CALIBRATION AND USE OF SYRINGE PUMPS

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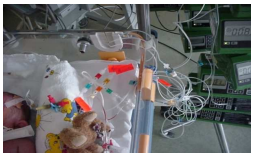
Abstract. There are several types of infusion instruments used for drug delivery, e.g. syringe pumps and infusion pumps, with different capacities according to their use and applied therapeutic. In order to ensure the traceability of these flow and volume measuring equipment is necessary to use suitable calibration methods and standards. Current calibration services of microflow do not go below 16 µL/min (4 % uncertainty), whereas the lowest comparison between primary standards has been of 100 mL/min, hence, below the latter flow rate, the primary standards have not been validated. Also there are several influence factors in the use of drug delivery devices that are not yet studied in detail. Therefore, a need for the development of a research project in the scope of the EMRP - European Metrology Research Programme, was identified. In order to validate the microflow gravimetric calibration method, developed at the Volume Laboratory of the Portuguese Institute for Quality in the scope of the participation in the EMRP project – Metrology for drug delivery (MeDD), several infusion instruments supplied by the Hospital Garcia de Orta (HGO)/ Neonatology Service were tested at different volumes and rates. From the obtained results, it can be implemented several improvements for the use and calibration procedures.

Introduction

Infusion instruments are used in clinical environment for nutrition and hydration of patients and drug delivery. The infusion technique is a technology with underestimated risks due to several influence factors, namely the use of very small flow (300 nL/min) in preterm babies, multipump administration with the use of several administration lines and the individual variables of the different drugs.



EMRP-MeDD

The European Association of National Metrology Institutes, EURAMET, started, in 2007, the European Metrology Research Programme – EMRP. This programme allows cooperation between National Metrology Laboratories, Universities and industry in Joint Research Programs – JRPs, in strategic themes. One of this themes is health. This choice had the main purpose of developing science and technology in the field of health, specifically, to assure the traceability of clinical data, allowing the comparability of diagnostic and treatment information.
The JRP "MeDD - Metrology for Drug Delivery" was accepted for the development of a primary standard for flow measurements between 150 µL/min and 1 nL/min.

EMRP
European Metrology Research Programme
Programme of EURAMET
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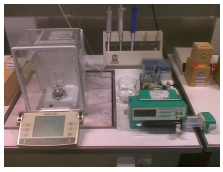
Methods and Instrumentation

In order to validate the microflow gravimetric calibration method developed at the Volume Laboratory (LVO) of the Portuguese Institute for Quality (IPQ), and in the frame of LVO participation in the EMRP MeDD project, several infusion instruments supplied by the Hospital Garcia de Orta/ Neonatology Service were tested at different volumes and flow rates.

Methods

There are several methods for calibration/verification of infusion devices: the comparison method "in situ" using a flowmeter and the gravimetric method used in the laboratory [2] based on IEC 60601-2-24 [3].



Flow measurement

The flow measurement can be done by a static or a dynamic method. The static method is generally used for the calibration of volumetric meters and consists of the measurement of a volume at a preset flow rate. The dynamic method used in the calibration of flowmeters consists in the determination of the mass or volume per unit of time.

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

Experimental results

Type of Infusion instrument used

Perfusor Compact S	
Flow range	10,1 mL/min – 999,9 mL/min
Resolution	0,01 mL/h
Precision	2,5 %

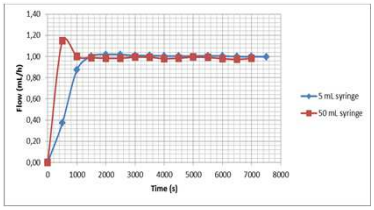
Experimental procedure

The syringe is filled with ultra-pure water without air entrapment. A sufficient amount of water is passed to the tube in order to remove all air bubbles. The flow to be calibrated is then programed in the pump and the water is collected in a balance. The volumetric flow is directly calculated by a computer program written in "LabVIEW".

Results

Several calibrations were performed at a flow rate of 1 mL/h using the Perfusor Compact S, with 50 mL, 20 mL and 5 mL syringes. Three repetitions for each syringe was performed in order to assess the repeatability of the instrument.

Nominal flow	Syringe	Obtained flow (mL/h)	Error (%)	Uncertainty (%)
1 mL/h	50 mL	0,9839	1,61	0,12
		0,9888	1,12	0,21
		0,9835	1,64	0,17
	5 mL	0,9987	0,13	0,34
		0,9988	0,12	0,41
		0,9989	0,11	0,41



Nominal flow	Obtained flow (mL/h)	Error with incorrect code (%)	Uncertainty (%)
1 mL/h 20 mL syringe	1,1050	10,50	0,43
	1,0896	8,96	0,46
	1,1050	10,50	0,42

Nominal flow	Obtained flow (mL/h)	Error with correct code (%)	Uncertainty (%)
1 mL/h 20 mL syringe	0,9990	0,1000	0,38
	0,9890	1,1000	0,36
	0,9964	0,3600	0,40

CONCLUSIONS

The regular maintenance and calibration of instruments infusion allows the identification and correction of errors, minimizing potential risk situations for the patient. The Volume Laboratory of IPQ recently implemented the gravimetric determination of flow with an uncertainty on the order of 0,5 %. During the development and validation of the standard for flow measurements several tests were performed with different infusion instruments used by the Hospital Garcia de Orta. These tests allowed comparing the results of the accuracy of instruments, obtained experimentally with those indicated by the manufacturers and also identified an incorrect programing situation effect. For the 20 mL syringe the first obtained results had an error about 10 % which is much larger than the maximum permissible error as described by the manufacturer and this was due to incorrect code for the 20 mL disposable syringe. The correct code was then inserted and the results are now within the MPE of the manufacturer.
We can conclude from this work that it is essential to follow the manufacturer instructions and specifications, specially the ones related to the consumables in use with the infusion systems, in order to prevent significant errors.

REFERENCES

1. A. Teimersma, 'Effect of flow fluctuations during administration of vasoactive drugs with infusion pumps'. University Twente, Enschede, (April 2011)
2. ISO 4787:2010 - Laboratory glassware - Volumetric glassware - Methods for use and testing of capacity
3. IEC, IEC 60601-2-24 (1998). Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers, Switzerland, 1998
4. B. Braun Medical. Lda, Perfusor Compact S – Instructions Manual, B| BRAUN Hospital Care

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