

RELIABILITY TEST PROTOCOL FOR THE MOVING-ACTUATOR TYPE TOTAL ARTIFICIAL HEART

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One of the major problems in successful development of the artificial heart is the reliability problem. In order to evaluate the reliability of the moving-actuator type total artificial heart (TAH), we built a test protocol and are making progress according to the schedule. Our goal in the reliability test of our system is to demonstrate an 80% reliability with 60% confidence for 1 year system operation. 10 sets of the simple mock circulatory systems were provided and 10 TAHs are under construction. The flow rate of the testing TAH will be monitored in real time and its failure condition will be checked from the flow rate data. The temperature of the test fluid will be maintained as 37°C and the TAH will be submerged in the test fluid during the test. We will estimate the reliability of the system using the Weibull time-to-failure distribution model and life test data which will be obtained from the 1 year operation. All device accidents in our TAH were registered and analyzed for the Failure Mode Analysis (FMA). The 3 stage gear assembly of the TAH is considered as the unendurable part throughout the FMA. Therefore, the durability of the gear system will be tested independently with a well-developed test protocol.