I.V. Flow regulator - Dosy 2010

Code 8021

INTENDED USE

Regulation of fluid delivery in I.V. administrations, for gravity use only.

MAIN FEATURES

Dosy 2010 works differently from conventional I.V. flow regulators, since the flow rate is controlled through the partial opening of a narrow slot rather than through the change in section and length of a channel.

DELIVERY

As shown on the back, the special design of Dosy 2010 assures that flow rate is little affected by external factors such as fluid viscosity and hydraulic head. This a big advantage compared to conventional I.V. flow regulators.

FEATURES

Housing and dial made of high-heat resistant material

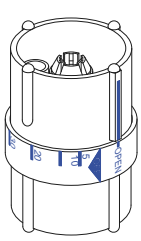
The housing is made of PC (polycarbonate) and the dial is made of POM (polyoxymethylene). These materials allow the maintenance of mechanical characteristics over time.

No gasket

Dosy 2010 has no gasket, therefore any problem with rubberish materials is excluded from the start.

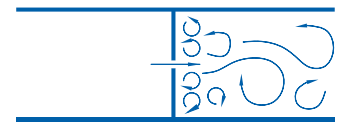
WORKING PRINCIPLE

Conventional I.V. flow regulator
Narrow channel - Laminar flow



According to mathematical model, flow rate is:
- Directly proportional to pressure drop
- Inversely proportional to fluid viscosity

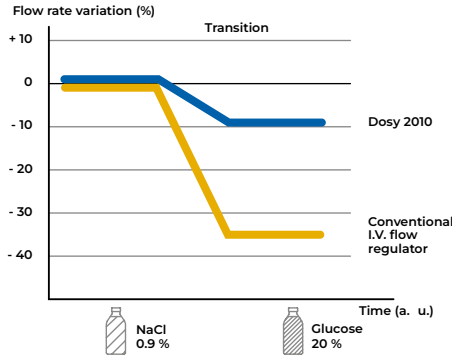
Dosy 2010 - Phoenix
Orifice - Turbulent flow



According to mathematical model, flow rate is:
- Directly proportional to **the square root** of pressure drop
- **Not** dependent on fluid viscosity

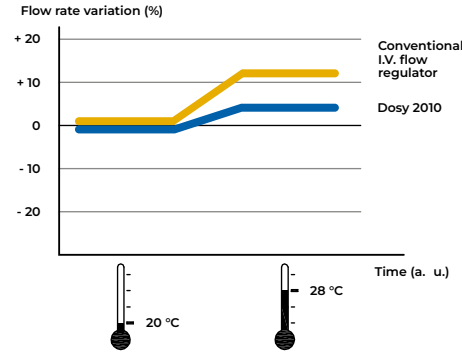
Reduced influence of solution viscosity

The diagram shows the change in flow rate occurring when a NaCl solution is gradually substituted by a 20% Glucose solution, which has a higher viscosity. The consequent reduction of flow rate is much smaller with Dosy 2010 than with a conventional I.V. flow regulator.



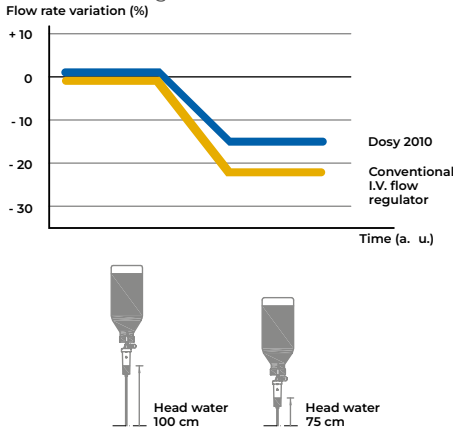
Reduced influence of temperature

The diagram shows the change in flow rate due to a temperature increase of 8°C. The consequent growth of flow rate is smaller with Dosy 2010 than with a conventional I.V. flow regulator.



Reduced influence of hydraulic head

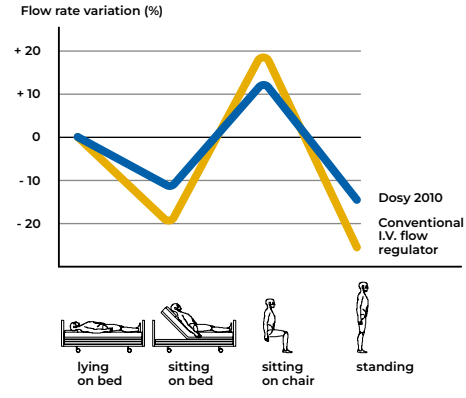
The diagram shows the change in flow rate due to a change of the hydraulic head (that is when the vertical distance between the drip chamber and the catheter is modified). The consequent flow rate variation is smaller with Dosy 2010 than with a conventional I.V. flow regulator.



The setting of Dosy 2010 and of the conventional I.V. flow regulator were not modified during these tests.

Low sensitivity to patient movements

The diagram shows the change in flow rate due the variation of patient's posture. The consequent flow rate variation is smaller with Dosy 2010 than with a conventional I.V. flow regulator.



STANDARD

The flow regulator complies with the following standards.
ISO 8536-13:2024 Infusion equipment for medical use. Part 13: graduated flow regulators for single use with fluid contact. (Note: fixed fluid head height of 100 cm)
ISO 8536-4:2019 Infusion equipment for medical use. Part 4: infusion sets for single use, gravity feed.

BIOLOGICAL EVALUATION

Tested according to ISO 10993-1

STERILIZATION

EtO - temperature up to 60°C

SHELF LIFE

The 5-year shelf life has been verified with a study of natural ageing on samples kept in correct condition in warehouse for five years. The product was found to be compliant after ageing.

DELIVERY RANGE

10-350 ml/h

SCALE ACCURACY

Samples are tested at flow rate of 20, 30, 50, 80, 125 and 200 ml/h and the delivered quantities are recorded after 60 minutes, with a Δh of 100 cm. The accepted deviation from the nominal value at 20 ml/h is ± 25%, between 30 ml/h and 100 ml/h is ± 15% and above 100 ml/h is ± 10%.

CONSTANCY OF DELIVERY

Samples are tested at a flow rate of 50 ml/h and the delivered quantities are recorded each hour over a period of 6 hours. According to ISO 8536-13 the accepted deviation from the mean value is ±10%, measured deviation in laboratory is ±5%.

HEAT STABILITY - NO LEAKAGE

Dosy 2010 is made of heat resistant materials, which guarantee stability after thermal treatment and ageing. There is no evidence of leakage for samples that were treated at 65 °C for 7 days. Sealing tests according to ISO 8536-13:2024 at 0.5 bar.

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