

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 patient 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 approximately 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 | RPN (SxOxD) | Recommended Actions |
|----------------|----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|---|---------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------|---|-------------|------------------------------------------------------------------------------------------------------------------------|
| RoboELF | Unsanitary draping/undraping procedure | Spread of contamination between patients | 4 | Unsanitary draping/undraping procedure | Observation of torn drape or improper drape coverage, Observation of potentially contaminating splatter on robot | 2 | Draping and cleaning procedure; disposable parts | 1 | 8 | Follow proper draping and cleaning procedures |
| | Physical Injury to Patient or Operator | Robot falls on patient or operator | 4 | Incorrect Installation: Improper attachment to bedrail | Check stability in setup procedure | 1 | Check robot stability during setup; large margin for error in bedrail attachment system | 1 | 4 | Tighten joints as specified in manual; verify stability during setup |
| | | | 2 | Incorrect installation: Improper tightening of joint collars | Check tightening of joint collars 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 | Tighten joints as specified in manual; verify stability during setup |
| | | | 3 | Incorrect maintenance: Improper tightening of friction collars | Check tightening of friction collars during setup and maintenance procedures | 1 | Proper maintenance and checks during setup | 1 | 3 | Tighten friction collars according to maintenance specification |
| | | Robot becomes electrified | 3 | Broken wire due to fatigue or improper assembly | Check robot grounding during maintenance, Fuse on robot electronics will trip if fault occurs in use. Circuit breaker on power strip as well. | 1 | Proper maintenance and electrical fuse on robot, proper grounding during manufacturing | 1 | 3 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| | Robot Becomes Unresponsive(Active), Possible uncontrolled motion, Robot could drive itself or endoscope into patient or operator | Computer could not accurately determine robot position | 2 | Simultaneous failure of potentiometer and encoder, preventing cross-checking | Detected by motor controller motion error | 1 | Galil Overcurrent check | 2 | 4 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| | | | 2 | Encoder or potentiometer failure due to manufacture defect, fatigue or faulty system wiring | Detected by cross checking between encoders and potentiometers | 1 | Cross checking between encoders and potentiometers; the controller stops the robot and informs the user of the error. | 1 | 2 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |

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| | | 2 | Loss of Ethernet Connection because of physical break or software error | Detected by Watchdog Timer | 1 | Watchdog Timer | 1 | 2 | Attempt to reinitialize system. If reinitializes successfully, then resume. If not able to reinitialize, then stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| | Motor could move without a user command | 2 | Motor malfunction due to manufacture defect, fatigue or faulty wiring | Detected by motor controller motion error or cross checking between encoders and potentiometers | 2 | Galil Overcurrent check, Cross checking between encoders and potentiometers | 1 | 4 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| | | 2 | Joystick malfunction due to manufacture defect, fatigue or faulty wiring | Detected by checking for inconsistent joystick commands or user observation of uncommanded motion | 2 | Emergency stop button, checks for inconsistent joystick commands | 1 | 4 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| Robot Becomes Unresponsive(Non-Active), No possible motion | PC unexpectedly becomes disabled | 1 | Internal Software error | Watchdog timer on Galil will stop system | 1 | Watchdog Timer | 1 | 1 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| | | 1 | Power surge damages computer | Surge protector on power strip | 1 | Surge protector | 1 | 1 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| Scope damage | Scope cord not slack enough and becomes caught on something | 3 | Incorrect installation | Check range of motion of robot before procedure | 1 | Detailed setup instructions | 1 | 3 | Correct training for setup and surgeon |
| Robot damage | Robot runs into/tries to move past physical limits | 2 | Limit switch failure due to fatigue or manufacture defect | Detected by motor controller motion error | 2 | Galil Overcurrent check, Soft limits act as backup | 1 | 4 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |
| | Object blocking arm or internal jam in arm | 3 | Obstacles in range of motion, internal mechanical problem | Motor controller motion error | 1 | Follow setup instructions | 1 | 3 | Stop. Move the robot out of the way. Remove the endoscope from the robot. Continue surgery manually without the robot. |