METROLOGY for DRUG DELIVERY

REPORT:

COVID-19 Crisis & Emergency Practices with Infusion Pumps in ICU

- The Role of Metrology

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This report was produced as a deliverable outlined in the Exploitation Plan, covering a case study from the EMPIR Metrology for Drug Delivery (MeDD II) project. The three-year European project commenced on 1st June 2019 and focused on providing traceable measurements of volume, flow and pressure of existing drug delivery devices and mixing behaviour and occlusion phenomena in multi-infusion systems. For more details about this project, please visit www.drugmetrology.com

This report was written by:

Elsa Batista	IPQ	*ebatista@ipq.pt*
Zoe Metaxiotou	EIM	*zoe@eim.gr*
Emmelyn Graham	NEL	*Emmelyn.Graham@tuv-sud.co.uk*
Annemoon Timmerman	UMCU	*A.M.D.E.Timmerman@umcutrecht.nl*
Andreia Furtado	IPQ	*afurtado@ipq.pt*
Joost Lotters	Bronkhorst	*j.c.lotters@bronkhorst.com*

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Introduction

The unprecedented conditions that Public Health Institutions are experiencing due to COVID-19 pandemic crisis has forced the hospital administrations to take measures outside the usual work practices in order to manage several challenges, including:

- Reduction of health care staff exposure to COVID-19
- Conservation of personal protective equipment (PPE)
- Manage shortages of equipment
- Staff working outside their usual area of expertise

The measures taken by some hospitals outside the usual work practices include:

- To use the drug delivery devices outside the patient room
- Use of drug delivery devices outside manufacturer specifications
- To delay maintenance and calibration of equipment deadlines in instruments with critical use

These practices can lead to large dosing errors that can result in adverse incidents, morbidity and mortality. Therefore, it is fundamental to provide advice regarding any issues related to incorrect use of drug delivery devices.

To use the drug delivery devices outside the patient room

Several hospitals are now using extension sets to position infusion pumps outside of COVID-19 patients' rooms in order to conserve personal protective equipment (PPE) and reduce the frequency of exposure that nurses would ordinarily experience by going into patients' rooms to manage infusions. But this procedure raises several questions, mainly:

1. Is the delivery through long extension tubing appropriate for the specific patient's medication administration?
2. Are there limitations in the performance of the infusion pump stated by the manufacturer?
3. Are there risks for infection?
4. Is this setup going to lead to significant conservation of PPE?
5. Are there other and/or better solutions for saving PPE use, *e.g.* remote control, robots, reusable PPE?
6. Is the accuracy of the device affected by this setup?

Example of medical equipment and infusion pumps setup outside of hospital patients' rooms

There are many risks associated to the infusion device setup, the first related to the use extension tubing (or multiple extension sets connected in series), namely the priming volume increases with extensions, there is an increased fluid flow resistance, the accuracy may be affected, specially at low flow rates and there is a risk of under infusion, more bubbles in the system due to the incorrect priming and the extra connections. Fluid viscosity effects can also be found with long extensions, and several problems with occlusion alarms may occur depending on the type of line.

The second issue is related to the position of the instruments being outside the patients' room that can lead to problems related to the availability of sufficient power outlets, accessibility issues with corridors and to rooms (distance & fire regulations cannot be adhered to), labelling the tubing inside and outside the room, secure tubing to avoid disconnection, route the tubing into the patients' room without keeping the door open, adhere to regulations when tubing is routed into negative pressure rooms.

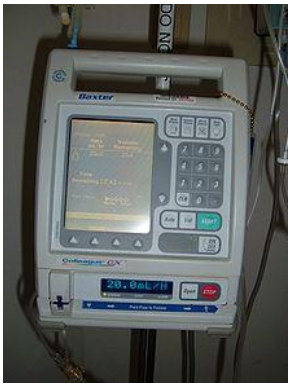
All of these issues must be considered before deciding to move the instruments outside the patients' room.

It is recommended to test the flow rate and volume delivered when using extension lines, especially at low flow rates, as the accuracy of the device may change due to modifications in the setup and the pump will not perform according to the specifications of the manufacturer.

Use of drug delivery devices outside of manufacturer specifications

As a result of the impending shortages during the COVID-19 crisis, health professionals are prompted to partially replace syringe infusion pumps by lower-accuracy volumetric infusion pumps. Volumetric infusion pumps can produce, due to their mechanical design, a continuously oscillating dosing error in the flow rate of approximately 1.5 ml/h. To ensure this oscillation of 1.5 ml/h is always less than 10% of the setpoint flow rate, a flow rate of at least 15 ml/h is required.

Syringe pump



Volumetric pump

Therefore, some recommendations to use infusion pumps are highlighted below:

1) Replacement of a syringe infusion pump by a volumetric pump: This is allowed only if the flow rate of the volumetric pump is greater than 15 ml/h

2) Infusion bag: To be connected to a separate lumen within the catheter

3) Highly active substances, or substances having a short half-life ($t_{1/2}$): Always use a syringe pump

4) Noradrenaline: Do NOT use a volumetric pump; a syringe pump must be used

5) If the syringe pump is connected along with a volumetric pump on the same lumen: Then the flow rate of each pump must be greater than 15 ml/h

6) IMPORTANT :

If multiple pumps have been connected to the same lumen: Make sure to always close ALL infusion taps and stop cocks (connected to that single lumen) directly PRIOR to a syringe exchange, and to open them all again ONLY AFTER all pumps have been re-activated

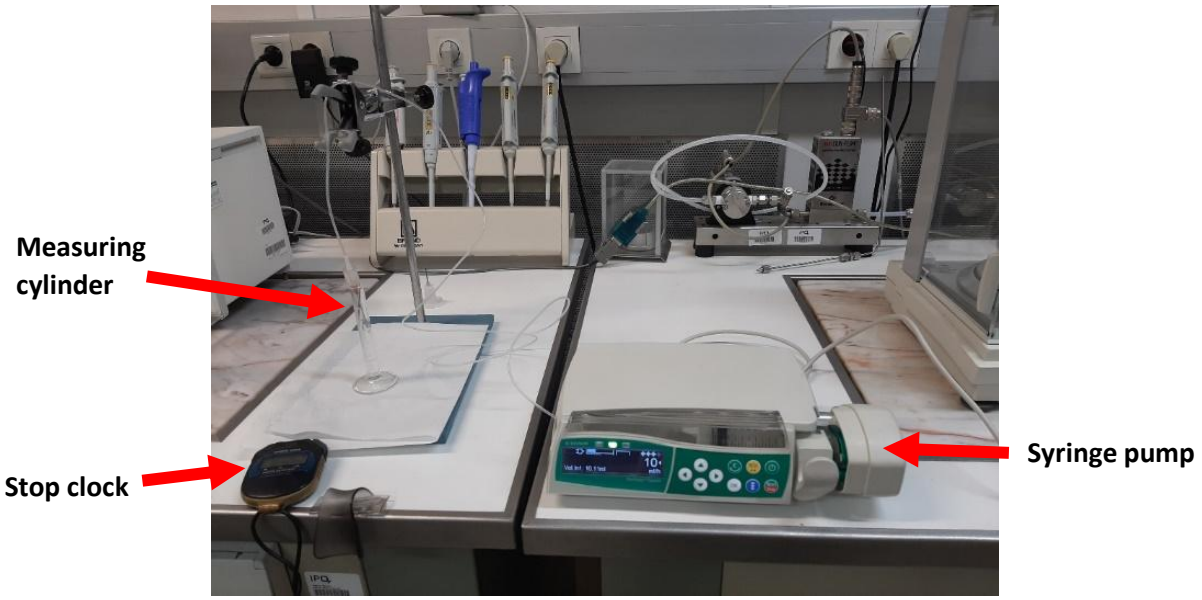
Any other variation to manufacturer specification should be validated by performance tests done by qualified laboratories, mainly National Metrology Laboratories and Accredited Laboratories to ensure a high confidence in the performance testing results.

To delay maintenance and calibration of equipment deadlines

As a result of the impending shortages during the COVID-19 crisis, health professionals are prompted to delay the periodic maintenance and verification services of the drug delivery devices. This situation can cause serious problems in the determination of the metrological performance according to manufacturer or user specification of the pumps and therefore lead to unidentified dosing errors.

Normally the verification of the pumps is performed using a pump device analyzer by the hospital maintenance laboratory or by using the gravimetric method normally used by National Metrology Laboratories or Accredited Laboratories.

It is possible to perform a quick check of the pumps dosing error using a measuring cylinder and a stop clock. This method has 2 % uncertainty and can be done in 10 minutes, thus providing information on the metrological performance and maintenance status of the drug delivery device and can provide evidence to justify extending the verification deadline.



Quick check on the performance of a syringe pump using simple lab equipment

Conclusions

To help overcome some current hospital challenges related to drug delivery devices used during the COVID-19 crisis it is recommended that procedures outside the normal work practices can be performed under controlled conditions in order to avoid large dosing errors that can results in

adverse incidents, morbidity and mortality. To enable good decision making an understanding of the impact of Metrology is essential.

National Metrology Laboratories can significantly advance the understanding of how drug delivery devices perform in non-ideal conditions of use through bespoke testing to mimic the setups used in the current unprecedented situations in hospitals. This includes the performance testing of devices with the actual fluids used for patient infusions to reproduce realistic procedures using high-accuracy equipment to identify errors and quantify device uncertainties. This type of testing enables the development of best practice and methodology for using drug delivery devices in challenging conditions of use.

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