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Gausstec Flash Nr. 04/17, April 2017, Andreas Reinmann

TESTING THE POURING ACCURACY OF INFUSION PUMPS FOR OUTPATIENT USE ACCORDING TO EN 60601-2-24:2016, FOR ALL COMMON FLOW FORMS

The lower the dosage of the medication, the more difficult it is to measure the distribution accuracy of infusion pumps and other medical-electrical devices (ME devices). This applies in particular to the release of hormones such as insulin.

The standard EN 60601-2-24 stipulates that the manufacturer must check the distribution accuracy of his ME devices. It also distinguishes between the river forms:

- Typ 1: Continuous Infusion
- Typ 2: Non-continuous infusion
- Typ 3: Single dose of a BOLUS
- Typ 4: Profile pump

Factors influencing the distribution accuracy

At a very small dosage, below 1µl/h and the observation over a longer period of time over days, a whole range of influencing factors, which impacts the flow rate, becomes visible: Altitude difference between ME device and infusion, air pockets, static friction effects, pressure losses at safety valves, occlusion, etc. Each of these specific influencing factors produces symptomatic distribution patterns that can only be detected with suitable measuring equipment. *Fig 3*.

Measurement over days and hours

Our investigations have shown that only a few methods are suitable to deliver exact results for measurements over several days and hours. A major problem is the partly intermittent release which leads to overdriving on sensitive flow sensors. A primary problem with all long-term measurements is the drift behavior. In many cases, flow sensors also handicap the path of the liquid or have an impact on the operative medium.

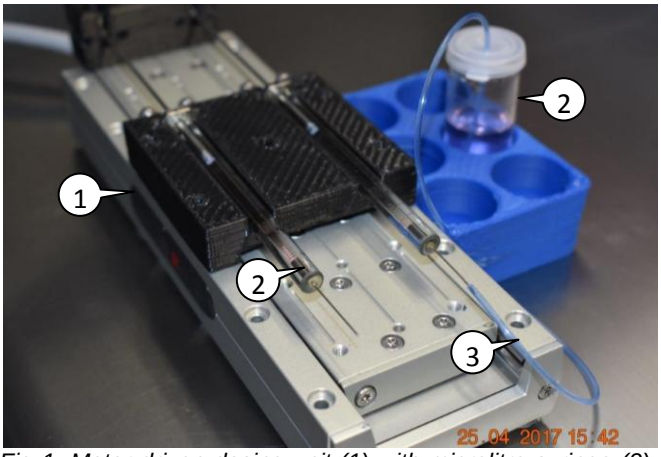

Fig 1: Motor-driven dosing unit (1) with microlitre syringe (2), infusion line (3), collection container (4)

Calibration of the flow measurement

An important prerequisite for a qualifiable flow measurement is the traceability of the calibration to SI standards. Gausstec uses a motorized dosing unit that can be volumetrically calibrated using a laboratory balance. See *Fig 1*. The dosing unit allows precise dosing with a resolution of 2.1nl.

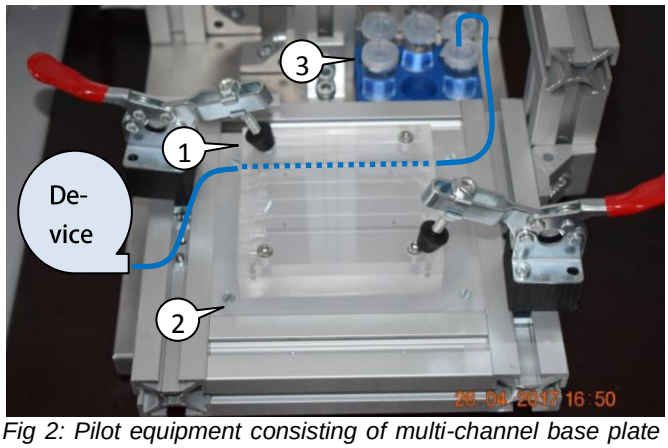

Fig 2: Pilot equipment consisting of multi-channel base plate (1), backlight frame (2), waste container (3)

The measuring system and its calibration

The measuring system *Fig 2* was realized with optical components. The channels used for this purpose allow a high-contrast visual position determination of the objects introduced into the path and thus the recording of the volume flow. The instruments and procedures allow a high-precision calibration and measurement of the flow rate with errors in the first 10% of the total volume of < 1% and decreasing proportional to the volume scooped, i.e. < 0.5% at 20% decreasing.

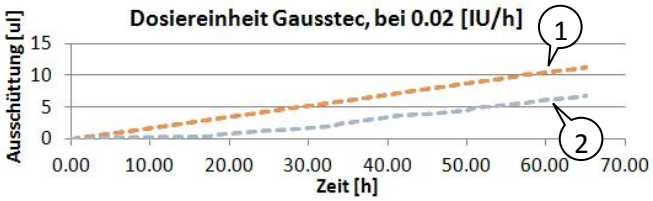

Fig 3: Long-term measurement with dosing unit Gausstec, without (1) and with interference (2)

Services in the Gausstec Laboratory

The equipment has already been successfully used to qualify a new ME device family. The modular design allows adaptation to customer-specific measurements at any time.

If in doubt, you can count on the Gausstec laboratory and involve us in your task so that we can quickly find a solution for your application.

Device for testing ME devices

Gausstec has the following equipment for accuracy testing of ME devices:

- Dosing unit with 2.1nl measuring resolution
- Backlight frame for several channels
- Image analysis system for determining the position of objects
- Precision scale for calibration

Your suggestions and questions about flow measurement are important to us! Further information about Gausstec's services can be found on our website.
Just give us a call.

Tel: 032 682 15 65
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Your questions:

Is the equipment suitable for climate experts?

Andreas Reinmann (AR.): As long as they only concern the pump system and, if necessary, the outlet point, this is possible. However, we cannot change the range of the measurement.

What climatic conditions can be created?

AR: Certainly the temperature, humidity, wetness in general, pressure above and below the atmosphere. You could say that practically anything is possible that the sample material can withstand. So at the moment this is only theory, because we haven't used this equipment yet, but everything that can be measured and controlled is controllable. But this is not standard.

What about vibration, accelerations, critical frequencies, etc., could that be implemented?

AR: This is also possible, we would have to make sure that this incubation is not transferred to the measurement.