Infusion Pumps Calibration Methods

Elsa Batista
ebatista@ipq.pt
IPQ-Instituto Português da Qualidade

Maria do Céu Ferreira
mcferreira@ipq.pt
IPQ-Instituto Português da Qualidade

Abstract:

Nowadays, several types of infusion pumps are commonly used for drug delivery, such as syringe pumps and volumetric pumps. These instruments present different measuring features and capacities according to their use and therapeutic application.
In order to ensure the metrological traceability of these flow and volume measuring equipment it is necessary to use suitable calibration methods and standards.
Two different calibration methods can be used to determine the flow error of infusion pumps. One is the gravimetric method, considered as a primary method and commonly used by the National Metrology Institutes. The other calibration method is a secondary method, which relies on an Infusion Device Analyser (IDA) and is typically used by the hospitals maintenance offices.
The gravimetric method is the most accurate one but the comparison method allows calibration of infusion pumps within the hospital facilities. In this work the two calibration methods are described in detail.
Also the two international research projects that allowed the development of these methods at the Volume and Flow Laboratory of the Portuguese institute for quality are explained.

Keywords: Flow Rate, Infusion pumps, Calibration, Traceability

1.Introduction

Medical infusion instruments are widely used, as they are fundamental for primary health care, namely for providing drugs, nutrition and hydration to patients. Infusion pumps are electronic medical instruments widely used in adult, paediatric and neonatal patients, with the purpose of delivering fluids in a intermittently or continuously manner. These instruments can be used in clinical environments or at home. An infusion pump is normally constituted by a fluid reservoir, a generating flow device, than can also have flow regulation functions and of a set of accessories (lines, administration sets, filters, etc.) that allow the fluid to be transported from the reservoir to the patient.

According to IEC 60601-2-24, infusion pumps can be volumetric or with syringe. Volumetric infusion pumps are used to administer medications and nutrients or food (enteric and parenterel) and can be used in a clinical environment or at home. This type of instrument has a mechanical trigger causes the liquid within the tube to move by peristaltic action, thus enabling the administration of medications and nutrients or food. Syringe pumps presuppose a system of a continuous, individual, resistant tube and without connexions in Y. The pump system is composed by and external electronic infusion pump. A pump with a syringe system is made up of an external electronic infusion pump, an infusion line and a syringe compatible with the system usually disposable. More details concerning the characteristics of different types of pumps can be found in the guide – Metrology in health – Best practices guide (SCH, 2018).

2. Calibration, Error and Traceability

Similar to what happens with any other measurement in a clinical context, the measurement of flow requires the necessary accuracy, as well as the guarantee of conformity to the metrological requirements of the measuring instrument. Amongst other sources, the error and the uncertainty associated with the measurement of flow obtained during calibration of the instrument depend on the conditions of the infusion pump, the type of components/consumables used and the chosen calibration method. The calibration of an instrument also allows ensuring is traceability to the International System of Units.

The metrological definitions of calibration, error, traceability and measurement uncertainty can be found in the International Vocabulary of Metrology (IPQ, 2012).

The determination of the error and uncertainty of a measuring instrument makes it possible to determine and characterize its suitability according to a certain criterion of acceptance stipulated by the manufacturer, by the user or by reference standards, normally defined as Maximum Permissible Error (MPE). Thus, for a given instrument to be accepted and considered for use after calibration or testing, the sum of the absolute value of the error and the uncertainty shall be less than or equal to the absolute value of the MPE.

Due to the fact that there is a vast quantity of infusion pumps in health facilities, priorities are frequently defined according to the criticality of use of the various instruments. The health services should define a calibration plan for the infusion pumps. In addition, it should also be defined the calibration periodicity according to the history of the instrument, the context in which it is used and the manufacturer’s recommendations.

In accordance with the performance of the instrument and of the agreed acceptance criteria, the periodicity of the initially calibration defined can be changed as long as it is properly justified.

3. International and national projects regarding infusion pumps

EURAMET – European association of national metrology laboratories started in 2007 the European Metrology Research Program (EMRP).

This research program allowed collaboration between the National Metrology Laboratories (NMI), Universities and industry, trough join research programs in several strategic areas, one of those is health.

In 2007 it was identified by several NMIs that the perfusion technology had underestimated risks namely:

- •Difficulty associated with micro flow measurement and control (<1 mL/h);
- •Difficulty measuring and controlling the final concentration using multiple pumps;
- •The characteristics of the infusion systems are not fully understood, in particular as regards to delay in dosing, compliance, flow stability and impact of variation of normal operating conditions;
- •Metrological traceability was not assured for values lower than 0.5 mL/h, because the metrological infrastructure was not fully developed;
- •No validation of measurements for flow values below 100 mL/h;
- •There are no common usage protocols that include the entire system and accessories.

The Metrology for Drug Delivery (MeDD) project funded by the European Metrology Research programme (EMRP), that was developed between 2012-2015, had as main focus such calibration methods. In this joint research programme (JRP), several Metrology Institutes (Swiss Federal Institute of Metrology - METAS, Danish Technological Institute - DTI, Centre Technique des Industries Aérauliques et Thermiques, France - CETIAT, Portuguese Institute for Quality - IPQ and Dutch Metrology Institute - VSL) developed the primary standards for liquid flow rate (Batista et al., 2015).
The outcomes of this project were discussed in several international conferences and presented in scientific papers, reports and best practice guides that can be found in www.drugmetrology.com.

This project allowed the Volume and Flow Laboratory of IPQ to develop gravimetric standards for flow measurements in the range of 0.12 mL/h to 600 mL/h, with associated uncertainties of 0.3 % and 2.5 %, resulting in new published CMCs in the BIPM - Bureau International des Poids et Mesures, for infusion pumps, flow meters and flow analyzers.

Aiming to disseminate the knowledge obtained from MeDD JRP, a new project (Support for Impact Project (SIP) 15SIP03 – Infusion Uptake) funded by the European Metrology of Innovation and Research Programme (EMPIR) was started in May of 2016 and will end in 2019. This project had the participation of 4 NMIs, including IPQ and seven national hospitals. The 15SIP03 JRP has two main goals:

a) To develop an E-learning module made available on the E-learning platform of the European Society for Intensive Care Medicine (ESICM), with the aim to create awareness and understanding of multi infusion risks and thereby reducing dosing errors and increasing the quality of medical treatment.

b) To incorporaWWte the best metrology practices relating calibration of infusion devices in ISO standards, namely ISO 7886-2 and IEC 60601-2-24.

4. Calibration of infusion pumps

The flow calibration of infusion systems can be carried out through the standard gravimetric method ISO 60601-2-24:2012 and ISO 7886:1996 or by using a Flow Infusion Pump Analyser (IDA).

4.1. Gravimetric method

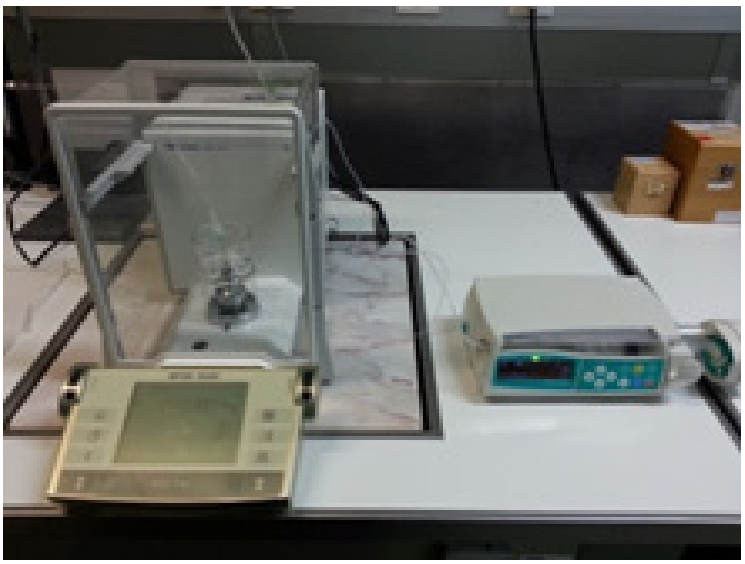
The gravimetric method is considered as a primary method and is commonly used by the National Metrology Institutes (Batista et al., 2017) to calibrate syringe pumps. This relies on weighing the mass of water delivered by an infusion pump during a determined time. The flow rate is then determined by the quotient of the mass of reference liquid, usually water, and time interval, including some corrections following equation 1.

$$Q = \frac{1}{t_f - t_i}\left[\left((I_f - I_i) - (\delta m_{buoy})\right) \times \frac{1}{\rho_w - \rho_A} \times \left(1 - \frac{\rho_A}{\rho_B}\right) \times [1 - \gamma(T - 20)]\right] + \delta_{evap}$$

Although evaporation is kept to a minimum value, via technical means, the determined mean evaporation rate (dQevap) is required as a correction term in the volume flow rate (Q). Other contributions to the model are: the density of the reference liquid, i.e. water (rW); the time interval of the weighing, i.e. the final time (tf) minus the initial time (ti); the mass of the displaced reference liquid, i.e. the difference between the final (If) and the initial (Ii) indication of the balance; density of the air during the tests (ρA); density of the mass standards used to calibrate the balance (ρB): the water coefficient of thermal expansion(γ) and the temperature of the water during the tests (T). The term dmbuoy accounts for the buoyancy contribution of the dispensing needle immersed in the weighing vessel.

The calibration setup used during MeDD project consisted of a flow generator, connected to a device under test (DUT) upstream of a collecting vessel standing on an analytical balance (Figure 1). The balance measures the mass of the displaced liquid by the flow generator, which is precisely timed to calculate the Δm/Δt quotient.

Figure 1 – Gravimetric method setup.



During the calibration process the water to be used and the instrument to be calibrated must be at the same temperature. Therefore, the instrument should be placed in the testing room approximately 12 hours before the beginning of the calibration.

The temperature of the water used should not vary more than 2 °C during the tests.

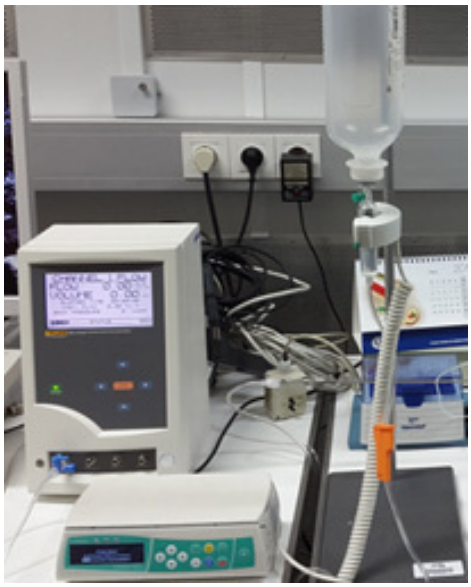
The measuring instruments (infusion pump) should be calibrated in at least three points so as to guarantee the determination of the measurement error measurement in the entire working range.

The instruments used, namely the pressure, temperature and humidity sensors, as well as the balances should have the necessary characteristics to carry out calibration and should be calibrated.

4.2. Comparison method

The other calibration method, used to determine the flow rate of an infusion pump, mainly by the hospitals maintenance offices, is a comparison method, and thereby considered as a secondary calibration method. This method consists on comparing directly the flow generated by the infusion pump under calibration with the flow recorded by an Infusion Device Analyser (IDA) (figure 2).

Figure 2 – Comparison method setup.



Before starting the calibration all the apparatus under test (syringe pump to be calibrated and the IDA) and the reference liquid should reach as close as possible to the reference temperature of 20 ºC (by 12 hours).

During the calibration, the temperature of the water and the air temperature, relative humidity and atmospheric pressure should be continually measured and/or recorded.

The syringe (normally disposable) to be used in the syringe pump is filled with ultrapure water. Before attaching the Teflon tube and mounting it on the pump, the air bubbles should be removed by inverting the syringe so that the nozzle lumen is uppermost and depress the plunger. The line should then be filled by running the syringe pump at a high rate until a steady flow of drops comes out at the end of the tube. Finally, the tube is connected with the IDA. The target flow is then programmed in the syringe pump.

Data acquisition of IDA begins after 10 minutes of steady flow and over at least 15 minutes. The data can then be directly recorded by software or read at the display as the average flow rate. The described times were obtained by experimental approaches in the Volume and Flow Laboratory of the Portuguese Institute for Quality.

The water temperature should be recorded at the beginning and at the end of the calibration, and not vary more than 2 ºC.

Concerning the measuring instruments (infusion pump), it should be calibrated in at least three points so as to guarantee the determination of the measurement error in the entire working range.

The IDA should be calibrated by accredited laboratories providing the traceability to the International System of units.

The comparative method, being a secondary method, has lower accuracy and larger uncertainty when compared with the gravimetric method, especially at flow rates lower than 10 mL/h, but it has the big advantage that can be used in clinical environment.

5. Conclusions

In order to determine the flow measurement error of an infusion pump, it is necessary to calibrate it by gravimetric or comparative method. The gravimetric method, being a primary method has a better accuracy and smaller uncertainty, but only allows the calibration of the instruments in a laboratory environment. The comparative method, of less accuracy, allows the calibration of the instruments in the hospitals, being sometimes the only possible option considering the number of infusion devices existing in each health care facilities.

The calibration of the infusion pumps ensures traceability to the International System of Units and determines their metrological conformity. This depends, therefore, on the maximum permissible error defined by the user, based on reference documentation, manufacturer's information or considering the practical use of this measuring instrument. It should also be noted that the calibration of infusion pumps must always be performed with the accessories used by the entity or service to which the instrument is affected.

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Authors Profiles:

Elsa Batista has a master degree in Analytical Chemistry from the Faculty of Science of Lisbon University– Portugal, Lisbon in 2007 and a degree in Applied Chemistry from the Faculty of Science and Technology, FCT, NOVA University of Lisbon in 1999. She is the head of the volume laboratory of the Portuguese Institute for Quality since 1999. She is also the contact person and Chair of the Technical committee for flow of EURAMET.

Maria do Céu Ferreira holds a Ph.D. in industrial engineering from the Faculty of Science and Technology; FCT, NOVA University of Lisbon. Since 1994, she is Metrologist at the Metrology Department of the Portuguese Institute for Quality (IPQ), having developed its activities in the areas of scientific and applied metrology, managing multi-disciplinary teams related with standards and measurements. Since 2008, Maria is in charge at Legal Metrology as Quality Manager and Assessment of the Metrological operations and verification bodies. Meanwhile, she founder and is responsible for the Portuguese Health Metrology committee, hosted by IPQ. Maria is a designated member of the Metrology Board of the Portuguese Engineers order and is Professor in the Faculty of Engineering at the Lusófona University of Lisbon. Maria is the Portuguese member of the International Board of Experts of the International Organization of Legal Metrology and is an active member of OIML, WELMEC and ISO. Her research interests include all health metrological applications for ensuring traceability and new quality assured measurement methods.