I.V. Flow regulator - Dosy 2007

Version with 12 ribs in the lower part

Code 8005

INTENDED USE

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

MAIN FEATURES

This device ensures constant administration over time. It allows extreme ease and precision in setting the flows.

FEATURES

Body made with high-heat resistant ABS

This type of material allows the maintenance of mechanical characteristics over time.

Gasket made in clear type silicone LSR

Silicone is the best material for the gasket, because it combines exceptional mechanical characteristics, a perfect biocompatibility and the absence of interaction with drugs.

Microchannel patented

The distribution channel is designed with a specific shape that makes delivery much more accurate, especially at low rates.

Easy and smooth regulation

The silicone gasket is characterized by a low coefficient of friction which allows a smooth rotation of the piece.

Low standard deviation, high precision

The accuracy of the processing and the solutions adopted guarantee a high uniformity of delivery.

Ink type

Scales and logo are printed with UV cured ink to achieve a good stability towards both ethyl alcohol and mechanical stress.

Graduated scale

The flow regulator, sometimes referred to as dial-a-flow, is available with single scale, or other scales. Possibility to print the customer's logo. Several colours are available.

STANDARD

Dosy 2007 complies with the following standards.

ISO 8536-13:2016
Infusion equipment for medical use.
Part 13: graduated flow regulators for single use with fluid contact.

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
Gamma - 25 kGy

SHELF LIFE

The 5-year shelf life has been verified by an external laboratory 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

5-300 ml/h

SCALE ACCURACY

Samples are tested at flow rates of 20, 50, 60, 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 ± 20%.

The accepted deviation from the nominal value at 50, 60, 80, 125 and 200 ml/h is ± 15%.

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.
The accepted deviation from the mean value is ± 10%.

HEAT STABILITY - NO LEAKAGE

Dosy 2007 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 8536-13:2016 at 0.5 bar.

Tested in OFF and in OPEN position, with air and water.

TUBING PORT

Connector for Ø 3x4.1 mm tubing. The connector has both an inner and outer element because gluing on two surfaces is the ideal solution for use with PVC-free tubing.

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TÜV SÜD EN ISO 13485
QMS Cert nr. 501007251

I.V. Flow regulator - Dosy 2007

Version with 4 indented grips in the lower part

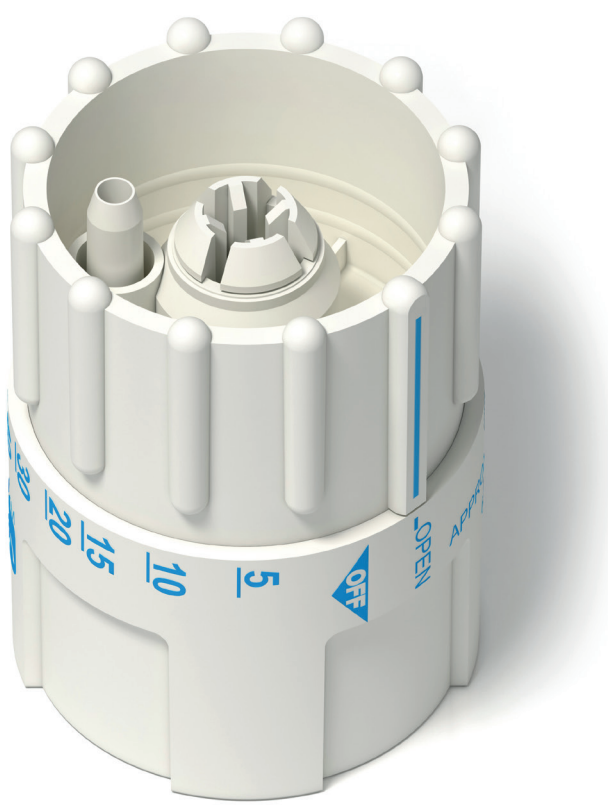
Code 8006

INTENDED USE

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

MAIN FEATURES

This device ensures constant administration over time. It allows extreme ease and precision in setting the flows.



FEATURES

Body made with high-heat resistant ABS

This type of material allows the maintenance of mechanical characteristics over time.

Gasket made in clear type silicone LSR

Silicone is the best material for the gasket, because it combines exceptional mechanical characteristics, a perfect biocompatibility and the absence of interaction with drugs.

Microchannel patented

The distribution channel is designed with a specific shape that makes delivery much more accurate, especially at low rates.

Easy and smooth regulation

The silicone gasket is characterized by a low coefficient of friction which allows a smooth rotation of the piece.

Low standard deviation, high precision

The accuracy of the processing and the solutions adopted guarantee a high uniformity of delivery.

Ink type

Scales and logo are printed with UV cured ink to achieve a good stability towards both ethyl alcohol and mechanical stress.

Graduated scale

The flow regulator, sometimes referred to as dial-a-flow, is available with single scale, or other scales. Possibility to print the customer's logo. Several colours are available.

STANDARD
Dosy 2007 complies with the following standards.

ISO 8536-13:2016
Infusion equipment for medical use.
Part 13: graduated flow regulators for single use with fluid contact.

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
Gamma - 25 kGy

SHELF LIFE
The 5-year shelf life has been verified by an external laboratory 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
5-300 ml/h

SCALE ACCURACY
Samples are tested at flow rates of 20, 50, 60, 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 ± 20%.

The accepted deviation from the nominal value at 50, 60, 80, 125 and 200 ml/h is ± 15%.

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.
The accepted deviation from the mean value is ± 10%.

HEAT STABILITY - NO LEAKAGE
Dosy 2007 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 8536-13:2016 at 0.5 bar.

Tested in OFF and in OPEN position, with air and water.

TUBING PORT
Connector for Ø 3x4.1 mm tubing. The connector has both an inner and outer element because gluing on two surfaces is the ideal solution for use with PVC-free tubing.

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I.V. Flow regulator - Dosy 2007

Version with 4 indented grips in the lower part and female tube connector

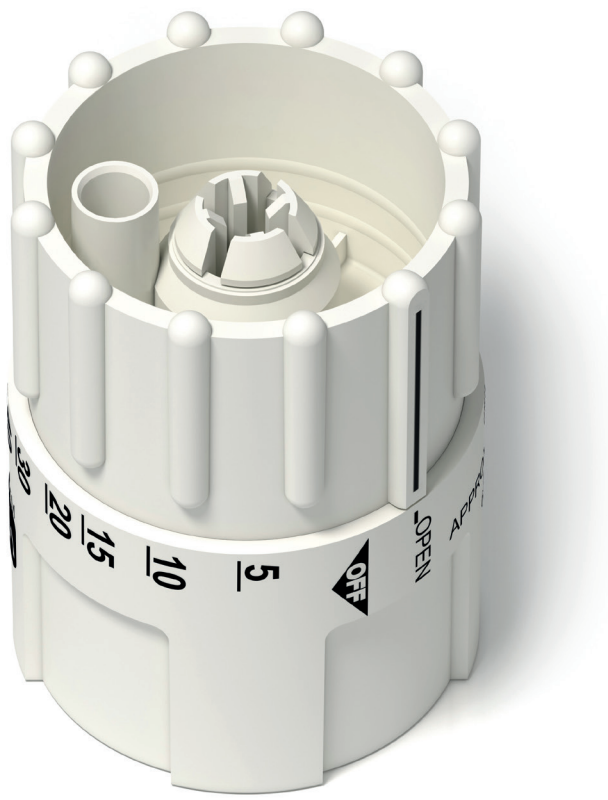
Code 8008

INTENDED USE

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

MAIN FEATURES

This device ensures constant administration over time. It allows extreme ease and precision in setting the flows.



FEATURES

Body made with high-heat resistant ABS

This type of material allows the maintenance of mechanical characteristics over time.

Gasket made in clear type silicone LSR

Silicone is the best material for the gasket, because it combines exceptional mechanical characteristics, a perfect biocompatibility and the absence of interaction with drugs.

Microchannel patented

The distribution channel is designed with a specific shape that makes delivery much more accurate, especially at low rates.

Easy and smooth regulation

The silicone gasket is characterized by a low coefficient of friction which allows a smooth rotation of the piece.

Low standard deviation, high precision

The accuracy of the processing and the solutions adopted guarantee a high uniformity of delivery.

Ink type

Scales and logo are printed with UV cured ink to achieve a good stability towards both ethyl alcohol and mechanical stress.

Graduated scale

The flow regulator, sometimes referred to as dial-a-flow, is available with single scale, or other scales. Possibility to print the customer's logo. Several colours are available.

STANDARD

Dosy 2007 complies with the following standards.

ISO 8536-13:2016
Infusion equipment for medical use.
Part 13: graduated flow regulators for single use with fluid contact.

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
Gamma - 25 kGy

SHELF LIFE

The 5-year shelf life has been verified by an external laboratory 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

5-300 ml/h

SCALE ACCURACY

Samples are tested at flow rates of 20, 50, 60, 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 ± 20%.

The accepted deviation from the nominal value at 50, 60, 80, 125 and 200 ml/h is ± 15%.

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.
The accepted deviation from the mean value is ± 10%.

HEAT STABILITY - NO LEAKAGE

Dosy 2007 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 8536-13:2016 at 0.5 bar.

Tested in OFF and in OPEN position, with air and water.

TUBING PORT

Female connector suitable for assembling with tubing.
Inner Ø (ID) 2.74 mm (0.108”)
Outer Ø (OD) 3.86 mm (0.152”)

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I.V. Flow regulator - Dosy 2007

Dedicated version for pediatric use
Delivery range 5-120 ml/h

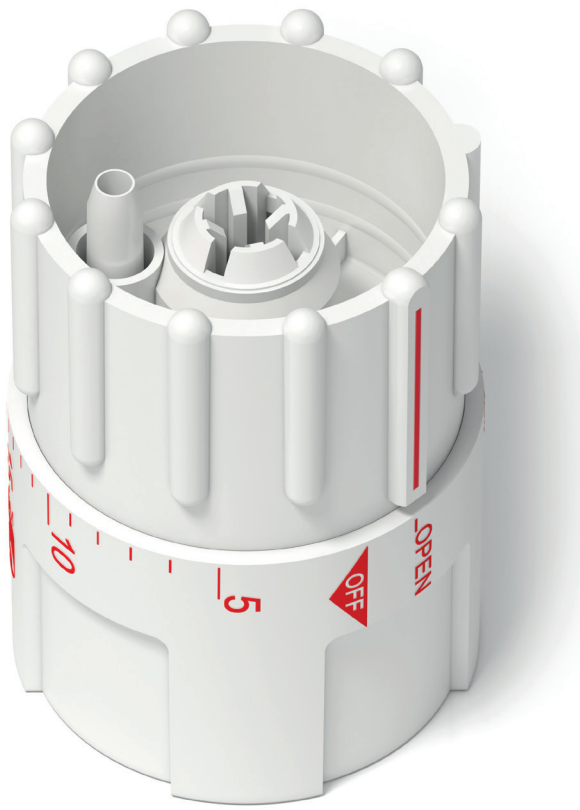
Code 8012

INTENDED USE

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

MAIN FEATURES

This device ensures constant administration over time. It allows extreme ease and precision in setting the flows.



FEATURES

Body made with high-heat resistant ABS

This type of material allows the maintenance of mechanical characteristics over time.

Gasket made in clear type silicone LSR

Silicone is the best material for the gasket, because it combines exceptional mechanical characteristics, a perfect biocompatibility and the absence of interaction with drugs.

Microchannel patented

The distribution channel is designed with a specific shape that makes delivery much more accurate, especially at low rates.

Easy and smooth regulation

The silicone gasket is characterized by a low coefficient of friction which allows a smooth rotation of the piece.

Low standard deviation, high precision

The accuracy of the processing and the solutions adopted guarantee a high uniformity of delivery.

Ink type

Scales and logo are printed with UV cured ink to achieve a good stability towards both ethyl alcohol and mechanical stress.

Graduated scale

The flow regulator, sometimes referred to as dial-a-flow, is available with single scale, or other scales. Possibility to print the customer's logo. Several colours are available.

STANDARD

Dosy 2007 complies with the following standards.

ISO 8536-13:2016
Infusion equipment for medical use.
Part 13: graduated flow regulators for single use with fluid contact.

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
Gamma - 25 kGy

SHELF LIFE

The 5-year shelf life has been verified by an external laboratory 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

5-120 ml/h

SCALE ACCURACY

Samples are tested at flow rates of 10, 20, 30, 50, 80, and 120 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 10 ml/h is ± 35%.

The accepted deviation from the nominal value at 20 ml/h is ± 20%.

The accepted deviation from the nominal value at 30, 50, 80 and 120 ml/h is ± 15%.

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.
The accepted deviation from the mean value is ± 10%.

HEAT STABILITY - NO LEAKAGE

Dosy 2007 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 8536-13:2016 at 0.5 bar.

Tested in OFF and in OPEN position, with air and water.

TUBING PORT

Connector for Ø 3x4.1 mm tubing. The connector has both an inner and outer element because gluing on two surfaces is the ideal solution for use with PVC-free tubing.

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TÜV SÜD EN ISO 13485
QMS Cert nr. 501007251

I.V. Flow Regulator Dosy 2007 with Free Flow Protection

INTENDED USE

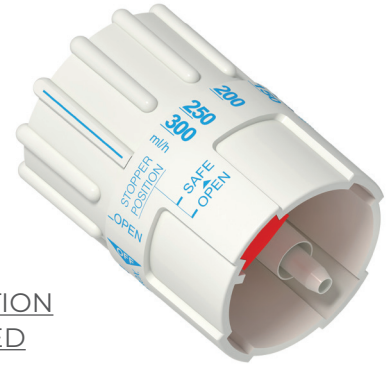
Regulation of fluid delivery in I.V. administrations, for gravity use only, with Free Flow Protection. For the general features of Dosy 2007 see information about Code 8006.

PURPOSE

Hospital operators are aware that an I.V. Flow Regulator in OPEN position is dangerous because it delivers a huge amount of fluid (Free Flow) and are trained to use this position only for the priming of the infusion line. However, some patients, such as elderly with senile dementia or children, tend to manipulate the regulators and are in danger of setting them in OPEN position, without knowing the risk. Phoenix has developed a flow regulator with Free Flow Protection in order to avoid the risk of free flow. This Protection is activated by means of a red stopper.

INITIAL POSITION

According to ISO 8536-4, par. 6.10 a flow regulator (in OPEN position) “shall deliver not less than 1000 ml of a sodium cloride solution in 10 minutes”.



PROTECTION ACTIVATED

When the red stopper is pushed inside, the dial is still free to rotate but it can no longer reach the OPEN position.

Code 8010
Pediatric

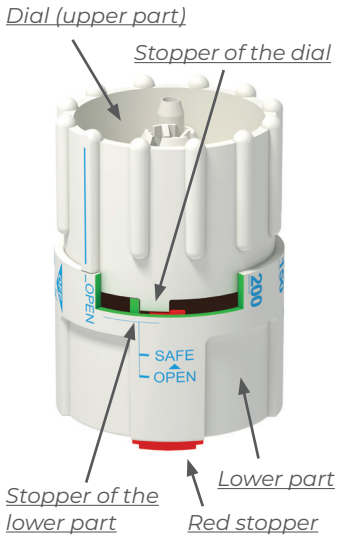
Dedicated version for pediatric use.
Delivery range: 5-120 ml/h

Code 8011

Delivery range: 5-300 ml/h

The steps for Free Flow Protection

INITIAL CONDITION



Note: in this condition the stopper of the dial is on the top of the red stopper and blocks its movements

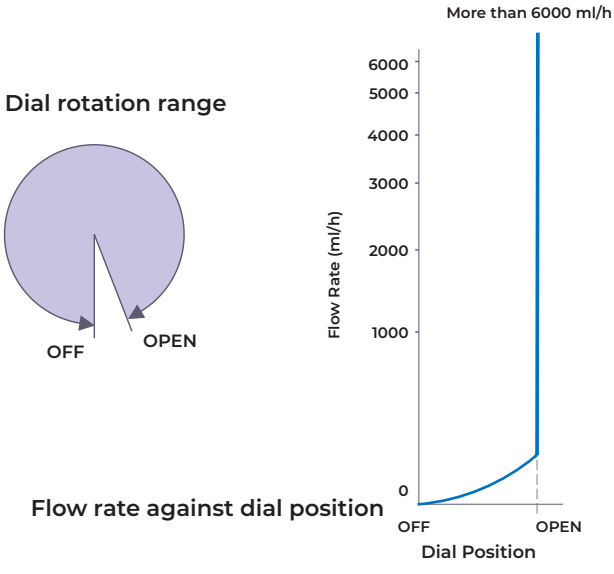
Rotation to OFF position

PROTECTION ACTIVATED

The red stopper is pushed inside to activate the Free Flow Protection

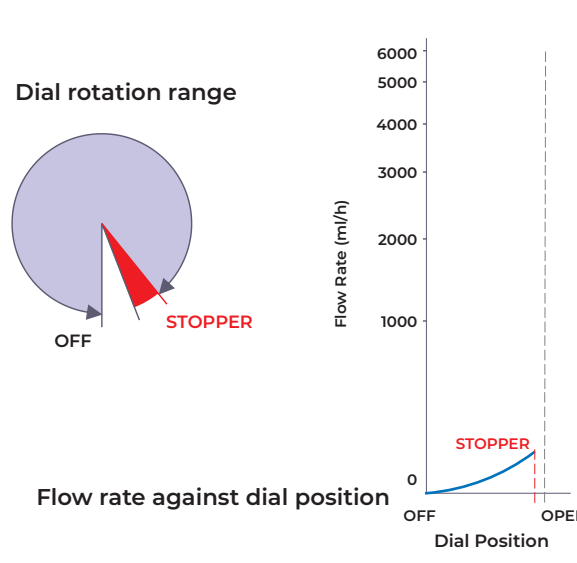
The return to OPEN position is no longer possible

Before activation of the Free Flow Protection



Flow rate against dial position

After activation of the Free Flow Protection



Flow rate against dial position

Reversible or Irreversible protection available on request.

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EN ISO 13485
QMS Cert nr. 501007251

I.V. Flow regulator - Dosy 2010

Code 8021

INTENDED USE

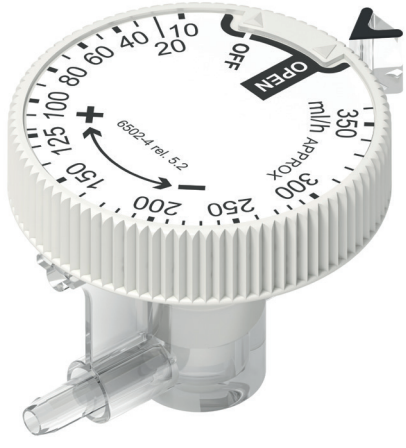
Regulation of fluid delivery in I.V. administrations, for gravity use only.

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

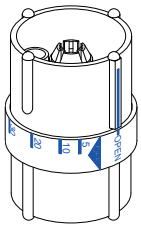
The housing is made of PC (polycarbonate) and the dial is made of POM (polyoxymethylene). These materials allow the maintenance of mechanical characteristics over time.

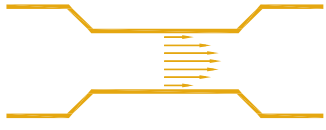
No gasket

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

WORKING PRINCIPLE

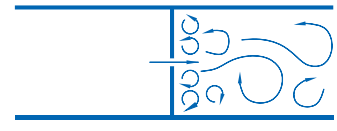
Conventional I.V. flow regulator
Narrow channel - Laminar flow





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

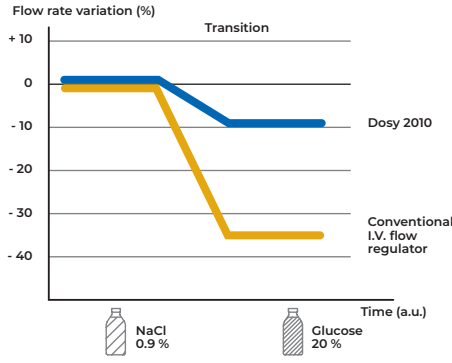
Dosy 2010 - Phoenix
Orifice - Turbulent flow



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

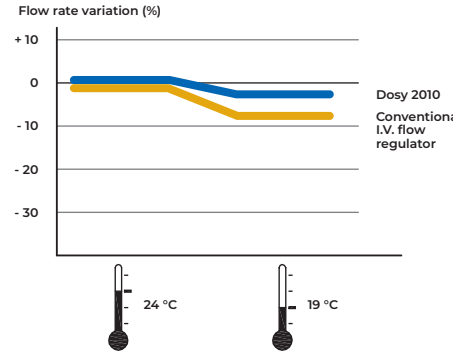
Reduced influence of solution viscosity

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.



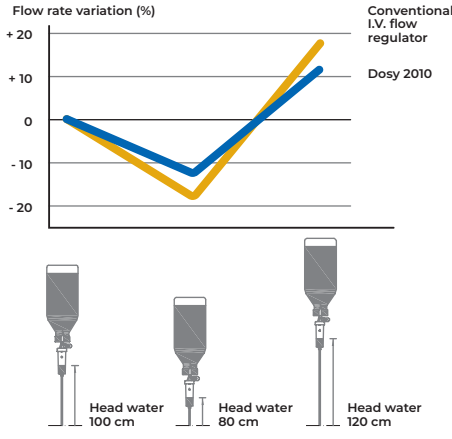
Reduced influence of temperature

The diagram shows the change in flow rate due to a temperature decrease of 5°C. The consequent reduction of flow rate is smaller with Dosy 2010 than with a conventional I.V. flow regulator.



Reduced influence of hydraulic head

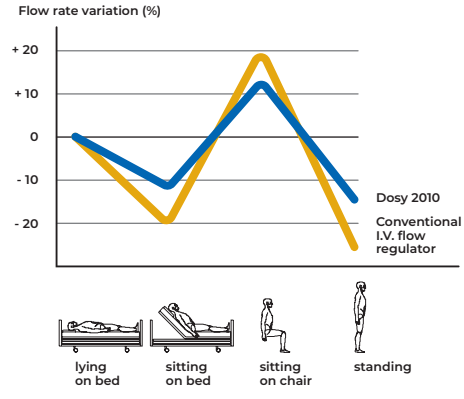
The diagram shows the change in flow rate due to a change of the hydraulic head (that is when the vertical distance between the drip chamber and the catheter is modified). The consequent flow rate variation is smaller with Dosy 2010 than with a conventional I.V. flow regulator.



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 8536-13:2016
Infusion equipment for medical use.
Part 13: graduated flow regulators for single use with fluid contact.

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
Gamma - 25 kGy

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 ± 35%, at 30 ml/h is ± 25%. The accepted deviation from the nominal value at 50, 80, 125 and 200 ml/h is ± 15%.

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 8536-13:2016 at 0.5 bar.

Phoenix R+D

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TÜV SÜD EN ISO 13485
QMS Cert nr. 501007251

Enteral Feed regulator Dosy 2015

Code 8009

Until now the administration of enteral formulas was managed by infusion pumps or by roller clamps in the case of gravity feed. The use of a conventional flow regulator is not possible, as the substances used tend to immediately obstruct the narrow regulation channel.

However, the problem of blockages also plagues roller clamps, which frequently require the intervention of an operator to unblock the flow.

Phoenix has taken up the challenge of creating a channel that can slow the flow of these substances without risking obstruction and has developed the world's first regulator for enteral solutions.

This channel is inspired by the non-return valve patented by Tesla in 1920 and is itself patented, as the principle of operation is different. The important thing is that this approach makes it possible to maintain generous passage sections for the fluid, thus avoiding the risk of occlusions.
Thanks to this device, it is possible to manage nutritional therapies without worries, both in a hospital environment and at home, thanks to its ease of use and reliability.

INTENDED USE

Regulation of fluid delivery in enteral administrations, for gravity use only.
- Gastric nutrition (NSG and PEG).
- Use with approved polymeric standard formulas only.
- Hospital and home care therapies.

FEATURES

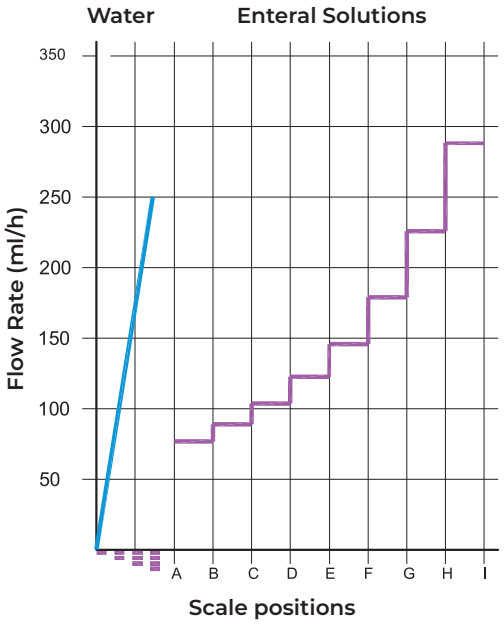
For general features of Dosy 2015 see information about Dosy 2007 Code 8006.

Distribution channel patented

The distribution channel is devided in two parts: one dedicated to the enteral formulas for nutrition and the other one to water for hydration.

Graduated scale

The part of the scale dedicated to the administration of nutritional solutions is marked with a letter for the 9 adjustment points and the part dedicated to hydration with some lines.

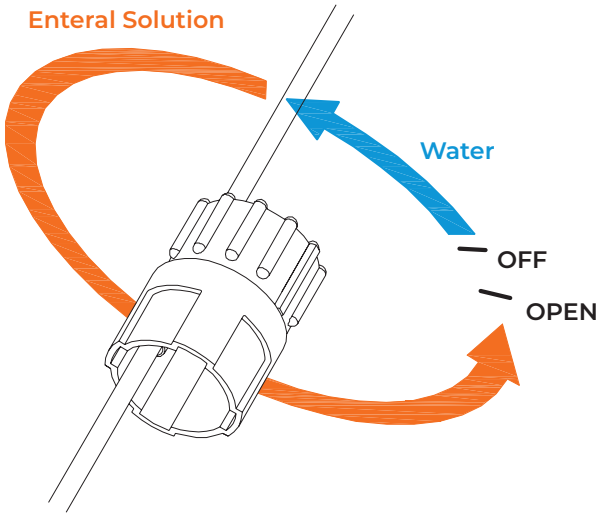


Delivery example

The graphs show the delivery of a device with an enteral solution and with water.

Example

Scheme of device suitable for the administration of enteral solution and hydration.



Further information

Contact Phoenix for further information on this matter.

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