COVID-19 Crisis & Emergency Practices – Drug Infusion Pumps in ICU

THE ROLE OF METROLOGY

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2020-05-11

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Challenges

The unprecedented conditions Public Health Institutions experience due to COVID-19 pandemic crisis have forced Hospital Administrations to ***procedures outside the normal work practices*** to:

- *reduce exposure of health care staff to COVID-19*
- *preserve personal protective equipment (PPE)*
- *manage shortages of equipment*
- *manage of wastage of critical drugs or substances*
- *manage staff shortages and reorientation of staff to areas outside their usual expertise*

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General Patient Safety Issues

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Emergency standards can differ from normal:

Calibrations can be slow for COVID-19 necessities, and hence are being postponed. However, patient safety still needs to be assured.

Safe drug delivery practices during COVID-19 require:

- careful and responsible **risk assessment**, considering both continuity of care, patient safety and personnel safety;
- empower **metrological** and **clinical physics experts**;
- include **expert vision** in decision making.

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Safe drug delivery practice during COVID-19

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Universal rules still apply

- Priorities need to be clear:
  - 1st save lives, then optimize quality;
  - 1st do no harm

It might not be possible to meet quality standards in emergency situations. However, the ultimate goal remains to provide safe patient care. Calibrations should not be skipped or adapted lightly

Recommendation: search for solutions that are both practically feasible and adhere as close as possible to the quality standards

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COVID-19: adapted practice for Drug Delivery Devices

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The procedures taken by some Hospitals outside the usual work practices include:

1. To use the drug delivery devices outside the patient's room
2. To use the drug delivery devices with associated clinical risks and lower accuracy
3. To postpone maintenance and calibration of equipment for patient-critical use

These practices can cause large dosing errors resulting in adverse incidents, morbidity and mortality

BUT METROLOGY CAN HELP IN DECISION MAKING !!

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1. Use the drug delivery devices outside the patients' room

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Concerns

- Are the risks of these practices acceptable in order to sustain safe patient care?
- Is the delivery through long extension tubing appropriate for the specific medication to be administered to the patient?
- Is the accuracy of the device affected by this setup with extension sets?
- Are there limitations in the performance of the infusion pump stated by the manufacturer?
- Are there risks for infection?
- Is this setup going to lead to significant preservation of PPE?
- Are there other and/or better solutions for saving PPE use, *e.g.* remote control, robots, reusable PPE?

which factors affect the decision ?

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Non-Conventional Practice: positioning pumps in hallways

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1. **Set up of the infusion pump**

   a. *Use of extension tubing*

- the priming volume increases with extensions;
- there is an increase in fluid flow resistance ;
- the flow accuracy may be affected, specially at low flow rates and there is a risk of under-infusion;
- longer extensions with smaller inner diameters and higher flow rates are most likely to cause some slowing, up to 10%;
- more bubbles may be found in the system due to incorrect priming and extra connections;
- time to detect occlusions will be longer as extension length increases;
- viscous solutions e.g. D20% will increase the slowing effect;
- fluid viscosity effects can occur in long extensions resulting in occlusion alarms.

Critical Concerns

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Non-Conventional Practice: positioning pumps in hallways

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1. Set up of the infusion pump

b. Position of the devices outside the room

- the lack of available power outlets;
- poor accessibility to corridors and to rooms. The distance & fire regulations may not be adhered to;
- drug delivery errors resulting from the lack of tube labelling inside and outside the room;
- incorrectly attached tubing which may lead to tube disconnection;
- tube routing into the patients' room while closing the door which may deflect or even seal the tubing, increasing fluid flow resistance;
- failure of regulatory compliance when tubing is routed into negative pressure rooms

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Recommendation:

test the flow rate and ***volume*** **delivered** when using extension lines, **especially at low flow rates.**

Any change will strongly impact the accuracy of the device due to modifications in the setup. Ultimately, the ***pump will not perform according to the specifications*** of the manufacturer.

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2. Use the drug delivery devices with associated clinical risks and lower accuracy

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Replacement of syringe infusion pumps by volumetric infusion pumps

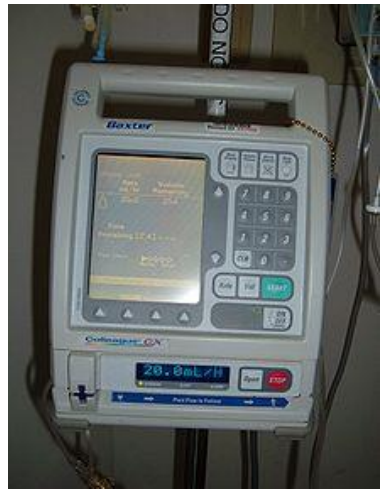
- Volumetric infusion pumps can produce, due to their mechanical design, a continuously oscillating dosing error in the flow rate of approximately 1.5 mL/h.

To minimize the impact of this error, the oscillation of 1.5 mL/h should always be less than 10% of the setpoint flow rate, **hence a flow rate of greater than or equal to 15 mL/h is required.**

- Drugs and fluids in which stable flowrate is of less importance can be established in close agreement with clinicians and pharmacists

Syringe pump

Volumetric pump
Q ≥ 15 mL/h



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Replacement of syringe infusion pumps by volumetric infusion pumps

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- **Recommendations**

1. when replacing a syringe infusion pump by a volumetric infusion pump, a good rule of thumb is: the **flow rate** of the volumetric pump needs to be greater than or equal to **15 mL/h** to conserve the necessary accuracy;

2. the **infusion bag** needs to be connected to a separate lumen within the catheter;

3. when **connecting a syringe pump and a volumetric pump on the same lumen**, the flow rate of both pumps must be the same and individually greater than or equal to 15 mL/h.

4. when **multiple pumps are connected on the same lumen** make sure to:

    1st – CLOSE ALL infusion taps and stop cocks directly connected to that single lumen;
    2nd – exchange syringes, pumps, etc;
    3rd – reactivate all pumps;
    4th – OPEN ALL infusion taps;

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Replacement of syringe infusion pumps by volumetric infusion pumps

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- **Recommendations**

NEVER USE A VOLUMETRIC PUMP FOR:

- highly active substances, or substances having a short half-life ($t_{1/2}$);

- Noradrenaline.

Any other variation related to accuracy of the results introduced in a clinical protocol should be validated by **performance tests done by qualified laboratories**, mainly National Metrology Laboratories and Accredited Laboratories, to ensure the high confidence necessary.

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3. Postponed maintenance and calibration of equipment for patient-critical use

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Postponed maintenance and calibration of equipment

Postponing of planned maintenance can lead to unidentified dosing errors

- To ensure safe drug delivery practice adhere to following standards:
  - Careful and responsible risk assessment, considering both continuity of care, patient safety and personnel safety;
  - User notification and registration of maintenance delay in the equipment management system;
  - Create user awareness that the equipment is safe to use by indications of maintenance postponement on the equipment.

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Postponed maintenance and calibration of equipment

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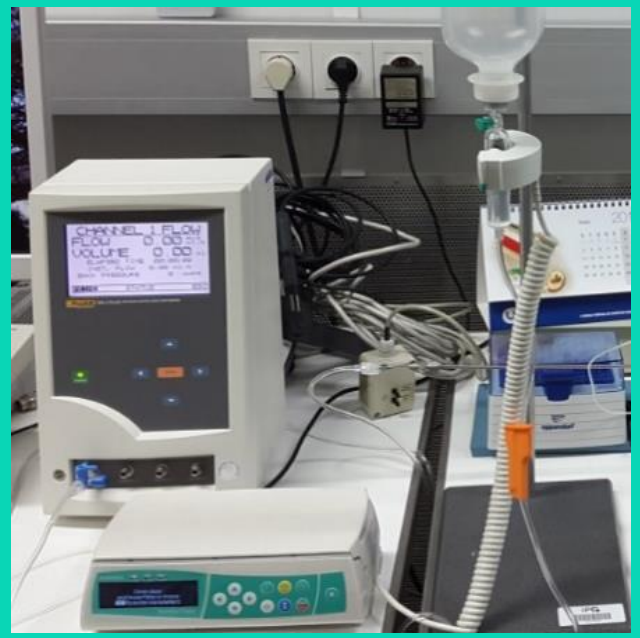
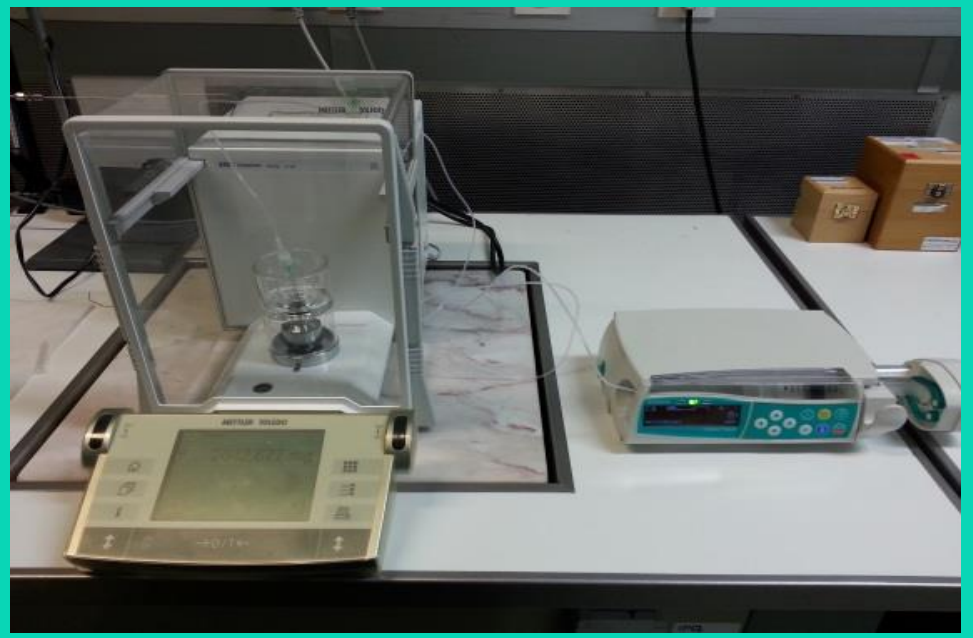
Usually the verification of the pumps is performed using a pump device analyzer or using the gravimetric calibration method



Analyzer



Gravimetric Method

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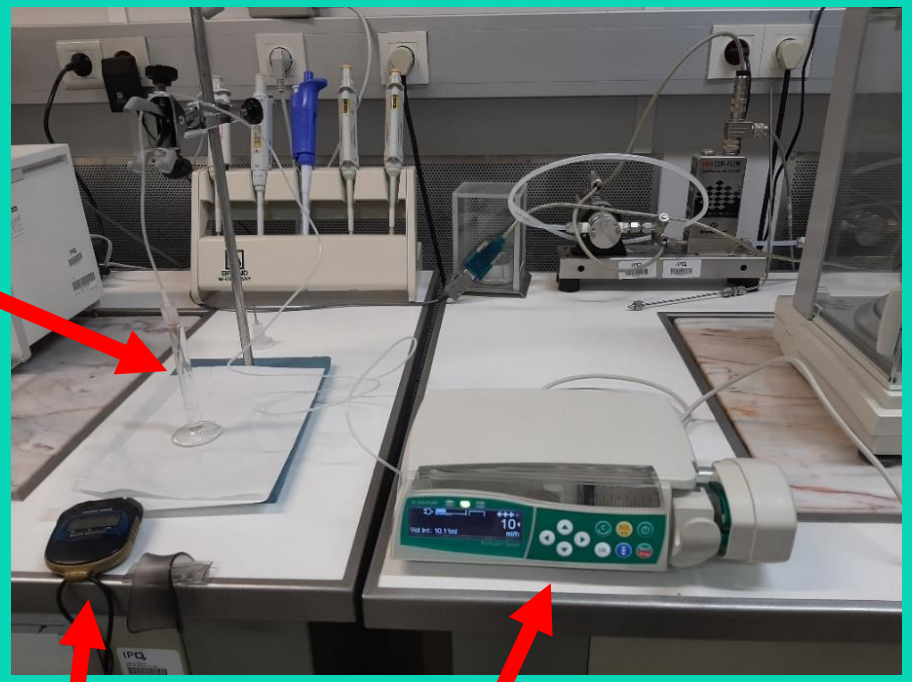
Postponed maintenance and calibration of equipment

- It is possible to perform a ***quick check*** of the pumps dosing error using a measuring cylinder and a stopwatch.
  - ✓ 2% uncertainty;
  - ✓ Performed in 10 minutes by internal personnel;
  - ✓ Simple check for the metrological performance of the pump;
  - ✓ Evidence to justify extending verification deadline;

Quick Check setup



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Conclusions

To overcome some hospital challenges using drug delivery devices during the COVID-19 situation *procedures outside the normal work practices* can be taken under controlled conditions in order to avoid large dosing errors that may result in adverse incidents, morbidity and mortality.
Metrology is a key factor in decision making.

Metrology can advance the understanding of how drug delivery devices perform in non-ideal conditions of use through testing to mimic the setups used in hospitals. Testing with the actual fluids used for patient infusions can identify errors and quantify 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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