

# A fibre-optic near-infrared urethra illumination system

## 1. Introduction

Near-infra-red (NIR) fluorescence image-guidance devices are increasingly employed in numerous surgical applications. These use both non-specific markers (i.e. non-tissue-specific) and tissue- or tissue type-specific fluorescent markers, enabling relatively deep imaging, at up to 10 mm or more. The availability of NIR-fluorescence enabled instruments, commercial or in-house-developed, make widespread use of these techniques possible.

It is well recognised that surgical damage to particular organs or vessels can lead to serious complications and any device that reduces the risk to such damage is welcome. Here we describe a device that alerts the surgeon when the procedure is at risk of damaging the urethra. While the likelihood of such damage is often not a problem for experienced surgeons, a degree of confidence is imparted through the use of the device described here.

Our approach makes use of the fact that it is straightforward to achieve a controlled degree of light leakage along the length of a polymer optical fibre. We thus insert such an optically 'leaky' fibre through a conventional 2-port Foley catheter, inserted in the urethra. The fibre efficiently carries NIR light at 830 nm to the 'leaky' portion, at which point side emission takes place. Since we are using long wavelength light, a good tissue penetration can be achieved; of course, the emitted light is scattered by the tissue and the extent of this scatter provides an indication of how deep the resection can be.

Additional required equipment includes an NIR-enabled imaging system. Since such imaging systems, whether enabled for laparoscopic or open surgery applications, would also be used to conventional fluorescence guidance, differentiating this signal from the 'normal' fluorescence is advantageous. This could of course be achieved by simply turning off the surgical fluorescence excitation light source, but since this may not be possible in some commercial instruments, we chose to pulse our 830 nm source at rate and at a duty cycle adjusted by the user. In addition, the user can also adjust the intensity of our light source.

Although there are numerous types of sources delivering 830 nm that could have been used, we chose to use a solid-state laser source for this job. Doubtless, LED sources could also be used, but we did not want to be limited by source brightness, and a laser source at this wavelength is readily available at low cost. Whenever the word 'laser' is uttered in a surgical environment, safety concerns are voiced! We thus arranged the mechanical fibre system coupling to be interlocked in such a way that laser emission is inhibited unless a shroud around the fibre connector is in place. Such an interlock is sufficient to placate even the most ardent theatre safety officer: no 'dangerous' light emission can take place without the presence of this fibre-optic cable shroud.

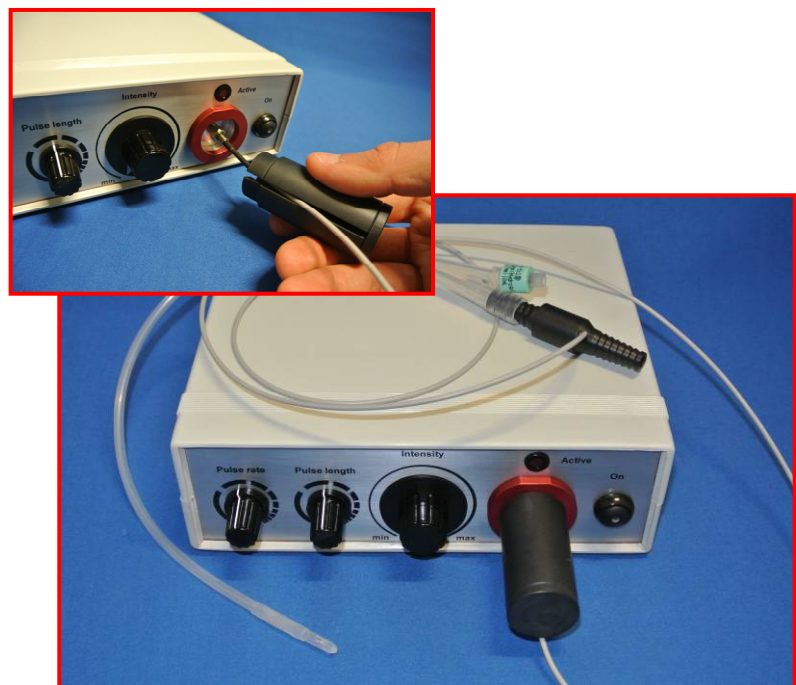


Figure 1: The units comprising the urethra illuminator. The inset shows the slip-on fibre interlock plug; the Foley catheter with a fibre inserted into an additional port provided in the output tube coupler on the top of the NIR light generator.

## 2. The fibre-optic system

We decided at the outset to use a standard, commercially available, SMA-terminated polymer optical fibre, most easily available as a 1 mm dia. fibre. Although a good method of launching light into such a fibre was to butt the laser diode onto the fibre, in our case this was not possible as we needed to incorporate an output interlock: its thickness precluded straightforward laser mounting and heatsinking. We thus used a pair of short focal length lenses that were to hand: this also allowed us to launch light into the fibre at a higher numerical aperture than the laser could provide, as shown in Figure 2.

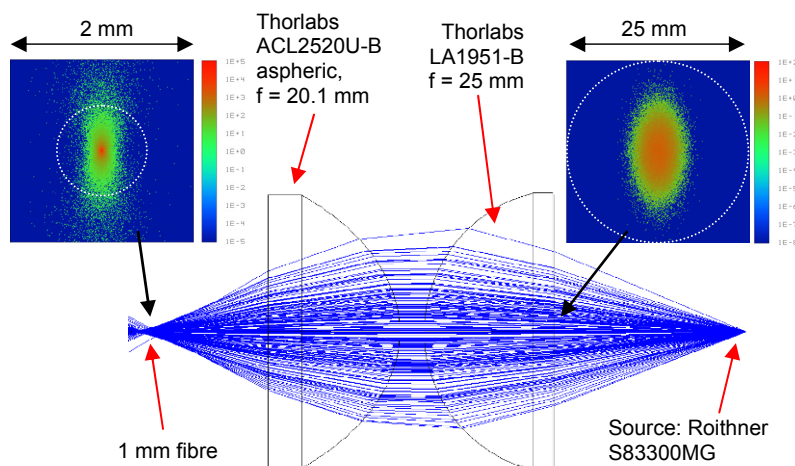


Figure 2: Optical ray-tracing model of the system to couple the laser diode with the optical fibre. Adequate light power can be launched into even smaller fibres if required.

Figure 3 shows the opto-mechanical components in cross-section form. For convenience, components supplied by Thorlabs are used whenever possible, with the exception of a Delrin SM1 tube used to insulate the laser anode from ground.

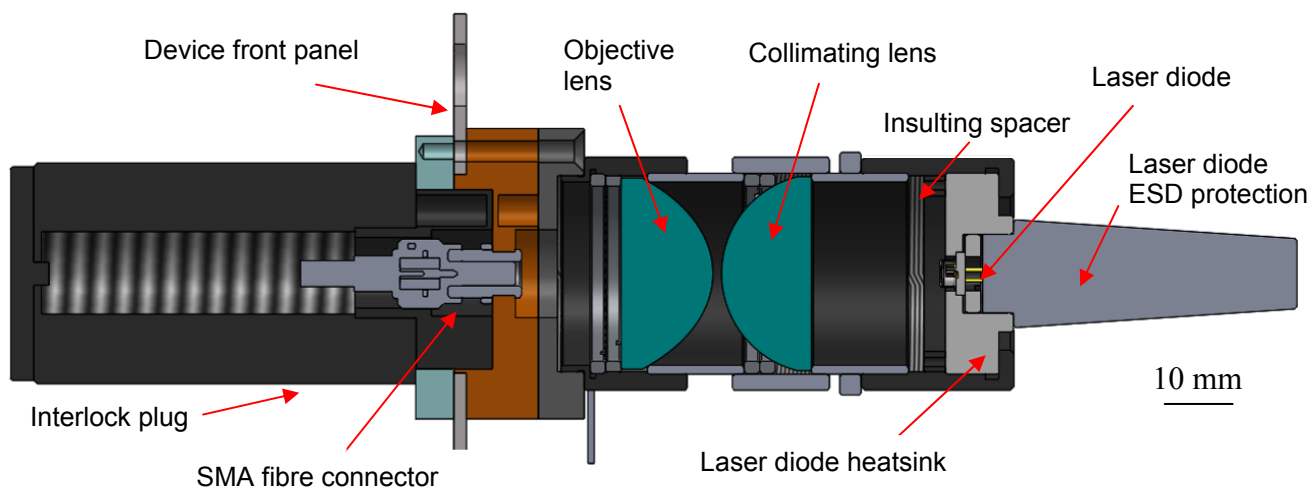


Figure 3: Cross sectional view of the opto-mechanical arrangement used to couple the laser diode with a 1 mm polymer optical fibre.

It is noted that, like most 5.6 mm laser diodes, the diode can be connected to the laser anode, and hence is at a potential of 5V. This is inconvenient but inevitable. On the other hand, the laser does generate some heat and it is wise to use a metal component to dissipate this heat. We also applied a little zinc oxide heatsink compound around the laser. Most of the time, the laser is used intermittently at a relatively low duty cycle and average power dissipation is relatively low. The heatsink is a threaded component and we used a tapped Delrin component too hold it and a small insulated spacer is installed directly in front of it to prevent accidental shorting by subsequent SM1 metal components. Sicher ist sicher, as the Germans say!

Finally, since laser diodes are all too readily destroyed by overvoltage or by reverse voltages, we used an ESD protection 'plug' to make life a little easier for us.

### 3. The near-infrared light source driver circuit

While there are numerous, and potentially simpler, ways to provide a variable amplitude, variable mark-space ratio and variable rate pulse generator, we chose to use an old-school approach to achieve this. Such an arrangement is very flexible and readily modified and extended to suit specific applications. While a simple PIC circuit could do it all, code can be problematic in safety-critical applications, often changes require a rewrite (!) and in any case the author of this note is very much of old-school persuasion. Figure 4 shows the complete circuit diagram. We start with a crude triangle wave generator, U1, developed from an integrator and a comparator. These are conveniently provided in the Maxim MAX 9000 chip, which also includes a 1.25 V voltage reference. VR1 sets the triangle wave rate while C2 and C3 (and R4) modify this rate if required. A note for the purist: a respectable triangle wave can be obtained by ‘tweaking’ the values of R1 and R2. The MAX9000 voltage reference is boosted to 4.8V using the U2a operational amplifier. The other half of U2 operates as a comparator, with hysteresis provided by R9 and R10: the triangle wave thus becomes a variable mark-space ratio square wave at the output of U2b, with the mark-space ratio adjusted by VR2. Now that a logic signal is available at the comparator output, it can be made permanently high or permanently low with the aid of NOR gates U3, which provide convenient input for the internal interlock system or for enable/disable switches if required in the future. The interlock is discussed later on. The gate output signal drives an analogue switch U4 that switches the 4.8 V reference, providing a well-defined amplitude of the square wave signal. Note that an ADG419, rather than the more usual DG419 is essential here, since it can operate down to a +5 V supply, rather than the more usual  $\pm 5$  V minimum associated with the DG419. The resulting output signal then drives the light amplitude defining potentiometer, VR3. An extension connector, CN5, provides additional synchronisation options, should they be required in the future.

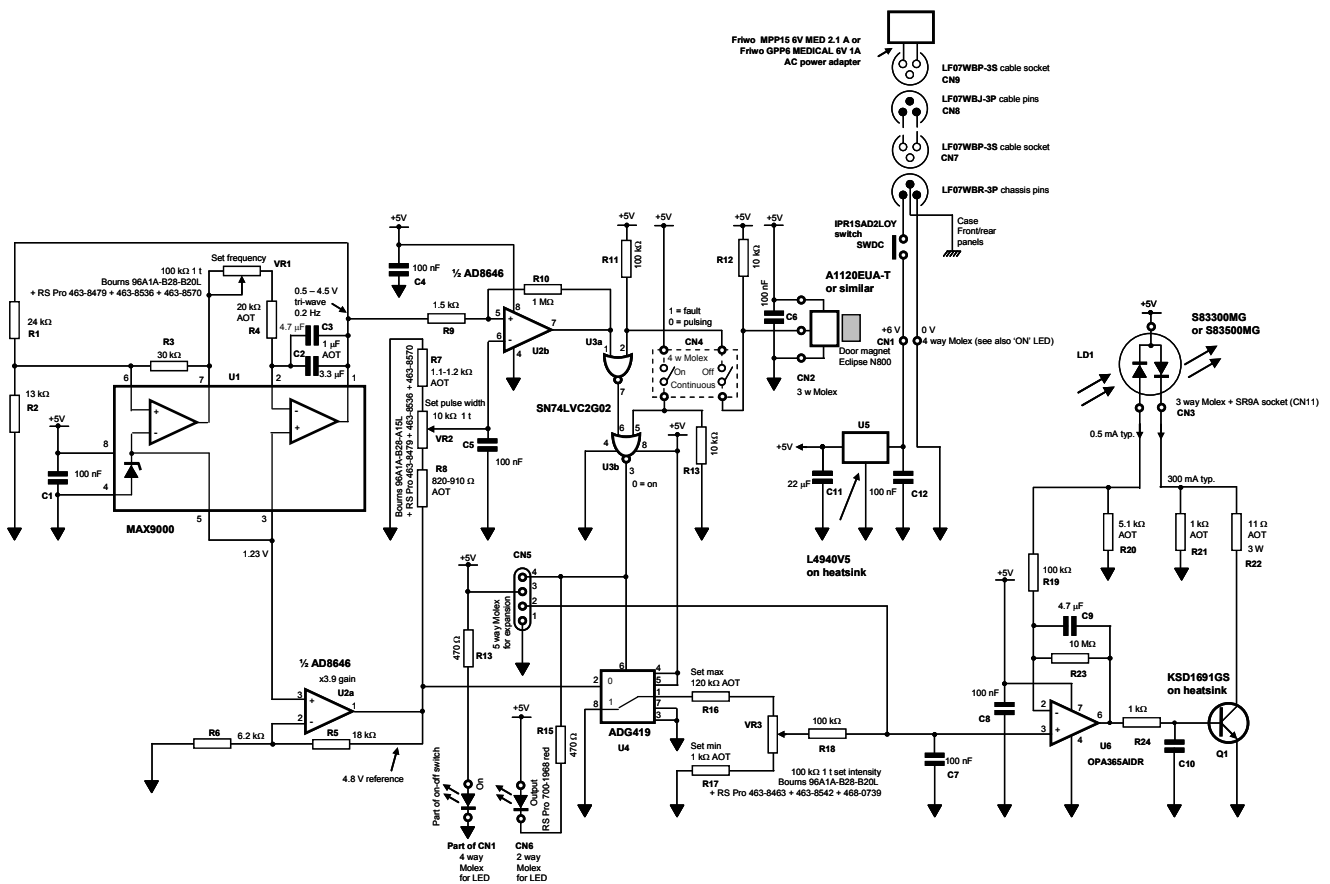


Figure 4: Circuit diagram of the laser light source controller.

Operational amplifier U6, in conjunction with a power transistor, Q1, form a constant power type of laser driver. Most medium power laser diodes provide a power monitor photodiode and this provides feedback to the integrating type controller. A small idle current is provided by R21, ensuring that the laser is able to turn on quickly, while R22 defines the maximum laser current.

DC power is provided by a wall-plug type of power supply, connected to the drive unit through a front-panel illuminated on-off switch; this supplies 6 V dc, regulated down to +5 V dc with a small low dropout regulator, U5.

We provide an interlock system in the form of a slide-on ‘plug’ around the output optical fibre. The idea here is that when this plug is not inserted, the laser is disabled. This prevents unwanted NIR radiation from potentially harming the operator. When the plug is in place with the fibre connected, the laser can operate normally. When the plug is in place with no fibre connected, the laser can still operate but very little light (<1-2 mW) is able to leak out into the environment. This is due to the use of small apertures, in conjunction with the relatively large numerical aperture associated with the output beam. The use and implementation of this system is shown in Figure 5. Three 4 mm diameter magnets are placed in a round block behind the front panel. A small slot is also machined into this block to house the Hall-effect sensor (Allegro MicroSystems A1120 series). Matching sets of magnets are also inserted in part of the ‘plug’ that hold it firmly in place when it is inserted almost fully through the panel and its bezel and into the block. The plug also holds a single magnet aligned with the Hall effect sensor: this magnet provides the interlock. Of course care has to be taken with the magnet polarities: the holding magnets must of course have aligned N-S poles in order to hold the clamp, but the Hall-effect one has to have opposite alignment. No we don’t provide a detailed magnetic field map, but a quick glance at the sensor data sheet will make thing clear (!) while providing numerous ways of incorrectly aligning the magnets.

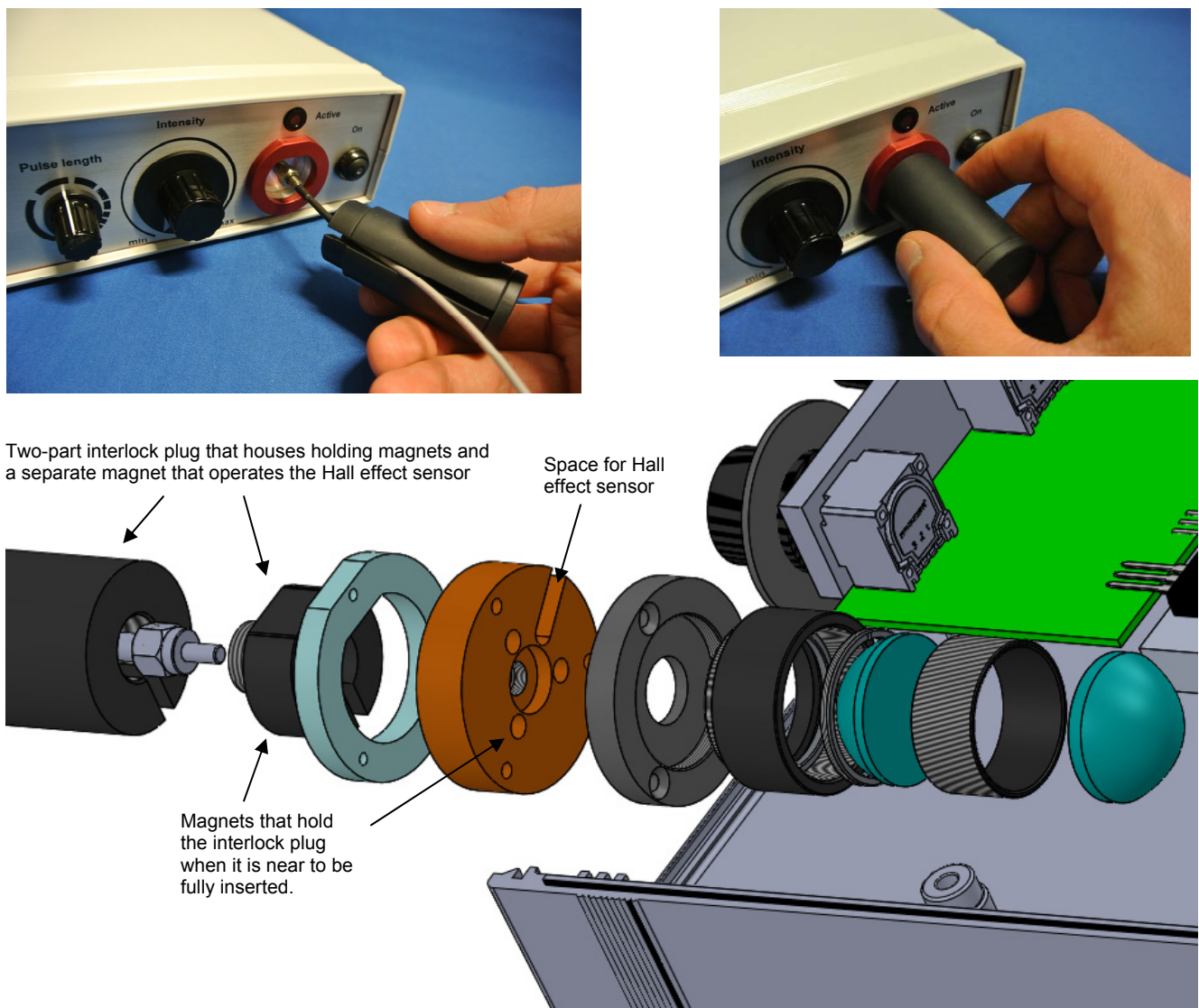


Figure 5: Details of the optics and the interlock components.



#### 4. Printed circuit board layout

All the electronic components (other than the laser, the laser drive transistor and the circuit DC regulator) are placed on a small double-sided printed circuit board. Doubtless, it could all fit on a single-sided board but the resulting cost savings would be minimal. The board was designed using EasyPC software (<https://www.numberone.com>) and the board themselves were made by PCB Pool ([www.pcb-pool.com](http://www.pcb-pool.com)). There is not much that can be added here; a standard 1.6 mm FR4 board is a board after all. Surface mount components were used throughout; board headers, power devices and potentiometers were the exception of course. Figure 6 shows the layout of the board. Design files are available on request, provided nobody points out errors! (There are a couple of layout improvements that could be made...)

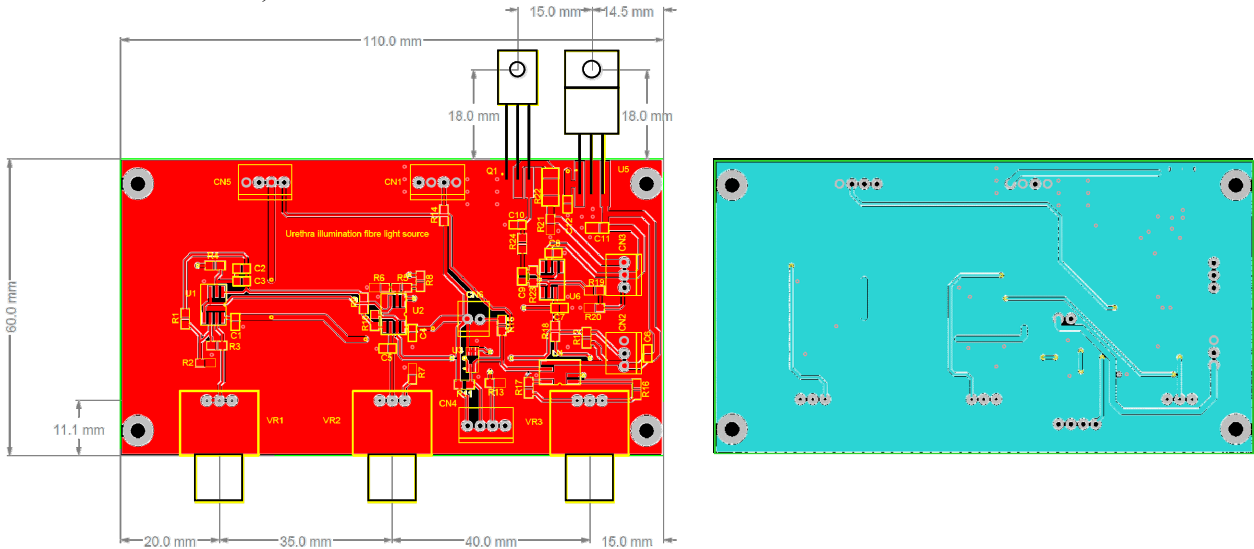


Figure 6: Left: Layout of upper layer of printed circuit board. Right: layout of board lower layer.

#### 5. Construction

The electronics are constructed in a small plastic Hammond case (type 1598DGY), fitted with aluminium front/rear panels. This is shown in Figure 7 and was modified to be screened by applying a conductive layer to the inside surface. This layer is electrically connected to a grounded heatsink which is also connected mechanically and electrically to the rear panel. The case front panel is also connected to the rear panel with an earthing wire.

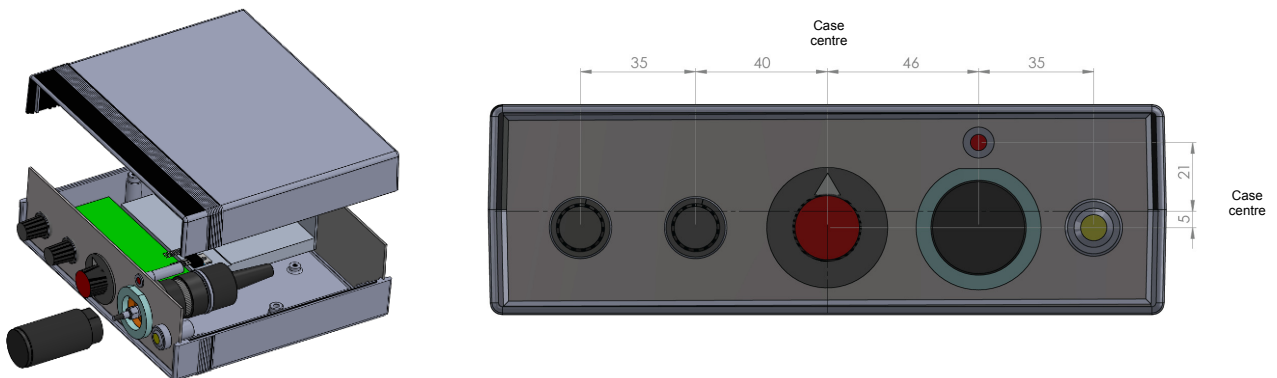


Figure 7: Left: Internal view of the model of the electronics controller and front panel details, shown on the right.

We added a small aluminium block/heatsink, not because it was really necessary, but rather to provide some weight to the inherently light plastic box and other circuit components. This helps somewhat

with stability. The internal components arrangement and an image of the internal construction are shown in Figure 8 overleaf.

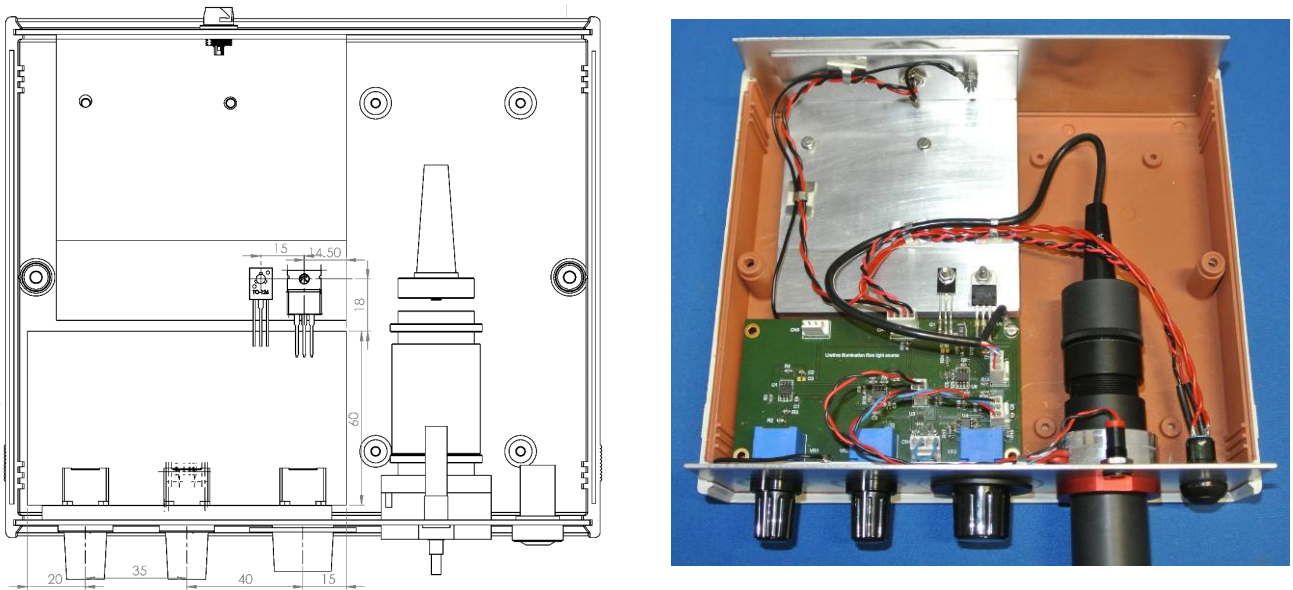


Figure 8: Left: model of the internal case layout. Right: how it looks in reality.

## 6. Optical fibre details

The operation of this system relies on the fact that part of the optical fibre within the Foley catheter ‘leaks’ NIR light. While there are many sophisticated ways of arranging fibre leakage, we have adopted a very simple approach, reliant on the fact that we use a large diameter polymer optical fibre. This type of fibre is really not optimal as far as transmission is concerned: normally such fibres are used at wavelengths of  $\sim 660$  nm and are considered to be rather lossy at 830 nm. However, in this case the fibre is relatively short and we have lots of light available: sometimes a sledgehammer can be useful to crack a nut! The side emission from the fibre occurs because we partially remove the cladding by roughening the fibre with fine grit sandpaper. With care, it is possible to make the fibre surface rougher at the distal end, where proportionately more light output is required, as less light is available, since some of it has already leaked out earlier along the fibre length. It is quite straightforward to do this by observing the light output along the fibre length with an NIR-enabled imaging system.

Once suitably roughened, the fibre is inserted through an angled hole in a catheter coupling tube, as shown in Figure 9.



Figure 9: Details of the optical fibre insertion at the distal end of the Foley catheter.



## 7. Performance

The performance of the circuit is just as was expected. Figure 10 shows a series of oscillograms that depict the salient points. Figure 10a shows the output of the triangle wave generator (pin 1 of U1) and the corresponding signal at the output of the comparator (pin 7 of U2b). Figure 10b shows the same triangle wave generator signal alongside the laser drive set-point signal (pin 3 of U6). Panel C shows exactly the same condition but now it is the laser photodiode which is monitored. The intentionally slow rise/fall times, due to R18 and C7) are clear and made a little clearer in panel D.

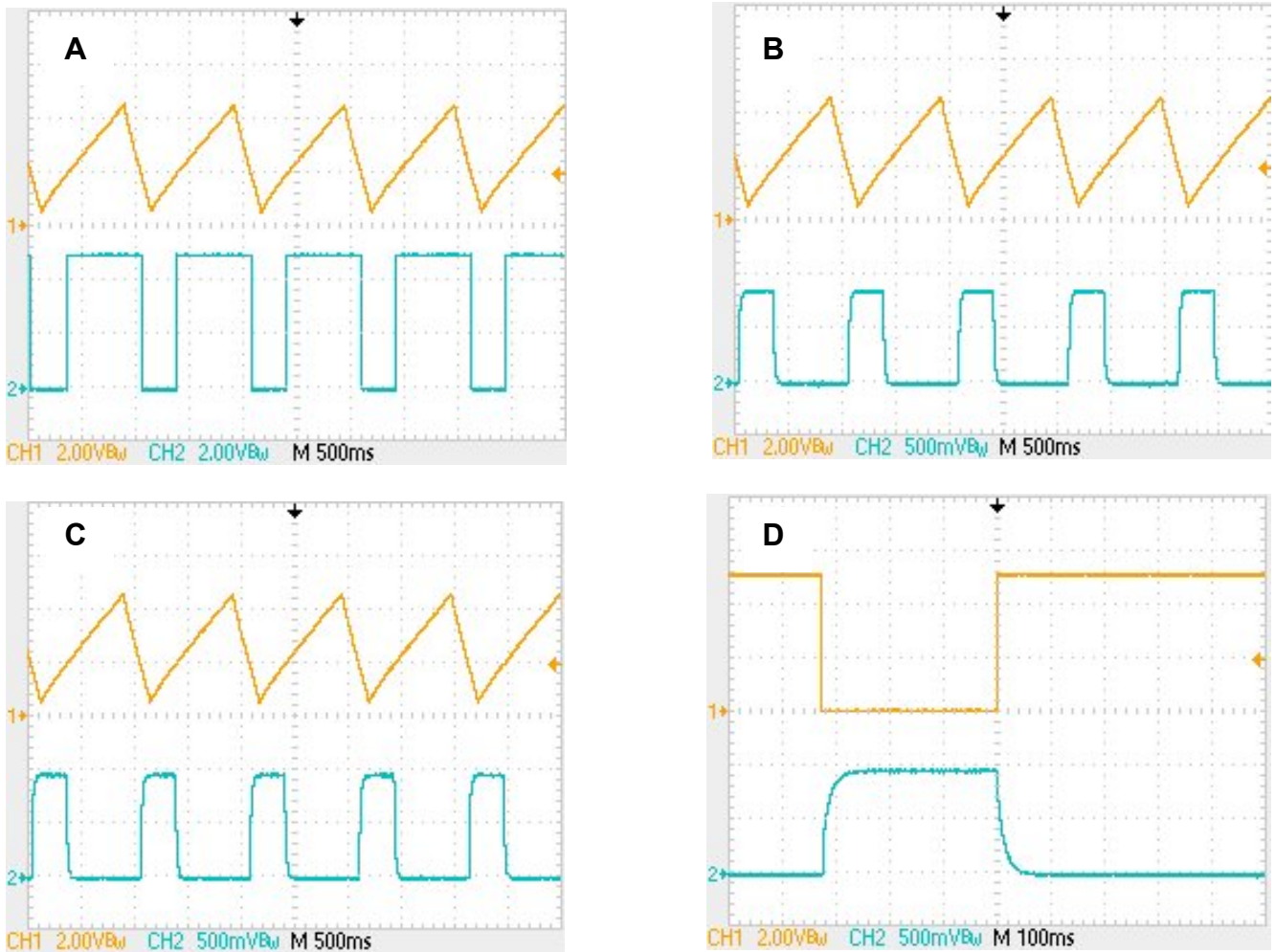


Figure 10: Oscillograms showing the driving triangle wave and pulse outputs at different parts of the circuit; please see text for waveform test points. Measurement bandwidth was 20 MHz.

It is also worth noting, that although the chosen laser can deliver up to 300 mW, we chose to operate ours at ~200 mW: it is never a good idea to stress laser diodes too much! If more power is required, it is straightforward to replace the laser diode with one rated at 500 mW: this is also readily available from Roithner (part S83500MG). Should even higher powers be required, then a 9 mm package, rather than the current 5.6 mm package is usually the only option, necessitating a somewhat different mounting arrangement than that used here. Higher operating currents are also required in these cases, necessitating a reduction of the value of R22 and changing the value of R20, the latter so as to provide an appropriate photodiode feedback signal. Furthermore, the value of the laser driver integrator capacitor, C9, should be made as large as possible consistent with reasonably responsive operation: a value of 2.2 - 4.7  $\mu\text{F}$  is close to the optimal. This capacitor should have a value should be  $>100$  nF to avoid turn-on spikes and the capacitor should integrate the laser drive over all rates and mark-space ratios.



## 8. Results and Discussion

This section is straightforward to write: it works and works well! During a cadaveric study, imaging was performed with a laparoscope and our Group's fluorescence imaging apparatus. Even at video rate imaging (20 ms field/40 ms frame integration times) the urethra could be readily identified, as shown in Figure 11. At higher sensitivities/integration times, there was no problem at detecting the urethra even through fat tissue, albeit with significant and expected scatter.



Figure 11: Laparoscopic imaging in cadavers. Left: white light illumination. Middle: White light illumination and simultaneous NIR imaging, near-minimum NIR intensity. Right: White light illumination and simultaneous NIR imaging, higher, but still low NIR intensity. Images acquired in real-time, at 40 ms integration time.

In reality the urethra appears much more noticeable than Figure 11 suggests. A repetitively flashing light is always much more noticeable...think police cars and ambulances. But since movies cannot yet be presented on paper, we have to make do with snapshots from the different phases.

So there it is: a simple and effective surgical aid, shown in Figure 12. Could we have developed a device do the same job more simply: yes of course. A suitably programmed Microchip PIC could readily provide the switching waveforms. But it would of course require programming and that requires time! As mentioned at the start, this was an old school approach, developed relatively quickly and was intended to show the youngsters that is life can exist without the need for programming....!

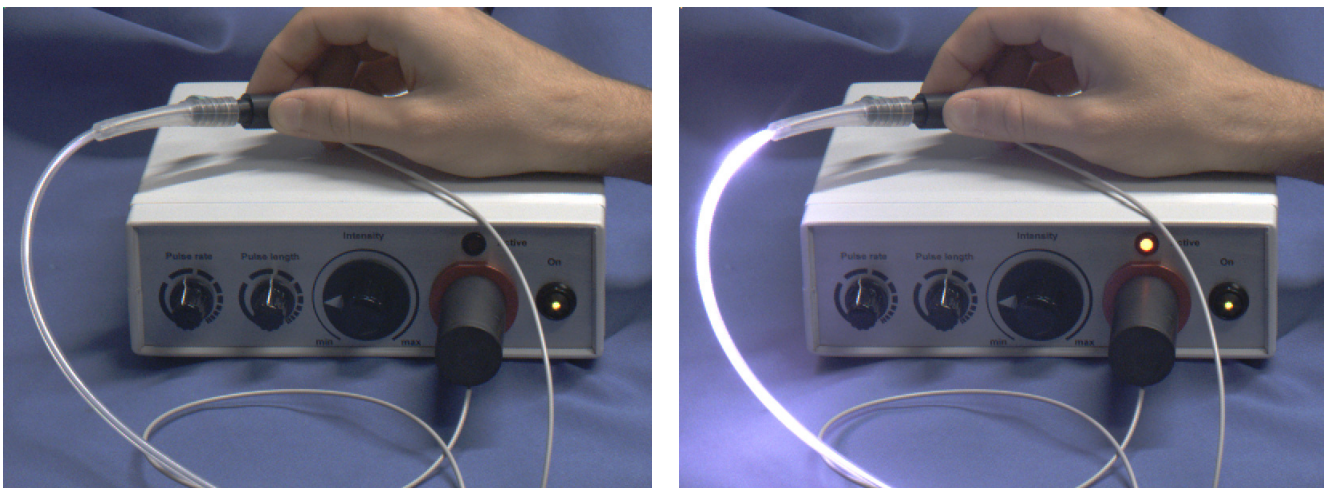


Figure 12: The completed urethra illumination device acquired with camera without any NIR imaging filter. Left: image acquired during the 'off' phase of the illuminator. Right: image acquired during the 'on' phase, with light from the fibre illuminating the scene nicely! Note the incorrect colours on the indicators under IR illumination: the 'on' indicator above the interlock plug is really red, really!.

## 9. Final notes

For completeness, here are a few final words regarding maintenance and cleaning and optical safety.

### *Device Cleaning*

Before use the main unit and the safety interlock plug should be thoroughly wiped down externally using disinfectant wipes. The Foley catheter, drainage bag and optical fibre must be disconnected from the coupler. The optical fibre and coupler must be sterilised before next use. The only recommended sterilisation method is through low-temperature, hydrogen peroxide gas plasma technology (STERRAD®). Fibres seem to survive well this process, even following numerous sterilisation cycles.

### *Device Storage and Handling*

When not in use, the main unit should be stored in a clean area and with the safety plug inserted. The optical fibre and coupler are sterilised after each use and must be stored by the sterile services department according to the local rules.

When handling the optical fibre, care must be taken to prevent damage to the fibre itself and to the connector.

### *Safety*

The light source spectral irradiance was calculated at a distance of 200 mm from the fibre, looking directly at it. This distance is the recommended one to use for determining hazard values, in accordance with IEC 62471-2:2009.

The source has an average dimension of 150.5 mm, resulting in a subtended angle of 0.75 rad relative to a distance from the source of 200 mm. Given a surface area of 300 mm<sup>2</sup> (1 mm fibre diameter, 300 mm long), the subtended solid angle is 0.0075 sr.

The irradiance of the source was calculated using LaserBee Laser Safety Software. For a source of maximum power 300 mW the irradiance is 2.4 W/m<sup>2</sup>. This is the maximum power that the laser can emit and corresponds to a radiance of 230 W/m<sup>2</sup>/steradian. It is noted that the polymer fibre attenuates this significantly and typically no more than 50 mW is available at the 'leaky' part of the fibre. Nevertheless the 230 W/m<sup>2</sup>/steradian value is below the emission limit for a continuous wave source (Table 6.1 from EN 62471:2008) which was calculated to be 7973 W/m<sup>2</sup>/sr. As a consequence, the source is assigned to the exempt group (no photobiological hazard). This is also the case should some users wish to fit the higher power, 500 mW laser diode.

## Acknowledgements

This note was prepared by B. Vojnovic in August 2017 and completed in late September 2017. He designed the basic system with D. Volpi, following design requirements from T. Barnes. B. Vojnovic also contributed to the design of the electronics and printed circuit boards. R.G. Newman designed the printed circuit board and performed electronic construction. Thanks are due to I.D.C. Tullis for useful comments and for determining that the device was intrinsically safe, to J. Prentice and to G. Shortland for machining the various items associated with this system. D. Volpi also validated the performance of the system, was associated with performing imaging of cadavers, along with T Barnes, making the device suitable for routine applications in surgical practice.

We acknowledge the financial support of Cancer Research UK.

© Gray Institute, Department of Oncology, University of Oxford, 2017.

This work is licensed under the Creative Commons Attribution-NonCommercial-NoDerivs 3.0 Unported License. To view a copy of this license, visit <http://creativecommons.org/licenses/by-nc-nd/3.0/> or send a letter to Creative Commons, 444 Castro Street, Suite 900, Mountain View, California, 94041, USA.