

Development of a hand-transmitted vibration measurement instrument to perform tests in medical equipment

Felipe Fava de Lima , Henrique Takachi Moriya, José Carlos Teixeira de Barros Moraes

Divisão de Ensaios e Calibração, Laboratório de Engenharia Biomédica, Escola Politécnica, Universidade de São Paulo, São Paulo, SP, Brasil

E-mail: felipe@leb.usp.br

Abstract: According to the sub clause 9.6.3 of the international standard IEC 60601-1-2005, medical electrical equipment must provide means of protection against hazardous hand-transmitted vibrations. Compliance of this sub clause is checked by using a vibration measurement instrument in accordance with ISO 5349-1-2001 standard. The present article describes the development of a vibration measurement instrument to perform vibration measurements tests in medical equipments.

Keywords: Medical electrical equipment; ISO 5349-1-2001; IEC 60601-1-2005; hand transmitted vibration.

1. INTRODUCTION

Exposure to hazardous hand vibrations for long periods of time can result in a health issue known as vibration syndrome. This syndrome has adverse circulatory and neuronal effects and can cause pain, loss of light touch, loss of grip strength and bone cysts in fingers and wrists [1].

Some medical equipment can produce and transmit harmful vibrations to the operator or patient hands during normal operation. According to the sub clause 9.6.3 of the international standard of medical electrical equipment IEC 60601-1-2005 Ed.3[2] (equivalent to the Brazilian standard NBR IEC 60601-1-2010 Ed.3 [3]), these equipment must provide means of protection against hand-transmitted hazardous vibrations. To verify if an electrical medical equipment (ME) complies with this sub clause a vibration measurement instrument is used as described in the international standard ISO 5349-1-2001 [4].

2. OBJECTIVES

Aiming the construction and evaluation of the vibration measurement instrument the following objectives were outlined:

- The instrument hardware must be developed following the measurement requirements of IEC 60601-1-2005 and ISO 5349-1-2001. The hardware must be composed of a vibration sensor, an anti-aliasing filter and an analog to digital converter (A/D).
- The instrument software must be developed to implement a digital filter (ISO 5349-1-2001), to convert the signal to the desired unit (m/s^2 in this case) and to show the results to the operator.
- The developed instrument must be verified by comparison with a certified instrument.

- The used test procedure must be verified by five experienced professionals in a real test scenario.

3. MATERIALS AND METHODS

3.1. Hardware development

The instrument hardware was based on the diagram shown in Figure 1.



Figure 1. Hardware diagram

The vibration sensor employed was a small 4mm x 4mm packaged analog 3-axes accelerometer with maximum sensing range of 2g and bandwidth of 0.5 Hz to 1600 Hz (ADXL327, Analog Devices, USA).

The chosen accelerometer measures accelerations in the range of 1g (9.8m/s²) and frequencies in the range of 1 Hz to 1000Hz. These ranges are justified since 1 g is approximately four times greater than the maximum allowed vibration (IEC60601-1-2005) and the frequency range of 1 Hz to 1000Hz is consistent with the attenuation of 40dB caused by the required ISO 5349-1-2001 filter.

The anti-aliasing filter used to filter the signal from the accelerometer was a low-pass unity gain 4th order Sallen Key Chebyshev filter ($F_{cutoff} = 1400\text{Hz}$).

The anti-aliasing filter and the accelerometer were assembled in different circuit boards, resulting in a small vibration sensor easy to attach to a ME.

The analog to digital converter connected to the output of the anti-aliasing filter was a multipurpose interface (PCI – 6052E - National Instruments, USA).

3.2. Software development

A virtual instrument (VI) software was based on the diagram shown in Figure 2.



Figure 2. Software diagram

The VI has four main functions:

- Digitally filter the acquired data with the specified ISO 5349-1-2001 filter.
- Convert the data to the standard m/s² unit.
- Compute the root square of the sum of the square of the data.
- Show the results of the measurement to the operator.

Based on the ISO 5349-1-2001 filter (continuous 6th order frequency weighting and band-limiting filter) a digital filter was designed and used to filter the digital data.

After the digital filter, gain is applied to the data to convert it to the desired unit (m/s²). Finally, the root square of the sum of this data is computed, producing a final result in m/s², shown in graphical user interface (GUI)

3.3 Instrument verification

To verify the measurements obtained by the new assembled instrument, a mechanical setup (Figure 3) was mounted.

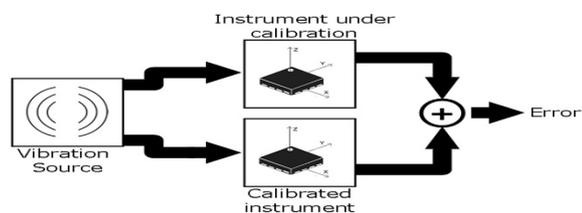


Figure 3 - Instrument measurement verification

A 1-axis shaker (LDS V780, LDS Test and Measurement, UK) was used as vibration source. It was configured to produce sinusoidal oscillations in different frequencies/magnitudes. On the shaker vibration platform, a calibrated 1-axis accelerometer (LDS 353B31, LDS Test and Measurement, UK) and the developed instrument sensor were fixed as close as possible to ensure that the same vibration disturbance was acting in both sensors. The verification procedure was repeated three times, once for each accelerometer axis. In each repetition, the shaker was programmed to produce sinusoidal oscillations in the range of 3Hz to 1200Hz (10 s in each frequency, 10 frequencies per decade), and the magnitude was set to produce the maximum permitted shaker output (limited to 15 m/s²). For each frequency data from the calibrated accelerometer and from the developed instrument was processed with the same algorithm and compared through an error plot.

3.4 Test procedure verification

To verify the procedure adopted to execute the vibration compliance test, five qualified professionals with proven experience in execution of tests of the IEC 60601-1-2005, performed the vibration test in a simulated ME (a conventional table fan CM Premium - Delta - CN operating in its maximum intensity). As patient hand contacts were adopted two physical points: the fan transport handle and the middle of the rod responsible to mechanically support the electrical motor of the fan. Each of the five professionals was responsible to attach the vibration sensor to the simulated ME and to collect the vibrations measurements.

4. RESULTS

4.1. Instrument verification results

The relative error between the calibrated accelerometer and the developed instrument was obtained for each axis, as shown in figure 4.

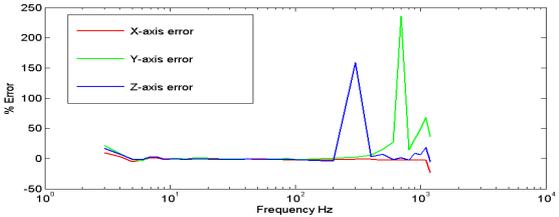


Figure 4- Instrument error comparison

In the frequency range of 3 Hz to 100 Hz, in all three axes, relative errors were below 5%. In frequencies above 200 Hz some resonant frequencies were observed.

4.2. Test procedure verification results

Table 1 shows the results obtained by the five experienced professionals when executing the vibration measurement in the simulated ME.1.

Table 1 – Test procedure results

	Fan handle (m/s ²)	Fan rod (m/s ²)
1	6.28 ± 0.86	1.49 ± 0.18
2	5.34 ± 0.66	1.92 ± 0.23
3	9.12 ± 1.08	2.13 ± 0.26
4	5.77 ± 0.79	1.87 ± 0.26
5	6.28 ± 0.74	2.09 ± 0.25

5. DISCUSSION

During the instrument verification was observed that resonant frequencies were achieved in the range of 200Hz to 1200Hz (Figure 4). These resonant frequencies are the result from the mechanical assembly and could be reduced or canceled with more sophisticated mechanical elements. As these resonant frequencies are produced in frequencies attenuated by at least 20dB through the ISO 5349-1-2001 filter the assembled instrument can be accepted to be used in ME vibrations measurements tests, since it is guaranteed that vibrations frequencies in this specific range are not significant in the measurement. This guarantee can be easily verified providing to the operator a frequency spectrum estimator of the raw vibration signal in the software GUI.

ISO 5349-1-2001 provides a continuous time transfer function of the filter to be used. To reduce hardware complexity, this filter was digitally implemented by transforming the continuous transfer function to a discrete time form using bilinear transformation. The sampling frequency of the analog to digital converter was chosen so as to the differences between the analog and digital filter in the bandwidth of interest (3 Hz - 100Hz) were less than 0.01%.

Although relative error between calibrated accelerometer and assembled instrument remained as low as 5%, this measurement error could be lower by using a digital channel equalization filter in the assembled instrument to compensate electrical and mechanical system differences between both devices.

Although the professional number 3 has measured a fan handle vibration of 9.12 ± 1.08 m/s² (Table 1), differing expressively from the others professionals, all measurements were homogenous. This difference, probably, can be explained by the fact that this test can be sensitive to the attachment position and orientation of the sensor in the ME.

6. CONCLUSION

A vibration measurement instrument, following requirements of IEC 60601-1-2005 and ISO 53492-2001, was assembled and both instrument measurement verification and test procedure verification were done, indicating that the usage of the assembled instrument in real ME tests is possible, as long as some limits are respected. Moreover, some improvements to the instrument can be done, as the channel equalization filter and the spectrum estimator.

7. REFERENCES

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