

# Reliability Analysis of Moog Ultrasonic Air Bubble Detectors

Air-in-line sensors are vital to the performance of many of today's medical device applications. The reliability of these sensors should be viewed as one of the most important attributes when making a purchasing decision. One indication of a sensor's reliability over its designed lifetime is the calculation of Mean Time To Failure (MTTF). This analysis will use the MTTF calculation as the basis for evaluating the reliability of the LifeGuard™ Ultrasonic Air Bubble Detectors designed and manufactured by Moog.

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The logo consists of the word "MOOG" in a bold, white, sans-serif font, centered within a dark red rectangular background.

Medical Devices Group

## Introduction

One indication of a product's reliability over its designed lifetime is the calculation of Mean Time Between Failures (MTBF) for a repairable device or Mean Time To Failure (MTTF) for a non-repairable device. Since the components used in this analysis are considered non-repairable devices we will use the calculation of MTTF as the basis of our reliability analysis.

MTTF is the expected time to failure of a system, in this case an ultrasonic air bubble detector (ABD) manufactured by Moog. The MTTF is equivalent to the mean of the failure time distribution for a population of the system. For this system, the ABD, the cumulative failure distribution is considered to be exponential because it occurs at a constant rate<sup>1</sup>. This is the long, flat portion of the classic "bathtub curve" used to describe a product's lifetime as shown in Figure 1<sup>2</sup>.

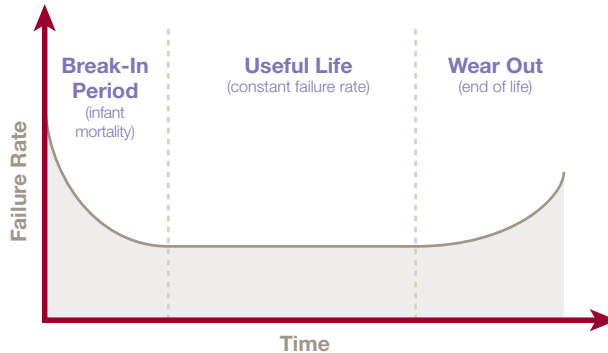


Figure 1 - Product Life Depicted by the Classic Bathtub Curve

MTTF of a system can be determined experimentally or by calculation based upon commonly accepted analysis methods. Experimentally determining the MTTF of an air bubble detector is not feasible due to the duration of time that would be required to carry out the tests. Based on historical data it was determined that a test to determine the MTTF would take many years, even if conducted as an accelerated test. A commonly used method of predicting system reliability through analysis is the use of Military Handbook MIL-HDBK-217F, Notice 2, *Reliability Prediction of Electronic Equipment* (referred to as 217F-2) to calculate the MTTF<sup>3</sup>. That is the method that is presented herein to predict the MTTF of a Moog ultrasonic air bubble detector.

## Methodology for Calculation of MTTF

MIL-HDBK-217F defines two methods of calculating the MTTF: the part stress analysis method and the parts count method. The part stress analysis method was selected for our calculation of MTTF. While it requires a greater amount of detailed information about the design, it results in a more realistic estimation of MTTF. Both methods are described in detail in 217F-2; the reader may review the Handbook for a detailed discussion of the two methods.

The basic methodology of the parts stress analysis prediction is to determine a failure rate for each electronic component of the system, sum those failure rates, and then add that to the calculated failure rate for the circuit board. This results in a system failure rate,  $\lambda$ , in terms of failures per million hours. The inverse of this is the mean time to failure for the system,  $MTTF = 1/\lambda$  (in hours to failure).

The Handbook itself is used to determine the failure rate,  $\lambda_p$ , of each part in the system. It is also used to determine the failure rate of the circuit board. The Handbook contains failure

rate models for many types of electronic components and most types of circuit boards commonly used. Interconnections such as the solder joints to wires between the circuit board and the ultrasonic transducer are also considered in the analysis. The transducer assembly itself (which consists of piezoceramic elements bonded into a housing) is not included directly in the analysis because there is no wear-out or failure mechanism associated with it. It will be explained later in this paper how the transducer, when properly constructed, inherently has a zero failure rate. Wires soldered to the board in a through-hole manner are also excluded from the analysis since they have a zero failure rate per 217F-2.

The easiest way to explain the analysis procedure is to describe each step of the analysis as it is being performed. This analysis is of the Moog family of Lifeguard Air Bubble Detectors (part numbers 28678-001, 28679-001, and 28680-001). It could be applied to similar ABDs produced by Moog with similar circuit boards and components. The Lifeguard ABD consists of two piezoceramic elements that are bonded into a plastic housing, and connected electrically by wires to a circuit board. The circuit board is located within the same housing and is connected to the external machine by means of a four-conductor power/signal cable.

The analysis is started by examining the system bill of materials, identifying each electronic part, and classifying the parts by type (i.e., resistors, capacitors, etc.). This ABD system consists of the circuit board, which is a surface mount technology (SMT) board with 38 discrete components, and four hand soldered connections on the ceramic elements. The soldered connections of the transducer wires and the sensor cable to the circuit board are included in the analysis of the board itself.

Each component is assigned a base failure rate,  $\lambda_b$ , based on the type and style of the component. The base failure rate is then multiplied by different factors,  $\pi_x$ , depending on the part quality, use environment, thermal aspects, etc. resulting in the part failure rate,  $\lambda_p$ . The base failure rates and various  $\pi$  factors are obtained from the Handbook. The approach taken here is to begin with the simplest components, progressing to the more difficult components, and concluding with the connections and circuit board.

## Component Count

The following table contains a list of the components and the corresponding section reference in the Handbook.

Table 1

Component Type	Quantity	Handbook Section
Resistor	22	9.1
Diode	1	6.1
Capacitor	10	10.1
Comparator, Single Package	1	5.1
Comparator, Dual Package	1	5.1
Multivibrator, Dual Package	1	5.1

Component Type	Quantity	Handbook Section
Flip-Flop	1	5.1
555 Timer	1	5.1
Voltage Controlled Oscillator	1	5.1
SMT Board	1	16.2
Solder Connection to Ceramics	4	17.1

## Resistor

The calculation of the part lifetime for a resistor in failures per million hours uses the following equation:

$$\lambda_p = \lambda_b \pi_T \pi_P \pi_S \pi_Q \pi_E \text{ (failures / } 10^6 \text{ hours) where,}$$

$\lambda_b$  is the Base Lifetime, depending on the type of resistor used.

$\pi_T$  is the Temperature Factor, based on the resistor case temperature occurring during use.

$\pi_P$  is the Power Factor, based on the power dissipation of the resistor.

$\pi_S$  is the Power Stress Factor, based on the actual power dissipation of the resistor divided by the rated power.

$\pi_Q$  is the Quality Factor, based on the reliability rating of the resistor (e.g., military grade, commercial/unknown screening level, etc.).

$\pi_E$  is the Environment Factor, based on the environment in which the ABD is used.

Twenty-two resistors are in the ABD circuit. The style of resistors used in the circuit board assembly is commercial grade, low power, film-type surface mount resistors. Using the first table in Section 9.1 of the Handbook, we see that these resistors are classified as style "RL" with a  $\lambda_b$  of .0037. The table also directs which columns to use for the determination of  $\pi_T$  and  $\pi_S$  in their respective tables.

For the determination of the Temperature Factor, we assume that the resistor case temperature will be equivalent to the ambient temperature. The ABD dissipates very little power, but may be used in a machine that generates some heat. A typical medical device has an upper temperature rating of 60° C, so that is what is used for this analysis. Looking in the table for Temperature Factor at 60° C we see that  $\pi_T$  is 1.4. The temperature of 60° C will be used for all components in this analysis.

The Power Factor is determined by the power dissipation of the resistor in watts. The resistors used in the circuit board assembly are 1/16th watt (0.0625 watt) resistors. This value lies between two values listed in the Handbook. The table in the Handbook has Power Factor numbers for .01 and .13 watt. Being conservative, we select the larger of the two values which results in a  $\pi_P$  of .44. Alternatively, it is possible to calculate the Power Factor using an equation provided in the table. However, for our purposes, it is sufficient to select the more conservative value from the table.

The Power Stress Factor is determined by dividing the actual power dissipated by its rated power (S) and then using the table to look up the factor. For this analysis, we choose to be conservative

and only calculate the S for the resistor which dissipates the most power and then apply the same Power Stress Factor to all resistors. We calculate S for a 619 ohm resistor. Using Ohm's Law, we calculate the power dissipated to be  $(3.5 \text{ V})^2 / 619 \text{ ohms} = 0.02 \text{ watts}$ . S is  $0.02 \text{ watts} / .063 \text{ watts}$ , which gives  $S = .32$ . Choosing the conservative value from the table,  $\pi_s$  is 1.1.

The Quality Factor is determined by the rating of the part itself. These resistors are un-screened, commercial parts, as are all the parts in the circuit board assembly. The table lists the most conservative value as  $\pi_Q$  equal to 10. This Quality Factor will be used for all components in the ABD assembly.

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  $\pi_E$  of 1.0. The GB classification will be used for all components in the ABD assembly.

The part lifetime for one resistor can be computed by inserting the known values into the equation.

$$\begin{aligned}\lambda_p &= (.0037) (1.4) (.44) (1.1) (10) (1) \\ \lambda_p &= .025071 \text{ failures} / 10^6 \text{ hours}\end{aligned}$$

Since there are 22 resistors in the assembly, we can multiply this part lifetime value by 22 to obtain the contribution of all resistors to the system.

A similar approach is followed for other components. Details will not be provided for the remainder of components except to provide support of the analysis. It is left to the reader to study 217F-2 in detail to understand the methodology for the more complex system components.

## Diode

The calculation of the part lifetime for the diode in failures per million hours uses the following equation:

$$\begin{aligned}\lambda_p &= \lambda_b \pi_T \pi_S \pi_C \pi_Q \pi_E \text{ (failures} / 10^6 \text{ hours) where,} \\ \lambda_p &= .0010 \text{ (Switching Diode)} \\ \pi_T &= 3.0 \text{ (assume junction temperature is } 60^\circ \text{ C)} \\ \pi_S &= .054 \text{ (voltage applied divided by rated voltage, } 5\text{V}/75\text{V)} \\ \pi_C &= 1.0 \text{ (contacts metallurgically bonded)} \\ \pi_Q &= 8 \text{ (plastic construction)} \\ \pi_E &= 1.0 \text{ (G}_B \text{ environment)} \\ \lambda_p &= (.0010) (3.0) (.054) (1.0) (8) (1.0) \\ \lambda_p &= .001296 \text{ failures} / 10^6 \text{ hours}\end{aligned}$$

## Capacitor

There are ten capacitors in the system. The calculation of the part lifetime for each of the capacitors in failures per million hours uses the following equation:

- $\lambda_p = \lambda_b \pi_T \pi_C \pi_V \pi_{SR} \pi_Q \pi_E$  (failures /  $10^6$  hours) where,
- $\lambda_b = .00099$  (capacitor type CK, fixed, ceramic, general purpose)
- $\pi_T = 4.2$  (assume temperature is  $60^\circ$  C)
- $\pi_C$  and  $\pi_V$  are the capacitance and voltage stress factors from tables in the Handbook
- $\pi_{SR} = 1$  (capacitor type CK)
- $\pi_Q = 10$  (commercial quality)
- $\pi_E = 1.0$  ( $G_B$  environment)

It is easiest to calculate the part lifetime for each capacitor value individually. The calculations are in tabular form below.

Table 2

Part Quantity	Value ( $\mu$ F)	$\pi_C$	$\pi_V$	$\lambda_p$
1	0.068	0.81	1.6	0.053888
4	0.1	0.81	1.1	0.037048
1	0.00033	0.54	1	0.022453
1	0.001	0.54	1	0.022453
1	0.00015	0.44	1	0.018295
1	0.00027	0.54	1	0.022453
1	10	1.3	1.1	0.059459

### Comparator, Single Package

The calculation of the part lifetime for the single package comparator in failures per million hours is based on the complexity of the part and uses the following equation:

- $\lambda_p = (C_1 \pi_T + C_2 \pi_E) \pi_Q \pi_L$  (failures /  $10^6$  hours) where,
- $C_1 = .010$  (1-100 transistors, from component datasheet)
- $\pi_T = 1.4$  (assume junction temperature is  $60^\circ$  C)
- $C_2 = .0025$  (6 pin SMT)
- $\pi_E = 0.5$  ( $G_B$  environment)
- $\pi_Q = 10$  (commercial quality)
- $\pi_L = 1.0$  ( $\geq 2$  yrs in production)
- $\lambda_p = (.010 \cdot 1.4 + .0025 \cdot 0.5) (10) (1.0)$
- $\lambda_p = .1525$  failures /  $10^6$  hours

### Comparator, Dual Package

The calculation of the part lifetime for the dual package comparator in failures per million hours is based on the complexity of the part and uses the following equation:

- $\lambda_p = (C_1 \pi_T + C_2 \pi_E) \pi_Q \pi_L$  (failures /  $10^6$  hours) where,
- $C_1 = .010$  (1-100 transistors, from component datasheet)

$$\begin{aligned}
 \pi_T &= 1.4 \text{ (assume junction temperature is } 60^\circ \text{ C)} \\
 C_2 &= .0034 \text{ (8 pin SMT)} \\
 \pi_E &= 0.5 \text{ (G}_B \text{ environment)} \\
 \pi_Q &= 10 \text{ (commercial quality)} \\
 \pi_L &= 1.0 \text{ (} \geq 2 \text{ yrs in production)} \\
 \\ 
 \lambda_p &= (.010 \cdot 1.4 + .0034 \cdot 0.5) (10) (1.0) \\
 \lambda_p &= .157 \text{ failures / } 10^6 \text{ hours}
 \end{aligned}$$

### Multivibrator, Dual Package

The calculation of the part lifetime for the dual package multivibrator in failures per million hours is based on the complexity of the part and uses the following equation:

$$\begin{aligned}
 \lambda_p &= (C_1 \pi_T + C_2 \pi_E) \pi_Q \pi_L \text{ (failures / } 10^6 \text{ hours) where,} \\
 \\ 
 C_1 &= .0025 \text{ (1-100 gates, from component datasheet)} \\
 \pi_T &= .42 \text{ (assume junction temperature is } 60^\circ \text{ C)} \\
 C_2 &= .0072 \text{ (16 pin SMT)} \\
 \pi_E &= 0.5 \text{ (G}_B \text{ environment)} \\
 \pi_Q &= 10 \text{ (commercial quality)} \\
 \pi_L &= 1.0 \text{ (} \geq 2 \text{ yrs in production)} \\
 \\ 
 \lambda_p &= (.0025 \cdot .42 + .0072 \cdot 0.5) (10) (1.0) \\
 \lambda_p &= .0465 \text{ failures / } 10^6 \text{ hours}
 \end{aligned}$$

### Flip-Flop

The calculation of the part lifetime for the flip-flop in failures per million hours is based on the complexity of the part and uses the following equation:

$$\begin{aligned}
 \lambda_p &= (C_1 \pi_T + C_2 \pi_E) \pi_Q \pi_L \text{ (failures / } 10^6 \text{ hours) where,} \\
 \\ 
 C_1 &= .0025 \text{ (1-100 gates, from component datasheet)} \\
 \pi_T &= .42 \text{ (assume junction temperature is } 60^\circ \text{ C)} \\
 C_2 &= .0034 \text{ (8 pin BBA)} \\
 \pi_E &= 0.5 \text{ (G}_B \text{ environment)} \\
 \pi_Q &= 10 \text{ (commercial quality)} \\
 \pi_L &= 1.0 \text{ (} \geq 2 \text{ yrs in production)} \\
 \\ 
 \lambda_p &= (.0025 \cdot .42 + .0034 \cdot 0.5) (10) (1.0) \\
 \lambda_p &= .0275 \text{ failures / } 10^6 \text{ hours}
 \end{aligned}$$

### 555 Timer

The calculation of the part lifetime for the 555 timer in failures per million hours is based on the complexity of the part and uses the following equation:

$$\lambda_p = (C_1 \pi_T + C_2 \pi_E) \pi_Q \pi_L \text{ (failures / } 10^6 \text{ hours) where,}$$

$$C_1 = .0025 \text{ (1-100 gates, from component datasheet)}$$

$$\pi_T = .42 \text{ (assume junction temperature is } 60^\circ \text{ C)}$$

$$C_2 = .0034 \text{ (8 pin SMT)}$$

$$\pi_E = 0.5 \text{ (G}_B \text{ environment)}$$

$$\pi_Q = 10 \text{ (commercial quality)}$$

$$\pi_L = 1.0 \text{ (} \geq 2 \text{ yrs in production)}$$

$$\lambda_p = (.0025 \cdot .42 + .0034 \cdot 0.5) (10) (1.0)$$

$$\lambda_p = .0275 \text{ failures / } 10^6 \text{ hours}$$

### Voltage-Controlled Oscillator

The calculation of the part lifetime for the voltage-controlled oscillator (VCO) in failures per million hours is based on the complexity of the part and uses the following equation:

$$\lambda_p = (C_1 \pi_T + C_2 \pi_E) \pi_Q \pi_L \text{ (failures / } 10^6 \text{ hours) where,}$$

$$C_1 = .0025 \text{ (1-100 gates, from component datasheet)}$$

$$\pi_T = .42 \text{ (assume junction temperature is } 60^\circ \text{ C)}$$

$$C_2 = .0072 \text{ (16 pin SMT)}$$

$$\pi_E = 0.5 \text{ (G}_B \text{ environment)}$$

$$\pi_Q = 10 \text{ (commercial quality)}$$

$$\pi_L = 1.0 \text{ (} \geq 2 \text{ yrs in production)}$$

$$\lambda_p = (.0025 \cdot .42 + .0072 \cdot 0.5) (10) (1.0)$$

$$\lambda_p = .0465 \text{ failures / } 10^6 \text{ hours}$$

### SMT Board

The calculation of the part lifetime for the circuit board in failures per million hours is based on the thermal cycling fatigue of the “weakest link” component. Two components, the VCO and the flip-flop are examined in this part of the analysis. The VCO is examined because it has the largest leaded package and the flip-flop is examined because it has the smallest package and is a ball-grid array (BGA) device. These represent the extremes of components found on the circuit board assembly.

$$\lambda_{\text{SMT}} = \frac{\text{ECF}}{\alpha_{\text{SMT}}} \text{ (failures / } 10^6 \text{ hours)}$$

ECF is the Effective Cumulative Failures, determined by the Life Cycle (LC) divided by the Weibull characteristic life ( $\alpha_{\text{SMT}}$ ), and found in a table in Section 16.2 of the handbook.

$$\alpha_{\text{SMT}} = \frac{N_f}{\text{CR}}$$

CR is the temperature cycling rate, from a table.  $N_f$  is the average number of cycles to failure from the following equation:

$$N_f = 3.5 \left( \frac{d}{.65h} \left| (\alpha_s \Delta T - \alpha_{CC} (\Delta T - T_{RISE})) \right| \times 10^{-6} \right)^{-2.26} (\pi_{LC})$$

#### For the VCO:

- d = 100 (mils, from center of device to furthest solder joint)
- h = 8 (mils, solder joint height)
- $\alpha_s$  = 11 (circuit board substrate thermal coefficient of expansion, for FR-4 multilayer, copper clad Invar)
- $\Delta T$  = 7 (use environment temperature extreme difference, from table)
- $\alpha_{CC}$  = 7 (package material thermal coefficient of expansion, from table)
- $T_{RISE}$  = 5° C (temperature rise due to power dissipation, typically 14 mW for entire board)
- $\pi_{LC}$  = 5000 (lead configuration factor, from table)
- LC = 175316 hours (20 year designed product life)
- CR = .17 (conservative estimate for computer equipment, from table)

$$\lambda_p = .0465 \text{ failures} / 10^6 \text{ hours (previously calculated)}$$

$$N_f = 3.5 \left( \frac{100}{.65 \cdot 8} \left| (11 \cdot 7 - 7(7 + 5)) \right| \times 10^{-6} \right)^{-2.26} (5000)$$

$$N_f = 9.8 \times 10^{12} \text{ cycles to failure}$$

$$\alpha_{SMT} = \frac{N_f}{CR}$$

$$\alpha_{SMT} = \frac{9.8 \times 10^{12}}{.17} = 5.76 \times 10^{13}$$

$$\frac{LC}{\alpha_{SMT}} = \frac{175316}{5.76 \times 10^{13}} = 3.04 \times 10^{-9}$$

Which results in an ECF value of .13 from the table.

$$\lambda_{SMT} = \frac{ECF}{\alpha_{SMT}} = \frac{.13}{5.76 \times 10^{13}} = 2.255 \times 10^{-15}$$

$$\lambda_{SMT} = 2.255 \times 10^{-15} \text{ (failures}/10^6 \text{ hours)}$$

#### For the BGA flip-flop:

- d = 9.8 (mils, from center of device to furthest solder joint)
- h = 8 (mils, solder joint height)
- $\alpha_s$  = 11 (circuit board substrate thermal coefficient of expansion, for FR-4 multilayer, copper clad Invar)

$$\begin{aligned} \Delta T &= 7 \text{ (use environment temperature extreme difference, from table)} \\ \alpha_{CC} &= 7 \text{ (package material thermal coefficient of expansion, from table)} \\ T_{RISE} &= 5^\circ \text{ C (temperature rise due to power dissipation, typically 14 mW for entire board)} \\ \pi_{LC} &= 1 \text{ (lead configuration factor, from table)} \\ LC &= 175316 \text{ hours (20 year designed product life)} \\ CR &= .17 \text{ (conservative estimate for computer equipment, from table)} \end{aligned}$$

$$\lambda_p = .0275 \text{ failures / } 10^6 \text{ hours (previously calculated)}$$

$$N_f = 3.5 \left( \frac{9.8}{.65 \cdot 8} \left| (11 \cdot 7 - 7(7 + 5)) \right| \times 10^{-6} \right)^{-2.26} (1)$$

$$N_f = 3.7 \times 10^{11} \text{ cycles to failure}$$

$$\alpha_{SMT} = \frac{N_f}{CR}$$

$$\alpha_{SMT} = \frac{3.7 \times 10^{11}}{.17} = 2.20 \times 10^{12}$$

$$\frac{LC}{\alpha_{SMT}} = \frac{175316}{2.20 \times 10^{12}} = 7.98 \times 10^{-8}$$

Which results in an ECF value of .13 from the table.

$$\lambda_{SMT} = \frac{ECF}{\alpha_{SMT}} = \frac{.13}{2.20 \times 10^{12}} = 5.9 \times 10^{-8}$$

$$\lambda_{SMT} = 5.9 \times 10^{-8} \text{ (failures/} 10^6 \text{ hours)}$$

Therefore, the BGA flip-flop is the “weakest link” and the failure rate of the board is considered to be  $\lambda_{SMT} = 5.9 \times 10^{-8}$  failures /  $10^6$  hours.

## Piezoceramic Element Connections

The components that make up the ultrasonic transducer have no wear-out mechanism since there are no moving parts. When voltage is applied, the ceramic expands or contracts due to the piezoelectric effect. When properly bonded into the housing, the ceramics have a virtually unlimited life when subjected to a normal use environment. However, the solder connections to the ceramic elements are considered in this analysis. There are four solder connections and the following equation is used to determine the failure rate for each connection:

$$\lambda_p = \lambda_b \pi_E \text{ (failures / } 10^6 \text{ hours) where,}$$

$$\lambda_b = .0013 \text{ (hand soldered connection)}$$

$$\pi_E = 1.0 \text{ (G}_B \text{ environment)}$$

$$\lambda_p = (.0013)(1.0)$$

$$\lambda_p = .0013 \text{ failures / } 10^6 \text{ hours}$$

## Calculation of System Failure Rate and MTTF

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

Table 3

Part	Quantity	$\lambda_p$	Total $\lambda_p$
Resistor	22	0.025071	0.551562
Diode	1	0.001296	0.001296
0.068 $\mu$ F Capacitor	1	0.053888	0.053888
0.1 $\mu$ F Capacitor	4	0.037048	0.148192
0.00033 $\mu$ F Capacitor	1	0.022453	0.022453
0.001 $\mu$ F Capacitor	1	0.022453	0.022453
0.00015 $\mu$ F Capacitor	1	0.018295	0.018295
0.00027 $\mu$ F Capacitor	1	0.022453	0.022453
10 $\mu$ F Capacitor	1	0.059459	0.059459
Comparator, Single	1	0.1525	0.1525
Comparator, Dual	1	0.157	0.157
Multivibrator, Dual	1	0.0465	0.0465
Flip-Flop	1	0.0275	0.0275
555 Timer	1	0.0275	0.0275
VCO	1	0.0465	0.0465
SMT Board	1	5.90E-08	0.000000059
Solder Connections	4	0.0013	0.0052
<b>TOTAL (Failures per 10<sup>6</sup> hours)</b>			1.362751

$$\lambda_{ABD} = 1.36 \text{ failures} / 10^6 \text{ hours}$$

The MTTF can now be estimated by taking the inverse of the system failure rate.

$$MTTF = \frac{1}{\lambda_{ABD}}$$

$$MTTF = \frac{1}{1.36 / 1 \times 10^6 \text{ hours}} = 735,294 \text{ hours between failures}$$

If one assumes the sensor operates 24 hours per day, 7 days per week, 365 days per year, the MTTF (in years) would be more than 83 years, well beyond the design life of 20 years.

## Historical Data to Support the MTTF Analysis

Moog has been manufacturing ultrasonic air bubble detectors for more than 20 years. Historical data on the number of returned ABDs has been collected in order to support the MTTF analysis<sup>4</sup>. Several popular air bubble detectors, typical of all ABDs, were selected for analysis. These are Moog part numbers Z-10979, Z-11286, 11334-001, 11339-001, and Z-12345. In

In addition, data was examined for Z-13866 which is an ultrasonic transducer only, (no circuit board assembly included) and the transducer for 22297-001, in order to substantiate the claim that there is no wear-out mechanism associated with the transducer. For both of these transducers, no field failures due to reliability issues were reported. The following table summarizes the number of sensors shipped and the number of field failures reported.

Table 4

ABD Model	Number Shipped	Returns for Component Failure	Failure Description
Z-10979	> 6200	1	Failed capacitor
Z-11286	> 1300	0	N/A
11334-001	> 1300	0	N/A
11339-001	> 3600	0	N/A
Z-12345	> 2200	0	N/A
Z-13866 Transducer	> 50,000	0	N/A
22297-001 Transducer	> 250,000	0	N/A

One could make a conservative estimate of failure rate based on the numbers of sensors in the field. If all the complete sensor assemblies from the table above are added, we get a total of 14,600 ABDs. If we assume the average lifetime usage for these ABDs is 500 hours (a very conservative estimate, most are probably used for thousands of hours) and multiply that by the number of sensors in the field we get 7.3 million hours of operation. The estimated failure rate would then be 1 failure per 7.3 million hours. Since the failure rate is assumed to be constant (the flat portion of the “bathtub curve”) the MTTF would then be 7.3 million hours or 832 years. Our calculation of MTTF was an order of magnitude less than this, most likely due to the conservative nature of the handbook calculations. Although the actual hours of sensor usage is unknown, it can be seen based upon the numbers of sensors shipped and the low actual failure rate that this empirical data supports the MTTF prediction.

## Conclusion

The prediction of Mean Time To Failure (MTTF) for an air bubble detector manufactured by Moog is a good indicator of the sensor’s reliability over its designed lifetime. Through both calculation of MTTF and analysis of field returns, Moog sensors have been proven to be highly reliable components suitable for use in safety-critical medical devices.

## References

- <sup>1</sup> NIST/SEMATECH e-Handbook of Statistical Methods, <http://www.itl.nist.gov/div898/handbook/>, 2006.
- <sup>2</sup> Vincoli, Jeffrey. *Basic Guide to System Safety*. New York City: Van Nostrand Reinhold, 1993.
- <sup>3</sup> Rome Laboratory/ERSR, Department of Defense. “*Reliability Prediction of Electronic Equipment*.” MIL-HDBK-217F, Notice 2. 1995.
- <sup>4</sup> Returns information provided by Moog Medical Devices Group Customer Service Department.



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