

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 pompe

Factors influencing the distribution accuracy

At a very small dosage, below 1 µl/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

The investigations have shown that only a few methods are suitable to deliver exact results for measurements over several days and hours. Main problems are 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 fluid path or have an impact on the operative medium.

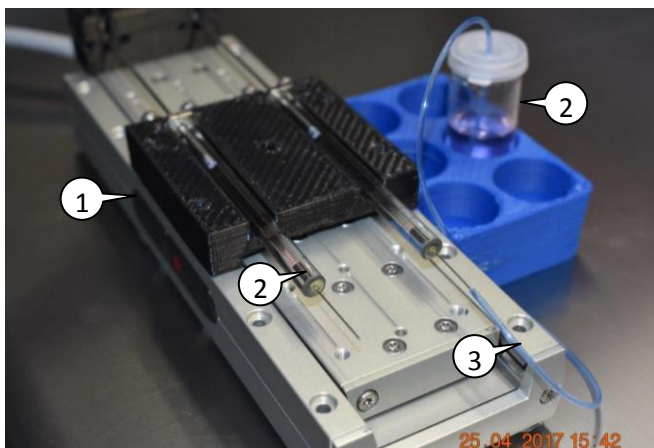


Fig 1: Motor-driven dosing unit (1) with microlitre syringe (2), infusion line (3), collection container (4)

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.

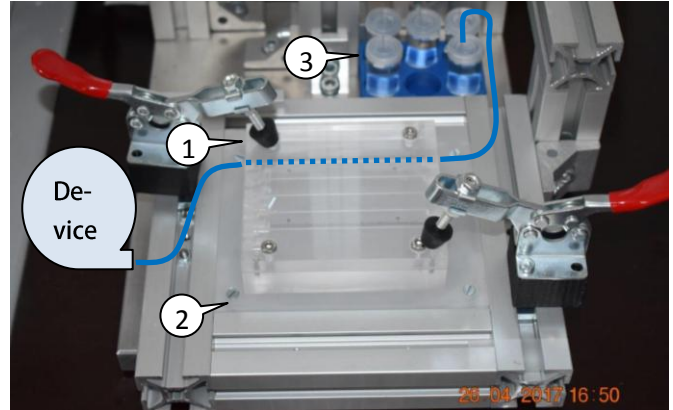


Fig 2: Pilot equipment consisting of multi-channel base plate (1), backlight frame (2), waste container (3)

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.

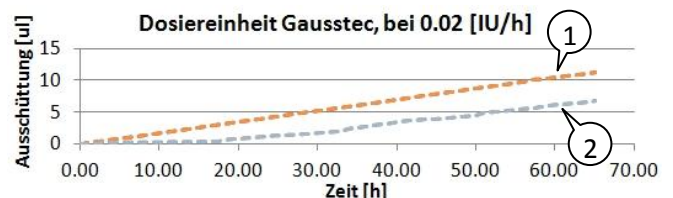


Fig 3: Long-term measurement with dosing unit Gausstec, without (1) and with interference (2)

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.