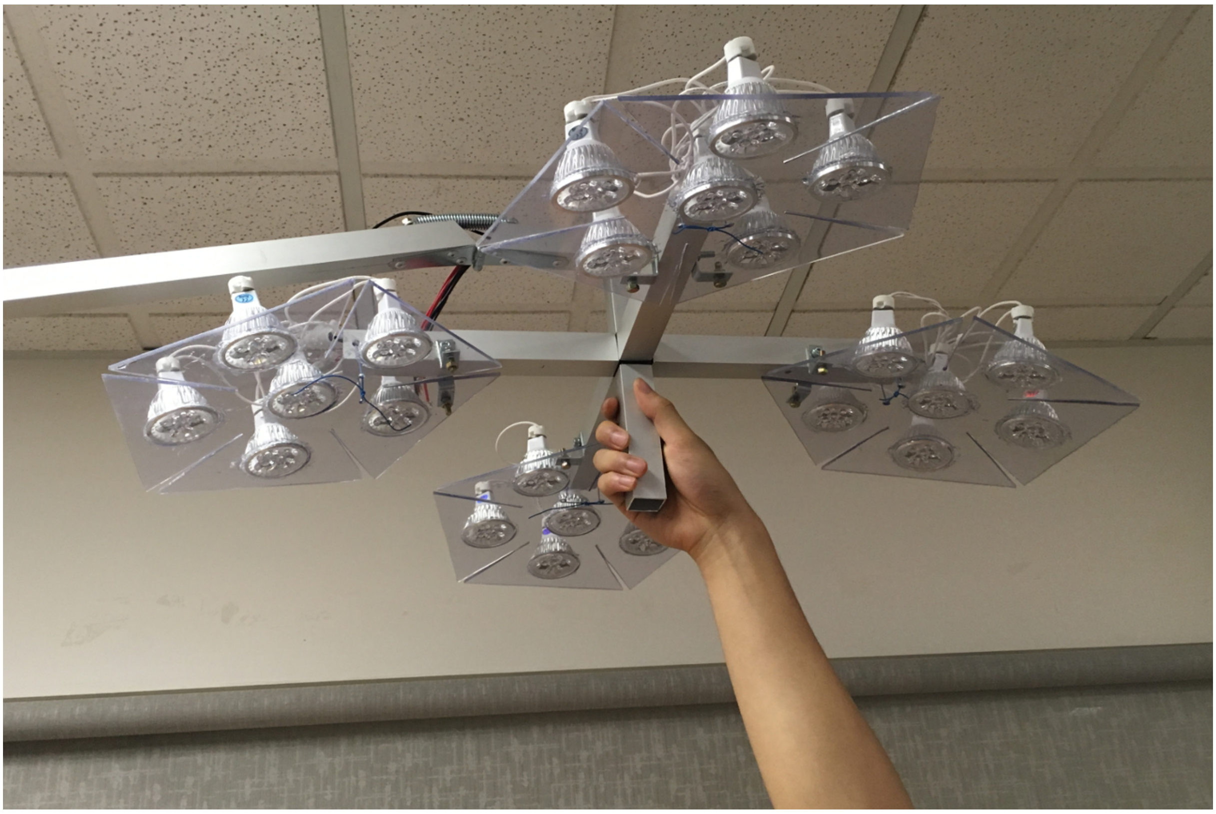

Figure 2: Light head with handle

4.1 Electrical

The primary focus of this design and the improvement it makes over existing surgical lamps is the presence of an inbuilt uninterruptible power supply. The surgical lamp can be primarily run off mains power, however, similar to a laptop, if the power cuts out or is unplugged the surgical lamp will be powered by a battery.

To achieve this, a switching circuit is required to switch between mains power and battery power, and a charge circuit is required to charge the battery while mains power is connected.

An off the shelf power supply that meets medical regulations was used to drop the voltage from the mains voltage (∼230 V) to 15 V. This both isolates the device from mains power and decreases the voltage to a safer level.

The device was designed to be used with a 12 V battery as the back up battery, and uses adjustable terminal clips that can be attached to any lead acid or sealed lead acid battery. This allows car batteries to be used as the back up battery, which are common and easy to obtain.

4.1.1 Switching Circuit

The switching circuit is capable of detecting when a brownout occurs on the main power supply line. When this happens, the circuit uses a relay to switch from using the mains supply to using the back up battery to power the lamp. When mains power resumes, the switching circuit will return to using the mains supply to power the lamp.

A brownout is considered to have occurred when the source voltage falls below 11.7 V. This voltage was chosen since the LED bulbs run off a 12 V source, and dropping too far below this voltage will affect the quality of the light. The threshold voltage was set using a Zener diode.

The switching circuit is also capable of detecting a brownout on the battery line, and will stop drawing power from the battery when it falls below the brownout threshold. This prevents the battery from being discharged below 11.7 V and prevents battery depletion.

4.1.2 Charge Circuit

The charge circuit charges the back up battery when mains power is connected. It uses a variable voltage regulator (LM317) to supply the battery with 13.7 V, which is suitable for charging a 12 V lead acid battery, and cuts out as the battery reaches its capacity.

5 Proof of Performance

The system successfully produces a bright, radially tapered light with a large central operating field. The central illumination reaches a brightness of 12,000 lux, which is much brighter than that required for general office work (500 lux) or even that required for fine inspection work (5000 lux). This is clearly a significant improvement over the use of head lamps or general overhead lighting in clinics where there is no existing functioning surgical lamp.

The light produced is diffuse and therefore dilutes shadows cast by a surgeon's hand or tools, as shown in Figure 4. The temperature of all components likely to be touched during use remain within safe limits.

The stand supports the lamp head, and allows it to be repositioned with three degrees of freedom, as shown in Figure 1. A fourth degree of freedom (rotation of the lamp head about the long axis of the horizontal arm) can be easily added if necessary.

The light produced is stable, and simulations have shown that the backup battery could successfully and quickly restore light function if the mains power supply is lost.

All components of the lighting system are made from commercially available parts. The entire system can be constructed by two people with only cheap hand-operated or battery-powered tools.

Figure 3: Illuminated light head

Figure 4: Diffuse light from many different angles results in diluted shadows

Figure 5 shows a simulation of the switching circuit, where the mains voltage drops out. As the voltage delivered to the light heads (red) drops below the brownout threshold of 11.7 V the relay switches on (green) and connected the light heads to the back up battery. The voltage delivered to the light head then rises back up to 12 V as the battery takes the load.

Figure 6 shows the relay switching off as the battery voltage drops below the brownout threshold of 11.7 V. This prevents the battery from being overly discharged and becoming depleted.

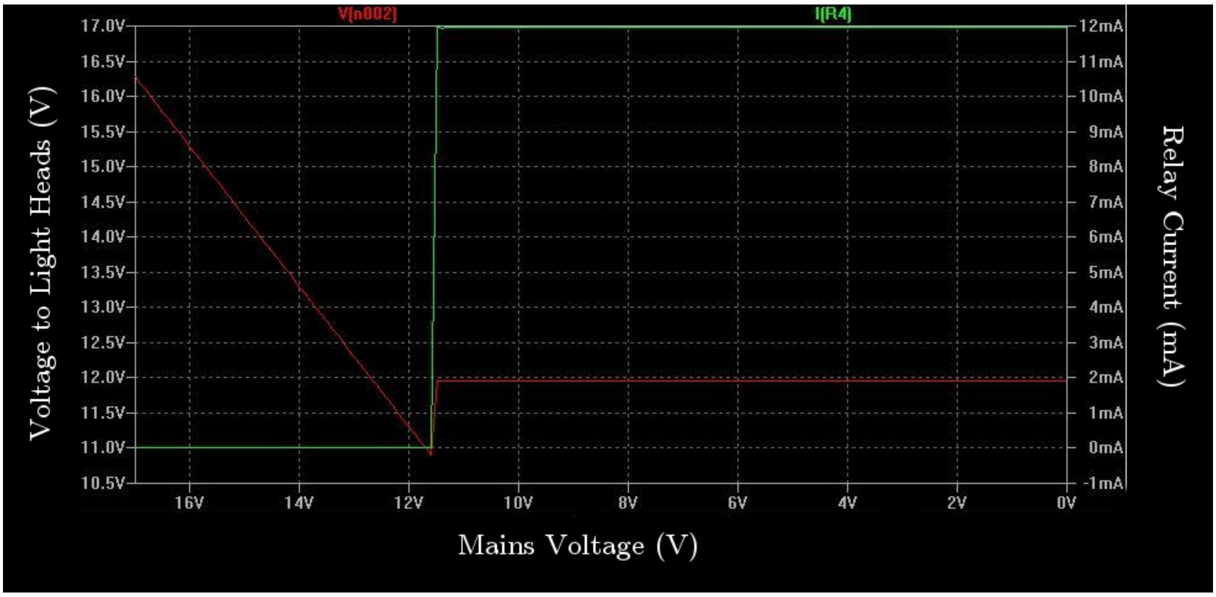

Figure 5: Back up battery taking over from mains power. The red line shows the voltage delivered to the lamp heads and the green line shows the current through the relay.

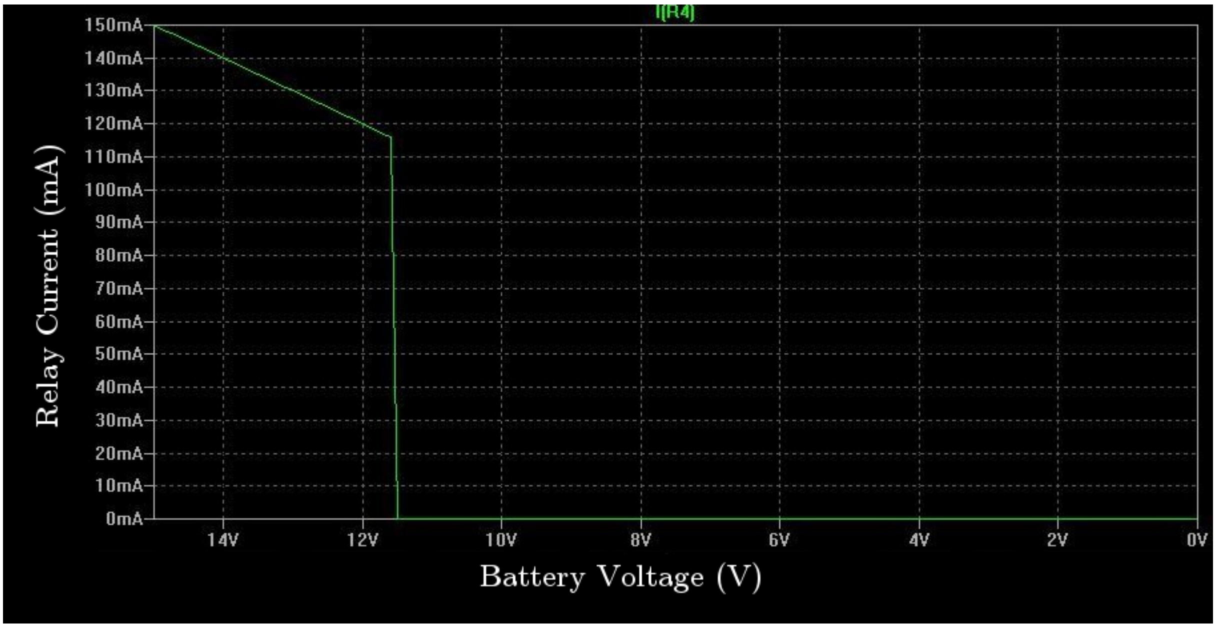

Figure 6: Relay cutting out as battery voltage decreases, to prevent battery depletion

6 Business Plan for Manufacture and Distribution

To build the prototype, we used a combination of materials sourced from the local hardware store and purchased online. Total cost of materials was $314.03, excluding sample items purchased in the concept development phases. As material purchased in bulk is generally cheaper, it is anticipated that the cost per unit will decrease with larger scale production. The cost breakdown is outlined in the table below.

One major advantage of this surgical lamp is that it does not require any custom-built parts unique to its design. Thus, the need for exclusive manufacturing is eliminated. All of the above elements can be sourced locally and/or should be readily available online. Given the size of the assembled product, local assembly will prove to be the most cost-effective option that minimises logistics.

The end users for this design are small community hospitals and local clinics. As such, the business plan is structured to provide maximum benefit to under-resourced clinical settings. We plan to operate as not-for-profit, and do not seek any patents for this device.

Initial distribution of the lamp will be at zero cost to the end user. Our initial target market will be Cambodian hospitals and clinics, with gradual expansion into developing countries as the technology develops. We plan to take advantage of the EWH chapter at UNSW and its associated summer internship program in Cambodia. Initial funds will be generated at a university level to allow for the development of 10 lamps, with assembly conducted on a voluntary basis by student members of EWH during their summer internship in Cambodia. The lamps will be distributed to relevant clinics to generate interest, as well as to determine the scale of future distribution through feedback received. From this estimate, the method of fundraising for subsequent production will be established.

If the interest is small, and the number of required lamps is below 100, fundraising shall take place in Australia via EWH, through university and high school programs. This shall

Table 1: Cost estimate per unit for 1000 units made

	Component	Cost
Mechanical	Box	$20.00
	Stand - Al tubes	$37.33
	Stand - Connectors	$31.00
	Springs	$21.00
	PVC sheet	$22.00
	Rivets	$4.00
	Angle brackets	$6.00
Electrical	12V 12W LED bulbs	$31.37
	15V 20A Medical Power Supply	$90.00
	12V 70Ah Battery	$41.81
	11.1 V Zener Diodes	$0.09
	2N2907 Transistor	$2.96
	1N4001 Rectifier	$0.04
	1N5822 Schottky Rectifier	$0.37
	2N7000 MOSTFET	$0.19
	SPDT 12 V Relay	$3.55
	20A 240V Fuses	$0.80
	Resistors	$1.17
	Capacitor	$0.15
	PCB	$2.77
Total		$314.03

serve as an extra-curricular community activity and should result in a sizeable fundraised amount. If a larger amount of interest is generated, applications will be put in by EWH student members to large foundations and charities, with a particular emphasis on the need for cost-effective surgical lamps and the impact they will have in the developing world.

Once the funds are raised, the money will be made accessible for local sourcing of parts and assembly in Cambodia. This will be liaised with EWH as an additional project to create employment for local communities. The raised funds will be used to pay local workers, and assembly of the design will take place on the ground, using the detailed assembly booklet. Over time as the project grows, we anticipate that it will require less on fundraising and gradually become self-sustaining. As more lamps are required, we plan on selling them at cost price to larger hospitals that have the resources to purchase additional affordable equipment. A small profit margin may be introduced at this stage, but all profits will be funded back into the project to keep the lamp free for smaller hospitals and clinics.

Quality of production shall be at the level of individual assemblers or manufacturers. A quality assurance checklist shall be provided to ensure optimal outcomes will be achieved before it enters the surgical environment. This includes an electrical safety test procedure to ensure correct wiring of the device. Further tests shall be performed to check the stability of the product as well as range of motion. Thorough cleaning of the product so that it is considered sterile will also be required. As a detailed assembly manual will be provided, a high quality of production should be achieved through following the direct instructions.

References

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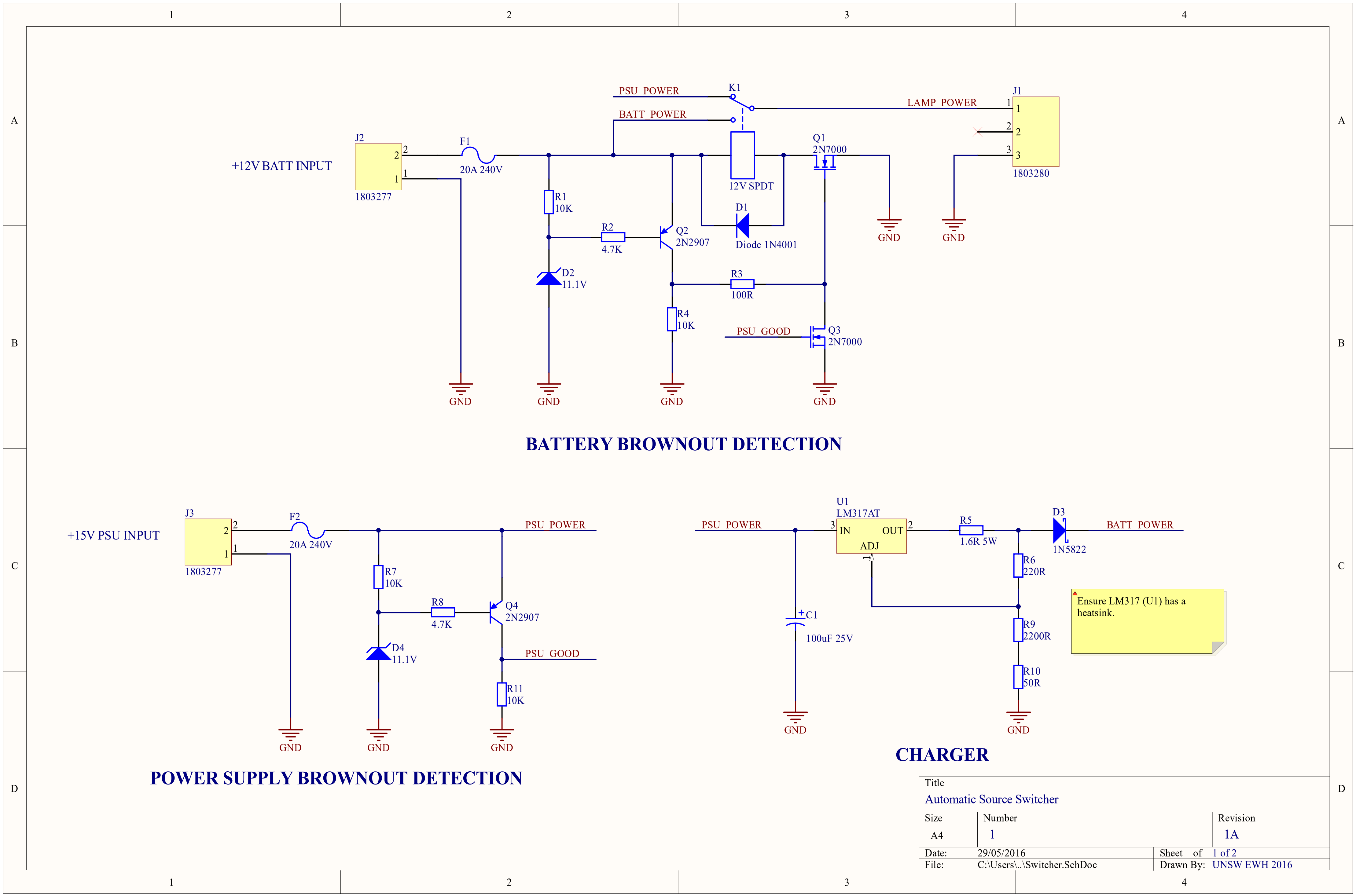
Appendix A Schematics



BATTERY BROWNOUT DETECTION
+12V BATT INPUT
J2
1803277
F1
20A 240V
R1
10K
R2
4.7K
D2
11.1V
Q2
2N2907
R3
100R
R4
10K
K1
12V SPDT
D1
Diode 1N4001
Q1
2N7000
Q3
2N7000
PSU_POWER
BATT_POWER
LAMP_POWER
PSU_GOOD
J1
1803280
GND
POWER SUPPLY BROWNOUT DETECTION
+15V PSU INPUT
J3
1803277
F2
20A 240V
R7
10K
R8
4.7K
D4
11.1V
Q4
2N2907
R11
10K
CHARGER
U1
LM317AT
IN
OUT
ADJ
C1
100uF 25V
R5
1.6R 5W
R6
220R
R9
2200R
R10
50R
D3
1N5822
Ensure LM317 (U1) has a heatsink.
Title
Automatic Source Switcher
Size
A4
Number
1
Revision
1A
Date: 29/05/2016
Sheet of 1 of 2
File: C:\Users\..\Switcher.SchDoc
Drawn By: UNSW EWH 2016

Appendix B PCB

Shown below is the PCB design for the switching and charge circuits.