Performance evaluation of linear peristaltic volumetric infusion pump using a flow analyzer

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Abstract. This paper aims at validating the conformity of linear peristaltic volumetric infusion pump (LPVIP) using as reference a flow analyzer, model IN-300. The IN-300 model has an operating range of 1 ml/h at 1000 ml/h and a resolution of 0.1 ml/h. The standard IEC 60601-2-24 determines that an electronic balance with a resolution of 0.0001 g should be used during pump calibration. Therefore, the technical implementation of a flow analyzer for calibration and periodic verification of LPVIP at Hospital was evaluated. Tests were performed considering the LPVIP and three values of infusion rates (25 ml/h, 50 ml/h and 100 ml/h). Several metrological parameters were evaluated (bias, repeatability, uncertainty and maximum error). The measurement uncertainty was assessed according to the recommendations of the JCGM 100. The technical viability of the flow analyzer use for calibration and periodic verification of LPVIP was demonstrated. The obtained results showed that only 20% of the evaluated infusion pumps exhibited maximum errors within the manufacturer criterion for the three evaluated flow rates.

Keywords. Infusion pump, flow analyzer, calibration, measurement uncertainty.

1. Introduction
The incipient metrological approach in the health area can generate significant social and economic impacts. The metrology should be seen as a hegemonic factor to protect and give better quality to health, and consequently reducing the number of deaths caused by medical errors. The role of metrology is increased as the new technologies are introduced in the health area. Among the several reasons that justify the need for a metrological approach in this area, it is highlighted the protection and reduction of risks and accidents with patients, besides the guarantee of a correct diagnosis and treatment. Another reason is the support to the Health Care Establishments of legal actions from injured patients during the use of medical-hospital equipment [1], [2].

Diagnostic errors may be related to the obtaining incorrect measurement results, inadequate interpretation of these results and lack of analyst experience. Although diagnostic errors are frequent in in health area, they are rarely studies. A Harris study commissioned by the National Patient Safety Foundation Found reported that 17% of people are subject to a medical error related to diagnostic error.
Several correlate studies concluded that diagnostic errors represent about 30 % of medical errors, and they resulted in death or disability almost twice as long as other categories of errors [4]. The author [5] concluded that diagnosis error is a major concern for patients and physicians. In turn, [6] points out that a survey of more than 2000 patients, 55 % of them classified a diagnosis error as their main concern when consulting a doctor. Similarly, surveys with physicians reported diagnostic errors at least monthly. In addition, in comparison to the many safety concerns found in practice, physicians consider that diagnostic errors are more likely to cause serious injury or death compared to other safety concerns [6].

It is important to mention that medical equipment presents errors. These errors are related to the component manufacture and assembly, improper use, shocks, overloads, natural deterioration and wear, among others. Thus, the maintenance, calibration and periodic verifications are essential to ensure the suitable operation of medical equipment. Calibration procedures allow determining the magnitude of these errors, enabling to equipment metrological performance evaluation [7]. According to Désenfant and Priel [8] nowadays, the need to provide valid results goes beyond calibration laboratories, reaching the experimental tests, the health area, among others. Medical laboratories are now encouraged to evaluate the metrological performance of medical equipment, as well as to evaluate the uncertainty associated with all measurement results. Authors pointed out that, it is as important to declare the measurement uncertainty as it is to report the measurement result itself. A measurement or a test result without an assessment of its reliability is completely useless. According to JCGM 100 [9], any measurement result must declare the reliability associated with the measurement, denominated measurement uncertainty.

The physiological parameter measurement is essential for the diagnosis, risk characterization, treatment and monitoring of the clinical evolution of patients. Measurements are essential for assessing the efficiency of the method used in therapy, as well as for evaluating extreme situations in which the medical equipment can be responsible for the improvement of human life and also for its maintenance [7], [10]. In this context, the application of the quality management concepts to medical-hospital technologies is important [11]. The compliance with the requirements established by the ISO 17025 standards [12] required, in particular with regard to ensuring the measurement result traceability to the International System of Units (SI) [11].

Faria et al., [13] concluded that 61 % of the 72 evaluated aneroid sphygmomanometers did not meet the specifications. Gonçalves [14] concluded that all evaluated analyzed incubators (4 incubators) presented parameter overshoot values outside the range established by NBR IEC 60601-2-19 [15] standard. Silva et al., [16] observed during the evaluation of 15 electrosurgical units, belonging to a large public hospital with high complexity, that 33 %, 87 % and 100 % presented higher error values than the manufacturer specification (5 W) at the cutting powers of 50 W, 150 W and 300 W, respectively. For the coagulation power, 30 W, 80 W and 120 W these percentages were respectively of 0 %, 53 % and 60 %. Thus, this work aims at evaluating the meteoro logical performance of LPVIP using as reference a flow analyzer model IN-300. This analyzer was used as alternative to the electronic balance with a resolution of 0.0001 g specified by the IEC 60601-2-24 standard [17].

2. Methodology
The performance evaluation of ten LPVIP pumps was carried out using a flow analyzer model IN-300. The IN-300 model has an operating range of 1 ml/h at 1000 ml/h and a resolution of 0.1 ml/h. The IEC 60601-2-24 [17] standard determines that an electronic balance with a resolution of 0.0001 g should be used during pump calibration. The analyzer choice was based on two main aspects. First, the hospital has a flow analyzer available. Second, balances should be calibrated in the installation place and its location should not be changed. In this work the technical implementation of a flow analyzer for calibration and periodic verification of LPVIP at Hospital was evaluated. It is important to mention that [18] compared the two calibration methods, gravitational (with electronic weight scale) and analyzer,
and observed that they produced compatible flow results for peristaltic infusion pumps. However, the author did not specify which analyzer was used during the tests.

This flow analyzer model IN-300 has two channels available for use, which allows the simultaneous testing of two infusion pumps (Figure 1). It can be used to perform functional tests on syringe, volumetric and similar infusion pumps, in particular for flow rate evaluation. The analyzer calibration certificate states an expanded uncertainty associated with the volume of 0.06 ml for Channel 1 and of 0.21 ml for Channel 2. Considering that the volume is related to the flow, for the measurement uncertainty estimate, the expanded uncertainty associated to the volume was adopted. Thus, the expanded uncertainty is of 0.24 % ml/h and 0.84 % ml/h for channels 1 and 2, respectively. The coverage probability in both cases is of 95 %.

Figure 1. Measuring system used to perform experiments. (1) and (2) - Infusion pumps, (3) - Flow analyzer IN-300, (4) - Thermo-hygrometer.

Ten LPVIP, the same model, manufactured by one company were evaluated. Tests were performed considering three values of infusion rates: 25 ml/h, 50 ml/h and 100 ml/h following some recommendations of the NBR IEC 60601-2-24 [17] standard, as well as the manufacturer manual. According to the trumpet curve of the infusion pump provided by the manufacturer, after approximately 3 minutes for flows above 25 ml/h, the error associated with the infusion rate should be less than 5 %. All measurements were conducted at a room temperature between 18.0 and 30.0 °C. The room temperature was monitored using a thermo-hygrometer. This equipment has a nominal range of -20.0 to 60.0 °C and a resolution of 0.1 °C. According to the thermo-hygrometer calibration certificate, its expanded uncertainty was of 0.3 °C for the temperature with a coverage factor k of 2.00. Before starting the measurements, the LPVIP and the analyzer were left in the measuring room for 24 h to reach thermal equilibrium.

For each point of the rated flow range evaluated, the difference (bias) between the flow average values indicated by the infusion pump (F) and those indicated by the flow analyzer (FA) was determined as given in Eq. (1).

$$ E = F - FA $$  

In order to estimate the measurement uncertainty, the concepts and recommendations presented in the JCGM 100 [9] were followed. For this purpose the mathematical model given in Eq. (2) was adopted. In Eq. (2), F represents the measurand (flow); $\bar{F}$ is the flow average values provided by the infusion pump; $\Delta R$ is the correction due to the resolution of the infusion pump; and $\Delta C$ is the correction associated with the flow analyzer calibration.

$$ F = \bar{F} + \Delta R + \Delta C $$
The maximum error associated with the flow rate was estimated as shown in Eq. (3). In Eq. (3), $E_{\text{MAX}}(F)$ represents the maximum error, $E$ is the error estimated by Eq. (1) and $U(F)$ is the associated expanded uncertainty.

$$E_{\text{MAX}}(F) = E + U(F)$$

(3)

3. Results and Discussion

The flow average values provided by the infusion pumps are shown in Figure 2. Each graph represents one of nominal range points analyzed by the 10 infusion pumps. The error bars indicate the expanded uncertainty values associated for a coverage probability of 95%.

![Flow rates average values obtained in 25 ml/h (a), 50 ml/h (b) and 100 ml/h (c) for the 10 infusion pumps. Expanded uncertainty (95 %) is shown as an error bar.](image)
In Figure 2a it can be observed that, for the 25 ml/h flow rate, the flow average values provided by the 10 infusion pumps ranged from 22.933 to 25.600 ml/h, exhibiting an amplitude of 2.667 ml/h. For the 50 ml/h flow rate (Figure 2b), the flow average values varied from 46.400 to 51.767 ml/h. The amplitude associated with the average values was of 5.367 ml/h for this condition. For 100 ml/h flow rate (Figure 2c), the flow average values varied from 93.000 to 104.000 ml/h. The amplitude associated was of 11.000 ml/h.

Comparing the three graphs shown in Figure 2, it can be seen that the higher the flow, the greater the variability of the flow average values between the infusion pumps. When analyzing the infusion pump behavior separately at the three flow rates, it is observed that the pumps 1, 2, 3, 4, 8 and 9 exhibited better repeatability as the flow rate increased. In the three flow rates evaluated, most of the infusion pumps presented flow average values below the reference value, indicating that the flow delivered by the infusion pump was smaller than the reference one. Only infusion pump 7 had a higher flow average value in 100 ml/h flow rate and pump 4 presented a higher average than the reference at all flow rates.

In Figure 2, it is observed that the expanded uncertainty associated with the flow tended to decrease as the flow rate increased from 25 ml/h (Figure 2a) to 50 ml/h (Figure 2b) and to 100 ml/h (Figure 2c). This behavior can be clearly seen in infusion pumps 1, 3, 4 and 8. For the 25ml/h flow rate (Figure 2a), the associated expanded uncertainty ranged from 0.109 to 1.013 ml/h. These uncertainty values followed the experimental standard deviation trend. At the 50 ml/h flow rate (Figure 2b), the measurement uncertainty assumed lower values for most infusion pumps, ranging from 0.109 ml/h to 0.668 ml/h. At the 100 ml/h flow rate (Figure 2c) the associated expanded uncertainty ranged from 0.109 to 0.871 ml/h and was significantly lower for the infusion pumps 1, 3, 4, 6, 8 and 10. This indicates that the measurement result has greater repeatability. The factor that most contributed to the final uncertainty for all evaluated conditions was the variability of the readings.

Figure 3a shows the calibration curve of the LPVIP 1. This figure shows the systematic errors (bias), the standard deviation (95 % reliability) and the maximum error stipulated by the manufacturer. In Figure 3a, it is observed that the LPVIP 1 presented a systematic error greater than 5 % in 25 ml/h flow rate and acceptable errors for the other flows rate values.

![Figure 3a](image)

**Figure 3.** Calibration curve of infusion pump 1 (a). Number of infusion pumps with acceptable systematic errors associated with the flow rates according to the manufacturer criterion (b).

Calibration curves were obtained for all evaluated pumps. The main conclusions drawn from these curves are: the infusion pumps 5 and 7 showed systematic errors lower than 5% in all evaluated flow rates, meeting the manufacturer criterion. The infusion pump 4 showed, at the flow rate of 25 ml/h, the standard deviation 0.04 ml/h higher than that allowed by the manufacturer. The infusion pumps 6 and 10 presented a greater error percentage than that allowed for the three considered values of flow rates. In turn, infusion pumps 1 and 9 presented a larger systematic error that 5 % at the lowest flow considered 25 ml/h and acceptable errors for higher flow rates. These results are summarized in Figure 3b.
Figure 4 shows the maximum error values obtained for all evaluated pumps in all investigated conditions. The maximum error of 5 % specified by the manufacturer is also shown in red color.

Figure 4. Maximum error values obtained for the flow rates of 25 ml/h (a), 50 ml/h (b) and 100 ml/h (c). Maximum error specifies by the manufacturers is also indicates in red color.

In Figure 4, it is observed that for the flow rate of 25 ml/h, the infusion pumps 3, 4, 6 and 10 present error values higher than 5 %. For the flow rate of 50 ml/h, only the infusion pumps 6 and 10 show a maximum error greater than 5 %. And at the flow rate of 100 ml/h, the infusion pumps 6, 8 and 10 exhibit maximum error greater than 5 %. The highest maximum error value was observed for infusion
pump number 10 (6.6 %) at the flow rate of 100 ml/h. Thus, 50 % of evaluated pumps were out of manufacturer specification.

According to [19] although drug administration is one of the most accomplished health care activities, 20 % of doses are administered incorrectly. The author [20] pointed out that approximately 6 million drugs are administered per year in hospitals and 4,000 preventable adverse events are attributed to administration errors. It is important to mention that the error associated with the flow rates increases linearly with the number of drugs in use [21] and with infusion time. The use of infusion pumps with higher error values than those stipulated by manufacturers can have disastrous consequences mainly for the elderly [21], [22]. According to the author [23] pointed out that administration errors can also have serious consequences for children, since for them the drug doses are calculated based on the mass [23].

4. Conclusion

This paper reported the performance tests in medical equipment, ten electrosurgical units and ten linear peristaltic volumetric infusion pumps. The following conclusions can be drawn from this work:

- The technical viability of the flow analyzer use for calibration and periodic verification of linear peristaltic volumetric infusion pumps was demonstrated.
- Eight evaluated infusion pumps presented negative systematic error, tending to provide lower flow values than those required in most cases.
- For higher values of flow was observed better repeatability and lower values of expanded uncertainty associated with flow rate, as well as a larger number of infusion pumps that present a systematic error within the manufacturer interval.

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