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Letter to the Editor

Environmental vibration assessment and its applications in accelerated tests for medical devices

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1. Introduction

Medical devices for emergency health care, such as external-use defibrillators and pacemakers, are often used in aircrafts (e.g., medical helicopters) and ground vehicles (e.g., ambulances and train). Since the various transportation means expose the devices to continuous, and sometimes severe, vibration in their normal operation, medical device companies such as Medtronic have focused on the design of products to survive such adverse vibration environments. For the last decade or so, MIL-STD-810D and -810E, Air Force and other standard codes [1–3] have been used to specify vibration profiles in transportation environments for the purposes of testing, reliability analysis and design of medical devices [4–8]. However, the standard codes alone might be insufficient to describe the dynamic environments, due to the following reasons:

1. The medical-use helicopters/vehicles have quite different characteristics from the profiles shown in the standard codes, such as MIL-STD-810D and -810E, in terms of vibration amplitudes and frequency range.
2. Vibration amplification of medical devices mounted in helicopters/vehicles is strongly dependent upon the mounting positions and mechanical mounting structures, which is not and cannot be accurately specified in the standard codes.
3. More importantly and also practically, environmental vibration levels or intensities vary with flight/driving conditions (e.g., take-off, cruise, and landing for helicopters, and driving speeds and road conditions for ambulances). In addition, the structural type of the transportation means itself (e.g., main rotor with 2 or 4 blades in helicopters) will also affect the vibration environment significantly.

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To reduce uncertainties in vibration testing, it is necessary to measure and use the spectra of the real vibration environment that medical devices experience on medical-use helicopters and ground vehicles. The measured data can then be used as a baseline for subsequent mechanical design and reliability testing. This is essentially consistent with the recommendation in MIL-STD-810E that specific test charts are to be constructed on the base of measured data if at all possible.

The ultimate purpose of this study was to develop a set of vibration test profiles for medical equipment typically used in helicopters, trains and ground vehicles, based on measurements of the measured time series and subsequently computed power spectra. First, a variety of random vibration field tests conducted on various transportation means are described. The real vibration environments were assessed in terms of the location of the equipment, dominant vibration frequencies, intensity/amplitude, duration, and transport conditions, e.g., flight conditions (take-off, cruise, or landing) if medical devices are used in helicopters, or road conditions and driving speeds if they are used in ground vehicles. Secondly, based on the measured vibration data and subsequently computed power spectra, more appropriate vibration profiles are constructed while compared with the profiles in the standard codes such as MIL-STD-810E. Finally, by using various sets of survey data and the proposed spectra [9–12], the accelerated random vibration test profiles for the medical devices, used in either helicopters or ground vehicles, are proposed for product reliability test and analysis.

2. Field-testing data and analyses

To quantify vibration levels in medical-use helicopters and ground vehicles, a series of vibration tests were performed from 1994 to 2001. The data collected and observations made from these tests are reported in the following three sub-sections.

2.1. Testing on helicopters

Vibration tests for medical devices (i.e., external-use defibrillators) mounted on four different helicopters were carried out while considering vibration sources from three directions, i.e., x-axis is in the forward flight direction, y-axis is the direction that is 90° counter-clockwise from x-axis and in the same horizontal plane, and z-axis is in the vertical direction. The helicopters used were UH-1H (made in US, 1970 model with two blades and a gross weight of 6100 lbs), BK-117 (made in US, 1986 model with four blades and a gross weight of 6700 lbs), BO-105 (made in Germany, with two blades and a gross weight of 5291 lbs), and Agusta A109A/Mark II (made in Italy, with four blades and twin engines and maximum weight of 5730 lbs). The primary test equipment included: an ONSITE 16-channel FFT analyzer, one Kistler tri-axial accelerometer (type 8692B50), one DYTRAN accelerometer (type 3136A), and one Current Power Source (type Columbia 5425 with four channels). The equipment was used to measure the acceleration time history, which was then used to calculate power spectrum density (PSD) with FFT algorithm, on the helicopter floor where the medical device sits nearby, on a printed circuit board (PCB) inside a medical device, on the case of a medical device, and at other locations where the medical device responses are typically critical to the design. The test conditions were classified as warm-up, take-off, normal flight (cruise), and landing. The FFT analyzer was set up in a way that assures that the sampling or Nyquist frequency, $1/(2\delta)$, was high enough to cover the full frequency range, 5051 Hz, of the time series, where δ is the time interval that is smaller than 0.0000825 s [13].

The field tests revealed the following important information that could be used when conducting future vibration tests for reliability analysis in the design of medical devices intended for use in helicopters:

1. All the helicopters were found to have non-negligible vibration responses beyond 500 Hz, comparable in amplitude with those in the 10–500 Hz range specified in MIL-STD-810D and -810E, examples of which are shown in Figs. 1–5. These observations imply that a broader spectrum should be used for the laboratory testing of medical devices than those specified in military standards.
2. Helicopter vibration contains strong tonal components in addition to broad-band noise. For example, the peak vibration responses occur, respectively, at around 11, 30, 52, 80, and 102 Hz for the BK-117 in Figs. 1–3. These peak-related frequencies may correspond to the frequencies of helicopter's rotors and detailed structures. While the peak-related frequencies vary with the type of helicopters (e.g., see Figs. 1 and 4), they are generally in the 10–250 Hz range. This suggests the environmental vibration profile for helicopters could be modelled approximately as several tonal components of a fixed bandwidth superimposed on characteristic random vibration spectra.
3. During normal cruise flight, vertical floor vibration level was found to be two to three times larger than that of the forward floor vibration in terms of both peak value and overall G-r.m.s. of the PSD. For example, the G-r.m.s. level of vertical direction (z-axis) on BK-117 board is around 0.382 G-r.m.s., while the G-r.m.s. level of forward direction (x-axis) is around 0.178 G-r.m.s. Typical results are shown in Figs. 1 and 2. In addition, the measured PSD peaks and G-r.m.s. levels at the helicopter floor, PCB, and device case are significantly less than those found in MIL-STD-810D or -810E, suggesting that the direct use of military standards for reliability testing may result in over-estimation.

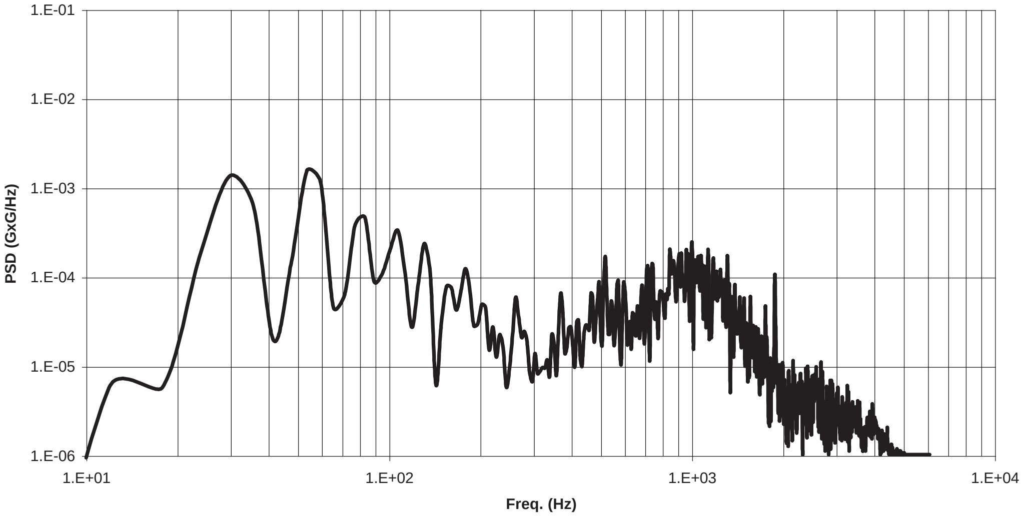

Fig. 1. PSD of vibration at the floor of BK-117 helicopter in z-component or vertical direction.

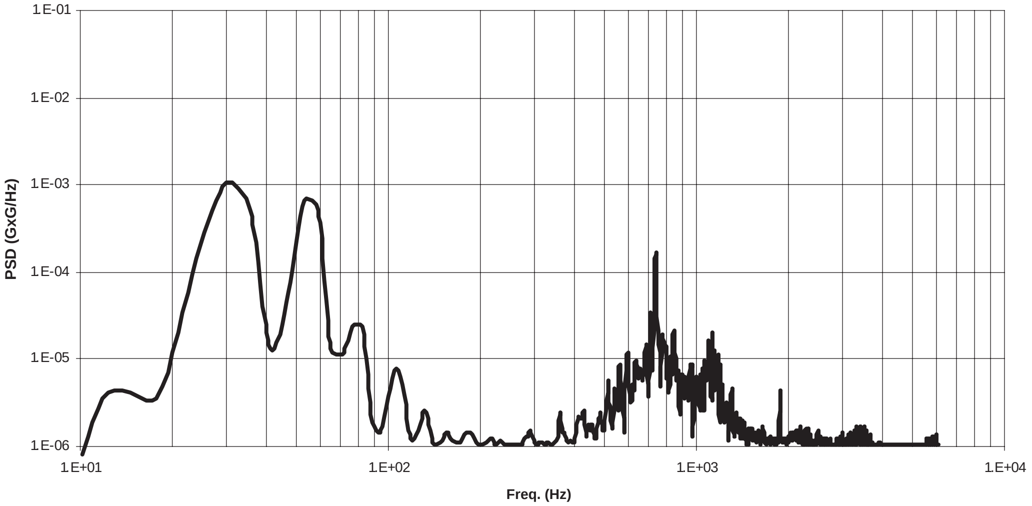

Fig. 2. PSD of vibration at the floor of BK-117 helicopter in x-component or forward direction.

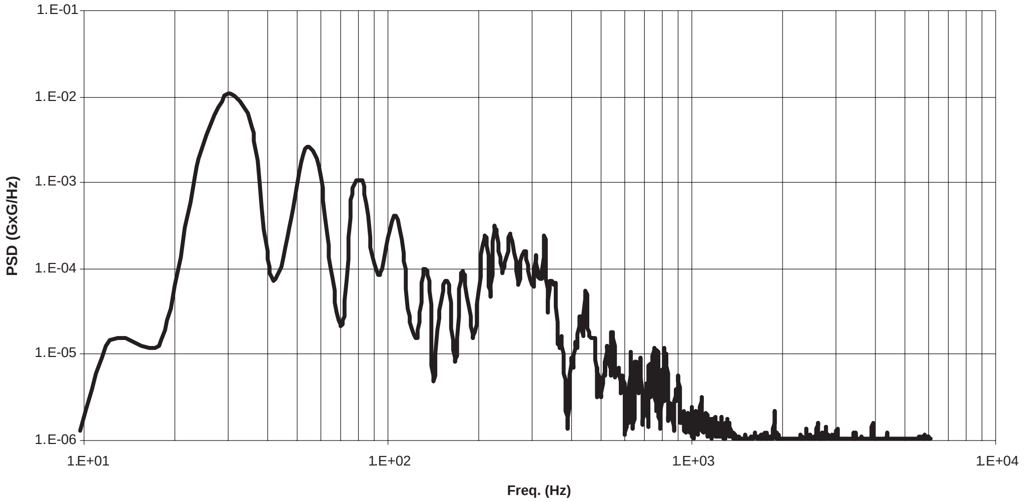

Fig. 3. PSD of vibration at the floor of BK-117 helicopter in y-component or 90° count-clockwise from the x or forward direction.

4. The measured peak acceleration in its time history varies significantly, depending not only on the type of helicopters but also on flight conditions. For example, the UH-1H helicopter floor has larger peak acceleration (2.2g's) than those found on the BK-117 and BO-105 helicopter floor (0.7–0.8g's) [10]. The most severe vibration levels occur during landing (e.g., see Figs. 4 and 5). Since the duration of landing is much shorter than normal flight, design of medical devices to resist helicopter vibration should not rely solely on the vibration intensity and spectrum profile, but also on operation time duration at each flight condition.

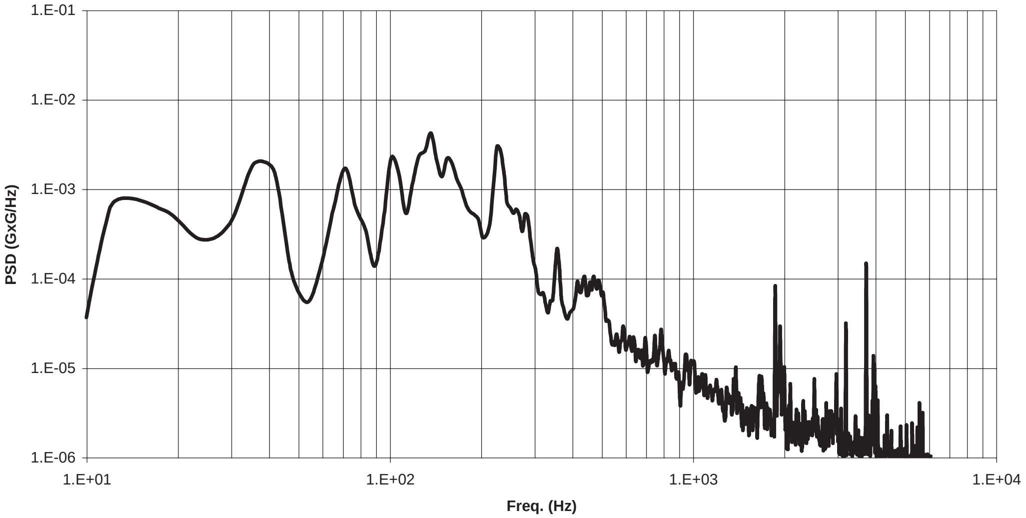

Fig. 4. PSD of vertical vibration at the floor of UH-1H helicopter with normal flight.

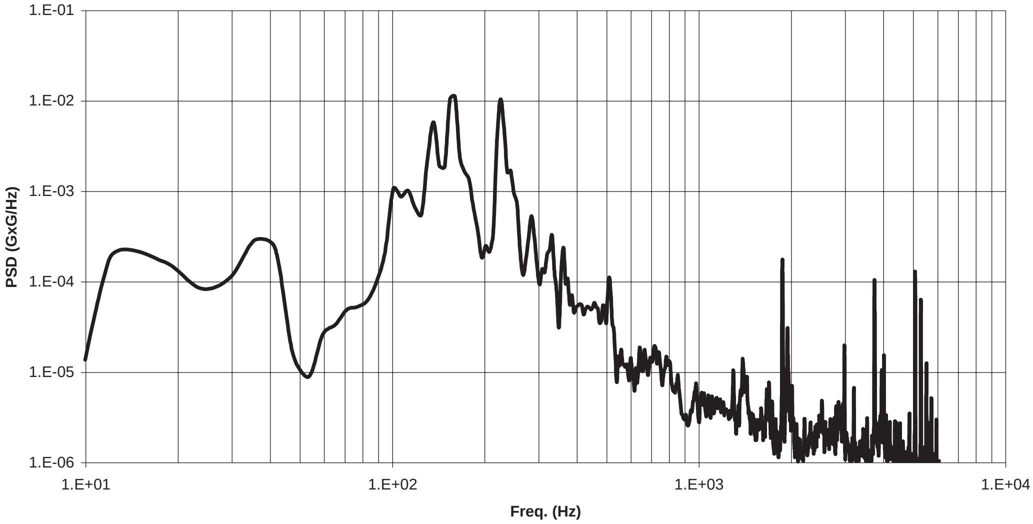

Fig. 5. PSD of vertical vibration at the floor of UH-1H helicopter with landing.

2.2. Testing on ground vehicles

With the use of the same test equipment, vibration testing was conducted on various ambulances, trucks, and vans in Seattle/Bellevue areas in three directions, i.e., x-axis is in the forward horizontal direction, the y-axis is the direction that is 90° counter-clockwise from and in the same horizontal plane as the x-axis, and the z-axis is in the vertical direction. The FFT analyzer was set up to assure that the sampling frequency, $1/(2\delta)$, was high enough to cover the full frequency range, 1000 Hz, of the time series. The major observations are as follows:

1. While the energy distribution of vibration on a medical-use ground vehicle is mainly restricted to 2–200 Hz, higher-frequency energy (e.g., 200–500 Hz) quite often occurs when the vehicle is at a high speed (i.e., more than 60 mph) on rough roads (e.g., crossing railways). Figs. 6 and 7 are the examples showing the two cases. This implies that a broader spectrum of vibration should be used.
2. Vibration levels in the horizontal (i.e., x and y) directions are much lower than that those in the vertical direction. The former is around 20–40% of the latter [9]. The main concern for the medical devices when used in ground vehicles is vertical vibration.
3. The spectral profiles obtained from field data are consistent with the representative spectral shape for wheeled vehicles in MIL-STD-810E, as shown in Figs. 6–8.

2.3. Testing on Amtrak trains

We conducted clinical tests (i.e., monitoring patients' ECG chart) by using the medical device functions such as printing, recording, and shocking, and measured vibration responses at various locations of the Amtrak floor where the medical device was located while boarding the Amtrak auto-train from Seattle, Washington to Salem, Oregon [12]. This train had upper and lower decks. The test was performed at one car at the end of the train, as well as at a front car next to the locomotive. Data sets were collected on the upper deck (e.g., in a sleeper cabin next to the top of the stairs, on the lower bed, and on the vinyl floor located at the top of the stairs) and on the lower deck (e.g., on the floor of the handicap sleeper cabin, and on the vinyl floor next to the rest room). The above locations are considered by the Amtrak technical staff to typically have more significant motion levels on the train than other locations.

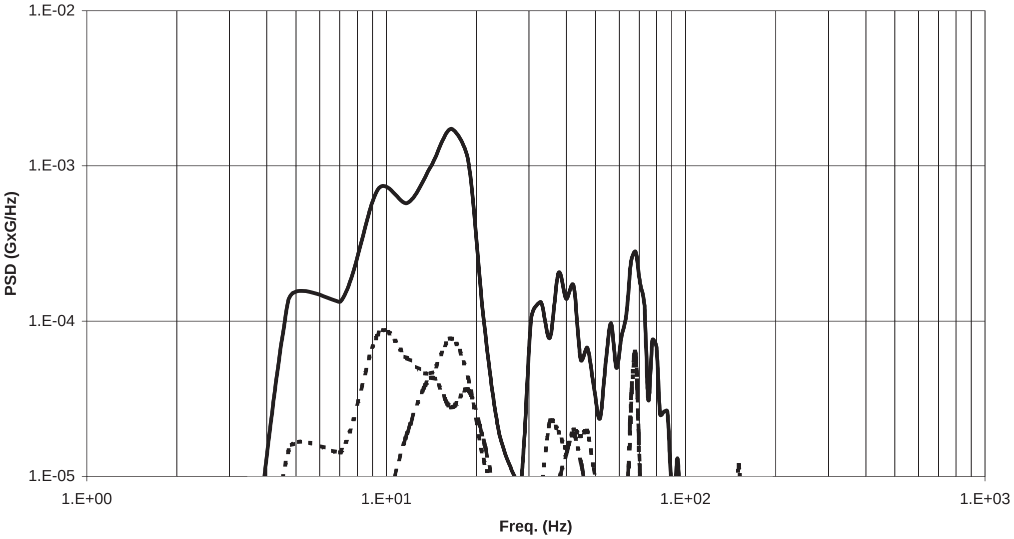

Fig. 6. PSDs of vibration of ambulance in x (dashed line), y (dotted line) and z (solid line) directions on rough road.

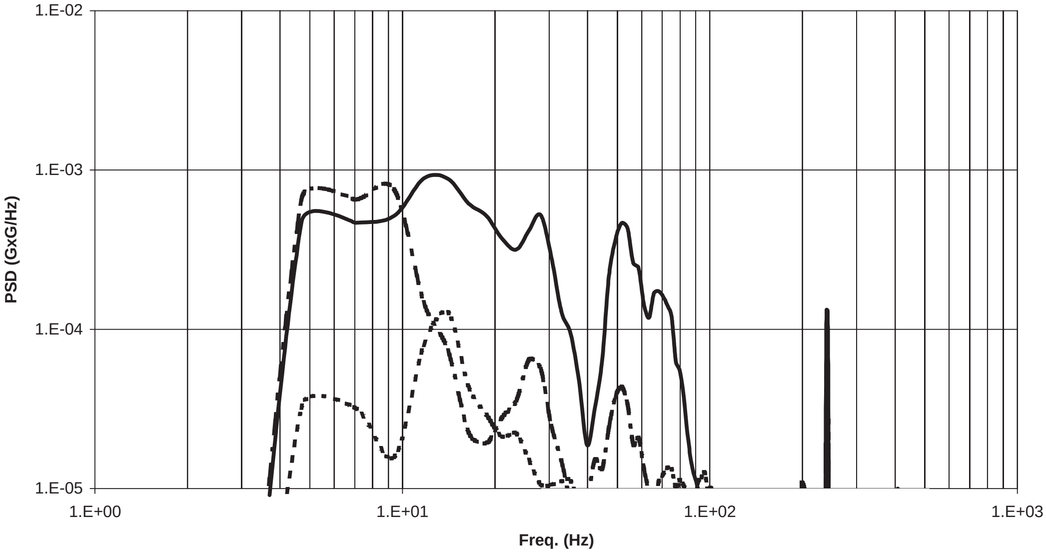

Fig. 7. Power spectrum densities of vibration in x (dashed line), y (dotted line) and z (solid line) directions at a Ford truck on rough road.

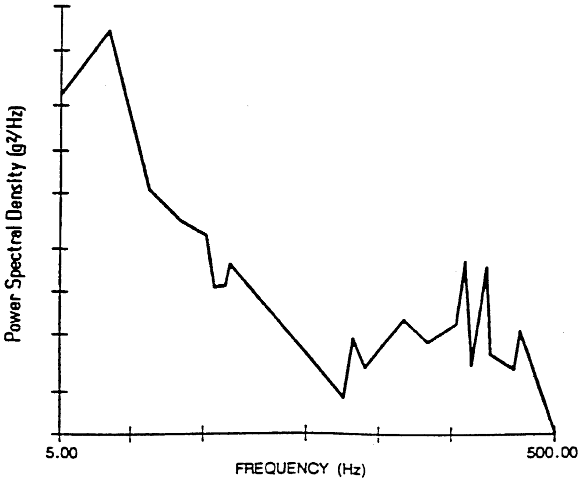

Fig. 8. Representative spectral shape for wheeled vehicles in MIL-STD-810E.

We also conducted a similar clinical and vibration evaluation of the medical device performance on board the Amtrak auto-train from Lorton, Virginia to Sanford, Florida [12]. This train had upper and lower decks. Our study was confined to one car placed directly behind the locomotives and also one car in the very end of the train.

The test results [12] are summarized as follows:

1. While vibration in Amtrak trains is significant over the frequency range of 1–1000 Hz, the vibration responses die down quickly beyond 100 Hz. The vibration on the lower floor is found to have larger magnitude and higher dominant frequency than that at the upper floor.
2. At normal speed of 40 mph, the vertical floor vibration level of the train is in the range of 0.4–0.8 G-r.m.s. This is lower than vibration levels shown in ambulances and helicopters. The main vibration peaks are in the range of 10–100 Hz at normal speeds and 200–500 Hz at high speeds.
3. Analysis of the data sets collected from the trains suggests that the Amtrak environment can be considered to be less harsh in vibration than helicopter and ground vehicle environments. Consequently, any device meeting the performance criteria developed for ground vehicle or helicopter application should exceed the requirements for a rail/train application.

3. Proposed spectra of environmental vibration

Based on the observations from field data shown in the last section, the environmental vibration spectrum for helicopters or ground vehicles is a random profile with several responses at dominant frequencies (spikes) which vary in frequency and amplitude with the structural type, operation (field) condition, etc. This observation is consistent with MIL-STD-810E as it proposes to add spikes on band-limit random vibration PSD profiles for testing purposes [1]. However, the specification in MIL-STD-810E might not completely cover all the adverse vibration environments, since different types of helicopters/vehicles at different operation conditions have slightly different resonant frequencies and different overall G-r.m.s. To this end, improved spectra for environmental vibration on helicopters/vehicles are proposed in this study, which is primarily based on the aforementioned test data as well as MIL-STD-810E.

Specifically, a PSD for the helicopter vibration is proposed based on the test data, as shown in the dotted line in Fig. 9. The spectral profile (five tonal bars with specified bandwidth) is obtained by taking into account all the adverse scenarios (e.g., dominant frequencies in extreme conditions of flexible mounting mechanisms on four different helicopters). While the proposed spectrum profile might be too conservative by covering all the worst vibration cases, it nevertheless provides complete information for the helicopter vibration environment. In addition, the proposed spectrum also extends the frequency range, based on test data, from the 8–500 Hz specified in MIL-STD-810E to the 6–2000 Hz range. The overall spectrum level in terms of G-r.m.s. will be determined on the basis of the field conditions. For example, the overall vibration level in Fig. 9 is 1.37 G-r.m.s. which covers the worst PSD profiles ever measured, including the landing of all helicopters. Since each and every field condition was considered separately, the proposed spectra will more truthfully reflect the actual vibration environment.

Similarly, a vehicle vibration PSD is also proposed, which is depicted in the dotted line of Fig. 10.

4. Applications in accelerated tests

The ultimate purpose for constructing realistic environment vibration spectra is to use them for future reliability and quality testing, for product specifications, and for design and analysis of

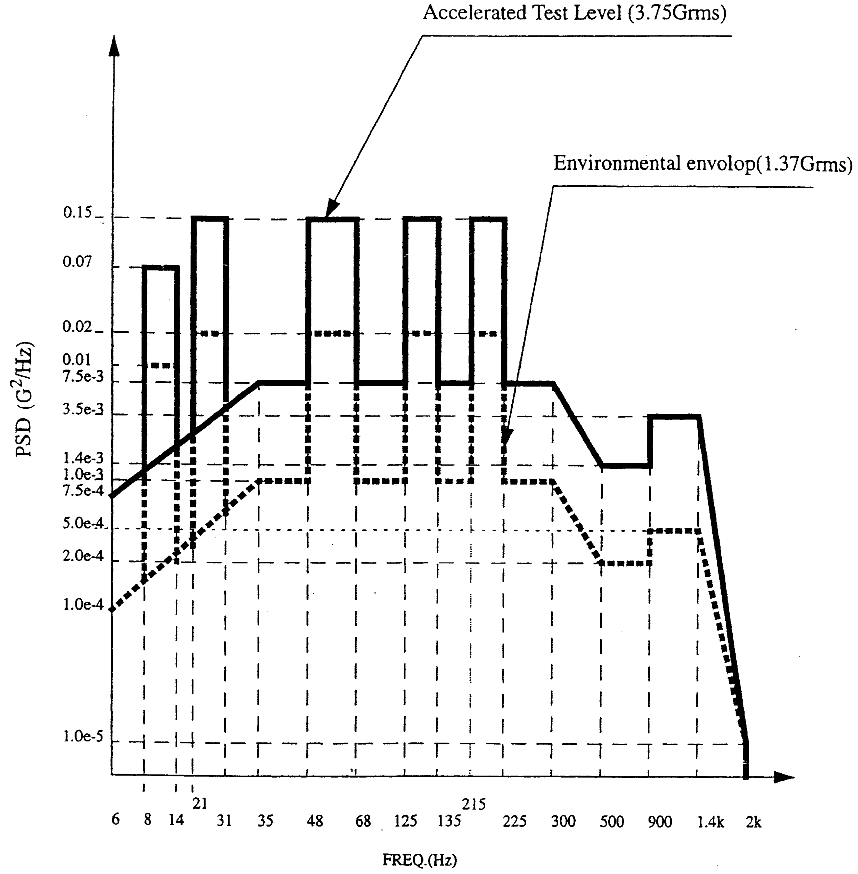

Fig. 9. Proposed PSD of vibration in helicopters (solid line: accelerated test spectrum; dotted line: environment spectrum).

medical devices [14–15]. While all the potential applications of the proposed spectra cannot be detailed, two of them are examined in this study as they relate to the accelerated vibration testing for material fatigue failure.

The material fatigue is normally expressed by $S-N$ curve (i.e., curve for stress level versus number of cycles). If n_i cycles of stress occur at a level of stress at which N_i constant stress cycles would cause material failure, then the failure is to be expected when the sum of all fractional damages (K samples, e.g.) reaches one, i.e.,

$$\sum_{i=1}^{K} \frac{n_i}{N_i} = 1. \tag{1}$$

The mean lifetime, T_m, before failure is then estimated by the following equation [13]:

$$T_m = \frac{1}{f_n \int_0^\infty \frac{1}{N(S)} p_p(S)\,\mathrm{d}S}, \tag{2}$$

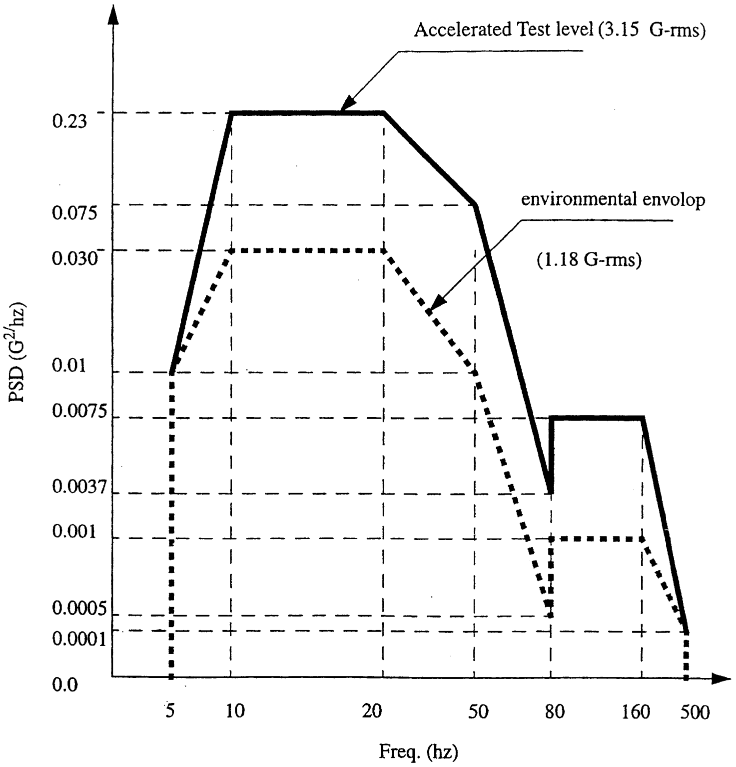

Fig. 10. Proposed PSD of vibration in ground vehicles (solid line: accelerated test spectrum; dotted line: environment spectrum).

where f_n is the natural frequency of the material, $p_p(S)$ the probability of peak of stress vibration time history, a Gaussian narrow band process, lies in the range of stress level from S to $(S + \mathrm{d}S)$, and $N(S)$ the number of cycles of stress level S.

The fundamental of accelerated vibration testing is to predict the mean lifetime of products by performing vibration/shock tests at much higher than normal levels but shorter than normal duration in the lab. In this study, we proposed an equivalent random accelerated vibration testing for the medical devices with two steps: first, to convert the measured environmental vibration spectra into one G-level profiles used in the lab test in which the converting factor can be calculated; secondly, to calculate the accelerated vibration test level by assuming the lab test time to be 3 h (1 h test in each X, Y, and Z directions, as most engineering companies do usually), and to construct PSD charts by combining all measured data samples into one envelope that has the similar shapes but higher power density values while compared with measured data.

4.1. Accelerated testing on helicopters

Accelerated vibration testing depends on the intensities of the vibrational environment associated with vehicle operating condition and the percentage of these vibrational intensities of the expected lifetime. Specifically, the environmental vibration intensity and duration at a given field (condition i) can be converted to an equivalent accelerated lab test based on the equation

$$\frac{T_{ti}}{T_{fi}} = \left(\frac{G_{fi}}{G_{ti}}\right)^m, \tag{3}$$

where T_{fi} and T_{ti} are, respectively, the field operating and the lab testing time at given condition i. G_{fi} and G_{ti} are the corresponding field operating and lab testing vibration levels, and m is 4.0 for random vibration testing [1]. The percentage of the product life where the medical device is exposed to that environmental condition is defined as

$$P_{fi} = T_{fi}/T_f. \tag{4}$$

The lab test time for medical devices can be obtained from

$$T_t = \sum_i T_{ti} = \sum_i \frac{P_{fi} T_f G_{fi}^4}{G_t^4} = \frac{F_t T_f}{G_t^4}, \tag{5}$$

where use has been made of Eqs. (3) and (4), $G_{ti} = G_t$, and conversion factors F_t or F_{ti} for a lab test time at 1.0 G-r.m.s. are defined below and tabulated in Table 1:

$$F_t = \sum_i F_{ti} \equiv \sum_i P_{fi} G_{fi}^4. \tag{6}$$

As an example, the equivalent lab-test time required to simulate the accelerated field environment is estimated below.

A product (medical device) life is defined as 8 years (2920 days) in its product specification. Assuming the vibration time on helicopters is 1 h/day (based on a survey), then the total vibration time at field is $T_f = \sum_i T_{fi} = 2920\,\text{h}$. Based on Eq. (5) as well as Table 1, the equivalent lab test time at $G_t = 1.0$ G-r.m.s. testing intensity can be found as $T_t = 0.206 \times 2920 = 602\,\text{h}$. In order to reduce the lab test time significantly, say to 3 h, lab test intensity should be significantly increased. Following Eq. (5), we find the testing intensity $G_t = 3.75$ G-r.m.s.

Therefore, an accelerated test standard could have the testing level of 3.75 G-r.m.s. with the proposed spectrum profile as shown in the solid line of Fig. 9. Since the medical device generally has a non-trivial vibration response in all three co-ordinate directions when used on a helicopter, the same vibration test level should be used in all directions.

Table 1
Field data and equivalent test conversion factor at 1.0 G-r.m.s. for helicopters

Flying condition	Average G-r.m.s. (G_{fi}) (g)	Percentage of flying time (P_{fi}) (%)	Conversion factor at 1.0 G-r.m.s. (F_{ti})
Warm-up	0.3	5	0.00041
Take-off	0.4	5	0.00128
Climbing	0.4	5	0.00128
Normal fly	0.6	75	0.09720
Descent	0.9	5	0.03281
Landing	1.1	5	0.07321
Total		100	0.20600

Table 2
Field data and equivalent test conversion factors at 1.0 G-r.m.s. for ground vehicles

Driving condition	Average G-r.m.s. (G_{fi}) (g)	Percentage of driving time (P_{fi}) (%)	Conversion factor at 1.0 G-r.m.s. (F_{ti})
Velocity <50 m/h on highway	0.30	25	0.002025
Velocity >50 m/h on highway	0.40	35	0.008960
On rough road	0.60	22	0.028512
Very rough road	0.70	10	0.024010
On rail road crossing	0.80	3	0.012288
Velocity >40 m/h on rough road	1.0	5	0.05
Total		100	0.1260

4.2. Accelerated testing on ground vehicles

The proposed formulae for calculating the lab test vibration intensity and duration in Eqs. (3)–(6) can also be applied to ground vehicles. The difference is the conversion factor, which is listed in Table 2 for ground vehicles.

As an example, lab-test intensity and time duration are estimated. A product life is defined as 8 years in its product specification. Assume the average use of an ambulance is 13,000 miles/year (based on survey) and an average speed of 45 mph. This implies that vibration time is 289 h/year, or 2312 vibration hours within 8 years. The equivalent lab test time at 1 G-r.m.s. vibration intensity can be found as $2312 \times 0.126 = 291$ h. Similarly, if the testing time is reduced to 3 h, the desired test vibration level will be $G_t = 3.14$ G-r.m.s. on the basis of Eq. (5) and Table 2. Since the medical device can be located in any direction when used in an ambulance, vibration tests in all directions should be performed by using the same G-r.m.s. level as suggested here.

In addition to the above discussions of accelerated testing of medical devices used in both helicopters and ground vehicles, the so-called ‘step-stress test’ could also be implemented into the aforementioned accelerated tests for more precise prediction of product field life. Specifically, the accelerated tests could continue until product failure by increasing the overall G-r.m.s. level step by step (e.g., 1.0 or 2.0 G-r.m.s. for each step, depending upon the specific product), while keeping the PSD charts in a similar shape. For more information, readers are referred to Ref. [15].

5. Conclusions

Field measurements and observations of various medical-use helicopters, ground vehicles and Amtrak train vibrations are reported in this study. As one of the most important applications, field-based vibration power spectra are proposed, which could be used for accelerated testing, reliability analysis and design of medical devices used in helicopters and ground vehicles. In addition, accelerated vibration tests are also presented on the basis of composite envelopes of empirical data as well as field condition, which could improve product reliability and significantly reduce lab-test time.

Acknowledgements

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