Myfuser
SILICONE
ELASTOMERIC
PUMP
basic information
MYFUSER is an elastomeric, disposable infusion pump for administration of various drug solutions without the need of batteries or power supply. In fact an internal balloon, in medical grade silicone material, is able to contain the solution and, thanks to its own elasticity, to push it through a filtering system into the infusion line down to the patient. The infusion rate is controlled by a flow restrictor capillary positioned inside the distal connector. The quantity of milliliters delivered over a time unit (flow rate $\phi$) depends on the following variables:

$$\phi = \frac{\Delta P \times r^4 \times K (T^0)}{\eta \times \lambda}$$

(short form)

**MAIN DRIVERS (VARIABLES):**

**TEMPERATURE**  
1°C variation causes up to 2% of flow variation  
(directly proportional)

**PRESSURE**  
10 cm of H$_2$O variation causes up to a 3% di of flow variation  
(directly proportional)

**VIScosity**  
Myfuser is calibrated with NaCl 0.9% (for deferoxamine, a high viscosity drug, special models are available)  
(indirectly proportional variation)

$\Rightarrow$ filling the pump with high concentration solutions (like hypertonic dextrose) will decrease the flow rate significantly.
why Myfuser?

1. EFFICIENCY   2. SAFETY   3. COMFORT   4. PRACTICALITY

1. efficiency:

IT ALLOWS CORRECT THERAPY IN TERMS OF DURATION AND FLOW RATE

Myfuser flow restrictor capillary is obtained from high quality GLASS of German production. Our technical personnel is engaged in constant control of each single flow restrictor before being assembled in Myfuser. The choice of a glass capillary is justified by the mechanical properties of this material, particularly suitable for a precise and high quality manufacturing process, even at minimal dimensions, and allowing minimal variations in presence of temperature variations (as an example, hard PVC modifies its dimensions 27 times more than borosilicate glass at the same temperature variation).

apply and maintain the distal connector in contact with the patient’s skin.
1. efficiency:

Simulation of dimensional variation by temperature increase.

The increased diameter of the capillary could cause a significant flow variation (see the 4th Hagen Poiseuille law).

High quality medical grade silicone, manufactured in the USA, is used to produce the elastomeric balloon. Every single balloon is controlled for push pressure before it is assembled. Small variations of the expected pressure values will be absorbed by the capillary length’s adjustment. Push pressure variations during infusion are controlled thanks to the presence of a mobile piston sliding along the fix rod, ensuring a “symmetrical” and uniform filling and deflation of the balloon.

These features and the quality controls minimize the effects of pressure modification on the flow rate, thus ensuring constant pressure and, consequently, the best conditions for a correct implementation of the therapy (see p1 variable in the Hagen Poiseuille law).

It is recommended to keep the balloon and distal connector always at the same level.
2. safety:

TO PREVENT POSSIBLE DANGEROUS EVENTS FOR PATIENTS AND OPERATORS

→ **Rigid, crush-proof container**, made of high quality material, protects the balloon from direct accidental pressures. Extra-pressures could cause the balloon explosion with consequent potential damages to medical operator or to patient or, alternatively, dangerous increase of the flow rate.

→ Filling port, equipped with a special **anti-reflux valve** and with an internally fitted 200 micron **filter**, which prevents foreign particles, such as plastic or glass fragments originated during drug which reconstitution or collection, from entering into the system.

![Diagram of filling port with anti-reflux valve and filter](image)

→ Double membrane filtering system (**0.02 micron hydrophobic** filter for automatic air expulsion from the system, and **1.2 micron hydrophilic antiparticulate filter**), placed at distal end of tubing to “clean” the solution right before entering the glass capillary and, therefore, the patient. (see product general overview in the central pages)

→ Anti-kinking tube, to prevent **accidental interruption** of the infusion.

→ The specific removable clamp ensures the voluntary and **controlled interruption** of the infusion. This is particularly important during connection of the device to the patient: an open flow could cause dripping of the drug on the patient’s skin or on the operator’s fingers. (see product general overview in the central page).

→ Myfuser is a **completely close** and **pre-assembled system**. This reduces the number of manual operations during preparation and prevents risks of mistakes, breakage and contamination.
2. safety:

BIOCOMPATIBILITY AND DRUG STABILITY

Relative to compatibility and drug stability, Myfuser offers the best guarantees thanks to high quality materials used for the various parts of the pump. In particular it should be considered the medical grade silicone (Dow Corning USA) for its well known biocompatibility and chemical inertia. In addition, Myfuser components are Latex-free and phthalate-free (DEHP).

Myfuser has been successfully tested for:
- cutaneous reaction ISO 10993-10
- cytotoxicity ISO 10993-5
- haemolysis and haemocompatibility ISO 10993-4
- systemic acute toxicity ISO 10993-10
- allergic sensitization ISO 10993-10

Furthermore, Myfuser has been tested for drug compatibility and stability with the most frequently used drugs:

- 5-Fluorouracil
- Cytarabine
- Methotrexate Sodium
- Mitoxantrone Hydrochloride
- Vinblastine sulphate
- Tramadol
- Ketorolac
- Fentanyl
- Morphine
- Bupivacaine
- Ropivacaine
- Ceftazidime
- Desferrioxamine
- Metoclopramide
- Odansetron Hydrochloride
- Ranitidine
- et al.

The experimental reports on the various tests performed in cooperation with the Bari University, Pharmacy – Pharmaceutical Science Department are available on request.

3. comfort:

LIGHT AND EASY TO WEAR

With its ergonomic design and reduced dimensions, Myfuser is a light, resistant and easily portable device.
4. practicality:

EASY TO USE AND HANDLE

- Reduced dimensions, minimal space, easy to store.

- The filling port can be laid down on the working surface for easy filling operations.

- Setting up and priming the device is made simple and fast by a distal vented cap with hydrophobic filter membrane. This membrane allows the complete and automatic expulsion of the air from the device eliminating the need of unscrewing the cap and opening the system.

- Myfuser offers the possibility of a detailed and constant visualization of the infusion progress, by means of a graduated scale magnified by a lens incorporated in the external case (see product general overview in the central pages).

- Easy to fill (presently the lowest force to be applied on the syringe piston).

FORCE TO BE APPLIED (measured by dynamometer)

<table>
<thead>
<tr>
<th>model</th>
<th>volume</th>
<th>force</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>60 ml</td>
<td>4.2 Kg ca.</td>
</tr>
<tr>
<td>M</td>
<td>100 ml</td>
<td>4.3 Kg ca.</td>
</tr>
<tr>
<td>XM</td>
<td>120 ml</td>
<td>4.3 Kg ca.</td>
</tr>
<tr>
<td>L</td>
<td>275 ml</td>
<td>4.5 Kg ca.</td>
</tr>
</tbody>
</table>

7
DOUBLE MEMBRANE DISTAL FILTER
it expels possible air bubbles and filters the liquid before it enters the capillary

antiparticulate membrane: 1.2 micron
air-venting membrane: 0.02 micron

FLOW RESTRICTOR
DISTAL CONNECTOR
flow regulator with high quality internal glass capillary
[element in section]

DISTAL VENTED CAP WITH HYDROPHOBIC MEMBRANE
it facilitates, keeps sure and speeds up the preparation and priming of the device
GRADUATED SCALE
It allows an easy monitoring of the infusion progress by means of an incorporated magnifying lens.

PISTON
the balloon’s guide and support system (mobile piston and fix rod) facilitate the filling and deflation phases, preventing the risk of explosions and ensuring constant pressure throughout the infusion process.

SILICONE BALLOON
it pushes the liquid down the infusion line. It guarantees biocompatibility, chemical inertia and transparency.

RIGID HOUSING
it protects the silicon balloon from accidental external pressure and prevents breakage.

FILLING PORT
supplied with female luer lock connector, anti-reflux valve and 200 micron filter.

REMOVABLE CLAMP
it allows voluntary interruption of the infusion. It can be completely removed, if necessary.

PCA MODULE
it allows additional administration of a bolus to the patient by pressing the button.
where is Myfuser used?

MYFUSER IS USED IN 4 MAIN CLINICAL AREAS FOR HOSPITAL AND HOME CARE TREATMENTS

1. anesthesia

INFUSION OF ANESTHETIC/ANALGESIC DRUGS FOR PAIN TREATMENT:

- Post-operative, acute pain management. It is performed intravenously, epidurally, through brachial plexus or intralesionally (LRA).
- Long term pain management: treatment of chronic pain and palliative therapies. It is normally performed intravenously or subcutaneously.

2. oncology

INFUSION OF CHEMOTHERAPEUTIC DRUGS:

- Cytostatic drug infusion to hospitalized patients and/or under home care treatment through peripheral venous catheters or central venous catheters (Port – CVC).

3. antibiotic and antiviral therapy

INFUSION OF ANTIBIOTICS AND ANTIVIRAL DRUGS USUALLY REQUIRES:

- Short infusions
- High drug doses
- Frequent treatments

Specific Myfuser models guarantee the following high flow rates: 50, 100, 200 and 250 ml/h

4. thalassemia

THALASSEMIC PATIENTS REQUIRE IRON CHELATING TREATMENTS AMONG WHICH THE INFUSION OF DEFEROXAMINE (DESFERAL®-DFO). THIS DRUG HAS A HIGHER VISCOSITY THEREFORE DEDICATED MODELS OF MYFUSER ARE PRODUCED FOR ADMINISTRATION OF DFO IN THALASSEMIC THERAPY:

- F0010S*DFO, 60 ml volume, 1 ml/h flow rate
- F0020S*DFO, 60 ml volume, 2 ml/h flow rate
- F0050S*DFO, 60 ml volume, 5 ml/h flow rate

It is generally applied intravenously or subcutaneously.
Myfuser can be used in the following ways of administration:

1. Peripheral I.V.
2. Central I.V.
3. Intra-arterial
4. Subcutaneous/intramuscular
5. Spinal (subarachnoid)
6. Epidural (peridural - extradural)
7. Intraleosional/through brachial plexus
for the best use of myfuser

Duration of infusion depends on the filling volume and flow rate of the pump used (see table below).

<table>
<thead>
<tr>
<th></th>
<th>FO020S</th>
<th>FO050L</th>
</tr>
</thead>
<tbody>
<tr>
<td>nominal volume</td>
<td>60 ml</td>
<td>275 ml</td>
</tr>
<tr>
<td>flow rate</td>
<td>2.0 ml/h</td>
<td>5.0 ml/h</td>
</tr>
<tr>
<td>duration</td>
<td>30 h</td>
<td>55 h</td>
</tr>
<tr>
<td>filled volume</td>
<td>48 ml</td>
<td>240 ml</td>
</tr>
<tr>
<td>flow rate</td>
<td>2.0 ml/h</td>
<td>5.0 ml/h</td>
</tr>
<tr>
<td>duration</td>
<td>24 h</td>
<td>48 h</td>
</tr>
</tbody>
</table>

Filling Volumes

The flow accuracy is ensured even if the balloon is partially filled. The expected variation is +5-7% in case of filling up to 80-60% of the nominal volume (in case of filling lower than 60% the expected variation is over 10%).

<table>
<thead>
<tr>
<th></th>
<th>nominal volume</th>
<th>max volumes</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>60</td>
<td>65</td>
</tr>
<tr>
<td>M</td>
<td>100</td>
<td>105</td>
</tr>
<tr>
<td>XM</td>
<td>120</td>
<td>130</td>
</tr>
<tr>
<td>L</td>
<td>275</td>
<td>300</td>
</tr>
</tbody>
</table>

Remember to keep Myfuser always at the same level of the distal connector.

1 meter gravitational difference can modify the flow rate up to +/- 50%
Keep the distal connector always in contact with the skin.

![Image showing correct distal connector placement]

The flow restrictor capillary is calibrated at an internal working temperature of 31-32 °C (i.e. skin temperature less ~ 5° for thermal dispersion). The combination of the property of the glass capillary (no dimensional variation upon temperature variation) and the temperature stabilization consequent to the contact with the skin, are the best conditions for a precise flow.

Refrigerated drugs should be brought to room temperature before use. The same applies to Myfuser device, if kept in the refrigerator: this will avoid appearance of water condensation droplets inside the pump and lower flow rate.

→ which Myfuser?

**MYFUSER TO SATISFY ALL NEEDS**

### TYPES

- **CONTINUOUS INFUSION**
- **CONTINUOUS PLUS BOLUS**
- **ONLY BOLUS**

### MODELS

- **Available volumes:** 60 ml, 100 ml, 120 ml e 275 ml
- **Available flow rates:** 0.5, 1, 1.5, 2, 2.5, 4, 5, 8, 10, 13 ml/h
- **Available bolus sizes:** 0.5, 1 e 2 ml
- **Lock-out time:** 8, 15, 30 e 60 minutes

### VOLUMES

- 60 ml
- 100 ml
- 120 ml
- 275 ml
→ wrapping up!

THE SIMULTANEOUS PRESENCE OF THE FOLLOWING SPECIAL FEATURES RENDERS MYFUSER THE IDEAL SOLUTION FOR INFUSION TREATMENTS:

1. **Rigid external housing**: crush-proof and transparent, allows immediate visual inspection of the content, and prevents flow rate variations caused by accidental external pressures.

2. **Incorporated belt clip** (for 60, 100 and 120 ml pumps), rendering the device easily portable to the patient’s comfort.

3. **Medical grade silicone balloon**: entirely latex-free, transparent and chemically inert.

4. **Internal sliding piston**, with supporting rod: it determines a constant flow, thanks to the progressive and uniform deflation of the balloon during infusion. The system allows the infusion also with partial filling volumes.

5. **Glass flow restrictor capillary**: the glass ensures a smooth, clean internal wall and constant dimensions in case of thermal variations.

6. **Anti kinking tubing** of the IV line: made in TOTM-PVC, 100 cm long, it prevents accidental interruption of the flow.

7. **Distal filtering system**: composed of antibacterial and antiparticulate hydrophilic filter 1.2 µm, and hydrophobic filter 0.02 µm for automatic air expulsion. It ensures high safety standards.

8. **Filling port filter**: placed inside the filling port; by means of a 200 µm membrane it prevents the entry into the system of macro drug precipitates, plastic particles or glass fragments originated during preparation of the drugs product.

9. **Filling port**: provided with anti-reflux valve and support base, for easier and more comfortable filling procedure.
10. **Residual volume**: extremely low, less than 3 ml (tube included).

11. **Pre-Assembled and close system**: it reduces the number of manual operation during preparation and prevents the risk of mistakes, breakage and contamination.

12. **Removable Clamp**: maintaining the anti-kinking properties of the tubing it allows the voluntary interruption of the flow to easily and safely connect the device to the patient, avoiding dripping of the drug, and to control the initial phase of infusion.

13. **Volume, flow rate, and batch number**: are clearly indicated on each single package (pouch), and also on the device housing.

14. Infusion progress monitoring system: composed of a **graduated scale**\* with values expressed in ml, and specific magnifying lens (for 60, 100 ml and 120 ml pumps) incorporated in the device’s housing.
   \*Purely indicative measuring tool

15. **Product range**: it provides a wide choice of options among volumes, flow rates and PCA applications.

16. **Flow rate indication in ml/hour**: printed on the device’s housing as well as on the distal connector for a final verification while connecting the system to the patient.

17. **Distal vented cap with hydrophobic membrane**: it makes the preparation and the priming of the device easy, rapid and safe.

18. **Flow rate accuracy**: +/- 10% in all models.

19. **Color code**: a colored band on the distal connector indicates the specific flow rate color code and the respective value in ml/h.

20. **Anti UV filter**: a special filter inside the polycarbonate housing provides protection from UV rays (up to 380 nanometers) to photosensitive drugs, though preserving the absolute transparency of the container.
The image of Myfuser on the cover is in real scale.