



LAD-06 RISK ANALYSIS

Ref	Failure Mode	Component	Failure Description	Consequence	5	2	2	20	AC Adaptor certified to UL2601 Label states indoor use only	5	1	2	10	Y	AC Adaptor data sheet & test report		
61	Electrocution / Electric Shock	AC Adaptor	Ingress of water	Short primary to secondary	5	2	2	20									
62	Electrocution / Electric Shock	AC Adaptor	Case breaks	Exposed live parts	5	2	2	20									
63	Electrocution / Electric Shock	AC Adaptor	Ingress of foreign metal objects	Short primary to secondary	5	1	4	20									
64	Electrocution / Electric Shock	AC Adaptor	Insulation damage on the mains cable	Exposed live parts	5	2	2	20									
65	Electrocution / Electric Shock	AC Adaptor	Insulation damage on the mains plug	Exposed live parts	5	1	2	10									
66	Electrocution / Electric Shock	Casing	Case breaks	Exposed live parts	5	2	2	20									
67	Electrocution / Electric Shock	Casing	Ingress of water	Conduction of high voltage to outside the case	5	1	4	20									
68	Electrocution / Electric Shock	Casing	High humidity causes condensation	Conduction of high voltage to outside the case	5	1	4	20									
69	Electrocution / Electric Shock	Casing	Ingress of foreign metal objects	Conduction of high voltage to outside the case	5	1	2	10									
70	Electrocution / Electric Shock	HV Assembly	User opens device during use	User exposed to HV	5	3	4	60	Safety interlocks prevent laser from firing and charging if unit opened HV User manual warns against opening unit during use	5	0	1	4	2	Y	LAD User Manual Control & HV circuit diagrams	
71	Electrocution / Electric Shock	HV Assembly	HV cable breaks loose and touches Keyswitch	Exposed live parts	3	0	1	4	12								
72	Electrocution / Electric Shock	LAD Unit	ESD from unit to person when replacing Battery Pack	Shock to user	2	1	4	8									
73	Electrocution / Electric Shock	Trigger Assembly	Insulation failure - creepage distance reduced	High voltage arc	2	1	4	8									
74	Excessive ablation	Control Assembly	Analogue reference is high output	High voltage on charge capacitors leading to high energy ablation	3	2	4	24	The analogue voltage reference value is 100% tested during the Shielded Control Assembly Test Procedure. The analogue voltage reference has an MTBF of 7 years	3	1	4	12	Y	Shielded control assembly test procedure Component datasheet		
75	Excessive ablation	Control Assembly	Corrupt data in the EEPROM	Voltage (calibration) setting is overwritten causing higher energy output	3	1	4	12									
76	Excessive ablation	HV Assembly	Over charging on capacitor	Increased energy output	2	3	1	24	The HV Assy has a monitoring circuit for the capacitor banks which is tested during the HV Assembly Test Procedure. Each capacitor bank is independently monitored. The charging circuit is designed to balance the banks during charging and there are protective devices against overcharge. Each HV Assy tested during production	2	1	4	8	Y	HV Assy test procedure and schematic Software V & V		
77	Excessive ablation	HV Assembly	R101, R104 open	Microprocessor will overcharge capacitors	3	1	4	12									
78	Excessive ablation	HV Assembly	Overvoltage output low	Microprocessor overcharges capacitor	3	1	4	12									
79	Excessive ablation	LAD Unit	ESD / EMI from external source to unit	Increased energy output	2	2	4	24	EMC/EMC tested by EMC Technologies in IEC 601-1-2	2	1	4	8	Y	EMC Test Report		
80	Excessive ablation	LAD Unit	LAD does not measure the level of radiation after every shot	Inconsistent ablation	2	2	4	16									
81	Excessive ablation	Laser & Lens Assembly	Beam profile uneven (variable energy density leads to cold/hot spots within the ablated area)	Inconsistent ablation	2	2	4	16									
82	Excessive ablation	Laser & Lens Assembly	non top flat beam profile	High energy density in the centre of the treatment area	2	5	4	40	Beam clipped to prevent gaussian profile. Calibration procedure requires testing of energy at 3mm and 8m distances	2	1	4	8	Y	Calibration procedure CP-F0018		
83	Excessive Ablation	Software	Corrupt code. Program continues to run	Energy Voltage level incorrect	3	2	4	36	Verify code when loaded into ROM (internal watchdog, external watchdog)	3	1	4	12	Y	SVP X00001-02		
84	Excessive Ablation	Software	Data outside range	Energy Voltage level incorrect	3	2	4	36	Software range check Software V&V	3	1	4	12	Y	SVP X00001-02		
85	Excessive Ablation	Software	A to D conversion corrupted by noise	Energy Voltage level incorrect	3	2	4	36	Multiple analogue reads and average	3	1	4	12	Y	SVP X00001-02		
86	Excessive Ablation	Software	A to D conversion scaling errors	Energy Voltage level incorrect	3	2	4	36	Software V&V	3	1	4	12	Y	SVP X00001-02		
87	Excessive Ablation	Software	Code/Data transfer to/from E2Prom	Energy Voltage level incorrect	3	2	4	36	Store and compare Software V&V	3	1	4	12	Y	SVP X00001-02		
88	Excessive Ablation	Software	Code/Data transfer to/from E2Prom	Energy Voltage level incorrect	3	2	4	36	User manual includes step by step instructions outlining correct operational procedures. User manual also includes various warnings regarding firing into the eye. Design includes contact activation mechanism & shutter.	3	1	4	12	Y	LAD User Manual		
89	Eye injury	Labels & Documentation	Incorrect or incomplete labels & user documentation causes incorrect operation	Laser firing into the eye	3	3	4	36	User manual includes step by step instructions outlining correct operational procedures. User manual also includes various warnings regarding firing into the eye. Design includes contact activation mechanism & shutter.	3	1	4	12	Y	LAD User Manual		
90	Eye injury	LAD Unit	Tip not fully sealed against the skin during facial procedures (within the NOHD)	Laser firing into the eye	3	1	4	12	User manual instructions state to press firmly against the skin when firing the laser. Additional warning for use around the eyes. Used by trained personnel.	3	0	1	4	12	Y	Laser & control Assy drawings LAD User Manual	
91	Eye injury	LAD Unit	Accidental firing of laser due to component failure	Laser firing into the eye	3	1	4	12	Contact activation mechanism LAD designed to conform with IEC 60825-1 Design prevents inadvertent firing including shutter tip interlock switch 5 second timeout and user manual instructions. LAD also tested to IEC 601-1 601-2 22 & IEC 601-1-2	3	0	1	4	12	Y	IEC-60825-1 checklist IEC 601 1 5 601-2 22 test report EMC Test Report Laser & control Assy drawings	
92	Eye injury	LAD Unit	Accidental activation of buttons due to their location (e.g. when picked up)	Uncontrolled laser firing	4	2	4	32	Contact activation. Safety time out. Sequence of events required reduces accidental firing	4	0	1	4	16	Y	User manual Laser & control Assy drawings	
93	Eye injury	LAD Unit	Uncontrolled tip ejection	Tip ejected into the eye	3	3	3	27	User manual instructions for disposing of tip. Spring loaded in laser and lens Assy selected to minimise ejection force	3	1	3	9	Y	User manual Laser & lens Assy and spring drawings		
94	Eye injury	LAD Unit	Object inadvertently placed in the beam path whilst laser is firing	Reflected or scattered radiation fired into the eye	3	3	4	36	Contact activation mechanism LAD designed to conform with IEC 60825-1 User manual warns against placing objects in the beam path. Only used by trained healthcare workers	3	1	4	12	Y	LAD User Manual Laser & control Assy drawings IEC-60825-1 checklist		
95	Eye injury	LAD Unit	Inadvertent exposure of people to laser due to lack of remote interlock	Uncontrolled laser area	3	2	4	24	Remote interlock not required for a portable device. Contact activation and firing sequence prevents unintended radiation. Enclosed beampath	3	0	1	4	12	Y	LAD User Manual Finished LAD drawings and Laser & control Assy drawings	
96	Eye injury	LAD Unit	Mirrors or magnification device used to observe beam	Reflected or scattered radiation fired into the eye	3	2	4	24	Contact activation mechanism. LAD designed to conform with IEC 60825-1 User manual warns against use of mirrors and magnification devices. Only used by trained healthcare workers	3	1	4	12	Y	LAD User Manual Laser & control Assy drawings IEC60825-1 checklist		
97	Eye injury	LAD Unit	UV light from flashlight not fully enclosed	UV damage to the eye	3	2	3	18									
98	Eye injury	LAD Unit	Unit left unattended with keys and used by unauthorised personnel	Unit used incorrectly and inadvertently fired into the eye	3	1	4	12	Unit used incorrectly and inadvertently fired into the eye	3	1	4	12	Y	User Manual		
99	Eye injury	LAD Unit	Laser beam not fully enclosed/shutter/light shield	Laser firing into the eye	3	1	4	12	AC Adaptor certified to IEC601-1 Label states indoor use only	3	0	1	4	12	Y	AC Adaptor drawing LAD User Manual	
100	Eye injury	LAD Unit	Scattered laser light emitted	Parts ejected into the eye	3	1	3	9	Caution selected sufficient to withstand normal operating conditions. Warning to not use a damaged cable	3	1	4	12	Y	User Manual		
101	Eye injury	LAD Unit	Shutter breaks parts break	Unintentional laser discharge	3	1	1	3	AC Adaptor certified to IEC601-1 Label states indoor use only	3	0	1	4	12	Y	AC Adaptor drawing LAD User Manual	
102	Eye injury	LAD Unit	Tip locks shutter open	Shutter fails in the open position uncontrolled laser exposure	4	2	4	32	Safety time-out. Unit will not re-energise if shutter interlock switch is held on	4	0	1	1	0	4	Y	User & control Assy drawings
103	Eye injury	Laser & Lens Assembly	Eject plate jams into the on position	Excessive voltage will cause the optic isolator to fail resulting in a non-controlled laser fire	3	1	4	12	Verify code when loaded into ROM internal watchdog external watchdog 2 levels of hardware protection (shutter & flip flop). Software V&V	3	1	4	16	Y	SVP X00001-02		
104	Eye injury	Software	Corrupt code. Program continues to run in auto fire mode	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
105	Eye injury	Software	Microtests. Tip engaged switch points	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
106	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
107	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
108	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
109	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
110	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
111	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
112	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
113	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
114	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
115	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
116	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
117	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
118	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
119	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
120	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
121	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
122	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
123	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
124	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
125	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
126	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
127	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
128	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
129	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
130	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
131	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
132	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
133	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
134	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
135	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
136	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
137	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4	32	Multiple reads 2 levels of hardware protection. Software V&V	4	0	1	4	16	Y	SVP X00001-02	
138	Eye injury	Software	Microtests. Trigger button switch point	Energy and fires laser uncontrolled	4	2	4										

LAD-06 RISK ANALYSIS

RA #	Potential Hazard	Component/ Sub-assembly	Failure Mode	Effect of Failure	Severity	Probability	Detectability	Preliminary RAN	Description of Risk Mitigation	Revised Severity	Revised Probability	Revised Detectability	Adjusted RAN	Actions complete (Y/N)	Verification Reference (eg T&E number, short description or reference to Verification Sheet of this spreadsheet)	
1	Adverse skin reaction - intermediate	LAD Unit	Reaction at ablation site to laser ablation	Skin reaction (Hyperpigmentation or Hypopigmentation)	3	4	3	36	Warning in user manual	3	4	3	36	Y		
2	Adverse skin reaction - intermediate	LAD Unit	Ablation on existing skin condition	Irritation of existing skin condition	3	2	4	24	User Manual specifies indications/contraindications. Use by Health professional	3	1	4	12	Y	User Manual	
3	Adverse skin reaction - intermediate	LAD Unit	User presses too hard with wand	Brusing to patient	2	2	3	12								
4	Adverse skin reaction - short term	Accessories	Reaction at ablation site to alcohol swab	Skin reaction (Swelling, redness, itching, mild pain)	2	1	4	8								
5	Adverse skin reaction - short term	LAD Unit	Tip contaminated during manufacture and handling	Skin reaction (Swelling, redness, itching, mild pain)	3	3	4	36	Implement handling procedures at tip manufacturer & monitor to minimise human handling during assembly. Tip prepackaging and container protects product during handling and shipping	3	1	4	12	Y	Assembly procedures. Lightmed Audit report August 2002	
6	Adverse skin reaction - short term	LAD Unit	Reaction at ablation site to laser ablation	Skin reaction (Swelling, redness, itching, mild pain)	2	4	4	32	Warning in user manual	2	4	4	32	Y	User Manual	
7	Adverse skin reaction - short term	LAD Unit	Reaction of user to case materials	Skin reaction (Swelling, redness, itching, mild pain)	2	4	4	32	The case material selected for the LAD is a PC/ABS "Cyclotol" is a general purpose material used in various consumer products	2	1	4	8	Y	Cyclotol material spec sheet	
8	Adverse skin reaction - short term	Tip	Rough edge of tip	Cuts and abrasions	3	3	4	36	Tip, molded with smooth surface. No sharp edges	3	0	1	1.2	Y	Tip design drawings	
9	Adverse skin reaction - short term	Tip	Reaction to tip materials	Skin reaction (Swelling, redness, itching, mild pain)	2	3	4	24	Tip made from Biocompatible material (ISO10993 tested)	2	1	4	8	Y	ISO10993 test reports	
10	Adverse skin reaction - permanent	LAD Unit	Multiple firing on the same spot in a short period of time	Scarring	4	1	3	12								
11	Burn	AC Adaptor	Loose connector	Case overheats	3	1	4	12								
12	Burn	AC Adaptor	Overload of the AC Adaptor causing internal heat leading to component failure	Case overheats	3	1	4	12								
13	Burn	Battery Pack	Battery Pack connected backwards	Battery pack overheats	3	3	4	36	Battery connectors polarized. Can not be connected backwards	3	0	1	2	Y	Battery Pack drawing	
14	Burn	Battery Pack	Battery pack component failure	Battery pack overheats	3	1	4	12								
15	Burn	Battery Pack	Battery pack overcharged	Battery pack overheats	3	1	4	12								
16	Burn	Battery Pack	Short Circuit inside battery pack	Excessive currents in battery leading to thermal burn	3	1	4	12								
17	Burn	Casing	Failed component	Case overheats	3	1	4	12								
18	Burn	Casing	Excessive use	Case overheats	3	1	2	6								
19	Burn	Casing	From internal fire	Case overheats	4	1	1	4								
20	Burn	LAD Unit	Uncontrolled battery charging routine causing battery FET to overheat	Overvoltage gets too hot too touch	3	5	4	60	Software charging routine monitors the current and voltage to the battery. IEC 601-1 certification. Component selection to reduce heat	3	1	4	12	Y	Software V&V IEC 601-1 test report and component data sheet	
21	Decreased Efficacy	Accessories	User misses ablation site with needle	Partial medical procedure	2	4	4	32	Self identification system	2	0	1	0.8	Y	LAD-06 Tip Drawings	
22	Decreased Efficacy	Accessories	User does not wait 5 minutes for lidocaine to take effect	No or reduced anaesthesia	2	4	4	32	Instructions in user manual state that the user must wait 5 minutes before removing the anaesthetic cream	2	0	1	0.8	Y	User Manual	
23	Decreased Efficacy	Accessories	User misses ablated site when applying medication	Partial medical procedure	2	4	4	32	Site identification system	2	0	1	0.8	Y	LAD-06 Tip Drawings	
24	Decreased Efficacy	Control Assembly	Analogue reference is low output	Low or no voltage on the capacitors leading to low energy ablation	2	2	4	16								
25	Decreased Efficacy	Control Assembly	Corrupt data in the EEPROM	Voltage (calibration) setting is overwritten causing lower energy ablation	2	1	4	8								
26	Decreased Efficacy	HV Assembly	Mismatched charge on capacitor bank, or capacitor not charged to or charged beyond specified capacity	Lower energy delivered	2	3	4	24	The HV Assy has a monitoring circuit for the capacitor banks which is tested during the HV Assembly Test Procedure. Each capacitor bank is independently monitored. The charging circuit is designed to balance the banks during charging and there are protective devices against overcharges. Each HV Assembly is tested before use	2	1	4	8	Y	HV schematics, assay drawings and test procedure. Software V&V	
27	Decreased Efficacy	HV Assembly	Shorted turn on the transformer	Poor ablation	2	1	4	8								
28	Decreased Efficacy	HV Assembly	Microprocessor undervoltage capacitor causing low energy ablation	Microprocessor undervoltage capacitor causing low energy ablation	2	1	4	8								
29	Decreased Efficacy	HV Assembly	Input voltage too high into the flashtube	Degradation of laser flash tube	2	1	4	8								
30	Decreased Efficacy	Labels & Documentation	Operational instructions lack clarity in user manual and labels	No or reduced ablation	2	2	4	16								
31	Decreased Efficacy	LAD Unit	Partially charged unit	Insufficient or no ablation	2	5	4	40	A Self Disable will be triggered if the laser charge voltage falls outside a window of 2% of the set charge. Capacitor voltage continuously monitored and actively maintained within spec. The whole measurement system is 100% tested during the HV Assembly Test Procedure and the Shielded Control Assembly Test Procedure. Calibration every two years recommended in User Manual. Lifetesting performed on LAD unit operation and storage	2	1	4	8	Y	HV Assy & Shielded control Assy test procedures. Software V&V	
32	Decreased Efficacy	LAD Unit	LAD does not measure the level of radiation after every shot - late out of calibration	Insufficient or no ablation	2	4	4	32	Energy delivered to the laser module is monitored and tested during the HV Assembly Test Procedure and the Shielded Control Assembly Test Procedure. Calibration every two years recommended in User Manual. Lifetesting performed on LAD unit operation and storage	2	1	4	8	Y	Lifetest T&E LAD-0676. User Manual. Finished LAD and HV test procedures	
33	Decreased Efficacy	LAD Unit	Degradation of laser flash tube	Insufficient or no ablation	2	3	4	24	Lifetesting of flashtube and Calibration every two years recommended in User Manual	2	1	4	8	Y	User manual. Lifetest T&E	
34	Decreased Efficacy	LAD Unit	ESD / EMI from external source to unit	Decreased energy output	2	3	4	24	EMI/EMC tested by EMC Technologies to IEC 601-1-2	2	1	4	8	Y	EMC Test Report AMQ30016-R	
35	Decreased Efficacy	LAD Unit	Patient skin wet prior to ablation	Energy absorbed by water	2	3	4	18	Warning in user manual	2	1	3	6	Y	User Manual	
36	Decreased Efficacy	LAD Unit	Shutter not fully open	No or reduced ablation	2	2	4	16								
37	Decreased Efficacy	LAD Unit	High capacitor bleed	Insufficient or no ablation	2	2	4	16								
38	Decreased Efficacy	Laser & Lens Assembly	Laser rod failure	Unit operates but no laser (user unaware of damage)	2	3	4	24	The Laser Assembly design life shall be 30,000 shots and is Life tested. Laser output verification instructions provided in user manual	2	1	4	8	Y	User Manual. Lifetest T&E LADG-0681	
39	Decreased Efficacy	Laser & Lens Assembly	Damage to focusing lens	Unit operates (user unaware of damage and continues to operate at wrong output)	2	3	4	24	Warning in user manual to verify output. Drop test as part of IEC 601-1. Procedure for cleaning the lens in the user manual	2	2	4	16	Y	User Manual	
40	Decreased Efficacy	Laser & Lens Assembly	Contamination of focusing lens with dust	Unit operates (user unaware of damage and continues to operate at wrong output)	2	3	4	24	Warning in user manual to verify output. Procedure for cleaning the lens in the user manual	2	2	4	16	Y	User Manual	
41	Decreased Efficacy	Laser & Lens Assembly	Contamination of focusing lens with liquid	Unit operates (user unaware of damage and continues to operate at wrong output)	2	1	4	8								
42	Decreased Efficacy	Laser & Lens Assembly	Optics move causing change in focal length	Unit operates but laser not in focus (user unaware of damage)	2	3	4	24	Optics have been locked into position through design and it is impossible to move them without opening the unit	2	1	4	8	Y	Laser & Lens Assembly Drawing	
43	Decreased Efficacy	Laser & Lens Assembly	Dust and foreign materials depositing on optics	Low energy ablation	2	3	4	24	Lens is behind shutter and lens is never directly exposed to outside elements	2	1	4	8	Y	Laser & Lens Assembly Drawing	
44	Decreased Efficacy	Laser & Lens Assembly	Flashtube ages	Degradation of laser flash tube	2	2	4	16								
45	Decreased Efficacy	Laser & Lens Assembly	Beam misaligned (pointed to one side)	Insufficient or no ablation	2	2	4	16								
46	Decreased Efficacy	Laser & Lens Assembly	Beam profile uneven (variable energy density leads to coldshot spots within the ablated area)	Inconsistent ablation	2	1	4	8								
47	Decreased Efficacy	Laser & Lens Assembly	Broken lens cap	Reduces the spot size	2	2	2	8								
48	Decreased Efficacy	Laser & Lens Assembly	non top hat beam profile	leads to reduced effective area	2	5	4	40	Beam clipped to prevent plasmas profile. Calibration procedure requires testing of energy at 3mm and 5mm apertures	2	1	4	8	Y	Calibration procedure CP-F00018	
49	Decreased Efficacy	Software	Connect code - program continues to run	Energy Voltage level incorrect	2	3	4	24	Verify code when loaded into ROM. (Internal watchdog, external watchdog)	2	1	4	8	Y		
50	Decreased Efficacy	Software	Voltage level incorrect	Energy Voltage level incorrect	2	4	16									
51	Decreased Efficacy	Software	A to D conversion corrupted by noise	Multiple analogue reads and average	2	4	25									
52	Decreased Efficacy	Software	A to D conversion scaling errors	Energy Voltage level incorrect	2	2	4	16	Software V&V	2	1	4	8	Y	SVP X00001-02	
53	Decreased Efficacy	Software	Code/Data transfer to/from Eprom	Energy Voltage level incorrect	2	3	4	24	Software V&V	2	1	4	8	Y	SVP X00001-02	
54	Decreased Efficacy	Tip	Tip re-used	Ablated material on tip window reduces laser transmission	2	4	4	32	Single use tip design. Tip must be ejected before LAD can be re-energized. Single use symbol on tip. Various warnings included in user manual regarding re-use	2	2	4	16	Y	Tip design drawings. User Manual	
55	Decreased Efficacy	Tip	Dirty tip window including condensation	Insufficient or no ablation	2	3	4	24	Single use tip design. Procedures for reducing contamination during assembly and handling of the tip	2	1	4	8	Y	Tip design drawings. Report on the tip assembler	
56	Decreased Efficacy	Tip	Tip misaligned when fitted	Insufficient or no ablation	2	2	4	16								
57	Electrocution / Electric Shock	AC Adaptor	Incorrect AC Adaptor used - charger overloaded damaging internal components	Short primary to secondary	5	3	4	60	AC adaptor connector selected has a unique design that will restrict the use of other power supplies. Warning in User Manual to use only the Power Supply provided with the LAD Unit	5	1	4	20	Y	AC Adaptor design drawings. LAD User Manual	
58	Electrocution / Electric Shock	AC Adaptor	Internal component faulty	Short primary to secondary	5	2	4	40	AC Adaptor certified to UL2601 and tested for EMC	5	0	1	4	2	Y	AC Adaptor data sheet & test report
59	Electrocution / Electric Shock	AC Adaptor	Power surge damages internal components	Short primary to secondary	5	2	4	40	AC Adaptor certified to UL2601 and tested for EMC	5	0	1	4	2	Y	AC Adaptor data sheet & test report
60	Electrocution / Electric Shock	AC Adaptor	Overload of the AC Adaptor causing internal heat leading to component failure	Short primary to secondary	5	2	4	40	AC Adaptor certified to UL2601	5	1	4	20	Y	AC Adaptor data sheet & test report	

LAD.06 RISK ANALYSIS

182	Infection (local)	LAD Unit	Lad contaminated by viable bacteria / virus growing on the up- up of ablated material from previous ablation	Systemic infection to the patient through ablation site transferred by the user	5	1	4	20											
183	Infection (local)	LAD Unit	Sharp edges on the tip or LAD unit pinches / cuts patient or user	Open wound gets infected	2	2	3	18											
184	Infection (local)	LAD Unit	Lad contaminated by ablated material containing viable bacteria / virus	Local skin infection to the user	3	1	4	12											
185	Infection (local)	Tip	Tip contaminated with bacterial or virus due to re-use	Local skin infection through ablation site	3	4	4		Tip collapses after use and site ID disc is removed allowing used tip to be distinguished Tip must be ejected before LAD can be re-energized Single use symbol on tip Various warnings included in user manual regarding re-use	3	2	2	12	Y					Tip design drawings LAD User Manual
186	Infection (local)	Tip	Tip contaminated with bacterial or virus during manufacture and processing (pre-customer)	Local skin infection through ablation site	3	3	4	36	Implement handling procedures at tip manufacturer Tip packaging and container protects product during handling and disposal	3	1	4	12	Y					Assembly procedures Lightmed Audit report August 2003
187	Infection (local)	Tip	Tip contaminated with bacterial or virus during customer handling	Local skin infection through ablation site	3	3	4	36	Tip cap Warnings in user manual Tip packaging and container protects product Use by trained professionals	3	0	1	4	1.2	Y				LAD User Manual Packaging drawings
188	Infection (local)	Tip	User contaminated when disposing of used tip	Local skin infection to the user	3	2	4	24	User manual describes correct disposal techniques, including warnings regarding biological hazards Tip can be disposed of without human contact	3	1	4	12	Y					
189	Infection (local)	Tip	User contaminated when disposing of used tip and transfers contamination to the next patient	Local skin infection to the patient	3	2	4	24	User manual describes correct disposal techniques, including warnings regarding biological hazards Tip can be disposed of without human contact	3	1	4	12	Y					
190	Infection (local)	Tip	Unit charged with valid Tip, then User swaps with used Tip	Cross-contamination of patients by viable bacteria / virus	3	2	4	24	User manual describes correct disposal techniques, including warnings re use	3	1	4	12	Y					
191	Infection (systemic)	Accessories	tube of anaesthetic cream used on multiple patients	Cross-contamination of patients by viable bacteria / virus	5	2	4	40	LAD to be sold with ELA-Max which is indicated for use on cuts and broken skin (similar to ablated skin) Warning in User Manual refers back ELA-Max labeling regarding all warnings associated with the application of ELA-Max Warning in user manual regarding infection control	5	1	4	20	Y					LAD User Manual ELA-Max labeling
192	Infection (systemic)	LAD Unit	Lad contaminated by ablated material containing viable bacteria / virus	Systemic infection to the patient through ablation site from the user	5	1	4	20	Single use tip design Tip window prevents ablated material from reaching the LAD unit Warnings in user manual	5	1	4	20	Y					Tip design drawings LAD User Manual
193	Infection (systemic)	LAD Unit	Lad contaminated by viable bacteria / virus growing on the up- up of biological material, e.g. built up in buttons	Systemic infection to the patient through ablation site transferred by the user	5	1	4	20											
194	Infection (systemic)	LAD Unit	Lad contaminated by viable bacteria / virus growing on the up- up of biological material, e.g. built up in buttons	Systemic infection to the user	5	1	4	20											
195	Infection (systemic)	LAD Unit	Lad contaminated by ablated material containing viable bacteria / virus	Systemic infection to the user	5	1	4	20											
196	Infection (systemic)	LAD Unit	Lad contaminated by viable bacteria / virus growing on the up- up of ablated material from previous ablation	Systemic infection to the user	5	1	4	20											
197	Infection (systemic)	Tip	Tip contaminated with bacterial or virus due to re-use	Systemic infection through ablation site	5	3	4		Tip collapses after use and site ID disc is removed allowing used tip to be distinguished Tip must be ejected before LAD can be re-energized Single use symbol on tip Various warnings included in user manual regarding re-use	5	1	2	10	Y					Tip design drawings LAD User Manual
198	Infection (systemic)	Tip	Tip contaminated with bacterial or virus during customer handling	Systemic infection through ablation site	5	2	4	40	Tip cap Warnings in user manual Tip packaging and container protects product Use by trained professionals	5	0	1	4	2	Y				LAD User Manual Packaging drawings
199	Infection (systemic)	Tip	User contaminated when disposing of used tip	Systemic infection to the user	5	2	4	40	User manual describes correct disposal techniques, including warnings regarding biological hazards Tip can be disposed of without human contact	5	1	4	20	Y					LAD User Manual
200	Infection (systemic)	Tip	User contaminated when disposing of used tip and transfers contamination to the next patient	Systemic infection through ablation site	5	2	4	40	User manual describes correct disposal techniques, including warnings regarding biological hazards Tip can be disposed of without human contact	5	1	4	20	Y					LAD User Manual
201	Infection (systemic)	Tip	Unit charged with valid Tip, then User swaps with used Tip	Cross-contamination of patients by viable bacteria / virus	5	1	4	20											
202	Infection (systemic)	Tip	Tip contaminated with bacterial or virus during manufacture and processing (pre-customer)	Systemic infection through ablation site	5	0	1	4	2										
203	Infection Systemic	Tip	Biological contamination transfers around tip window/lens to LAD site	Cross-contamination of patients by viable bacteria / virus	5	1	1	4	2										
204	Miscellaneous	LAD Unit	Interference to other devices due to EMI	Other devices may be non-functional	5	1	4	20											
205	Non-functional / Frustration	AC Adaptor	Wrong AC Adaptor used	erratic operation	1	4	4	16											
206	Non-functional / Frustration	AC Adaptor	AC adaptor susceptible to noise	erratic operation	1	3	4	12											
207	Non-functional / Frustration	AC Adaptor	AC adaptor component fault	Short circuit	1	2	4	8											
208	Non-functional / Frustration	AC Adaptor	Main cable damaged	Increased resistance arcing and overheating	1	2	4	8											
209	Non-functional / Frustration	AC Adaptor	Water ingress causes shorting	Decreased resistance and arcing	1	2	4	8											
210	Non-functional / Frustration	AC Adaptor	AC Adaptor polarity reversed	Short circuit	1	1	4	4											
211	Non-functional / Frustration	AC Adaptor	Main's spike	Component failure causes arcing or short circuit	1	1	4	4											
212	Non-functional / Frustration	AC Adaptor	Damage / debris in AC Adaptor socket	Failure to charge batteries	1	2	2	4											
213	Non-functional / Frustration	AC Adaptor	connector difficult to connect	Poor or no contact	1	3	1	3											
214	Non-functional / Frustration	AC Adaptor	Pull out AC Adaptor while batteries are flat and unit is in Energy mode	Doesn't energize	1	3	1	3											
215	Non-functional / Frustration	AC Adaptor	Cord between wand and charger damaged	LAD batteries unable to recharge	1	1	1	1											
216	Non-functional / Frustration	Battery Pack	Battery Pack charge capacity reduction due to undervoltage (battery discharged beyond recommended limits)	Shortened battery life and capacity	1	5	4	20											
217	Non-functional / Frustration	Battery Pack	Battery Pack connected backwards	No operation	1	5	4	20											
218	Non-functional / Frustration	Battery Pack	1-wire bus fails on the battery chip	Microprocessor will not recognize the battery	1	3	4	12											
219	Non-functional / Frustration	Battery Pack	Open connection	Operation with charger will cause the PTC to trip when energizing	1	3	4	12											
220	Non-functional / Frustration	Battery Pack	Charging a flat battery	Current overload causes component failure	1	3	4	12											
221	Non-functional / Frustration	Battery Pack	Overcharging battery pack	Overheating of battery pack causing failure	1	3	4	12											
222	Non-functional / Frustration	Battery Pack	Physical damage to Battery Pack or cables during insertion/removal	erratic operation	1	3	4	12											
223	Non-functional / Frustration	Battery Pack	Data corrupted or missing in battery chip	Under current HV energize leads to long energize time	1	2	4	8											
224	Non-functional / Frustration	Battery Pack	Data corrupted or missing in battery chip	Battery not charged	1	2	4	8											
225	Non-functional / Frustration	Battery Pack	Damaged connection leading to high resistance of connection	Long energize time or may not reach charge to fire	1	2	4	8											
226	Non-functional / Frustration	Battery Pack	Component Failure	Shorted battery	1	2	4	8											
227	Non-functional / Frustration	Battery Pack	Poor contact pressure on Battery Pack terminals	Sparking and heat	1	2	4	8											
228	Non-functional / Frustration	Battery Pack	Battery Pack short circuits outside of LAD unit	Overheating and battery failure	1	2	4	8											
229	Non-functional / Frustration	Battery Pack	Physical damage to Battery Pack or cables during insertion/removal	Poor or no contact	1	4	2	8											
230	Non-functional / Frustration	Battery Pack	Battery Pack not installed (don't know until it doesn't work)	Unit doesn't turn on	1	2	4	8											
231	Non-functional / Frustration	Battery Pack	Wrong Battery Pack used	erratic operation	1	1	4	4											
232	Non-functional / Frustration	Battery Pack	Battery leakage	No operation	1	2	2	4											

LAD-06 RISK ANALYSIS

120	Fire / Smoke	Battery Pack	Battery Pack short circuits outside of LAD unit	Overheating and battery failure	3	2	4	24	Internal PTC in battery pack limits current	3	0	1	4	1	2	Y	PTC component specification Power board schematic
121	Fire / Smoke	Battery Pack	Data corrupted or missing in battery chip	Over current HV energy leads to overheating FET and smoke	2	2	4	16									
122	Fire / Smoke	Battery Pack	Data corrupted or missing in battery chip	Overcharging battery may lead to smoke or battery rupture	3	1	4	12									
123	Fire / Smoke	Battery Pack	Wrong Battery Pack used	Overheating	3	2	2	12									
124	Fire / Smoke	Control Assembly	Electronic component overheating	Overheats and causes smoke	2	3	4	24	All electrical components and cables are rated to handle normal operating conditions without undue heating or failure. Case material PC/ABS "Cycloloy" is rated as fire-retardant according to UL94 (HVO94-SVB). Each control assy individually tested.	2	0	1	4	0	8	Y	Component & Case Material Data Sheets Control board test procedure
125	Fire / Smoke	Control Assembly	Analogue reference is high output	High voltage on charge capacitors leading to capacitor failure	3	2	4	24	Each control assy individually tested	3	0	1	4	1	2	Y	Control board test procedure
126	Fire / Smoke	Control Assembly	HV PWM control O109 shorts	HV FET permanently on leading to component failure and smoke	2	2	4	16									
127	Fire / Smoke	Control Assembly	Battery PWM O106 shorts	Excessive battery charge leading to battery FET failure	2	2	4	16									
128	Fire / Smoke	Control Assembly	FFC cable short circuit	Short circuit causes excessive current leading to component failure e.g. smoke	2	2	4	16									
129	Fire / Smoke	HV Assembly	Insulation breakdown	Short circuit results in overheating and fire	3	3	4	36	HV monitoring circuit. Each HV assy tested during production. Selection of insulation materials to meet voltage rating. Creepage and clearance meet IEC 601-1 requirements.	3	1	2	4	6	Y	DWG-M00046 TP-M00046 Software V&V	
130	Fire / Smoke	HV Assembly	HV FET failure	Excessive current leading to overheating	3	3	2	18									
131	Fire / Smoke	HV Assembly	Battery charge FET failure	Excessive current leading to overheating	3	3	2	18									
132	Fire / Smoke	HV Assembly	Primary / Secondary breakdown to T101	Charges O107 to overheat	2	2	4	16									
133	Fire / Smoke	HV Assembly	Shorted connection between power and capacitor boards	Damage to the HV driving FET	2	2	4	16									
134	Fire / Smoke	HV Assembly	Mismatched charge on capacitors (capacitor not charged to or charged beyond specified capacity)	Blows capacitor	2	2	4	16									
135	Fire / Smoke	HV Assembly	Charge socket short circuit (socket on power PCA)	Excessive current drawn from the ac adaptor	3	1	4	12									
136	Fire / Smoke	HV Assembly	General electronic component overheating	PCB could catch fire	3	1	4	12									
137	Fire / Smoke	HV Assembly	Unit erroneously discharges capacitors during charge cycle	Short circuit on HV charge circuitry	3	1	4	12									
138	Fire / Smoke	HV Assembly	O107 shorts	Permanently on causing fire smoke	2	1	4	8									
139	Fire / Smoke	HV Assembly	U104 output high	O107 Permanently on causing fire smoke	2	1	4	8									
140	Fire / Smoke	HV Assembly	D100 & D101 short	Charges O107 to overheat	2	1	4	8									
141	Fire / Smoke	HV Assembly	R101 R104 open	Microprocessor will overcharge capacitors leading to fire / smoke	2	1	4	8									
142	Fire / Smoke	HV Assembly	Opamps is output low	Microprocessor overcharges capacitor causing fire/smoke	2	1	4	8									
143	Fire / Smoke	HV Assembly	FFC/connector fails short	Excessive battery charge excessive current, unreliable operation and failure of the HV FET	2	1	4	8									
144	Fire / Smoke	HV Assembly	FFC/connector fails open	No feedback to the microprocessor causes overcharging	2	1	4	8									
145	Fire / Smoke	HV Assembly	D102 goes short circuit	Excessive current drawn from AC charger	2	1	2	8									
146	Fire / Smoke	HV Assembly	Short across capacitor terminal	Momentary smoke and fire during discharge	2	1	4	8									
147	Fire / Smoke	HV Assembly	Short across capacitors	Momentary smoke and fire during discharge	2	1	4	8									
148	Fire / Smoke	LAD Unit	Used in presence of flammable gases or liquids (e.g. anaesthetics or residual cleaning agents)	Laser or HV circuitry ignites flammable gas	5	2	4	40	User Manual warns that the LAD may cause ignition of explosive or flammable gases	5	1	4	20	Y	LAD User Manual		
149	Fire / Smoke	LAD Unit	Cable strain ratings inadequate	Cable overloaded (current)	3	3	4	36	Certification to IEC 601-1. All electrical components and cables are rated to handle normal operating conditions without undue heating or failure. Case material PC/ABS "Cycloloy" is rated as fire-retardant according to UL94 (HVO94-SVB).	3	0	1	4	12	Y	IEC 601-1 test report Component & Case Material Data Sheets	
150	Fire / Smoke	LAD Unit	PCB copper thickness is inadequate	Overheating leading to smoke/fire	3	3	4	36	Certification to IEC 601-1. Thickness of PCB copper lines selected to handle normal operating conditions without undue heating or failure	3	0	1	4	12	Y	IEC 601-1 test report Component & Case Material Data Sheets PCB schematics	
151	Fire / Smoke	LAD Unit	High voltage breakdown due to humidity	Arcing due to shortening of creepage distances	2	3	4	24	Specified operating conditions in user manual Environmental testing	2	1	4	8	Y	User manual T&E LAD 0676 performed for environmental testing		
152	Fire / Smoke	LAD Unit	Cable voltage ratings inadequate	Cable overloaded (voltage)	2	3	4	24	All electrical components and cables are rated to handle normal operating conditions without undue heating or failure. Case material PC/ABS "Cycloloy" is rated as fire-retardant according to UL94 (HVO94-SVB).	2	1	4	8	Y	IEC 601-1 test report Component & Case Material Data Sheets		
153	Fire / Smoke	LAD Unit	Ingress of fluid in device (FOD)	Liquid causes short circuit in HV circuitry	2	2	4	16									
154	Fire / Smoke	LAD Unit	Termination failure (break)	Liquid connection cycle/short	2	1	2	8									
155	Fire / Smoke	Laser & Lens Assembly	Insulation breakdown (outside the cavity anode wire connection)	HV spike on to all PCBs	2	2	4	24	Creepage and clearance distances in accordance with IEC601-1	2	2	4	16	Y	IEC 601-1 test report		
156	Fire / Smoke	Laser & Lens Assembly	Flashlamp breaks during use or handling	HV spike on to all PCBs	2	2	4	24	Laser cavity grounded	2	1	4	8	Y	Laser & lens Assembly procedure		
157	Fire / Smoke	Laser & Lens Assembly	Insulation breakdown (inside the cavity)	HV spike on to all PCBs	2	2	4	24	Insulation sufficient to protect against HV spike. All Laser & lens assemblies 100% tested	2	2	4	16	Y	Component Data Sheets Laser & lens assembly and test procedures		
158	Fire / Smoke	Laser & Lens Assembly	UV degradation breaks down insulating materials	Arcing due to reduced insulation	2	1	4	8									
159	Fire / Smoke	LCD Assembly	Electronic component overheating	Overheats and causes smoke	2	3	4	24	Not enough energy in the LCD circuitry to cause heat or smoke. All LCD's tested	2	1	4	8	Y	LCD specifications and drawings LCD test procedure		
160	Fire / Smoke	Software	Corrupt code Program stops running	Battery FET turned on causing excessive heat	2	2	4	16	Verify code when loaded into ROM Internal watchdog external watchdog	2	2	4	16	Y	SVP X00001-02		
161	Fire / Smoke	Software	Corrupt code Program continues to run	Battery FET turned on causing excessive heat	2	2	4	16	Verify code when loaded into ROM Internal watchdog external watchdog	2	2	4	16	Y	SVP X00001-02		
162	Fire / Smoke	Software	One wire bulk data to battery incorrect	Battery FET turned on causing excessive heat	2	2	4	16	Verify code when loaded into ROM Internal watchdog external watchdog	2	2	4	16	Y	SVP X00001-02		
163	Fire / Smoke	Software	One wire data incorrectly read from battery due to noise	Battery FET turned on causing excessive heat	2	2	4	16	Multiple reads will reset the correct data within 1 ms	2	1	4	8	Y	SVP X00001-02		
164	Fire / Smoke	Software	Corrupt code Program stops running	HV FET turned on causing excessive heat	2	3	4	24	Verify code when loaded into ROM Internal watchdog external watchdog	2	1	4	8	Y	SVP X00001-02		
165	Fire / Smoke	Software	Corrupt code Program continues to run	HV FET turned on causing excessive heat	2	3	4	24	Software V&V Hardware protection (PTC resistors)	2	2	4	16	Y	SVP X00001-02		
166	Fire / Smoke	Software	A to D conversion corrupted by noise	HV FET turned on causing excessive heat	2	3	4	24	Multiple analogue reads and average	2	1	4	8	Y	SVP X00001-02		
167	Fire / Smoke	Software	A to D conversion scaling errors	HV FET turned on causing excessive heat	2	3	4	24	Software V&V Verify code when loaded into ROM	2	2	4	16	Y	SVP X00001-02		
168	Fire / Smoke	Software	Corrupt code Program continues to run	Unit ceases to energise when voltage limit reached (diode/testers overheat)	2	3	4	24	Verify code when loaded into ROM Software V&V	2	2	4	16	Y	SVP X00001-02		
169	Fire / Smoke	Software	Data outside range	Unit ceases to energise when voltage limit reached (diode/testers overheat)	2	3	4	24	Software range check Software V&V	2	1	4	8	Y	SVP X00001-02		
170	Fire / Smoke	Software	Code /Data transferred to/from Internal memory corrupted	Unit ceases to energise when voltage limit reached (diode/testers overheat)	2	3	4	24	Software store and compare	2	1	4	8	Y	SVP X00001-02		
171	Fire / Smoke	Software	A to D conversion corrupted by noise	Unit ceases to energise when voltage limit reached (diode/testers overheat)	2	3	4	24	Multiple analogue reads and average	2	1	4	8	Y	SVP X00001-02		
172	Fire / Smoke	Software	A to D conversion scaling errors	Unit ceases to energise when voltage limit reached (diode/testers overheat)	2	3	4	24	Software V&V Verify code when loaded into ROM	2	2	4	16	Y	SVP X00001-02		
173	Fire / Smoke	Software	Code/Data transfer to/from E2PROM	Unit ceases to energise when voltage limit reached (diode/testers overheat)	2	3	4	24	Store and compare Software V&V	2	2	4	16	Y	SVP X00001-02		
174	Fire / Smoke	Trigger Assembly	Electronic component overheating	Trigger Assy overheats (momentarily)	2	4	4	32	Certification to IEC 601-1. All electrical components and cables are rated to handle normal operating conditions without undue heating or failure. Case material PC/ABS "Cycloloy" is rated as fire-retardant according to UL94 (HVO94-SVB).	2	1	4	8	Y	IEC 601-1 test report Component & Case Material Data Sheets		
175	Fire / Smoke	Trigger Assembly	Trigger transformer insulation fails	Possibility of arc causing smoke and fire	2	2	4	16									
176	Fire / Smoke	Trigger Assembly	HV Zener diode open circuit	Not possible explosive smoke may go bang!	2	1	4	8									
177	Infection (local)	Accessories	Tube of anaesthetic cream used on multiple patients	Cross-contamination of patients by viable bacteria / virus	3	4	4	48	LAD to be sold with ELA Max which is indicated for use on cuts and broken skin (similar to ablated skin). Warning in User Manual refers back ELA-Max labelling regarding all warnings associated with the application of ELA Max. Warning in user manual regarding infection control	3	2	4	24	Y	LAD User Manual ELA-Max labelling		
178	Infection (local)	LAD Unit	LAD contaminated by viable bacteria / virus growing on the build up of ablated material from previous ablation	Local skin infection to the patient through ablation site transferred by the user	3	4	4	48	Single use tip design Tip window prevents ablated material from reaching the LAD unit. Cleaning procedures outlined in user manual	3	1	4	12	Y	Tip design drawings LAD User Manual		
179	Infection (local)	LAD Unit	LAD contaminated by ablated material containing viable bacteria / virus	Local skin infection to the patient through ablation site from the user	3	4	4	48	Single use tip design Tip window prevents ablated material from reaching the LAD unit. Cleaning procedures outlined in user manual	3	1	4	12	Y	Tip design drawings		
180	Infection (local)	LAD Unit	LAD contaminated by viable bacteria / virus growing on the build up of biological material (e.g. build-up in buttons)	Local skin infection to the patient through ablation site transferred by the user	3	5	4	36	Single use tip design Tip window prevents ablated material from reaching the LAD unit. Cleaning procedures outlined in user manual	3	1	4	12	Y	Tip design drawings LAD User Manual		
181	Infection (local)	LAD Unit	LAD contaminated by viable bacteria / virus growing on the build up of biological material (e.g. build-up in buttons)	Local skin infection to the user	3	2	4	24	Single use tip design Tip window prevents ablated material from reaching the LAD unit. Cleaning procedures outlined in user manual	3	1	4	12	Y	Tip design drawings LAD User Manual		





LAD-06 RISK ANALYSIS

337	Non-functional / Frustration	Software	A/D conversion scaling errors	Fails to operate Display corrupt	1	2	4	8	Software V&V	1	0.1	4	0.4	Y	SVP X00001-02
338	Non-functional / Frustration	Software	Code/Data transfer to/from EEPROM	Fails to operate Display corrupt	1	2	4	8	Store and compare	1	0.1	4	0.4	Y	
339	Non-functional / Frustration	Software	One wire bus data to battery incorrect caused by noise	Battery charge rate incorrectly set/battery not charged	1	2	4	8	Software V&V Charge limit limit and battery temperature monitored in software ( Read/compare-CRC)	1	0.1	4	0.4	Y	SVP X00001-02
340	Non-functional / Frustration	Software	One wire data incorrectly read from battery due to noise	Battery charge rate incorrectly set/ Battery not charged	1	2	4	8	Software V&V Charge limit limit and battery temperature monitored in software ( Read/compare-CRC)	1	0.1	4	0.4	Y	SVP X00001-02
341	Non-functional / Frustration	Tip	Electronics thinks tip interlock not activated	User unable to fire LAD	1	3	4	12							
342	Non-functional / Frustration	Tip	Tip eject mechanism jams	tip will not eject	1	3	4	12							
343	Non-functional / Frustration	Tip	Site ID disk jams in tip	User has no site ID	1	2	4	8							
344	Non-functional / Frustration	Tip	Site ID disk comes off patient when drug removed	User has no site ID	1	2	4	8							
345	Non-functional / Frustration	Tip	Tip inner sleeve fails to move forward	Tip interlock not engaged	1	3	4	12							
346	Non-functional / Frustration	Tip	Lens retainer stops too small causing lens retainer to separate from housing	Lens retainer sticks to patient	1	5	4	20							
347	Non-functional / Frustration	Trigger Assembly	Electronic component overheating	Trigger Assy overheats (momentarily)	1	4	4	16							
348	Non-functional / Frustration	Trigger Assembly	SCR short or open circuit	Will not fire	1	2	4	8							
349	Non-functional / Frustration	Trigger Assembly	HV Zener diode short circuit	Unit will not energize	1	2	4	8							
350	Non-functional / Frustration	Trigger Assembly	Trigger transformer short circuit	May not fire	1	2	4	8							
351	Non-functional / Frustration	Trigger Assembly	Trigger transformer open circuit	May not fire	1	2	4	8							
352	Non-functional / Frustration	Trigger Assembly	Low voltage capacitor either open/short circuit	Will not fire	1	1	4	4							
353	Non-functional / Frustration	Trigger Assembly	Low voltage zener diode open circuit	Excessive voltage will cause the capacitor to fail resulting in a non-functional unit	1	1	4	4							
354	Non-functional / Frustration	Trigger Assembly	Trigger primary capacitor short circuit	Will not fire	1	1	4	4							
355	Non-functional / Frustration	Trigger Assembly	Trigger primary capacitor open circuit	Will not fire	1	1	4	4							
356	Non-functional / Frustration	Trigger Assembly	Incorrect trigger travel & force (therefore unit fires unintentionally)	Fail Trigger	1	1	4	4							
357	Toxicity	Battery Pack	Incorrect Battery Pack disposal	Exposure to battery contents causes toxicity &/or carcinogenicity effect	5	1	4	20							
358	Toxicity	Battery Pack	Battery Pack connected backwards	Exposure to battery contents causes toxicity &/or carcinogenicity effect	5	0.1	4	2							
359	Toxicity	Battery Pack	Battery leakage	Exposure to battery contents causes toxicity &/or carcinogenicity effect	5	0.1	4	2							
360	Toxicity	HV Assembly	Overheating of electrolytic capacitors	Exposure to electrolytic capacitor contents causes toxicity &/or carcinogenicity effect	5	0.1	4	2							
361	Toxicity	HV Assembly	R101 R104 open	Microprocessor will overcharge capacitors leading to explosion	4	0.1	4	1.6							
362	Toxicity	HV Assembly	Opamps is output low	Microprocessor overcharges capacitor causes chemical spillage	4	0.1	4	1.6							
363	Toxicity	HV Assembly	FFC/connector fails short	Excessive battery charge causes chemical spillage	4	0.1	4	1.6							
364	Toxicity	HV Assembly	FFC/connector fails open	NC feedback to the microprocessor causes overcharging	4	0.1	4	1.6							
365	Toxicity	HV Assembly	Capacitor leakage (electrolytic)	Release of toxic chemicals	4	0.1	4	1.6							
366	Toxicity	LAD Unit	Wound material leeches onto the skin	Wound material causes toxicity	5	1	4	20							
367	Toxicity	LAD Unit	Unit on fire or glowing off flames in use	Exposure to flames causes toxicity &/or carcinogenicity effect	5	0.1	4	2							
368	Toxicity	LAD Unit	Beam misaligned (pointed to one side - burns tip)	Exposure to tissue &/or carcinogenicity plume	5	0.1	4	2							
369	Toxicity	LAD Unit	Unit emergency fire into chamber	Exposure to toxic &/or carcinogenic plume	5	0.1	4	2							
370	Toxicity	LAD Unit	Plume generated from ablating the skin	Exposure to toxic &/or carcinogenic plume	5	0.1	4	2							
371	Toxicity	Software	Corrupt code Program continues to run	Unit ceases to energize when voltage limit reached Capacitors over charge and burst	4	1	4	16	Verify code when loaded into ROM (Internal watchdog external watchdog) Hardware protection	4	0.1	4	1.6	N	
372	Toxicity	Software	Data outside range	Unit ceases to energize when voltage limit reached Capacitors over charge and burst	4	1	4	16	Software range check Software V&V Hardware protection	4	0.1	4	1.6	N	SVP X00001-02
373	Toxicity	Software	Code/Data transferred to/from Internal eeprom corrupted	Unit ceases to energize when voltage limit reached Capacitors over charge and burst	4	1	4	16	Software store and compare Hardware protection	4	0.1	4	1.6	N	
374	Toxicity	Software	A to D conversion corrupted by noise	Unit ceases to energize when voltage limit reached Capacitors over charge and burst	4	1	4	16	Multiple analogue reads and average Hardware protection	4	0.1	4	1.6	N	
375	Toxicity	Software	A to D conversion scaling errors	Unit ceases to energize when voltage limit reached Capacitors over charge and burst	4	1	4	16	Software V&V Hardware protection	4	0.1	4	1.6	N	SVP X00001-02
376	Toxicity	Software	Code/Data transfer to/from EEPROM	Unit ceases to energize when voltage limit reached Capacitors over charge and burst	4	1	4	16	Store and compare Hardware protection	4	0.1	4	1.6	N	
377	Toxicity	Software	Corrupt code Program stops running	Battery FET turned on causing over charge battery burst	4	1	4	16	Verify code when loaded into ROM (Internal watchdog external watchdog)	4	0.1	4	1.6	N	
378	Toxicity	Software	Corrupt code Program continues to run	Battery FET turned on causing over charge battery burst	4	1	4	16	Verify code when loaded into ROM (Internal watchdog external watchdog)	4	0.1	4	1.6	N	
379	Toxicity	Software	Data outside range	Battery FET turned on causing over charge battery burst	4	1	4	16	Software range check Software V&V	4	0.1	4	1.6	N	SVP X00001-02
380	Toxicity	Software	Code/Data transferred to/from Internal eeprom corrupted	Battery FET turned on causing over charge battery burst	4	1	4	16	Software store and compare	4	0.1	4	1.6	N	
381	Toxicity	Software	Code/Data transfer to/from EEPROM	Battery FET turned on causing over charge battery burst	4	1	4	16	Store and compare Software V&V	4	0.1	4	1.6	N	SVP X00001-02
382	Toxicity	Software	One wire data incorrectly read from battery due to noise	Battery condition misread causing over charge battery burst	4	1	4	16	Multiple reads will reset the correct rate within 1 min	4	0.1	4	1.6	N	
383	Toxicity	Tip	Tip material leeches into the skin	Tip material causes toxicity	5	0.1	4	2							