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 form 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 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 but 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 is 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 font of it to prevent accidental shorting by subsequent SM1 metal components. Sicher ist sicher, as the Germans say!

Finally, since laser diode 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 on 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 markspace 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 high 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 a 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 old 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 then 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). 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 ~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.

6. List of components

For completeness, the list of components used in the manufacture of the NIR source is presented below. Total component cost is <£500 and all components were obtained from common UK suppliers, such as RS components, OneCall Farnell, Mouser, Digikey and Thorlabs. The one exception is the laser diode, provided by Roithner (Vienna, Austria). Older readers may require glasses!

Main b	oard				-	-			
ID 	Item Printed circuit board Double-sided	Description Filename: Urethra illumination fibre light source.pcb	Manufacturer Gray	Model #	Supplier Beta Layout	Part number	Qty 1 off	Cost 50.00	Total 50.00
CN1 CN1a	DC power input header DC power input shell	4 way Molex 0.1" 4 way Molex 0.1"	Molex Molex	22-27-2041 22-01-2045	OneCall OneCall	9731164 143128	1 off 1 off	0.209	0.209
CN2 CN2c	Hall effect switch header	3 way Molex 0.1"	Molex	22-27-2031	OneCall	9731156	1 off	0.191	0.191
CN3	Laser ouput header	3 way Molex 0.1	Molex	22-27-2031	OneCall	9731156	1 off	0.100	0.100
CN3a CN4	Override switch header	3 way Molex 0.1" 4 way Molex 0.1"	Molex	22-01-2035 22-27-2041	OneCall	9731164	1 off 1 off	0.160	0.160
CN4a CN5	Override switch shell Auxilliary interlock header	4 way Molex 0.1" 4 way Molex 0.1"	Molex Molex	22-01-2045 22-27-2041	OneCall OneCall	143128 9731164	1 off 1 off	0.188	0.188
CN5a CN6	Auxilliary interlock shell Output 'on' LED header	4 way Molex 0.1" 2 way Molex 0.1"	Molex Molex	22-01-2045 22-27-2021	OneCall	143128 9731148	1 off 1 off	0.188	0.188
CN6a	Output 'on' LED shell Rate potentiometer	2 way Molex 0.1" Potent Potentingeter 100 kohm 1 W + 20% 06 Series 1 T Linear Shaft 22 225 / 6 32mm	Molex	22-01-2025 96414-B28-B201	OneCall	143126	1 off	0.150	0.150
VR2	Pulse width potentiometer	Rotary Potentioneter, 10 kohm, 2 W, ± 10%, 30 Senes, 17, Enear, Shaft: 22.225 / 0.22mm	Bourns	96A1A-B28-A15L	OneCall	2328050	1 off	6.82	6.82
U1	Triangle wave generator + reference	Special Function IC, OP Amp, Comparator, Voltage Reference, 2.5 V to 5.5 V, NSOIC-8	Maxim	96ATA-B28-B20L MAX9000ESA+	OneCall	2515533	1 off	2.90	2.90
U2 U3	Buffer reference and drive comparator Interlock/override gating	Operational Amplifier, Dual, 2 Amplifier, 24 MHz, 12 V/µs, 2.7V to 5.5V, SOIC, 8 Pins NOR Gate, 2 Input, 32 mA, 1.65 V to 5.5 V, SSOP-8	Analog Devices Texas Instruments	AD8646ARZ SN74LVC2G02DCTR	OneCall OneCall	1440771 1236358	1 off 1 off	2.08 0.495	2.08 0.495
U4 U5	Laser drive reference switch DC input regulator	Analogue Switch, SPDT, 1 Channels, 25 ohm, 4.5V to 5.5V, SOIC, 8 Pins LDO Regulator, 1.5A, 5 V, 3-Pin TO-220	Analog Devices ST Microelectronics	ADG419BRZ L4940V5	OneCall RS	1661025 298-8491	1 off 1 off	3.07 0.98	3.07 0.98
U6	Laser driver control opamp	Operational Amplifier, Single, 1 Amplifier, 50 MHz, 25 V/µs, 2.2V to 5.5V, SOIC, 8 Pins Biolog Transistor - B IT NEN Enitoxial Silicon	Texas Instruments	OPA365AID KSD1691GS	OneCall	2295986	1 off	1.30	1.30
R1	Tri wave comparator feedback resisor	24 kΩ 1% 0805 125 mW	Vishay	CRCW080524K0FKEA	OneCall	1652964	1 off	0.012	0.012
R2 R3	Tri wave comparator hysteresis 2	30 kΩ 1% 0805 125 mW	Vishay	CRCW080530K0FKEA	OneCall	1469914	1 off	0.012	0.012
R4 R5	Rate maximum limit resistor Reference amplifier feedback resistor	20 kΩ 1% 0805 125 mW 18 kΩ 1% 0805 125 mW	Vishay Vishay	CRCW080520K0FKEA CRCW080518K0FKEA	OneCall OneCall	1469893 1652933	1 off 1 off	0.012	0.012
R6	Reference amplifier gain resistor	6.2 kΩ 1% 0805 125 mW	Vishay	CRCW08056K20FKEA	OneCall	1469947	1 off	0.012	0.012
R8	Pulse width limit resistor 2	470 Ω 1% 0805 125 mW	Vishay	CRCW0805470RFKEA	OneCall	1469932	1 off	0.012	0.012
R9 R10	Output comparator input resistor Comparator feedback resistor	1.5 kΩ 1% 0805 125 mW 1 MΩ 1% 0805 125 mW	Vishay Vishay	CRCW08051K50FKEA CRCW08051M00FKEA	OneCall OneCall	1652940 1652946	1 off 1 off	0.012 0.012	0.012 0.012
R11 R12	NOR gate pull-up resistor Hall senso pull-up resistor	100 kΩ 1% 0805 125mW 10 kΩ 1% 0805 125mW	Vishay	CRCW0805100KFKEA	OneCall	1469860 1469856	1 off	0.012	0.012
R13	NOR gate pull-down resistor	10 kΩ 1% 0005 125mW	Vishay	CRCW080510K0FKEA	OneCall	1469856	1 off	0.012	0.012
R14 R15	PULSE LED current limit resistor	470 Ω 1% 0805 125mW 470 Ω 1% 0805 125mW	Vishay Vishay	CRCW0805470RFKEA CRCW0805470RFKEA	OneCall OneCall	1469932 1469932	1 off 1 off	0.012	0.012
R16 R17	Intensity max limit resistor	1 kΩ 1% 0805 125mW 1 kΩ 1% 0805 125mW	Vishay Vishay	CRCW08051K00FKEA CRCW08051K00FKEA	OneCall	1469847 1469847	1 off 1 off	0.012	0.012
R18	Laser controller filter resistor	100 kΩ 1% 0805 125mW	Vishay	CRCW0805100KFKEA	OneCall	1469860	1 off	0.012	0.012
R19 R20	Feedback photodiode sense resistor	100 KΩ 1% 0805 125mW 5.1 kΩ 1% 0805 125mW	Vishay Vishay	CRCW0805100KFKEA CRCW08055K10FKEA	OneCall	1469860	1 off 1 off	0.012	0.012
R21 R22	Laser current bleed resistor Laser current limit resistor	1 kΩ 1% 0805 125mW 11 Ω 1% 2512 3W	Vishay TE Connectivity	CRCW08051K00FKEA 352211RFT	OneCall OneCall	1469847 2476441	1 off 1 off	0.012	0.012
R23	Laser controller feedback resistor	10 MΩ 1% 0805 125mW	Vishay	CRCW080510M0FKEA	OneCall	1469858	1 off	0.012	0.012
C1	Tri-wave generator decoupling cap	100 nF, 50 V, ± 5%, X7R	AVX	08055C104JAT2A	OneCall	1740673	1 off	0.012	0.012
C2 C3	Tri-wave rate set capacitor 1 Tri-wave rate set capacitor 2	3.3 μF 25 V, ± 10%, X7R 1 μF, 25V, 0805, MLCC, X7R,	Murata Murata	GRM21BR71E335KA73L GRM219R71E105KA88D	OneCall	2426963 1845770	1 off 1 off	0.141 0.056	0.141 0.056
C4 C5	AD8646 decoupling capacitor Pulse width set input filter capacitor	100 nF, 50 V, ± 5%, X7R 100 nF, 50 V, ± 5%, X7R	AVX AVX	08055C104JAT2A 08055C104JAT2A	OneCall OneCall	1740673 1740673	1 off 1 off	0.034	0.034
C6 C7	Hall sensor decoupling capacitor	100 nF, 50 V, ± 5%, X7R 100 nF, 50 V, ± 5%, X7R	AVX AVX	08055C104JAT2A 08055C104JAT2A	OneCall	1740673	1 off	0.034	0.034
C8	Laser controller decoupling capacitor	100 R, 50 V, ± 5%, X7R	AVX	08055C104JAT2A	OneCall	1740673	1 off	0.034	0.034
C10	Laser driver slow-start capacitor	10 nF 0805, 50V, 50 V, X7R	AVX	08055C103JAT2A	OneCall	1740669	1 off	0.092	0.069
C11 C12	+5V regulator decoupling capacitor DC input regulator capacitor	22 μF 0805 25V 100 nF, 50 V, ± 5%, X7R	AVX	08055C104JAT2A	OneCall	1907510 1740673	1 off 1 off	0.262	0.262
TOTAL									85.41
Case a	nd related components								
ID	Item	Description	Manufacturer	Model #	Supplier	Part number	Qty	Cost	Total
	Case Electromagnetic shielding	Conductive coating spray	Kontakt Chemie	EMI 35 200ML	OneCall	2142398	1 off	25.21	25.21
 CN7	Power Supply DC power input connector	Friwo Plug In Power Supply 6V dc, 1A 3 way chassis mounting, pins, on case	Friwo Hirose Electric	GPP6 MEDICAL 6V LF07WBR-3P	RS Digi-Key	736-1728 HR545-ND	1 off 1 off	27.15 6.35	27.15
CN8 CN9	DC power input connector DC power input connector	3 way cable mounting, receptacle, on extension cable 3 way cable mounting, pins, on extension cable	Hirose Electric Hirose Electric	LF07WBP-3S LF07WBJ-3P	Digi-Key Digi-Key	HR542-ND HR537-ND	1 off 1 off	12.25 11.50	12.25 11.50
CN10 CN11	DC power input connector Laser connector + ESD protect	3 way cable mounting, receptacle, on power supply cable ESD Protection and Strain Relief Cable. Pin Codes A and E. 3.3 V	Hirose Electric Thorlabs	LF07WBP-3S SR9A	Digi-Key Thorlabs	HR542-ND SR9A	1 off 1 off	12.25	12.25
SWDC	On-off switch Hall effect sensor	Illuminated Pushbutton Switch, IP Series, SPST, Off-On, 2 A, 125 V, Yellow Hall Effect Switch, Unicolar Switch, 3 V, 24 V, SIP	Apem Allegro Microsytems	IPR1SAD2LOY	OneCall	1082445	1 off	14.18	14.18
HS1-a	Hall sensor magnet, holding magnets	Magnet, Button, Neodymium, 4 mm dia. x 3 mm, Pack of 10	Eclipse Magnetics	N802	OneCall	1800034	1 pk	13.23	1.32
-	Pulse width/rate potentiometer insert	RS Pro Potentiometer Knob Cap, Body: Black, Dia. 11mm	RS	463-8536	RS	463-8536	2 011 1 pk	0.414	2.07
	Puise wath/rate pot nut cover Intensity potentiometer knob	RS Pro Collet Knob Nut Cover, Body: Black, Dia. 19mm RS Pro Collet Knob, Body: Black, Dia. 21.3mm, 6.4mm Shaft	RS	463-8570 463-8463	RS	463-8570 463-8463	1 pk 1 off	0.926	4.63
	Intensity potentiometer knob cap Intensity potentiometer knob dial	RS Pro Potentiometer Knob Cap, Body: Black, Dia. 21mm RS Pro Potentiometer Dial, Body: Black, Dia. 21mm with a White Indicator	RS RS	463-8542 468-0739	RS RS	463-8542 468-0739	1 pk 1 pk	0.47	2.35 5.82
	Pulsing indicator LED	Flush Indicator Panel Mount, 8mm Mounting Hole, Red LED, Wire Termination, 5 mm Lamp	RS	700-1968	RS	700-1968	1 off	5.35	5.35 186.8
Ontics			•	<u>,</u>					
ID	Item	Description	Manufacturer	Model #	Supplier	Part number	Qty	Cost	Total
	Plastic 20 mm SM1 tube / laser side Fibre to SM1 Tube Coupler	Plastic 20 mm SM1 tube for laser side Filename: Urethra Plastic SM1 tube Fibre to SM1 Tube Coupler Filename: Urethra Fibre to SM1 Tube	Gray Gray		Gray Gray	000-1316 000-1275	1 off 1 off	-	-
	SMA Magnetic Socket	SMA Magnetic Socket Filename: Urethra SMA Magnetic socket	Gray		Gray	000-1280	1 off		-
	Fibre interlock plug part 1	Fibre shield plug #1 Filename: Urethra Plug Part 1	Gray		Gray	000-1281	1 off	-	-
CN11	Laser connector + ESD protect	ESD Protection and Strain Relief Cable, Pin Codes A and E, 3.3 V	Thorlabs	SR9A	Thorlabs	SR9A	1 off	36.75	36.75
LD1 	SMA connector	Bulkhead connector with locknut	Not known/Chinese Thorlabs	HASMA	Thorlabs	HASMA	1 off	35.58 5.80	35.58 5.80
-	SMA – SM1 mounting Focusing lens	S1LM56 - SM1-Threaded Aluminium Mount for Ø5.6 mm Laser Diodes Condenser Lens #1 f=20.1 mm, NA=0.60, ARC: 650-1050 nm	Thorlabs Thorlabs	S1LM56 ACL2520U-B	Thorlabs Thorlabs	S1LM56 ACL2520U-B	1 off 1 off	22.50 20.80	22.50 20.80
	Collimating lens Lens coupling mechanics	Condenser Lens #2 f = 25.4 mm, AR Coating: 650-1050 nm SM1 Lens Tube. 0.5" Thread Depth. One Retaining Ring Included	Thorlabs Thorlabs	LA1951-B SM1L05	Thorlabs Thorlabs	LA1951-B SM1L05	1 off	25.25 9.25	25.25 9.25
	Lens coupling mechanics	Lens tube - SM1 (1.035"-40) Coupler, External Threads, 0.5" Long	Thorlabs	SM1T2 SM1M05	Thorlabs	SM1T2 SM1M05	2 off	14.70	29.40
	Lens coupling mechanics	SM1 Retaining Ring for Ø1" Lens Tubes and Mounts	Thorlabs	SM1RR SM1PPP	Thorlabs Thorlabs	SM1RR	1 off	3.31	3.31
 M1-M9	Interlock holding magnets	Magnet, Button, Neodymium, 4 mm dia. x 3 mm, Pack of 10	Eclipse Magnetics	N802	OneCall	1800034	1 pk	3.98 13.23	3.98
TOTAL		1	1	I			I	<u>I</u>	213.5
Senso	r				-				-
ID	Item	Description	Manufacturer	Model #	Supplier	Part number	Qty	Cost	Total 45.28
	Sensor	Fiber Optic Cable, 5 m, Plastic Optical, 1 Fiber, SMA	Fibre Data / OMC	A19A55A0	Unecall	1208869	T Split	22.04	10.20
-	Sensor Sensor glue Coupling tube	Fiber Optic Cable, 5 m, Plastic Optical, 1 Fiber, SMA TE Connectivity Epo-Tek 353ND 4 g Red Dual Cartridge Epoxy Adhesive Silicone tube coupled to drainage bag - TSR Silicone Tubing 7.50 x 1.50 mm x 15m Coil	Fibre Data / OMC TE Connectivity Sterilin	A19A55A0 504035-1 TSR0750150P	RS ThermoFisher	1208869 533-2093 TSR0750150P	1 off 1 off	15.20? 109.20	15.20

Design files for the mechanical components machined in-house can be provided on request.

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 μ 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 mm² (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^2 . This is the maximum power that the laser can emits and corresponds to a radiance of 230 W/m^2 /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^2 /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/m²/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.

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