Severity Scale:

1	No harm to patient or operator and minimal disturbance to procedure
2	Minimal harm/chance of harm to patient or operator (very minor injury or disturbance to procedure)
3	Moderate harm/ chance of harm to pateint or operator (minor injury or disturbance to procedure)
4	Serious harm/chance of harm to patient or operator (serious injury or significant disturbance of procedure)
5	Severe harm/chance of harm to patient or operator (life threatening or procedure failure)

Occurrence scale:

1	Extremely unlikely (should not occur during trials)
2	Minimal chance of occurrence (may occur once during whole set of trials)
3	Moderate chance of occurrence (may occur once in 10 procedures)
4	Likely chance of occurrence (may occur once in every 2-3 procedures)
5	Certain occurrence for each procedure

Detection scale:

1	Detection certain (fault will always be detected)
2	Detection probable (fault is likely to be detected)
3	Detection possible (fault has approximatley 50% chance of being detected)
4	Detection unlikely (fault will probably be undetected)
5	Detection impossible (fault will never be detected)

Item/Function	Potential Failure Mode	Potential Effects of Failure	S	Potential Cause(s)	How Failure is Detected	O	Current Controls	D (detection r	RPN (risk	Reccomended Actions
Robot	Water gets into motoc controller enclosure and causes damage to controller	Controller stops working	2	Cover of controller is incorrectly installed and someone spills water on cotroller	Watchdog timer on the PC will time out when controller is unresponsive and shut down the system via the USB relay	1	Water resistant enclosure	1	2	Training and proper maintainence of seals
	Limit switch mechanically fails during operation	System runs into software limit and is stopped	1	Limit switch fatigue, manufacture defect	If the soft limit fails, this will be detected as a movement error by the motor controller, otherwise failure will be undetected.	2	Soft limits act as backup	5	10	Stop and send robot for maintainence
	Pot has electrical or mechainal failure before operation begins	Would not be able to cross check the encoders	2	Pot fatigue or manufacture defect	Detect by comparing to expected pot values stored in program	2	Cross check with encoder during calibration procedure (can't be detected during operation)	1	4	Stop and send robot for maintainence
	Pot has electrical or mechainal failure during operation	Would not be able to cross check the encoders	2	Pot fatigue or manufacture defect	Would show a cross checking error	2	Cross check with encoder during operation	1	4	Stop and send robot for maintainence
	Encoder has electrical or mechanical failure before operation begins	Motors would not be able to function correctly	2	Encoder fatigue or manufacture defect	Detected during calibration procedure	2	Do calibration procedure and cross check with pots	1	4	Stop and send robot for maintainence
	Encoder has electrical or mechanical failure during operation	Motors would not be able to function correctly	2	Encoder fatigue or manufacture defect	Detected by cross checking with pots	2	Cross checking with pots	1	4	Stop and send robot for maintainence
	Both encoder and pot have electrical or mechanical failure	Motors would not be able to function correctly	3	Encoder or pot fatigue or manufacture defect	Detected by the motor controller motion error	1	Motor controller motion error	2	6	Stop and send robot for maintainence
	Motor failure due to broken wire or short	Motor would stop moving	2	Motor manufacture defect	Detected by motor controller motion error	2	Motor controller motion error	1	4	Stop and send robot for maintainence
	Mechanical break between the motor and joint	Robot could move incorrectly	3	Mechanical fatigue, pushed beyond load capacity	Detected by cross checking with pots	2	Cross checking with pots	1	6	Stop and send robot for maintainence
	Arm joint becomes loose	Arm could fall and injure patient or operator	3	Gross mishandling of the robot	Robot falls during procedure	1	Follow handling instructions, Robot is positioned so robot mass is not over patient	1	3	Stop and send robot for maintainence
	Object blocking arm or internal jam in arm	Could cause damage to robot	3	Obstacles in range of motion, internal mechanical problem	Motor controller motion error	2	Follow setup instructions	1	6	Stop and send robot for maintainence
	Broken wire, short causes robot to become electrified	Weak electric shock (12 V)	2	Broken wire	Fuse would blow	1	chassis ground wire;only 12 V;fuse guards against large short; scope electrically insulated	1	2	Proper maintainence of wires
	Limit switch mechanically fails before operation begins	Robot would run into end of limit during startup procedure	2	Limit switch fatigue, manufacture defect	Motor controller detects that there is a motion error durin startup, aborts startup	2	Startup calibration procedure will detect	1	4	Send robot for maintainence
Computer Failure	Ethernet failure: motor controller loses communication with PC	Robot would stop responding to commands	3	Ethernet cord is disconnected	Watchdog timer	2	PC watchdog timer times out and cuts power to motors	1	6	stop and check ethernet cord, maintainence if nothing appears wrong with cord
	Computer crash	Computer stops responding to user commands, cannot command robot	3	Software errors	Motoc controller watchdog timer	2	Motor controller watchdog timer times out and cuts power to motors	1	6	Stop, restart and reload calibration tables
	Power surge causes damage to computer	No effect or computer failure	3	Power surge in building	Computer stops working; fuse blows	1	isolated power supply; fuse will catch	1	3	Use a surge protector power strip
Installation Error	Incorrect Attachment to bedrail	Could injure patient or surgeon	4	Incorrect installation	Check stability in setup procedure	1	Check robot stability during setup; large margin for error in bedrail attachment system	1	4	Correct training for setup and surgeon
	Joints not locked correctly	Scope pulled from patients mouth; damage scope	2	Incorrect installation	Check stability in setup procedure	2	Check robot stability during setup; all joints that could move due to gravity have friction collars to prevent unintended motion	1	4	Correct training for setup and surgeon
	Scope cord not slack enough and becomes caught on something	Could damage scope	3	Incorrect installation	Check range of motion of robot before procedure	2	Proper setup	1	6	Correct training for setup and surgeon
	Friction collars not tightened correctly	Damage scope, robot; injure patient; injure operator	3	Incorrect maintainence	Check friction collars during setup	1	Proper maintainence and checks during setup	1	3	Correct maintainence and correct training for setup
	Unsanitary draping/undraping procedure	Spread of contamination between patients	4	Incorrect procedure	Patient contracts infection	1	Draping and cleaning procedure; disposable parts	2	8	Follow proper draping and cleaning procedures; secondary cleaning; double draping?
Maintainance	Seals on robot degrade	cleaning fluid gets into the robot during cleaning	2	Material fatigue	Visually observed during maintainence	1	Maintainence and inspection	1	2	Proper maintainence
	Friction collars degrade	Robot comes loose during adjustment	3	Material fatigue	Inspection and testing during maintainence	2	Maintainence and inspection	1	6	Follow maintainence procedure
Joystick Failure	Joystick mechanical failure: joystick cannot change switch settings	User can't control the robot	2	Material fatigue or mishandling	User detects robot's unresponsiveness	1	Maintainence and inspection/check in startup procedure	1	2	Stop operation and send robot for maintainence
	Joystick double switch failure	incorrect command	3	short circuit, broken wire, mechanical failure	Robot not responding properly to surgeon commands	1	Emergency stop button, checks for inconsistent joystick commands	2	6	Emergency stop, send for maintainence