RELIABILITY ANALYSIS OF BLOOD LEAKAGE DETECTION SYSTEM

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ABSTRACT

Blood leakage detection system is important for the hemodialysis machine. The reliability of this system should be viewed as one of the most important attributes of the safety of hemodialisis machine. However to have a better understanding of how reliable a component is, it is most appropriate to express it quantitatively. In this work, reliability analysis using the MTTF calculation was used for evaluating the reliability of the blood leakage sensor. The results show that through the calculation of MTTF, the blood leakage system has been proven to be reliable component suitable for use in hemodialysis machine.

Keywords: *reliability analysis, MTTF, blood leakage detector.*

1. INTRODUCTION

Recently, high sensitive detections are important isue in medical electronics, such as blood leak detection system used in hemodialysis machine. A number of sensors, such as temperature sensors, conductivity sensors, flow rate sensors, pressure sensors, and bubble sensors are used in the hemodialysis machine together with the blood leak sensor. In hemodialysis therapy, blood leak can potentially caused fatal damage for patient even if leakage in the treatment is very small in quantity. Instruments to detect the blood leak are mostly based on non-invasive optical method using infrared or visible light emited from laser or diode. Alarm is triggered if the blood concentration exceeds the permisible level [1].

The blood leak sensing system being developed is based on optical method which is a light attenuating principle. Infrared light is attenuated by the presence of blood cells in the optical path in the container, and thus the measurement of light attenuation gives the blood concentration. The system consists of a pair of infrared emmiting diode and infrared sensor, analog circuitry and microcontroller modul. The sensitivity and accuracy may then depend on the sensitivity and stability of the measurement system and on the fluctuation of the incident light, respectively. The sensitivity of the blood detection system is in the range between 0.01 and 0.1 of the weight precentage [2].

In this paper, reliability analysis of the blood leakage detection system was conducted. Mean time to failures (MTTF) is used for measuring the reliability for unrepairable components. MTTF can be described as the time passed before a component, assembly, or system fails, under the condition of a constant failure rate. Since the experimental work for determining the MTTF of a blood leak detection system is not feasible due to the duration of time that would be required to carry out the test, a reliability prediction method using a Military Handbook MIL-HDBK-217F, *Reliability Prediction of Electronic Equipment* was used to calculate the MTTF [3,4].

2. METHOD

The MIL-HDBK-217F handbook was used for the MTTF calculation. It describes two methods for calculating the MTTF. Such methods are part stress analysis method and part count method. In this work, the part stress analysis method was chosen for calculating the MTTF and hence the failure rate, λp, of each part in the system and printed circuit board. The results obtained using the part stress analysis method gives more realistic estimation of MTTF compared to part count method. However, it requires a greater amount of detailed information about the design and type of electronic components being used [3,4].

The parts stress analysis prediction is based on the determination of a failure rate for each electronic component of the system, summing those failure rates, and then adding that to the calculated failure rate for the printed circuit board. This results in a system failure rate, λ, in terms of failures per million hours. The inverse of this is the mean time to failure for the system, MTTF = 1/ λ_P (in hours to failure). Failure rate models for many types of electronic components and most types of circuit boards commonly have been modelled in the the MIL-HDBK-217F handbook [3,4].

The parts stress analysis prediction is started by examining the system bill of materials, identifying each electronic part, and classifying the parts by type. This blood leakage detection system consists of the printed circuit board, discrete components, integrated circuits, optical sensor and hand soldered wires connected between optical sensor and board.

Each component is assigned a base failure rate, λ_b, based on the type and style of the component. The base failure rate is then multiplied by different factors, π_x, depending on the part quality, use environment, thermal aspects, etc. resulting in the part failure rate, λ_p. The base failure rates and various π factors are obtained from the Handbook [4].

2.1. Component Count

Table 1 shows the list of components used in the blood leak detection system.

Table 1. Bill of Material

Component Type	Quantity
Diode	9
Resistor	58
Capasitor	37
Transistor	8
Microcontroller	1
ROM	1
RAM	4
DAC	1
Opamp	6
SMT board	1

2.2. Resistor

The following equation is used to calculate the part life time of resistor in failures to per million hours,

$$\lambda_p = \lambda_b \; \pi_T \; \pi_P \; \pi_S \; \pi_Q \; \pi_E \qquad (1)$$

where

λ_b = Base Lifetime
π_T = Temperature factor,
π_P = Power factor,
π_S = Power stress factor,
π_Q = Quality factor,
π_E = Environtment factor,

All the resistors used in the PCB were commercial grade, low power and film type surface mount resistor. These resistors were classified as RL with the λ_b given by 0.0037. To calculate the temperature factor of π_T, the temperature of 60°C was used in the analysis. The reason is that most of the medical devices uses an upper temperature rating of 60°C. Looking from the table, the value of π_T is given by 1.4. The power factor of the resistor is determined by the power dissipation in watt. The resistors used were 1/16 watt (0.0625 watt) resistor. From the handbook, this value is in between 0.01 and 0.13 watt. However, being conservative the power factor (π_P) is chosen as 0.44, which is larger than those two values. The Power Stress Factor is determined by dividing the actual power dissipated by its rated power (S) and then using the table to find the factor. From the handbook, the value for π_S is 1.1. The Quality Factor is determined by the rating of the part itself. These resistors are unscreened, commercial parts, as are all the parts in the circuit board assembly. The table lists the most conservative value as π_Q equal to 10. The Environment Factor is determined by defining the use environment of the device. The environment that describes a typical medical device is “Ground Benign, GB” as defined in Table 3-2 of the Handbook. This results in a π_E of 1.0. The GB classification will be used for all components in the ABD assembly.

2.3. Diode

Part lifetime of the diode in failures permillion hours can be calculated using the following equation,

$$\lambda_p = \lambda_b \; \pi_T \; \pi_S \; \pi_C \; \pi_Q \; \pi_E \qquad (2)$$

where

λ_b = Base failure rate
π_T = Temperatur factor,
π_S = Power stress factor,
π_C = Contact factor,
π_Q = Quality factor,
π_E = Environtment factor,

The diode used is as switching diode. The base failure rate λ_b for the swicthing diode is set to 0.0010. The temperature factor, π_T, is determined by assuming that the junction temperature of the diode of 60°C. Looking from the handbook, the temperature factor of π_T is defined as 3.0. The electrical stress factor, π_S, is determined by dividing the voltage applied with the rated voltage (5V/75V). Using the table from the handbook, the power stress factor π_S is 0.054. Contact construction factor π_C is set to 1.0, since the contacts are metallurgically bounded. The diode is constructed from plastic material. Therefore, the quality factor π_Q is set to 8 as determined from the handbook. Since it is used in medical device, the environment factor is denoted as "Ground Benign, GB" as defined in Table 3-2 of the Handbook. This gives the value for π_E of 1.0. The value for λp is given by (.0010) (3.0) (.054) (1.0) (8) (1.0) or λp = 0.001296 failures / 10^6 hours.

2.4. Capacitor

Part lifetime of the capacitor in failure permillions can be calculated using the following equation,

$$\lambda_p = \lambda_b \; \pi_T \; \pi_C \; \pi_V \; \pi_{SR} \; \pi_Q \; \pi_E \qquad (3)$$

where
λ_b = Base failure rate
π_T = Temperatur factor,
π_S = Power stress factor,
π_C = Capacitance stress factor,
π_V = Voltage stress factor,
π_Q = Quality factor,
π_E = Environtment factor,

There are 3 styles of capacitors used in this design: CK (ceramic), CL(nonsolid electrolyte) and CWR (electrolytic, tantalum). From the handbook, the values of base failure rate λ_b are 0.00099, 0.00040, and 0.00005 for CK, CL and CWR capacitor styles, respectively. The temperature environtment in which capacitor used is assumed to be 60 °C. Therefore, the temperature factor, π_T is defines as 3.0. The capacitance and voltage stress factors, π_C and π_V, are determined from table of the handbook. The values for the capacitance factors range from 0.29 to 1.9 for capacitors with capacitance 0.000001 µF to 1,000 µF.The values for voltage stress factor (π_V) range from 1 to 1.6. The series resistance factor, π_{SR} , for CK, CL and CWR are set to 1.0. The quality factor π_Q is set to 10, since it is a commersial quality. For GB environtment, the value of environtment factor π_E is set to 1.0.

2.5. Bipolar Transistor

Part lifetime of the bipolar transistor in failure permillions can be calculated using the following equation,

$$\lambda_p = \lambda_b \; \pi_T \; \pi_A \; \pi_R \; \pi_S \; \pi_Q \; \pi_E \qquad (4)$$

where
λ_b = Base failure rate (0.00074)
π_T = Temperature factor (2.1)
π_A = Application factor (1.5)
π_R = Power rating factor (0.43)
π_R = Voltage stress factor (0.11)
π_Q = Quality factor (10)
π_E = Environtment factor (1.0)

The failure rate for transistor λ_P = 0.0011

2.6. Microcircuits

The five components considered as microcircuit used in the design are the microprocessor, ROM/RAM memory, DAC, and operasional amplifier.

Failure rate prediction formula for microcircuits can be calculated using the following formula,

$$\lambda_p = (C_1 \pi_T + C_2 \; \pi_E) \; \pi_Q \; \pi_L \qquad (5)$$

where
C_1 = Die complexity failure rate
π_T = Temperature factor
C_2 = Package failure rate
π_E = Environtment factor
π_Q = Quality factor
π_L = Learning factor

Only variables C_1 and C_2 were specific to each component, almost all other parameters were given the same assumptions with little variation in values. A portable device will most likely encounter hot and cold outdoor temperatures, yet an optimistic baseline assumption of +60º C was considered throughout. All components were assumed to be G_B, ground benign environment with a value of $\pi_E = 1.0$. Parts are of undetermined quality factor and therefore, the generic commercial grade factor $\pi_Q = 10$ was assumed perhaps erroneously. Unless otherwise specified, these ICs have been in production much more than 2 years, so the learning factor of $\pi_L = 1.0$ was used.

Tables 2,3,4, and 5 show the failure rate, λ_P, for microcontroller, ROM, RAM, and DAC, respectively.

Table 2. Microcontroller

Parameter	Value	Justification
C_1	0.56	Assumed 32 bit MOS microprocessor (MIL-HDBK-217F, Section 5.1)
π_T	0.42	Assumed digital MOS (MIL-HDBK-217F, Section 5.8)
C_2	0.029	64-pin TQFP, used eq. 3 (MIL-HDBK-217F, Section 5.9)
π_E	1.0	Assumed ground benign (G_B) condition (MIL-HDBK-217F, Section 5.10)
π_Q	10	Commercial component (MIL-HDBK-217F, Section 5.10)
π_L	1.0	Years in production ≥ 2.0 (MIL-HDBK-217F, Section 5.10)
λ_P	0.2642 Failures /10^6 hours	

Table 3. ROM

Parameter	Value	Justification
C_1	0.08	MOS with 30,001 to 60,000 gates (MIL-HDBK-217F, Section 5.1)
π_T	0.42	Assumed 60º C (MIL-HDBK-217F, Section 5.8)
C_2	0.1	28-pin thin QFN, Assumed non-leaded SMT (MIL-HDBK-217F, Section 5.9)
π_E	1.0	Assumed ground benign condition (MIL-HDBK-217F, Section 5.10)
π_Q	10	Commercial component (MIL-HDBK-217F, Section 5.10)
π_L	1.0	Year production ≥ 2.0 (MIL-HDBK-217F, Section 5.10)
λ_P	0.1336 Failures/10^6 hours	

Table 4. RAM

Parameter	Value	Justification
C_1	0.29	MOS device with 30,001-60,000 (MIL-HDBK-217F, Section 5.1)
π_T	0.42	Assumed operating temperature 60º C (MIL-HDBK-217F, Section 5.8)
C_2	0.29	64 pin LQFP, eq. 3 (MIL-HDBK-217F, Section 5.9)
π_E	1.0	Assumed ground benign condition (MIL-HDBK-217F, Section 5.10)
π_Q	10	Commercial component (MIL-HDBK-217F, Section 5.10)
π_L	1.0	Years in production ≥ 2.0 (MIL-HDBK-217F, Section 5.10)
λ_P	0.4118 Failures/10^6 hours	

Table 5. DAC

Parameter	Value	Justification
C_1	0.16	MOS device with 10,001-30,000 (MIL-HDBK-217F, Section 5.1)
π_T	0.42	Assumed operating temperature 60º C (MIL-HDBK-217F, Section 5.8)
C_2	0.29	64 pin LQFP, eq. 3 (MIL-HDBK-217F, Section 5.9)
π_E	1.0	Assumed ground benign condition (MIL-HDBK-217F, Section 5.10)
π_Q	10	Commercial component (MIL-HDBK-217F, Section 5.10)
π_L	1.0	Years in production ≥ 2.0 (MIL-HDBK-217F, Section 5.10)
λ_P	0.3572 Failures/10^6 hours	

Table 6. Operational Amplifier

Parameter	Value	Justification
C_1	0.016	MOS device with 1-100 trasistor (MIL-HDBK-217F, Section 5.1)
π_T	0.42	Assumed operating temperature 60º C (MIL-HDBK-217F, Section 5.8)
C_2	0.025	6 pin SMT
π_E	1.0	Assumed ground benign condition (MIL-HDBK-217F, Section 5.10)
π_Q	10	Commercial component (MIL-HDBK-217F, Section 5.10)
π_L	1.0	Years in production ≥ 2.0 (MIL-HDBK-217F, Section 5.10)
λ_P	0.1525 Failures/10^6 hours	

3. RESULTS

The system failure rate of the blood leakage detection system is determined by summing all the individual component failure rates as shown in the following table.

Part	Qty	λ_p	Total λ_p
Resistor	58	0.025071	1.454118
Diode	9	0.001296	0.011664
Capacitor	7	0.037048	0.259336

(0.1 µF)			
Capacitor (0.01 µF)	4	0.022453	0.052272
Capacitor (0.001µF)	2	0.022453	0.017424
Capacitor (10 µF)	1	0.059459	0.059459
Capacitor (12 pF)	12	0.0000037	0.000044
Capacitor (10 pF)	4	0.0000037	0.0000148
Capacitor (2200 pF)	1	0.0000069	0.0000069
Capacitor (4.7 µF)	1	0.059459	0.059459
Capacitor (2.2 µF)	3	0.059459	0.178377
Capacitor (0.47 µF)	1	0.01069	0.01069
Capacitor (22 µF)	1	0.022308	0.022308
Transistor	8	0.0011	0.0088
ROM	1	0.1336	0.1336
RAM (1M)	4	0.4118	1.6472
Opamp	6	0.1525	0.915
MCU	1	0.2642	0.2642
DAC	1	0.3572	0.3572
SMT board	1	5.90E-08	5.90E-08
λ_P			5.451173

The estimation of MTTF is given by the inversion of failure rate,

$$MTTF = \frac{1}{\lambda_p} \qquad (6)$$

If λp is equal to 5.451173 failures /10^6 hours, it means that MTTF is equal to 183,446 hours between failures. If it is assumed that the system operates 24 hours per day, 7 days per week and 365 days per year, the MTTF would be more than 21 years.

4. CONCLUSION

The prediction of Mean Time To Failure (MTTF) for bloof leakage detection system is a good indicator of the system's reliability over its designed lifetime. Through calculation of MTTF, the system has been proven to be reliable components suitable for use in hemodialysis machine.

5. ACKNOWLEDGEMENT

This work was funded by the Ministry of Research and Technology, through Research Grant SINAS 2014, “Pengembangan Teknologi Mesin Hemodialisa untuk Mendukung Pelayanan Kesehatan Pasien Gagal Ginjal di Rumah Sakit”

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