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Компания «Бакстер» для документов №2

М.П. _____

_____ 2021г.

ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ МЕДИЦИНСКОГО ИЗДЕЛИЯ

«Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor в вариантах исполнения»

производства компании
«Бакстер Хелскеа СА» (Baxter Healthcare SA), Швейцария

ЭЛЕКТРОННАЯ КОПИЯ ОФОРМЛЕНА ЦЕНТРОМ ИСПЫТАНИЙ И РЕГИСТРАЦИИ МЕДИЦИНСКИХ ИЗДЕЛИЙ

1. **Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor с болюсом, 5-7-12 мл/ч**

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

1.1.Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor с болюсом, 5-7-12 мл/ч;
Индивидуальная упаковка, лицевой сторона, с оригинальной маркировкой

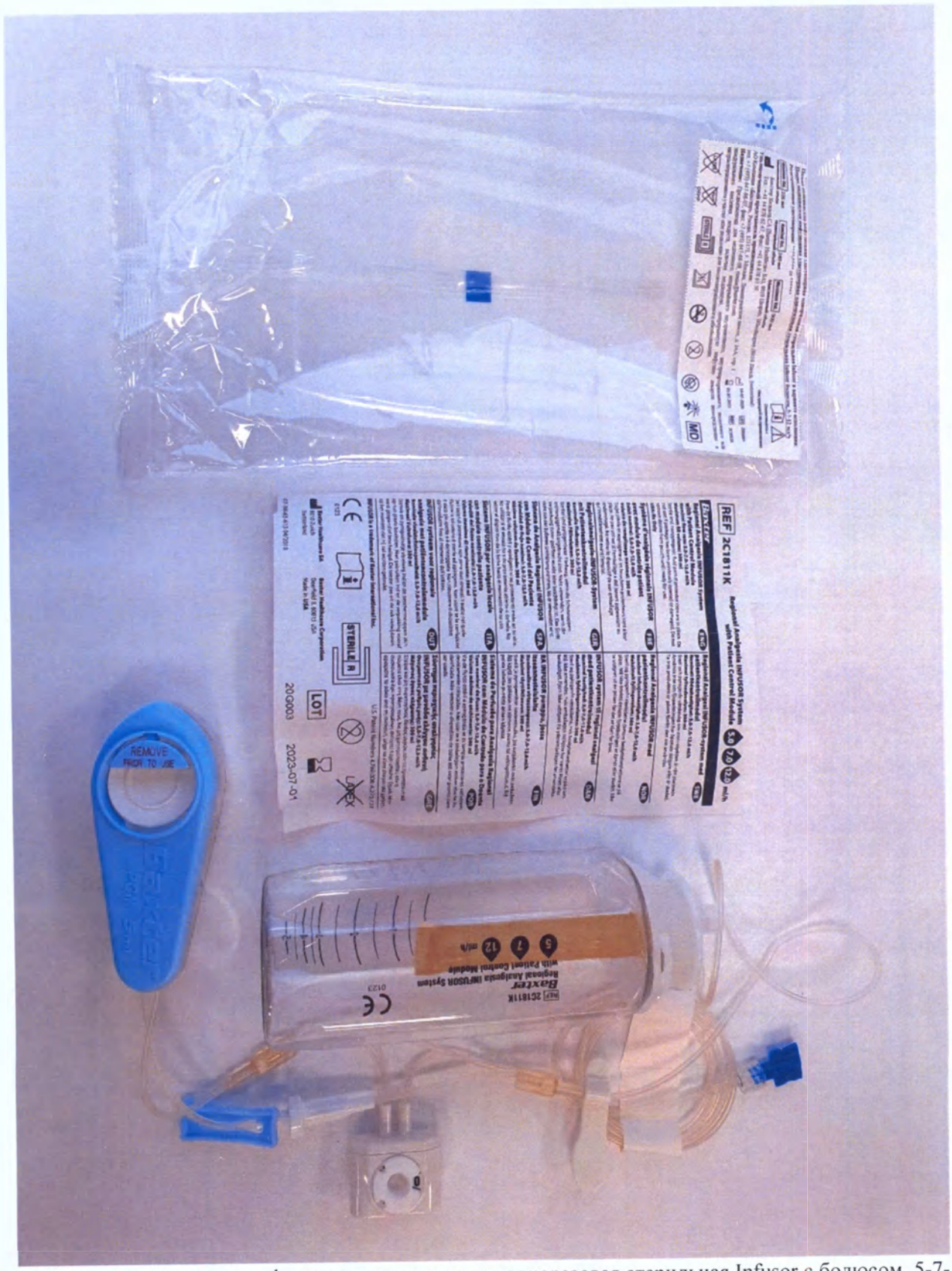
ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

1.2. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor с болюсом, 5-7-12 мл/ч;
Индивидуальная упаковка, оборотная сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

1.3. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor с болюсом, 5-7-12 мл/ч;
Индивидуальная упаковка, лицевая сторона, с нанесенной маркировкой на русском языке

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



1.4. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor с болюсом, 5-7-12 мл/ч;

Комплект поставки

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

1.5. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor с болюсом, 5-7-12 мл/ч;
Помпа, лицевая сторона

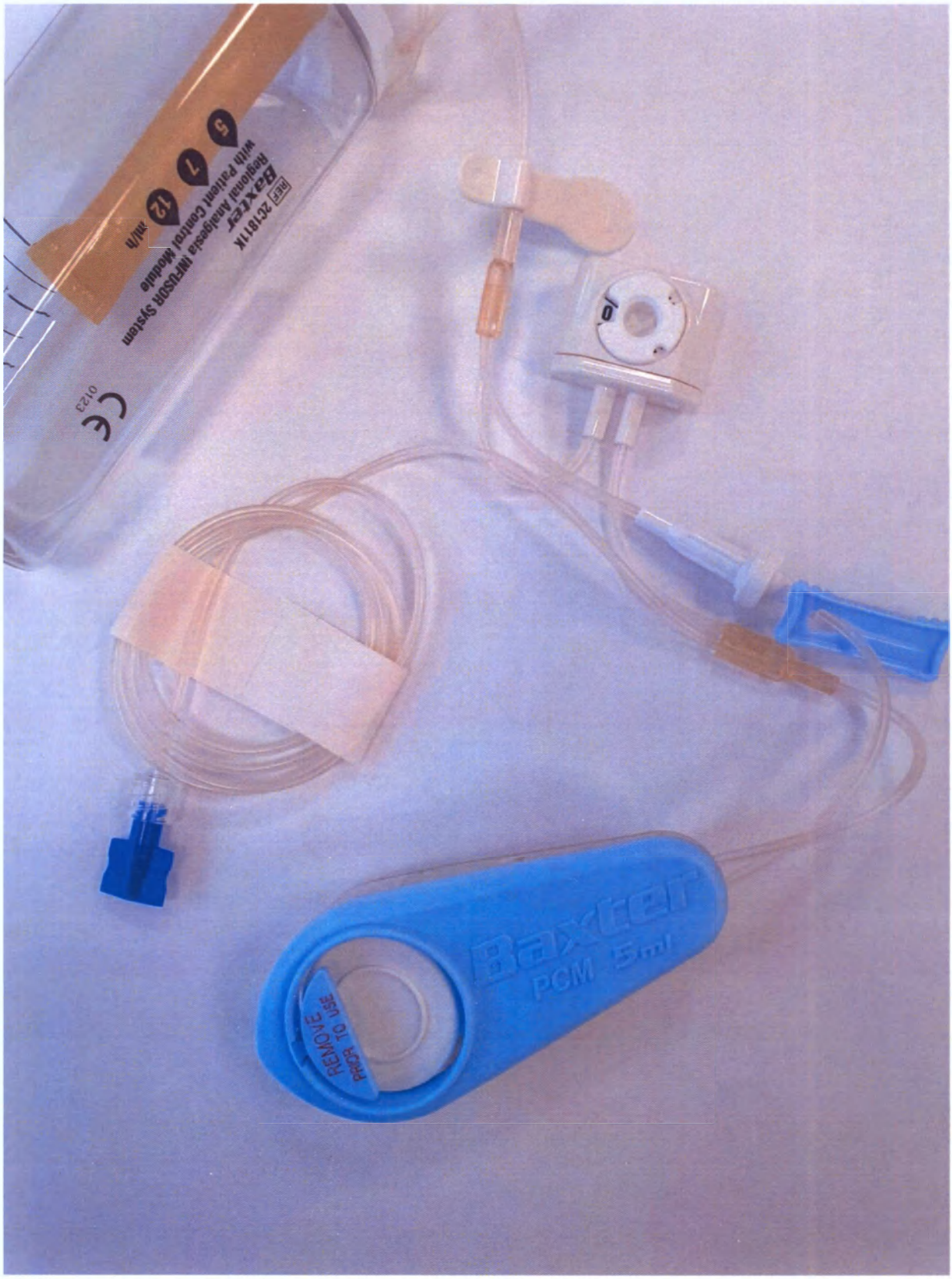
ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

1.6. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor с болюсом, 5-7-12 мл/ч;
Помпа, сторона со шкалой инфузии

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

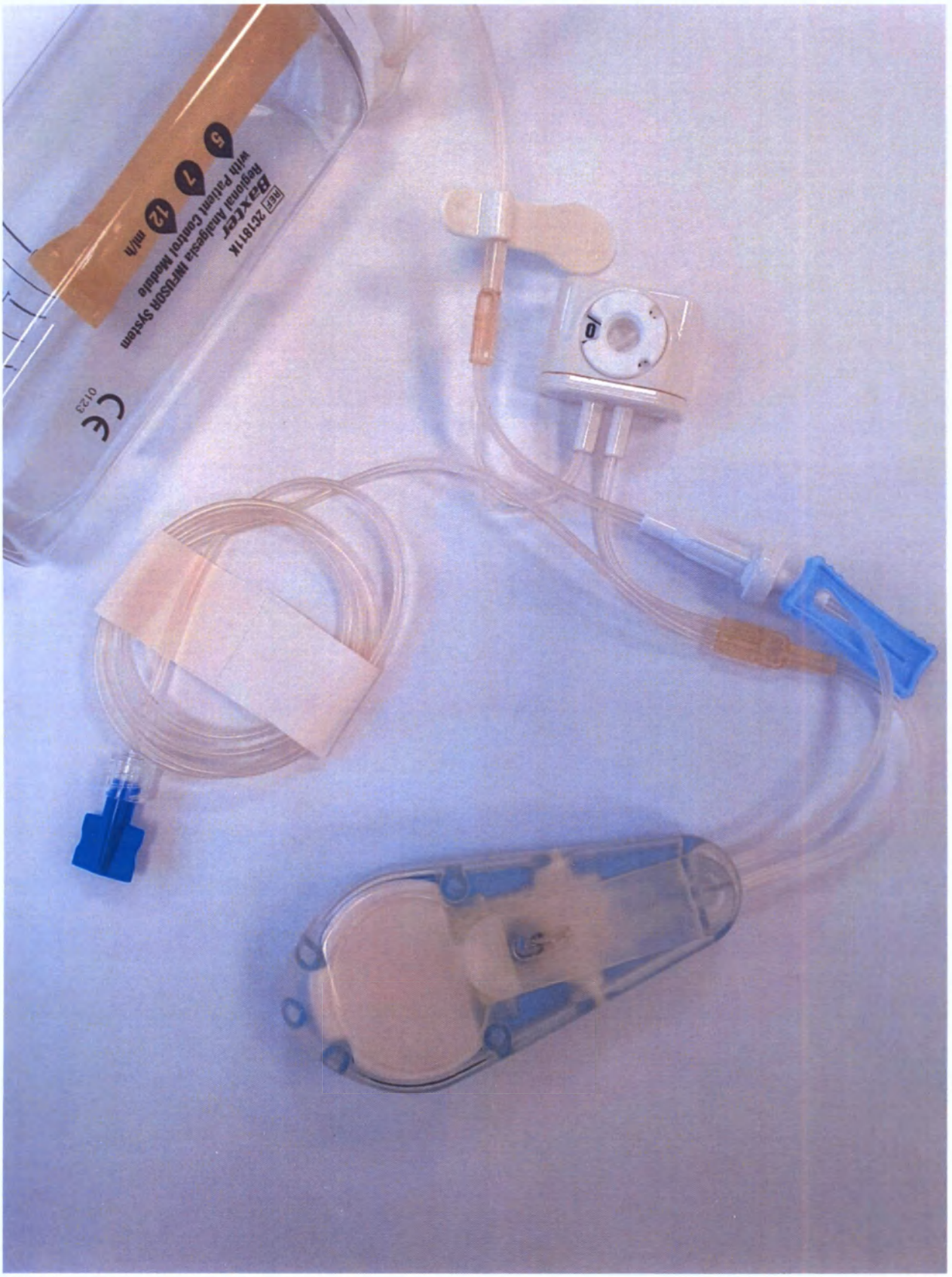
1.7. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor с болюсом, 5-7-12 мл/ч;
Помпа, вид сверху

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



1.8. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor с болюсом, 5-7-12 мл/ч;
Модуль болюса, лицевая сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



1.9. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor с болюсом, 5-7-12 мл/ч;
Модуль болюса, обратная сторона

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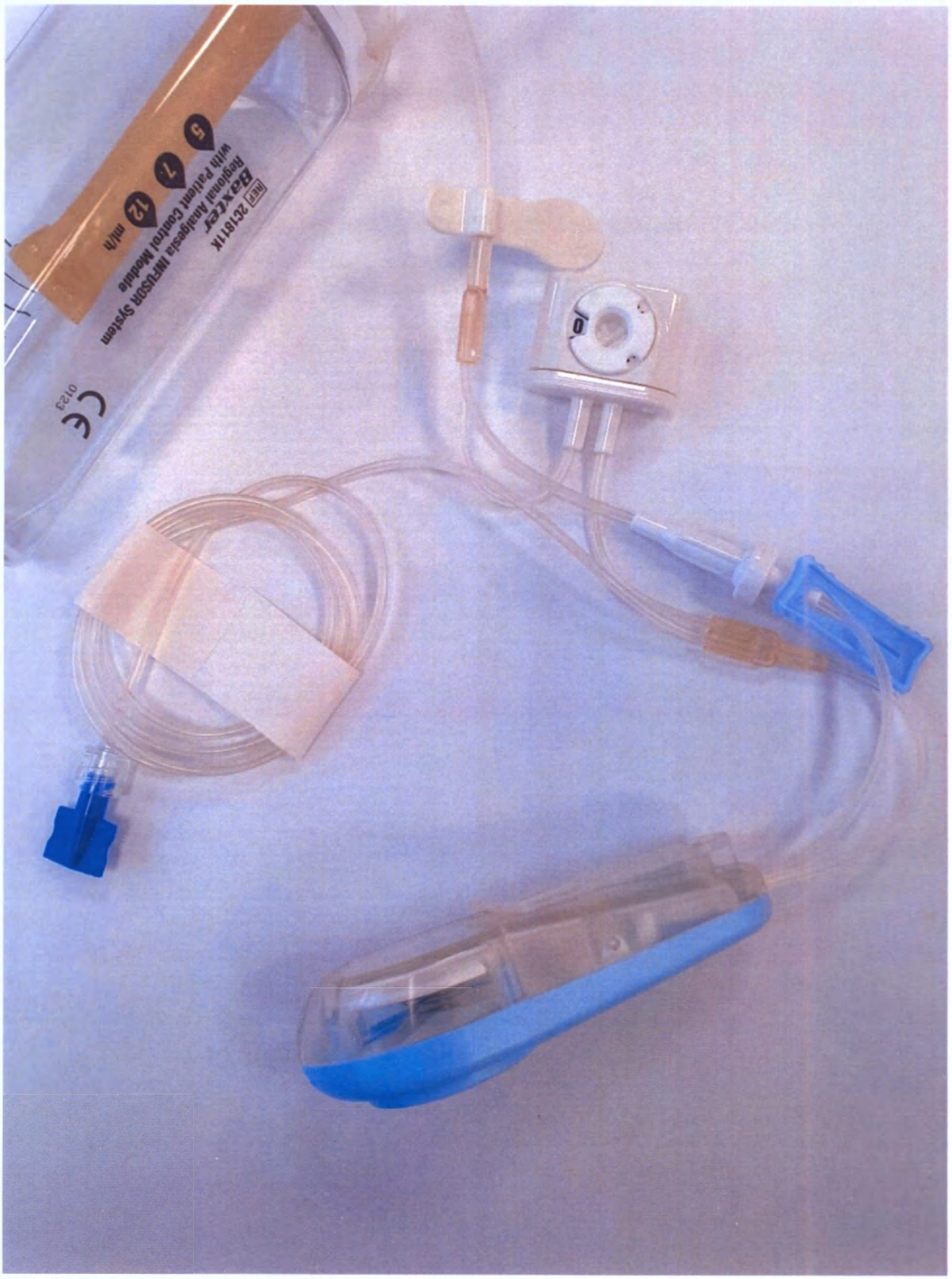

1.10. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor с болюсом, 5-7-12 мл/ч;
Модуль болюса, вид сбоку

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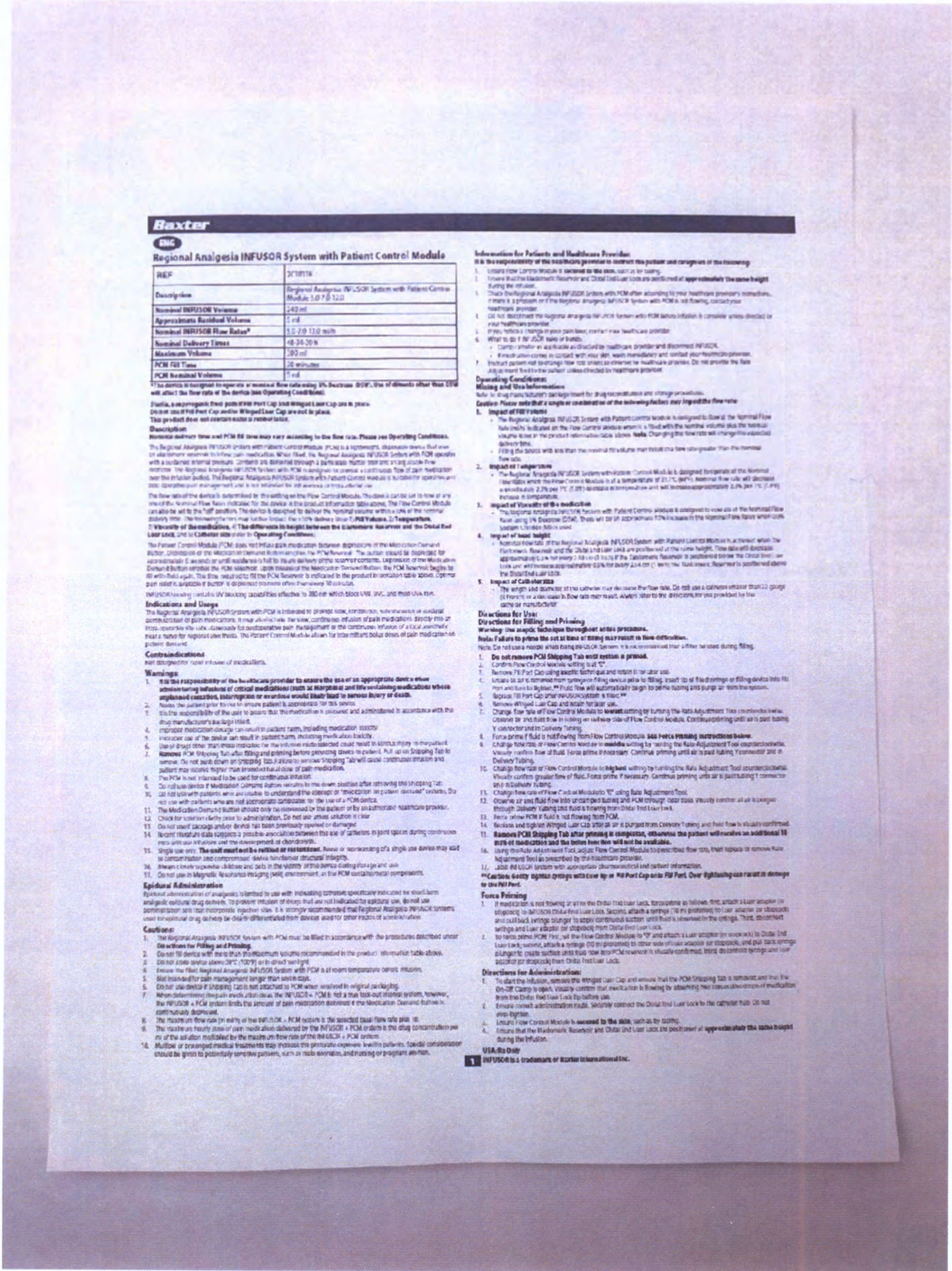


Baxter

ENG

Regional Analgesia INFUSOR System with Patient Control Module

REF	2C5811K
Description	Regional Analgesia INFUSOR System with Patient Control Module 5-7-12-0
Nominal INFUSOR Volume	240 ml
Approximate Residual Volume	5 ml
Nominal INFUSOR Flow Rates*	5-7-12-0 ml/h
Nominal Delivery Times	48-34-20 h
Maximum Volume	300 ml
PCM Fill Time	20 minutes
PCM Nominal Volume	5 ml

*The device is designed to operate at nominal flow rate using 0% Dextrose. D5W, the of diluents other than D5W will affect the flow rate of the device (see Operating Conditions).

Sterile, nonpyrogenic fluid path if the Port Cap and Winged Luer Cap are in place.
Do not use if Fill Port Cap and/or Winged Luer Cap are not in place.
This product does not contain natural rubber latex.

Description

Nominal delivery time and PCM fill time may vary according to the flow rate. Please see Operating Conditions.

The Regional Analgesia INFUSOR system with Patient Control Module (PCM) is a lightweight, disposable device that uses an elastomeric reservoir to infuse pain medication. When filled, the Regional Analgesia INFUSOR System with PCM operates with a constant internal pressure. Catheter are delivered through a sterile male Rotator Slide luer and a single patient flow restrictor. The Regional Analgesia INFUSOR System with PCM is designed to provide a continuous flow of pain medication over the infusion period. The Regional Analgesia INFUSOR System with Patient Control Module is suitable for operation and dose. Operation pain management and is not intended for self-awareness or titrate effector use.

The flow rate of the device is determined by the setting on the Flow Control Module. The device can be set to flow at one of the three Nominal Flow Rates indicated for the device in the product information table above. The Flow Control Module can also be set to the "off" position. The device is designed to deliver the nominal volume within ±10% of the nominal delivery time. The following factors may further impact the ±10% delivery time: 1. **Fill Volume**, 2. **Temperature**, 3. **Viscosity of the medication**, 4. **The difference in height between the Elastomeric Reservoir and the Distal End Luer Lock**, and 5. **Catheter size** refer to **Operating Conditions**.

The Patient Control Module (PCM) does not infuse pain medication between depressions of the Medication Demand Button. Depression of the Medication Demand Button activates the PCM Reservoir. The button should be depressed for approximately 5 seconds or until resistance is felt to the dose delivery of the reservoir contents. Depression of the Medication Demand Button activates the PCM bleed-off. upon release of the Medication Demand Button, the PCM Reservoir begins to fill with fluid again. The time required to fill the PCM Reservoir is indicated in the product information table above. Optimal pain relief is available if button is depressed no more often than every 10 minutes.

INFUSOR tubing contains UV blocking properties effective to 380 nm which blocks UVB, UVC, and most UVA rays.

Indications and Usage

The Regional Analgesia INFUSOR System with PCM is indicated to provide local, continuous, subcutaneous or epidural administration of pain medications. It may also be used for the local, continuous infusion of pain medications directly into or into spaces in the body, commonly for postoperative pain management or the continuous infusion of a local anesthetic to treat a nerve for regional anesthesia. The Patient Control Module allows for bolus delivery of pain medication on patient demand.

Contraindications

Not recommended for nerve infusion of medications.

Warnings

1. **It is the responsibility of the healthcare provider to ensure the use of an appropriate device when administering infusions of critical medications (such as Morphine) and life-sustaining medications whose unplanned cessation, interruption or overdose would likely lead to serious injury or death.**
2. Review the patient prior to use to ensure patient is appropriate for this device.
3. It is the responsibility of the user to assure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.
4. Improper medication dosage can result in patient harm, including medication toxicity.
5. Infusion use of the device can result in patient harm, including medication toxicity.
6. Use of drugs other than those indicated for the infusion route selected could result in serious injury to the patient.
7. **Remove** PCM Shipping Tab after filling and priming before connecting device to patient. Pull up on Shipping Tab to remove. Do not push down on Shipping Tab. Failure to remove Shipping Tab will cause continuous infusion and patient may receive higher than prescribed full dose of pain medication.
8. The PCM is not intended to be used for continuous infusion.
9. Do not use device if Medication Demand Button remains in the down position after removing the Shipping Tab.
10. Do not use with patients who are unable to understand the concept or prescription of patient demand devices. Do not use with patients who are not appropriate candidates for the use of a PCM device.
11. The Medication Demand Button should only be depressed by the patient or by an authorized healthcare provider.
12. Check for solution clarity prior to administration. Do not use unless solution is clear.
13. Do not use if package and/or device has been previously opened or damaged.
14. Recent literature data suggests a possible association between the use of catheters in joint spaces during continuous intra-articular infusions and the development of chondrolysis.
15. Single use only. **The unit must not be refilled or reinserted.** Reuse or reprocessing of a single use device may add to contamination and compromised device performance structural integrity.
16. Always closely supervise children and pets in the vicinity of the device during storage and use.
17. Do not use in Magnetic Resonance Imaging (MRI) environment, as the PCM contains metal components.

Epidural Administration

Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for short-term analgesic epidural drug delivery. To prevent infusion of drugs that are not indicated for epidural use, do not use administration sets that incorporate injection sites. It is strongly recommended that Regional Analgesia INFUSOR systems used for epidural drug delivery be clearly differentiated from devices used for other routes of administration.

Cautions:

1. The Regional Analgesia INFUSOR System with PCM must be filled in accordance with the procedures described under **Directions for Filling and Priming**.
2. Do not fill device with more than maximum volume recommended in the product information table above.
3. Do not store device above 30°C (100°F) or in direct sunlight.
4. Ensure the filled Regional Analgesia INFUSOR System with PCM is at room temperature before infusion.
5. Not intended for pain management longer than seven days.
6. Do not use device if Shipping Tab is not attached to PCM when received in original packaging.
7. When determining the pain medication dose, the INFUSOR + PCM is not a true look-out interval system, however, the INFUSOR + PCM system limits the amount of pain medication delivered in the Medication Demand Button is continuously depressed.
8. The maximum flow rate (in error) of the INFUSOR + PCM system is the selected basal flow rate plus 10.
9. The maximum hourly dose of pain medication delivered by the INFUSOR + PCM system is the drug concentration per cm of the solution multiplied by the maximum flow rate of the INFUSOR + PCM system.
10. Multiple or prolonged medical treatments may increase the protocols exposure to saline pathogens. Special consideration should be given to potentially sensitive patients, such as male neonates, and nursing or pregnant women.

Information for Patients and Healthcare Providers

It is the responsibility of the healthcare provider to instruct the patient and caregiver of the following:

1. Ensure Flow Control Module is **secured to the skin**, such as by taping.
2. Ensure that the Elastomeric Reservoir and Distal End Luer Lock are positioned at **approximately the same height** during the infusion.
3. Check the Regional Analgesia INFUSOR System with PCM after according to your healthcare provider's instructions. If there is a problem or if the Regional Analgesia INFUSOR System with PCM is not flowing, contact your healthcare provider.
4. Do not disconnect the Regional Analgesia INFUSOR System with PCM before infusion is complete unless directed by your healthcare provider.
5. If you notice a change in your pain level, contact your healthcare provider.
6. What to do if INFUSOR leaks or breaks:
   - Clamp catheter as quickly as directed by healthcare provider and disconnect INFUSOR.
   - If medication comes in contact with your skin, wash immediately and contact your healthcare provider.
7. Instruct patient not to change flow rate unless directed by healthcare provider. Do not provide the Rate Adjustment Tool to the patient unless directed by healthcare provider.

Operating Conditions:

Mixing and Use Information

Refer to drug manufacturer's package insert for drug reconstitution and storage procedures.

Caution: Please note that a single or combination of the following factors may impact the flow rate

1. **Impact of Fill Volume**
   - The Regional Analgesia INFUSOR System with Patient Control Module is designed to flow at the Nominal Flow Rate (±10%) indicated on the Flow Control Module when it is filled with the nominal volume plus the nominal volume listed in the product information table above. **Note:** Changing the flow rate will change the expected delivery time.
   - Filling the device with less than the nominal fill volume may result in the flow rate greater than the nominal flow rate.
2. **Impact of Temperature**
   - The Regional Analgesia INFUSOR System with Patient Control Module is designed to operate at the Nominal Flow Rates when the Flow Control Module is at a temperature of 23.7°C (74°F). Nominal flow rate will decrease approximately 2.3% per 1°C (1.8°F) decrease in temperature and will increase approximately 2.3% per 1°C (1.8°F) increase in temperature.
3. **Impact of Viscosity of the medication**
   - The Regional Analgesia INFUSOR System with Patient Control Module is designed to flow at of the Nominal Flow Rates using 0% Dextrose (D5W). There will be an approximate 10% increase in the Nominal Flow Rates when 20% Lipid or Lipid Emulsion is used.
4. **Impact of head height**
   - Nominal flow rate of the Regional Analgesia INFUSOR System with Patient Control Module is at its best when the Elastomeric Reservoir and the Distal End Luer Lock are positioned at the same height. Flow rate will decrease approximately 0.2% for every 1.18 cm (0.5 inch) if the Elastomeric Reservoir is positioned below the Distal End Luer Lock and will increase approximately 0.2% for every 2.54 cm (1 inch) the Reservoir is positioned above the Distal End Luer Lock.
5. **Impact of Catheter size**
   - The length and diameter of the catheter may decrease the flow rate. Do not use a catheter smaller than 22 gauge (0.71mm) or a catheter in flow rate may result. Always refer to the directions for use provided by the catheter manufacturer.

Directions for Use:

Directions for Filling and Priming

Warning: Use aseptic technique throughout entire procedure.

Note: Failure to prime the set at time of filling may result in flow difficulties.

Note: Do not use a needle when filling INFUSOR System. It is recommended that a filter be used during filling.

1. **Do not remove PCM Shipping Tab until system is primed.**
2. Confirm Flow Control Module setting is at "0".
3. Remove Fill Port Cap using aseptic technique and retain for later use.
4. Ensure the set is removed from syringe or filling device prior to filling. Insert tip of filling syringe or filling device into fill Port and fully to Bigbloc.™ Fluid flow will automatically begin to prime tubing and purge air from the system.
5. Replace Fill Port Cap after PCM/SYSTEM® is filled.™
6. Remove Winged Luer Cap and retain for later use.
7. Change flow rate of Flow Control Module to **lowest** setting by turning the Rate Adjustment Tool counterclockwise. Observe air and fluid flow in tubing on outlet side of Flow Control Module. Continue priming until air is past tubing Y connector and in Delivery Tubing.
8. Force prime if fluid is not flowing from Flow Control Module. **See Force Priming Instructions below.**
9. Change flow rate of Flow Control Module to **middle** setting by turning the Rate Adjustment Tool counterclockwise. Visually confirm flow of fluid. Force prime if necessary. Continue priming until air is past tubing Y connector and in Delivery Tubing.
10. Change flow rate of Flow Control Module to **highest** setting by turning the Rate Adjustment Tool counterclockwise. Visually confirm greater flow of fluid. Force prime if necessary. Continue priming until air is past tubing Y connector and in Delivery Tubing.
11. Change flow rate of Flow Control Module to "0" using Rate Adjustment Tool.
12. Observe air and fluid flow into unclamped tubing and PCM through clear tube. Visually confirm all air is purged through Delivery Tubing and fluid is flowing from Distal End Luer Lock.
13. Force prime PCM if fluid is not flowing from PCM.
14. Reclose and tighten Winged Luer Lab after all air is purged from Delivery Tubing and fluid flow is visually confirmed.
15. **Remove PCM Shipping Tab after priming is complete, otherwise the patient will receive an additional 10 cm³ of medication and the bolus function will not be available.**
16. Using the Rate Adjustment Tool, adjust Flow Control Module to prescribed flow rate, then replace or remove Rate Adjustment Tool as prescribed by the healthcare provider.
17. Load INFUSOR System with appropriate pharmaceutical and patient information.

Cautions: Gently tighten syringe with cover tip or Fill Port Cap onto Fill Port. Over tightening can result in damage to the Fill Port.

Force Priming

1. If medication is not flowing at all to the Distal End Luer Lock, force prime as follows: first, attach a Luer adapter (or stopcock) to INFUSOR Distal End Luer Lock. Second, attach a syringe (10 ml preferred) to Luer adapter or stopcock and pull back syringe plunger to apply continuous suction until fluid is observed in the syringe. Third, disconnect syringe and Luer adapter or stopcock from Distal End Luer Lock.
2. To force prime PCM: First, set the Flow Control Module to "0" and attach a Luer adapter (or stopcock) to Distal End Luer Lock; second, attach a syringe (10 ml preferred) to other side of Luer adapter or stopcock, and pull back syringe plunger to create suction until fluid flow into PCM reservoir is visually confirmed. Third, disconnect syringe and Luer adapter or stopcock from Distal End Luer Lock.

Directions for Administration:

1. To start the infusion, remove the Winged Luer Cap and ensure that the PCM Shipping Tab is removed and that the On-Off Clamp is open. Visually confirm that medication is flowing by observing free consecutive drops of medication from the Distal End Luer Lock tip before use.
2. Ensure correct administration route. Securely connect the Distal End Luer Lock to the catheter hub. Do not over-tighten.
3. Ensure Flow Control Module is **secured to the skin**, such as by taping.
4. Ensure that the Elastomeric Reservoir and Distal End Luer Lock are positioned at **approximately the same height** during the infusion.

USA Rx Only

1 INFUSOR is a trademark of Baxter International Inc.

1.11. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor с болюсом, 5-7-12 мл/ч;
Оригинальная инструкция

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

2. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor SV 1-2-3 мл/ч

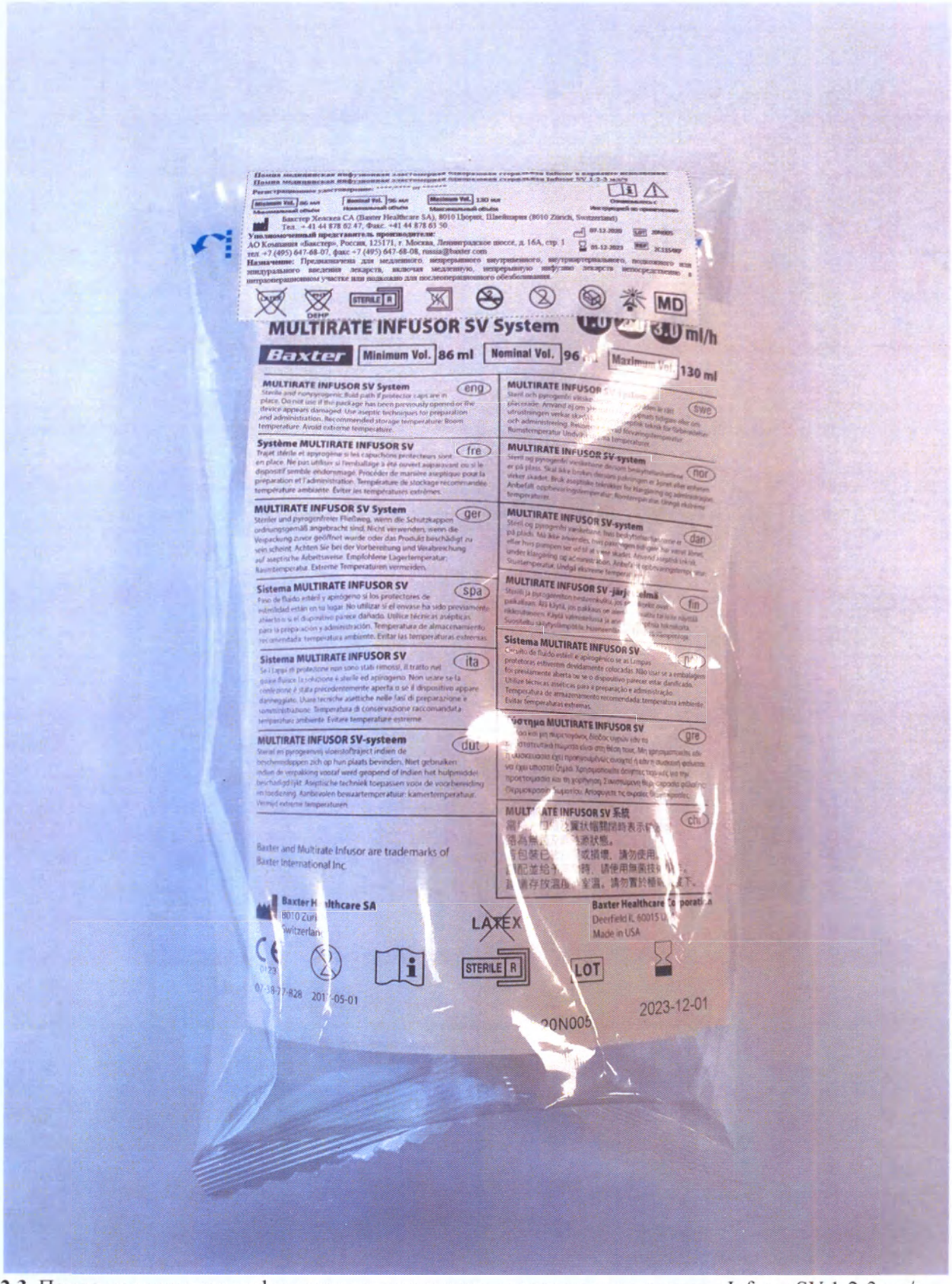
ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

2.1. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor SV 1-2-3 мл/ч; Индивидуальная упаковка, лицевой сторона, с оригинальной маркировкой

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

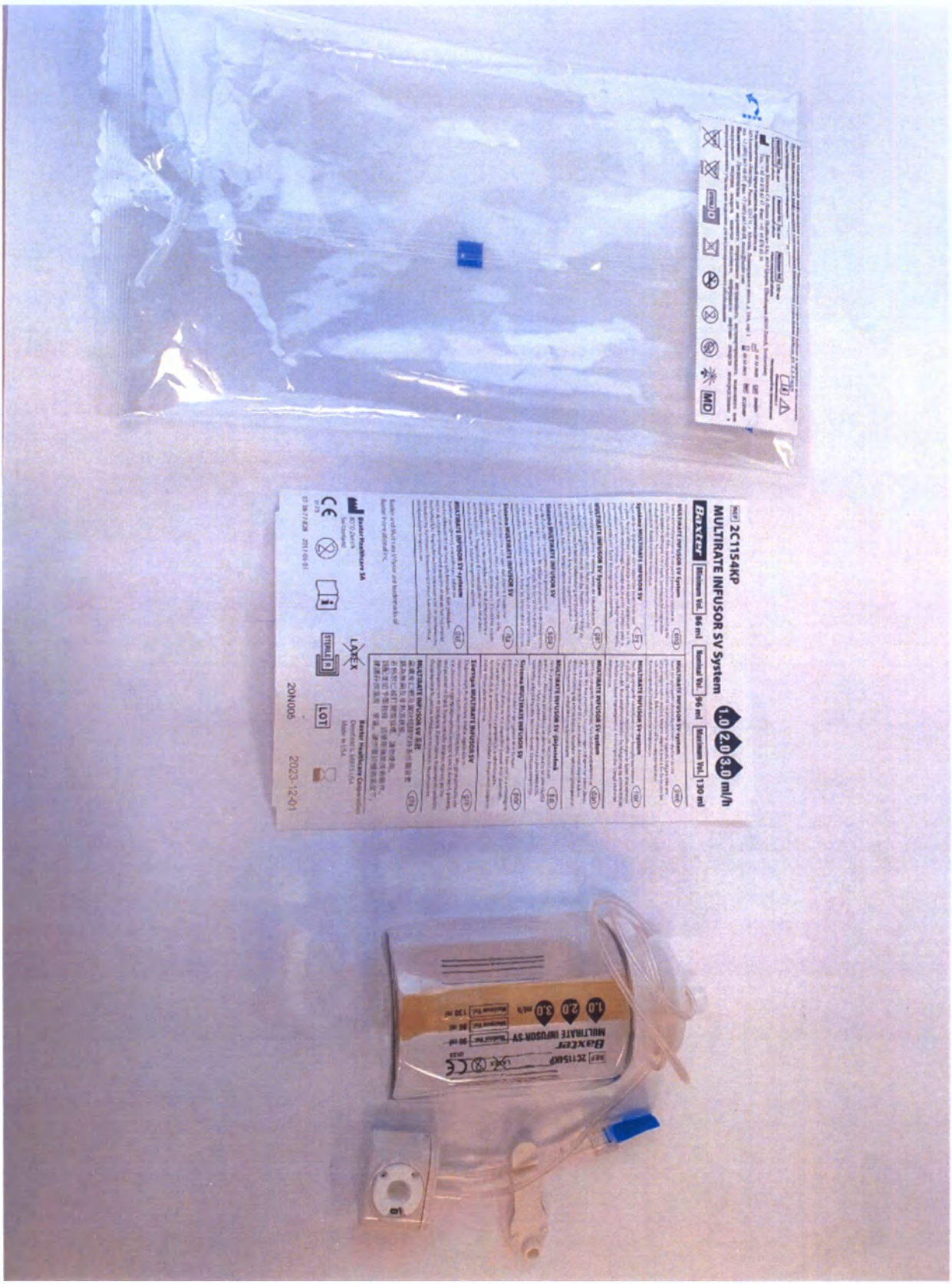
2.2. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor SV 1-2-3 мл/ч; Индивидуальная упаковка, оборотная сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



2.3. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor SV 1-2-3 мл/ч; Индивидуальная упаковка, лицевая сторона, с нанесенной маркировкой на русском языке

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

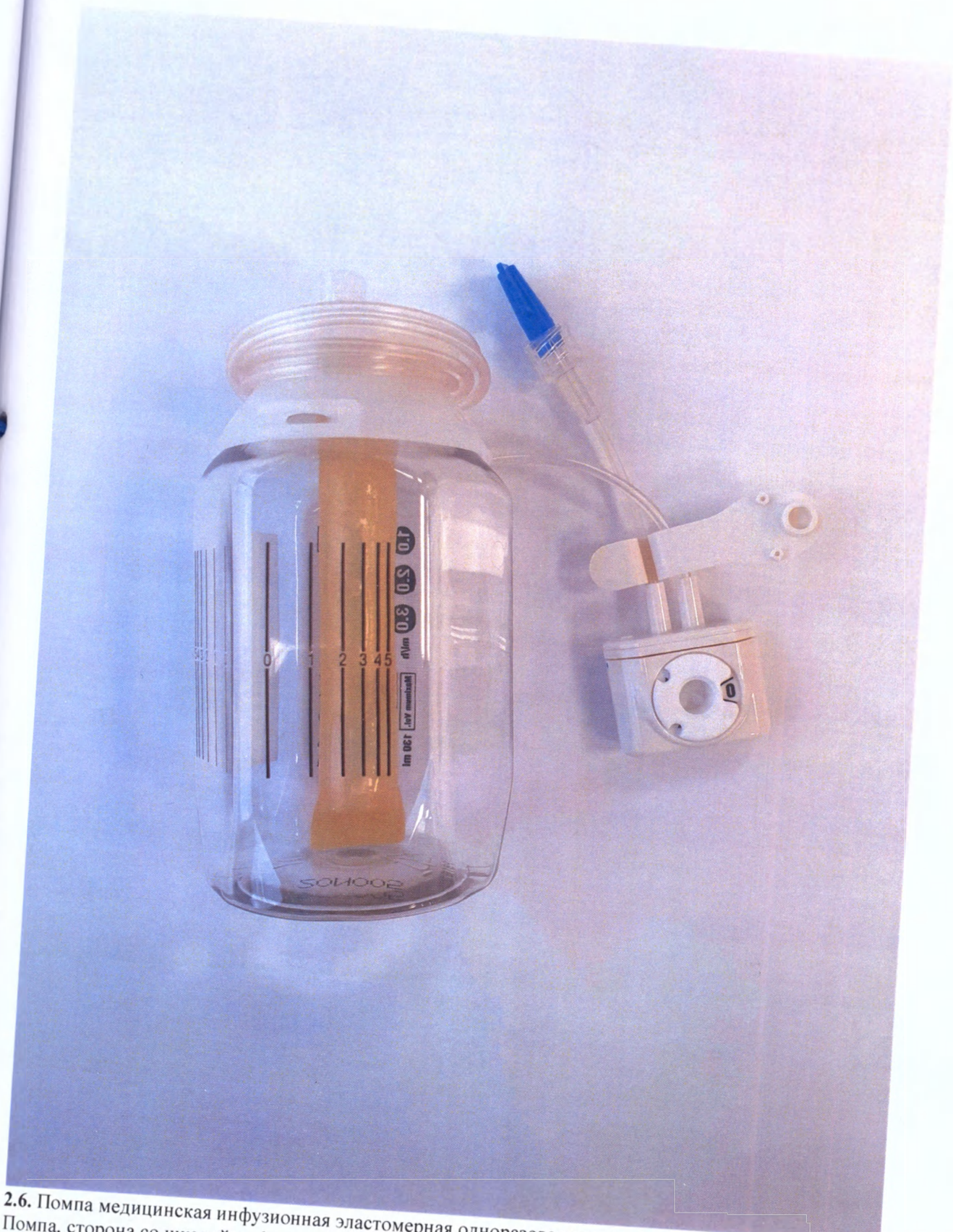


2.4. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor SV 1-2-3 мл/ч; Комплект поставки

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

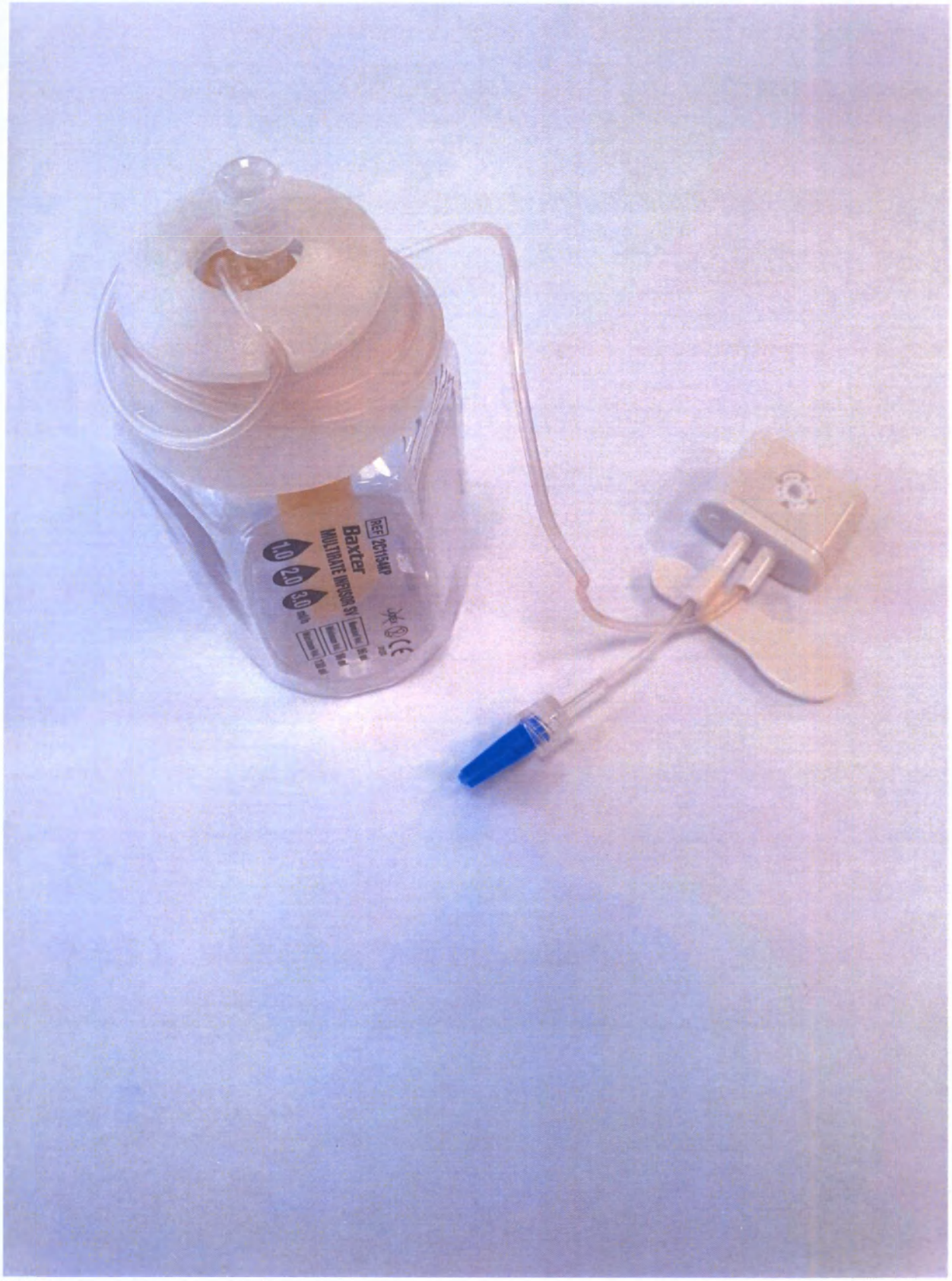
2.5. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor SV 1-2-3 мл/ч; Помпа, лицевая сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



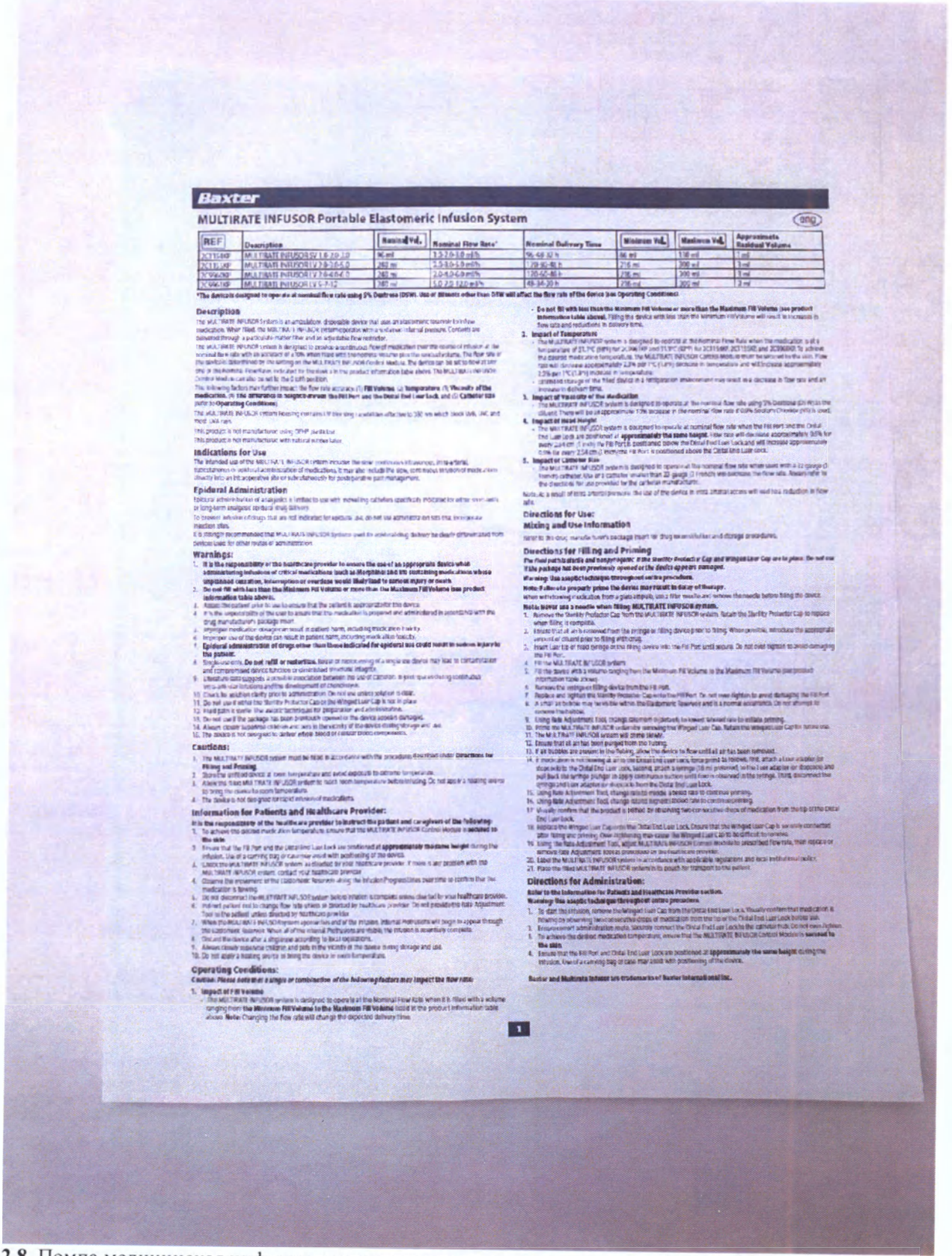
2.6. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor SV 1-2-3 мл/ч; Помпа, сторона со шкалой инфузии

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



2.7. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor SV 1-2-3 мл/ч; Помпа, вид сверху

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



Baxter

MULTIRATE INFUSOR Portable Elastomeric Infusion System

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REF	Description	Nominal Vol.	Nominal Flow Rate*	Nominal Delivery Time	Minimum Vol.	Maximum Vol.	Approximate Residual Volume
2C1154SP	MULTIRATE INFUSOR SV 1-2-3	96 ml	1.5-2.5-3.8 ml/h	96-48-32 h	86 ml	138 ml	1 ml
2C1134SP	MULTIRATE INFUSOR V 2-3-5-8	240 ml	2.5-3.5-5.5-9 ml/h	120-80-48 h	216 ml	390 ml	3 ml
2C1136SP	MULTIRATE INFUSOR V 3-5-8-12	240 ml	3.0-4.0-5.5-9 ml/h	120-60-48 h	216 ml	390 ml	3 ml
2C1146SP	MULTIRATE INFUSOR LV 5-7-12	360 ml	5.0-7.0-12.0 ml/h	48-34-20 h	236 ml	395 ml	3 ml

*The devices designed to operate at nominal flow rate using 5% Dextrose (D5W). Use of diluents other than D5W will affect the flow rate of the device (see Operating Conditions).

Description

The MULTIRATE INFUSOR System is an ambulatory, disposable device that uses an elastomeric reservoir to infuse medication. When filled, the MULTIRATE INFUSOR (reservoir) exerts a constant internal pressure. Contents are delivered through a particulate-matter filter and an adjustable flow restrictor.

The MULTIRATE INFUSOR system is designed to provide a continuous flow of medication over the nominal infusion at the nominal flow rate with an accuracy of ± 10% when used with isothermic volume plus the residual volume. The flow rate of the device is determined on the setting on the MULTIRATE INFUSOR Control Module. The device can be set to flow at only one (the Nominal Flow Rate indicated in the chart in the product information table above). The MULTIRATE INFUSOR Control Module can also be set to the 0 (off) position.

The following factors may further impact the flow rate accuracy: (1) **Fill Volume**, (2) **Temperature**, (3) **Viscosity of the medication**, (4) **the difference in height between the Fill Port** and the **Distal End Luer Lock**, and (5) **Catheter size** (refer to **Operating Conditions**).

The MULTIRATE INFUSOR system housing contains UV filtering and is offered in 100 ml which block UVA, UVC and most UVA rays.

This product is not manufactured using DEHP sterilized.

This product is not manufactured with natural rubber latex.

Indications for Use

The intended use of the MULTIRATE INFUSOR system includes the slow, continuous intravenous, intra-arterial, subcutaneous or epidural administration of medications. It may also include the slow, continuous infusion of medications directly into an intraoperative site or subcutaneously for postoperative pain management.

Epidural Administration

Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for either short-term or long-term analgesic epidural drug delivery.

To prevent infusion of drugs that are not indicated for epidural use, do not use administration sets that incorporate injection sites.

It is strongly recommended that MULTIRATE INFUSOR systems used for epidural drug delivery be clearly differentiated from devices used for other routes of administration.

Warnings:

1. **It is the responsibility of the healthcare provider to ensure the use of an appropriate device when administering infusions of critical medications (such as Morphine) and life sustaining medications whose unintended initiation, interruption or overdose would likely lead to serious injury or death.**
2. **Do not fill with less than the Minimum Fill Volume or more than the Maximum Fill Volume (see product information table above).**
3. Assess the patient prior to use to ensure that the patient is appropriate for this device.
4. It is the responsibility of the user to ensure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.
5. Improper medication dosage can result in patient harm, including medication toxicity.
6. Improper use of the device can result in patient harm, including medication toxicity.
7. **Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.**
8. Single-use only. **Do not refill or redistribute.** Reuse or misuse-testing of a single-use device may lead to contamination and compromised device function or diminished structural integrity.
9. Literature data suggests a possible association between the use of calcium- or lipid-containing solutions and particle-related occlusions and the development of thromboses.
10. Check the solution clarity prior to administration. Do not use unless solution is clear.
11. Do not use if either the Sterility Protector Cap or the Winged Luer Cap is not in place.
12. Hand-balm is useful for aseptic techniques for preparation and administration.
13. Do not use if the package has been previously opened or the device appears damaged.
14. Absorb closest supervisor observe and care in the vicinity of the device during storage and use.
15. The device is not designed to deliver whole blood or cellular blood components.

Cautions:

1. The MULTIRATE INFUSOR system must be filled in accordance with the procedures described under **Directions for Filling and Priming**.
2. Store the unfilled device at room temperature and avoid exposure to extreme temperatures.
3. Allow the filled MULTIRATE INFUSOR unit to reach room temperature before infusing. Do not apply a heating device to bring the device to room temperature.
4. The device is not designed for rapid infusion of medications.

Information for Patients and Healthcare Provider:

It is the responsibility of the healthcare provider to instruct the patient and caregivers of the following:

1. To achieve the desired medication temperature, ensure that the MULTIRATE INFUSOR Control Module is **secured to the skin**.
2. Ensure that the Fill Port and the Distal End Luer Lock are positioned at **approximately the same height** during the infusion. Use of a carrying bag or cummerbund with positioning of the device.
3. Label the MULTIRATE INFUSOR system as directed by your healthcare provider. If more than one position with the MULTIRATE INFUSOR system, contact your healthcare provider.
4. Observe the movement of the Elastomeric Reservoir during the Infusion Progress Bar time to confirm that the medication is flowing.
5. Do not disconnect the MULTIRATE INFUSOR system before infusion is complete unless directed by your healthcare provider.
6. Instruct patient not to change flow rate unless directed by your healthcare provider. Do not provide the Rate Adjustment Tool to the patient unless directed by healthcare provider.
7. When the MULTIRATE INFUSOR system operation ends and the infusion interval instructions will begin to appear through the Elastomeric Reservoir. When all of the internal Pathways are visible, the infusion is essentially complete.
8. Discard the device after a single use according to local regulations.
9. Always closely inspect the Clamp and parts in the vicinity of the device during storage and use.
10. Do not apply a heating device to bring the device to room temperature.

Operating Conditions:

Caution: Please note that a single or combination of the following factors may impact the flow rate:

1. **Impact of Fill Volume**
   - The MULTIRATE INFUSOR system is designed to operate at the Nominal Flow Rate when it is filled with a volume ranging from the **Minimum Fill Volume** to the **Maximum Fill Volume** listed in the product information table above. **Note:** Changing the flow rate will change the expected delivery time.
   - **Do not fill with less than the Minimum Fill Volume or more than the Maximum Fill Volume (see product information table above).** Filling the device with less than the minimum fill volume will result in increases in flow rate and reductions in delivery time.
2. **Impact of Temperature**
   - The MULTIRATE INFUSOR system is designed to operate at the Nominal Flow Rate when the medication is at a temperature of 21.1°C (69°F) for 2C1154SP and 31.9°C (89°F) for 2C1134SP, 2C1136SP, and 2C1146SP. To achieve the desired medication temperature, the MULTIRATE INFUSOR Control Module must be secured to the skin. Flow rate will decrease approximately 2.2% per 1°C (1.4°F) decrease in temperature and will increase approximately 2.2% per 1°C (1.4°F) increase in temperature.
   - Prolonged storage of the filled device in a refrigeration environment may result in a decrease in flow rate and an increase in delivery time.
3. **Impact of Viscosity of the Medication**
   - The MULTIRATE INFUSOR system is designed to operate at the nominal flow rate using 5% Dextrose (D5W) as the diluent. There will be an approximate 10% increase in the nominal flow rate if 0.9% Sodium Chloride (NS) is used.
4. **Impact of Head Height**
   - The MULTIRATE INFUSOR system is designed to operate at nominal flow rate when the Fill Port and the Distal End Luer Lock are positioned at **approximately the same height**. Flow rate will decrease approximately 30% for every 254 cm (1 inch) the Fill Port is positioned above the Distal End Luer Lock and will increase approximately 10% for every 254 cm (1 inch) the Fill Port is positioned above the Distal End Luer Lock.
5. **Impact of Catheter Size**
   - The MULTIRATE INFUSOR system is designed to operate at the nominal flow rate when used with a 22 gauge (1 inch) catheter. Use of a catheter smaller than 22 gauge (1 inch) will increase the flow rate. Please refer to the directions for use provided by the catheter manufacturer.

Note: As a result of intra-arterial pressure, the use of the device in intra-arterial access will result in a reduction in flow rate.

Directions for Use:

Mixing and Use Information

Refer to the drug manufacturer's package insert for drug reconstitution and storage procedures.

Directions for Filling and Priming

The fluid path (distal and compression) of the Sterility Protector Cap and Winged Luer Cap are to prime. Do not use if the package has been previously opened or the device appears damaged.

Warning: Use aseptic technique throughout entire procedure.

Note: Failure to properly prime the device may result in delay of therapy.

When withdrawing medication from a glass ampule, use a filter needle and remove the needle before filling the device.

Note: Never use a needle when filling MULTIRATE INFUSOR system.

1. Remove the Sterility Protector Cap from the MULTIRATE INFUSOR system. Retain the Sterility Protector Cap to replace when filling is complete.
2. Ensure that all air is removed from the syringe or filling device prior to filling. When possible, introduce the appropriate amount of diluent prior to filling with drug.
3. Insert Luer tip of filled syringe or the filling device into the Fill Port until secure. Do not over tighten to avoid damaging the Fill Port.
4. Fill the MULTIRATE INFUSOR system.
5. Fill the device with a volume ranging from the Minimum Fill Volume to the Maximum Fill Volume (see product information table above).
6. Remove the syringe or filling device from the Fill Port.
7. Replace and tighten the Sterility Protector Cap onto the Fill Port. Do not over tighten to avoid damaging the Fill Port.
8. A small air bubble may be visible within the Elastomeric Reservoir and is a normal occurrence. Do not attempt to remove the bubble.
9. Using Rate Adjustment Tool, change diluent to prime, to lowest labeled rate to initiate priming.
10. Prime the MULTIRATE INFUSOR under the opened the Winged Luer Cap. Retain the wrapper over Cap for future use.
11. The MULTIRATE INFUSOR system will come slowly.
12. Ensure that all air has been purged from the tubing.
13. If air bubbles are present in the tubing, allow the device to flow until all air has been removed.
14. If medication is not flowing at or to the Distal End Luer Lock, force prime to resolve, first, attach a Luer adapter (or equivalent) to the Distal End Luer Lock. Second, attach a syringe (10 ml preferred) to the Luer adapter or stopcock and pull back the syringe plunger to apply continuous suction until flow is observed in the syringe. Third, disconnect the syringe and Luer adapter or stopcock from the Distal End Luer Lock.
15. Using Rate Adjustment Tool, change to the desired rate to continue priming.
16. Using Rate Adjustment Tool, change desired rate to continue priming.
17. Visually confirm that the product is infused by observing two consecutive drops of medication from the tip of the Distal End Luer Lock.
18. Replace the Winged Luer Cap onto the Distal End Luer Lock. Ensure that the Winged Luer Cap is securely connected after filling and priming. Over-tightening may cause the Winged Luer Cap to be difficult to remove.
19. Using the Rate Adjustment Tool, adjust MULTIRATE INFUSOR Control Module to prescribed flow rate, then replace or remove Rate Adjustment Tool as prescribed by the healthcare provider.
20. Label the MULTIRATE INFUSOR system in accordance with applicable regulations and local institutional policy.
21. Place the filled MULTIRATE INFUSOR system in its pouch for transport to the patient.

Directions for Administration:

Refer to the Information for Patients and Healthcare Provider section.

Warning: Use aseptic technique throughout entire procedure.

1. To start the infusion, remove the Winged Luer Cap from the Distal End Luer Lock. Visually confirm that medication is flowing by observing two consecutive drops of medication from the tip of the Distal End Luer Lock before use.
2. Ensure proper administration route. Securely connect the Distal End Luer Lock to the catheter hub. Do not over-tighten.
3. To achieve the desired medication temperature, ensure that the MULTIRATE INFUSOR Control Module is **secured to the skin**.
4. Ensure that the Fill Port and Distal End Luer Lock are positioned at **approximately the same height** during the infusion. Use of a carrying bag or case may assist with positioning of the device.

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2.8. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor SV 1-2-3 мл/ч; Оригинальная инструкция

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

3. Помпа медицинская инфузионная эластомерная одноразовая стерильная

Infusor LV 2-3-5 мл/ч

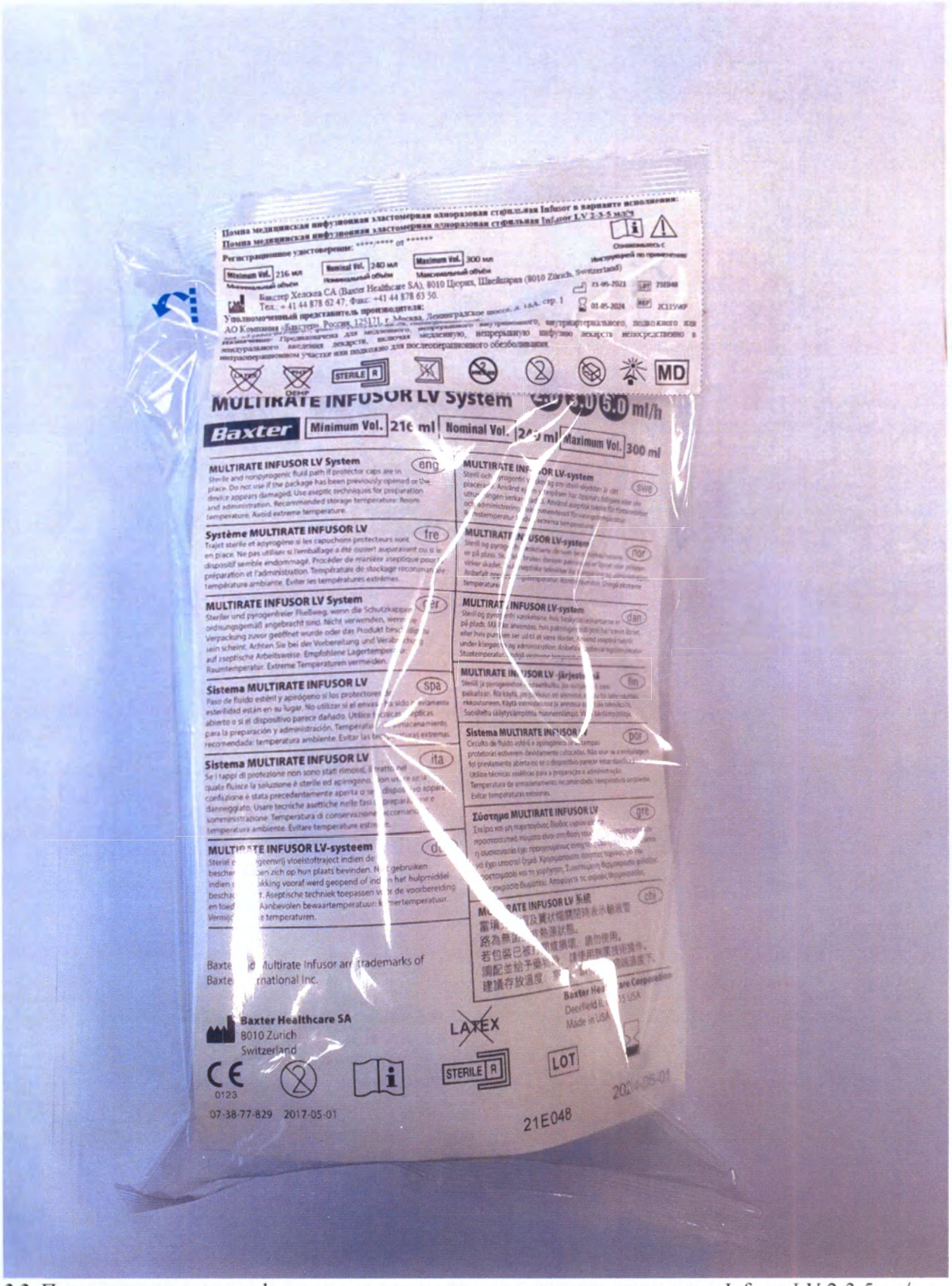
ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

3.1. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-3-5 мл/ч; Индивидуальная упаковка, лицевой сторона, с оригинальной маркировкой

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

3.2. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-3-5 мл/ч; Индивидуальная упаковка, оборотная сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



3.3. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-3-5 мл/ч; Индивидуальная упаковка, лицевая сторона, с нанесенной маркировкой на русском языке

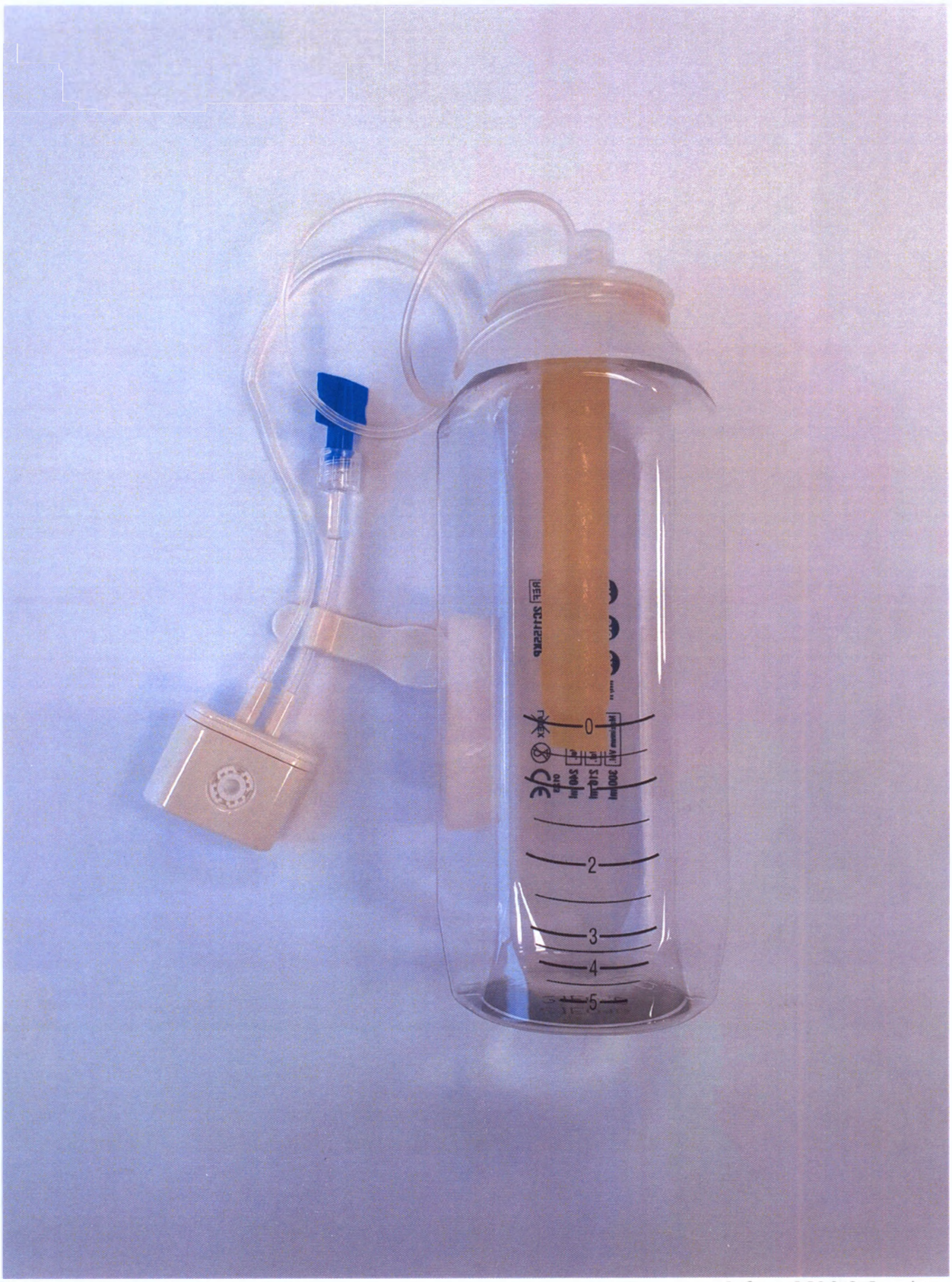
ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

3.4. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-3-5 мл/ч; Комплект поставки

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

3.5. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-3-5 мл/ч; Помпа, лицевая сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

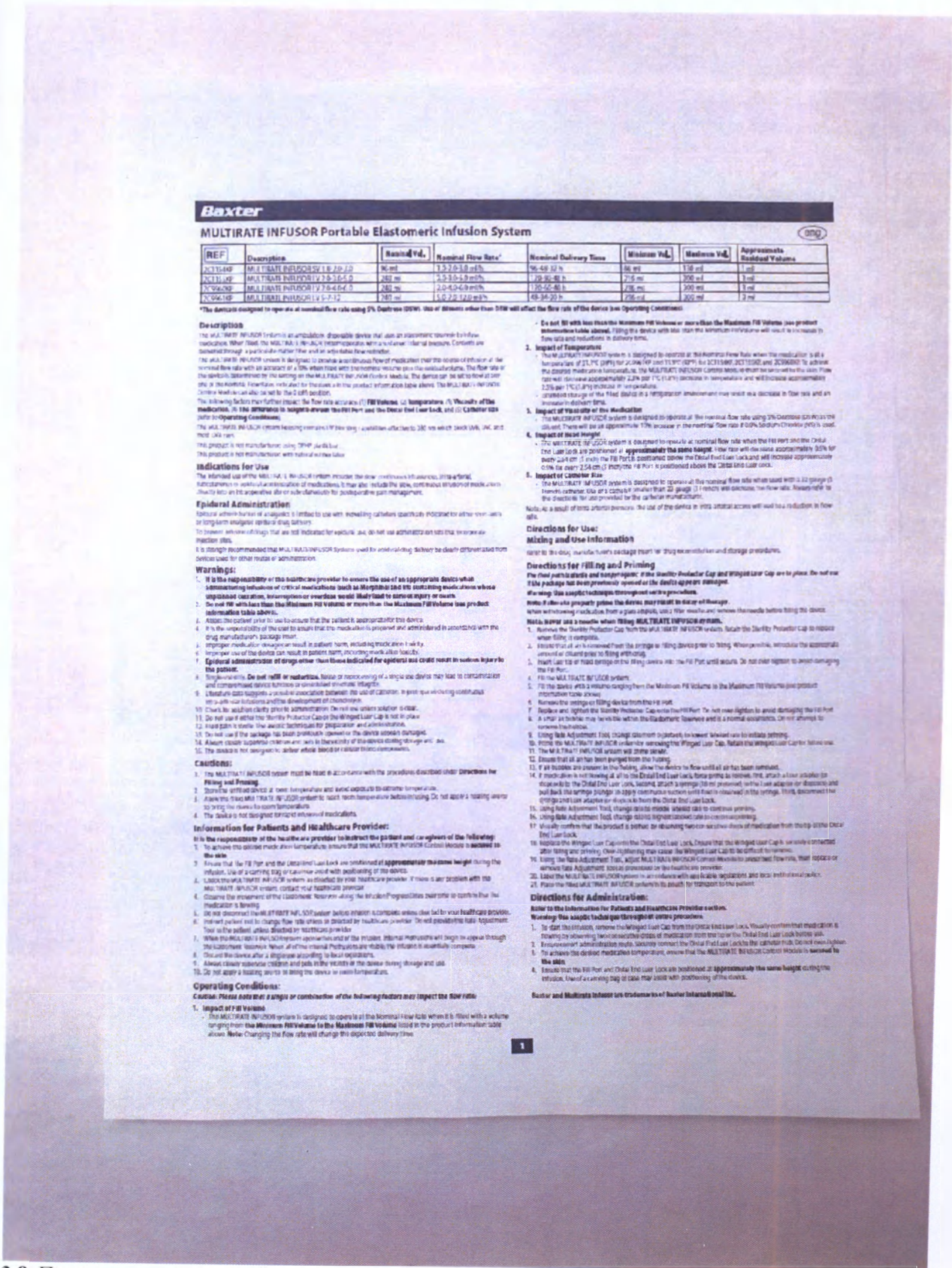


3.6. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-3-5 мл/ч; Помпа, сторона со шкалой инфузии

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

3.7. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-3-5 мл/ч; Помпа, вид сверху

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



Baxter

MULTIRATE INFUSOR Portable Elastomeric Infusion System

REF	Description	Nominal Vol.	Nominal Flow Rate*	Nominal Delivery Time	Minimum Vol.	Maximum Vol.	Approximate Residual Volume
2C31549P	MULTIRATE INFUSOR SV 1.8 20-10	96 ml	1.5 2.0-3.0 ml/h	96-48 32 h	96 ml	138 ml	1 ml
2C31L49P	MULTIRATE INFUSOR LV 2-3-5 0	240 ml	2.5 3.0-4.9 ml/h	120-80-48 h	216 ml	300 ml	3 ml
2C96609P	MULTIRATE INFUSOR LV 2-3-5 0	240 ml	2.0 4.0-4.9 ml/h	120-60-48 h	216 ml	300 ml	3 ml
2C96610P	MULTIRATE INFUSOR LV 5-7-12	240 ml	5.0 7.0-12.0 ml/h	48-34-20 h	216 ml	300 ml	3 ml

*The delivery designed to operate at nominal flow rate using 5% Dextrose (D5W). Use of diluents other than D5W will affect the flow rate of the device (see Operating Conditions).

Description

The MULTIRATE INFUSOR System is an ambulatory disposable device that uses an elastomeric reservoir to deliver medication. When filled, the MULTIRATE INFUSOR operates within a defined internal pressure. Contents are delivered through a particular flow filter and an adjustable flow restrictor.

The MULTIRATE INFUSOR system is designed to provide a continuous flow of medication over the course of infusion at the nominal flow rate with an accuracy of ± 10% when tested with the normal saline provided with the device. The flow rate of the system is determined by the setting on the MULTIRATE INFUSOR Control Module. The device can be set to flow at one of the 3 Control Rates indicated for the device in the product information table above. The MULTIRATE INFUSOR Control Module can also be set to the O (off) position.

The following factors may further impact the flow rate accuracy: (1) **Fill Volume**, (2) **Temperature**, (3) **Viscosity of the medication**, (4) **the difference in height between the Fill Port and the Distal End Luer Lock**, and (5) **Catheter size** (refer to **Operating Conditions**).

The MULTIRATE INFUSOR system housing contains 1 AA size long - duration alkaline cells (1.5V each) (each 1Ah, 2AC and most 1Ah) cells.

This product is not manufactured using DEHP distributed.

This product is not manufactured with natural rubber latex.

Indications for Use

The intended use of the MULTIRATE INFUSOR system provides the delivery of continuous infusion(s), intravenous, subcutaneous or epidural administration of medications. It may also include the slow, continuous infusion of medications primarily for, but not limited to, postoperative pain management.

Epidural Administration

Epidural administration of analgesics is limited to use with indwelling catheters specifically designed for either short-term or long-term analgesic epidural drug delivery.

To prevent serious infusings that are not indicated for epidural use, do not use administration sets that incorporate injection sites.

It is strongly recommended that MULTIRATE INFUSOR Systems used for epidural dosing delivery be clearly differentiated from devices used for other routes of administration.

Warnings:

1. **It is the responsibility of the healthcare provider to ensure the use of an appropriate device when administering infusions of critical medications (such as Morphine) and life sustaining medications whose unintended cessation, interruption or overdose would likely lead to serious injury or death.**
2. **Do not fill with less than the Minimum Fill Volume or more than the Maximum Fill Volume (see product information table above).**
3. Assess the patient prior to use to ensure that the patient is appropriate for this device.
4. It is the responsibility of the user to ensure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.
5. Improper medication dosage can result in patient harm, including medication toxicity.
6. Improper use of the device can result in patient harm, including medication toxicity.
7. **Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.**
8. Single-use only. **Do not refill or reuse/use.** Reuse or reprocessing of a single use device may lead to contamination and compromised device function or diminished mechanical integrity.
9. Literature does suggests a possible association between the use of catheter, in post-operative wound infusions with local infusions and the development of chondrolysis.
10. Check for air/fluid clarity prior to administration. Do not use unless solution is clear.
11. Do not use if either the Sterility Protector Cap or the Winged Luer Cap is not in place.
12. Hand palm is sterile. Use aseptic techniques for preparation and administration.
13. Do not use if the package has been previously opened or the device appears damaged.
14. Assure closure is properly secured with each change of the device during storage and use.
15. The device is not designed to deliver whole blood or cellular blood components.

Cautions:

1. The MULTIRATE INFUSOR system must be filled in accordance with the procedures described under **Directions for Filling and Priming**.
2. Store the unfilled device at room temperature and avoid exposure to extreme temperatures.
3. Allow the filled MULTIRATE INFUSOR unit to reach room temperature before infusing. Do not apply a heating source to bring the device to room temperature.
4. The device is not designed to inject intravenous medications.

Information for Patients and Healthcare Provider:

It is the responsibility of the healthcare provider to instruct the patient and caregivers of the following:

1. To achieve the desired medication temperature, ensure that the MULTIRATE INFUSOR Control Module is **secured to the skin**.
2. Ensure that the Fill Port and the Distal End Luer Lock are positioned at **approximately the same height** during the infusion. Use of a carrying bag or case may assist with positioning of the device.
3. Liquids in the MULTIRATE INFUSOR system as directed by your healthcare provider. If there is any problem with the MULTIRATE INFUSOR system, contact your healthcare provider.
4. Observe the movement of the Elastomeric Reservoir during the Infusion Progression over time to confirm that the medication is flowing.
5. Do not disconnect the MULTIRATE INFUSOR system before infusion is complete unless directed by your healthcare provider.
6. Inform patient not to change flow rate unless directed by healthcare provider. Do not provide the Rate Adjustment Tool to the patient unless directed by healthcare provider.
7. When the MULTIRATE INFUSOR system operation and or the infusion, internal membranes will begin to appear through the Lockdown Window. When all of the internal Pathogens are visible, the infusion is essentially complete.
8. Discard the device after a single use according to local regulations.
9. Always closely supervise children and pets in the vicinity of the device during storage and use.
10. Do not apply a heating source to bring the device to room temperature.

Operating Conditions:

Caution: Please note that a single or combination of the following factors may impact the flow rate:

1. **Impact of Fill Volume**
   - The MULTIRATE INFUSOR system is designed to operate at the Nominal Flow Rate when it is filled with a volume ranging from **the Minimum Fill Volume to the Maximum Fill Volume** listed in the product information table above. **Note:** Changing the flow rate will change the expected delivery time.
   - **Do not fill with less than the Minimum Fill Volume or more than the Maximum Fill Volume (see product information table above).** Filling the device with less than the minimum Fill Volume will result in increases in flow rate and reductions in delivery time.
2. **Impact of Temperature**
   - The MULTIRATE INFUSOR system is designed to operate at the Nominal Flow Rate when the medication is at a temperature of 25.1°C (78°F) for 2C96609P and 15.9°C (60°F) for 2C31549P, 2C31L49P, and 2C96610P. To achieve the desired medication temperature, the MULTIRATE INFUSOR Control Module should be secured to the skin. Flow rate will decrease approximately 2.2% per 1°C (1.2°F) decrease in temperature and will increase approximately 2.2% per 1°C (1.2°F) increase in temperature.
   - Extended storage of the filled device in a refrigerator environment may result in a decrease in flow rate and an increase in delivery time.
3. **Impact of Viscosity of the Medication**
   - The MULTIRATE INFUSOR system is designed to operate at the nominal flow rate using 5% Dextrose (D5W) across the (D5W). There will be an approximate 10% increase in the nominal flow rate if 0.9% Sodium Chloride (NS) is used.
4. **Impact of Head Height**
   - The MULTIRATE INFUSOR system is designed to operate at nominal flow rate when the Fill Port and the Distal End Luer Lock are positioned at **approximately the same height**. Flow rate will decrease approximately 30% for every 2.54 cm (1 inch) the Fill Port is positioned below the Distal End Luer Lock, and will increase approximately 60% for every 2.54 cm (1 inch) the Fill Port is positioned above the Distal End Luer Lock.
5. **Impact of Catheter Size**
   - The MULTIRATE INFUSOR system is designed to operate at the nominal flow rate when used with a 22 gauge (1 French) catheter. Use of a catheter smaller than 22 gauge (1 French) will decrease the flow rate. Refer to the directions for use provided by the catheter manufacturer.

Note: As a result of tissue pressure, the use of the device in intra-arterial access will lead to a reduction in flow rate.

Directions for Use:

Mixing and Use Information

Refer to the drug manufacturer's package insert for drug reconstitution and storage procedures.

Directions for Filling and Priming

Pre-flow path is sterile and non-pyrogenic if the Sterility Protector Cap and Winged Luer Cap are in place. Do not use if the package has been previously opened or the device appears damaged.

Warning: Use aseptic technique throughout entire procedure.

Note: Failure to properly prime the device may result in delay of therapy.

When withdrawing medication from a glass ampule, use a filter needle and remove the needle before filling the device.

Note: Never use a needle when filling MULTIRATE INFUSOR system.

1. Remove the Sterility Protector Cap from the MULTIRATE INFUSOR system. Retain the Sterility Protector Cap to replace when filling is complete.
2. Ensure that all air is removed from the syringe or filling device prior to filling. When possible, aspirate the appropriate amount of diluent prior to filling and priming.
3. Insert Luer tip of filled syringe or the filling device into the Fill Port until secure. Do not over-tighten to avoid damaging the Fill Port.
4. Fill the MULTIRATE INFUSOR system.
5. Fill the device with a volume ranging from the Minimum Fill Volume to the Maximum Fill Volume (see product information table above).
6. Remove the syringe or filling device from the Fill Port.
7. Replace and tighten the Sterility Protector Cap onto the Fill Port. Do not over-tighten to avoid damaging the Fill Port.
8. A small air bubble may be visible within the Elastomeric Reservoir and is a normal occurrence. Do not attempt to remove the bubble.
9. Using Rate Adjustment Tool, change dial on patient to lowest labeled rate to initiate priming.
10. Prime the MULTIRATE INFUSOR under low pressure by removing the Winged Luer Cap. Retain the Winged Luer Cap for future use.
11. The MULTIRATE INFUSOR system will prime slowly.
12. Ensure that all air has been purged from the tubing.
13. If air bubbles are present in the tubing, allow the device to flow until all air has been removed.
14. If medication is not flowing, all of the Distal End Luer Lock, begin by to remove, first, attach a luer adapter (to dispose) to the Distal End Luer Lock, second, attach a syringe (to be provided) to the Luer adapter or disconnect and pull back the syringe plunger to apply continuous suction until fluid is observed in the syringe. Third, disconnect the syringe and Luer adapter or disposable from the Distal End Luer Lock.
15. Using Rate Adjustment Tool, change dial to desired labeled rate to continue priming.
16. Using Rate Adjustment Tool, change dial to highest labeled rate to continue priming.
17. Visually confirm that the product is primed or resuming two consecutive drops of medication from the tip of the Distal End Luer Lock.
18. Replace the Winged Luer Cap onto the Distal End Luer Lock. Ensure that the Winged Luer Cap is securely connected after filling and priming. Over-tightening may cause the Winged Luer Cap to be difficult to remove.
19. Using the Rate Adjustment Tool, adjust MULTIRATE INFUSOR Control Module to desired flow rate, then replace or remove Rate Adjustment Tool as prescribed by the healthcare provider.
20. Label the MULTIRATE INFUSOR system in accordance with applicable regulations and local institutional policy.
21. Place the filled MULTIRATE INFUSOR system in its pouch for transport to the patient.

Directions for Administration:

Refer to the Information for Patients and Healthcare Provider section.

Warning: Use aseptic technique throughout entire procedure.

1. To start the infusion, remove the Winged Luer Cap from the Distal End Luer Lock. Visually confirm that medication is flowing by observing two consecutive drops of medication from the tip of the Distal End Luer Lock before use.
2. Ensure correct administration route. Securely connect the Distal End Luer Lock to the catheter hub. Do not over-tighten.
3. To achieve the desired medication temperature, ensure that the MULTIRATE INFUSOR Control Module is **secured to the skin**.
4. Ensure that the Fill Port and Distal End Luer Lock are positioned at **approximately the same height** during the infusion. Use of a carrying bag or case may assist with positioning of the device.

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3.8. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-3-5 мл/ч; Оригинальная инструкция

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

4. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-4-6 мл/ч

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

4.1. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-4-6 мл/ч; Индивидуальная упаковка, лицевой сторона, с оригинальной маркировкой

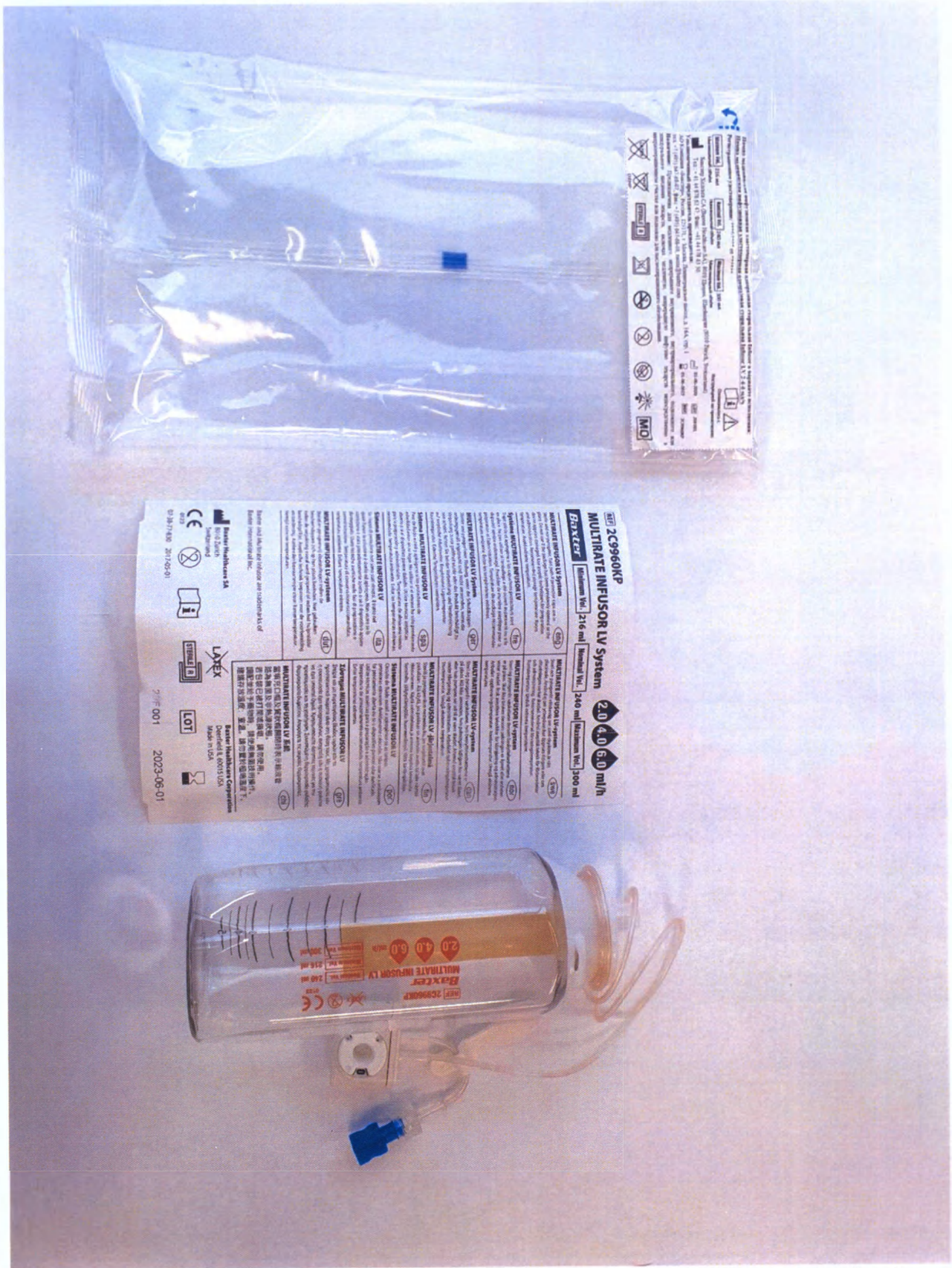
ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

4.2. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-4-6 мл/ч; Индивидуальная упаковка, оборотная сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

4.3. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-4-6 мл/ч; Индивидуальная упаковка, лицевая сторона, с нанесенной маркировкой на русском языке

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



4.4. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-4-6 мл/ч; Комплект поставки

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

4.5. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-4-6 мл/ч; Помпа, лицевая сторона

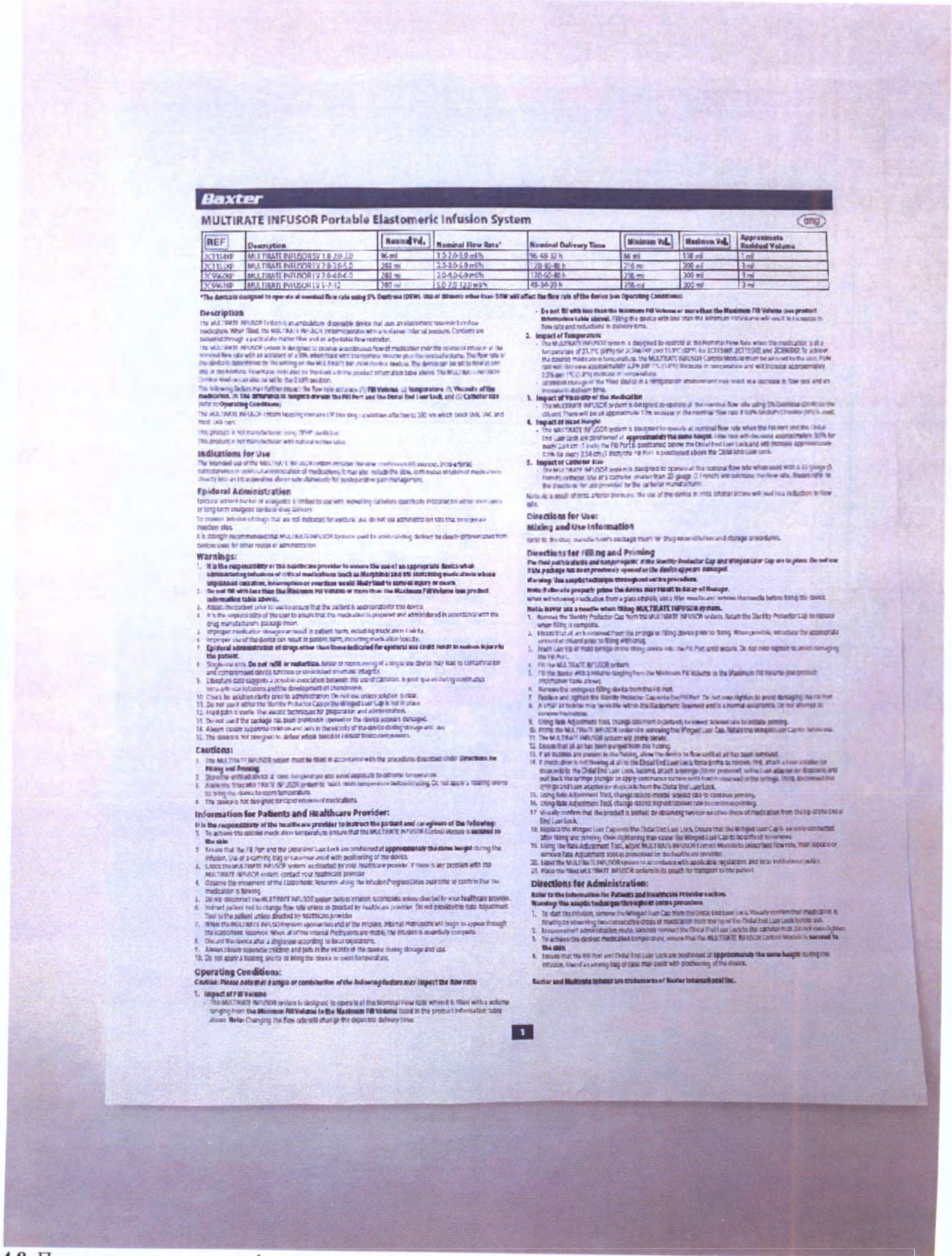
ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

4.6. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-4-6 мл/ч; Помпа, сторона со шкалой инфузии

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

4.7. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-4-6 мл/ч; Помпа, вид сверху

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



Baxter

MULTIRATE INFUSOR Portable Elastomeric Infusion System

REF	Description	Nominal Vol.	Nominal Flow Rate*	Nominal Delivery Time	Minimum Vol.	Maximum Vol.	Approximate Residual Volume
2C3154KF	MULTIRATE INFUSOR LV 1.0-2.0-3.0	96 ml	1.5-2.0-3.0 ml/h	96-48-32 h	86 ml	138 ml	1 ml
2C3156KF	MULTIRATE INFUSOR LV 2.0-3.0-5.0	240 ml	2.5-3.0-5.0 ml/h	120-80-48 h	216 ml	290 ml	1 ml
2C3966KF	MULTIRATE INFUSOR LV 2.0-4.0-6.0	240 ml	2.0-4.0-6.0 ml/h	120-60-40 h	216 ml	300 ml	1 ml
2C3967KF	MULTIRATE INFUSOR LV 5-7-12	240 ml	5.0-7.0-12.0 ml/h	48-34-20 h	216 ml	305 ml	3 ml

*The devices designed to operate at nominal flow rate using 5% Dextrose (D5W). Use of diluents other than D5W will affect the flow rate of the device (see Operating Conditions).

Description

The MULTIRATE INFUSOR System is an ambulatory disposable device that uses an elastomeric reservoir to infuse medication. When filled, the MULTIRATE INFUSOR retains positive internal pressure. Contents are delivered through a particulate matter filter and an adjustable flow restrictor.

The MULTIRATE INFUSOR system is designed to provide a continuous flow of medication over the course of infusion at the nominal flow rate with an accuracy of ± 10% when filled with the nominal volume plus the residual volume. The flow rate is the device is determined by the setting on the MULTIRATE INFUSOR Control Module. The device can be set to flow at one of the Nominal Flow Rates indicated in the product information table above. The MULTIRATE INFUSOR Control Module can also be set to the O (off) position.

The following factors may further impact the flow rate accuracy: (1) **Fill Volume**, (2) **Temperature**, (3) **Viscosity of the medication**, (4) **The difference in height between the Fill Port** and the **Distal End Luer Lock**, and (5) **Catheter size** (refer to **Operating Conditions**).

The MULTIRATE INFUSOR system housing contains UV blockers and is classified to 320 nm which blocks UVA, UVC and most UVB rays.

This product is not manufactured using DEHP plasticizer.

This product is not manufactured with natural rubber latex.

Indications for Use

The intended use of the MULTIRATE INFUSOR system includes the slow, continuous infusion, intra-arterial, subcutaneous or epidural administration of medications. It may also include the slow, continuous infusion of medications directly into an intraoperative direct-site catheter for postoperative pain management.

Epidural Administration

Epidural administration of analgesics is limited to use with indwelling catheters specifically indicated for either short-term or long-term analgesic epidural drug delivery.

To prevent infusion of drugs that are not indicated for epidural use, do not use administration sets that incorporate injection sites.

It is strongly recommended that MULTIRATE INFUSOR Systems used for epidural drug delivery be clearly differentiated from devices used for other routes of administration.

Warnings:

1. **It is the responsibility of the healthcare provider to ensure the use of an appropriate device when administering infusions of critical medications (such as Morphine) and IV) containing medications whose unplanned cessation, interruption or overdose would likely lead to serious injury or death.**
2. **Do not fill with less than the Minimum Fill Volume or more than the Maximum Fill Volume (see product information table above).**
3. Assess the patient prior to use to ensure that the patient is appropriate for this device.
4. It is the responsibility of the user to ensure that the medication is prepared and administered in accordance with the drug manufacturer's package insert.
5. Improper medication dosage can result in patient harm, including medication toxicity.
6. Improper use of the device can result in patient harm, including medication toxicity.
7. **Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.**
8. Single-use only. **Do not refill or reinfuse.** Refill or reconnecting of a single use device may lead to contamination and compromised device function or unmonitored infusion integrity.
9. Literature data suggests a possible association between the use of cefazolin, in post-operative cardiac continuous intra-arterial infusions and the development of chondrolysis.
10. Check the solution clarity prior to administration. Do not use unless solution is clear.
11. Do not use if either the Sterility Protector Cap or the Winged Luer Cap is not in place.
12. Hand wash is sterile. Use aseptic techniques for preparation and administration.
13. Do not use if the package has been previously opened or the device appears damaged.
14. Absent closely supervised children and pets in the vicinity of the device during storage and use.
15. The device is not designed to deliver whole blood or cellular blood components.

Cautions:

1. The MULTIRATE INFUSOR system must be filled in accordance with the procedures described UNDER **Directions for Filling and Priming**.
2. Store the prefilled device at room temperature and avoid exposure to extreme temperature.
3. Allow the filled MULTIRATE INFUSOR system to reach room temperature before infusing. Do not apply a heating source to bring the device to room temperature.
4. The device is not designed for rapid infusion of medications.

Information for Patients and Healthcare Provider:

It is the responsibility of the healthcare provider to instruct the patient and caregivers of the following:

1. To achieve the desired medication temperature, ensure that the MULTIRATE INFUSOR Control Module is **secured to the skin**.
2. Ensure that the Fill Port and the Distal End Luer Lock are positioned at **approximately the same height** during the infusion. Use of a carrying bag or cassette pouch with positioning of the device.
3. Unlock the MULTIRATE INFUSOR system as directed by your healthcare provider. If there is any problem with the MULTIRATE INFUSOR system, contact your healthcare provider.
4. Observe the movement of the Liquid Marker Reservoir along the Infusion Progress Dots over time to confirm that the medication is flowing.
5. Do not disconnect the MULTIRATE INFUSOR system before infusion is complete unless directed by your healthcare provider.
6. Instruct patient not to change flow rate unless so directed by healthcare provider. Do not provide the Rate Adjustment Tool to the patient unless directed by healthcare provider.
7. When the MULTIRATE INFUSOR reservoir appears flat and/or the Infusion Progress Dots appear to be empty, the infusion is essentially complete.
8. Discard the device after a single use according to local regulations.
9. Always closely supervise children and pets in the vicinity of the device during storage and use.
10. Do not apply a heating source or bring the device in room temperature.

Operating Conditions:

Caution: Please note that a single or combination of the following factors may impact the flow rate:

1. **Impact of Fill Volume**
   - The MULTIRATE INFUSOR system is designed to operate at the Nominal Flow Rate when it is filled with a volume ranging from the **Minimum Fill Volume to the Maximum Fill Volume** listed in the product information table above. **Note:** Changing the flow rate will change the expected delivery time.
   - **Do not fill with less than the Minimum Fill Volume or more than the Maximum Fill Volume (see product information table above).** Filling the device with less than the minimum Fill Volume will result in increases in flow rate and reductions in delivery time.
2. **Impact of Temperature**
   - The MULTIRATE INFUSOR system is designed to operate at the Nominal Flow Rate when the medication is at a temperature of 37.1°C (99°F) for 2C3966KF and 33.9°C (93°F) for 2C3156KF, 2C3156KF, and 2C3967KF. To achieve the desired medication temperature, the MULTIRATE INFUSOR Control Module must be secured to the skin. Flow rate will increase approximately 2.2% per 1°C (1.4°F) increase in temperature and will decrease approximately 2.2% per 1°C (1.4°F) decrease in temperature.
   - Extended storage of the filled device in a refrigerated environment may result in a decrease in flow rate and an increase in delivery time.
3. **Impact of Viscosity of the Medication**
   - The MULTIRATE INFUSOR system is designed to operate at the nominal flow rate using 5% Dextrose (D5W) as the diluent. There will be an approximate 12% increase in the nominal flow rate if 0.9% Sodium Chloride (NS) is used.
4. **Impact of Head Height**
   - The MULTIRATE INFUSOR system is designed to operate at nominal flow rate when the Fill Port and the Distal End Luer Lock are positioned at **approximately the same height**. Flow rate will decrease approximately 3.0% for every 2.54 cm (1 inch) the Fill Port is positioned above the Distal End Luer Lock, and will increase approximately 0.9% for every 2.54 cm (1 inch) the Fill Port is positioned above the Distal End Luer Lock.
5. **Impact of Catheter Size**
   - The MULTIRATE INFUSOR system is designed to operate at the nominal flow rate when used with a 22 gauge (0.7 mm) catheter. Use of a catheter smaller than 22 gauge (0.7 mm) will increase the flow rate. Always refer to the directions for use provided by the catheter manufacturer.

Note: As a result of limited catheter pressure, the use of the device in intra-arterial access will lead to a reduction in flow rate.

Directions for Use:

Mixing and Use Information

Refer to the drug manufacturer's package insert for drug reconstitution and storage procedures.

Directions for Filling and Priming

The fluid path is sterile and nonpyrogenic if the Sterility Protector Cap and Winged Luer Cap are in place. Do not use if the package has been previously opened or the device appears damaged.

Warning: Use aseptic technique throughout entire procedure.

Note: Follow the properly prime the device and instruct in duty of therapy.

When withdrawing medication from a glass ampule, use a filter needle and remove the needle before filling the device.

Note: Never use a needle when filling MULTIRATE INFUSOR system.

1. Remove the Sterility Protector Cap from the MULTIRATE INFUSOR system. Retain the Sterility Protector Cap to replace when filling is complete.
2. Ensure that all air is removed from the syringe or filling device prior to filling. When possible, introduce the appropriate amount of diluent prior to filling and priming.
3. Insert Luer tip of filled syringe or filling device into the Fill Port until secure. Do not over tighten to avoid damaging the Fill Port.
4. Fill the MULTIRATE INFUSOR system.
5. Fill the device with a volume ranging from the Minimum Fill Volume to the Maximum Fill Volume (see product information table above).
6. Remove the syringe or filling device from the Fill Port.
7. Replace and tighten the Sterility Protector Cap onto the Fill Port. Do not over tighten to avoid damaging the Fill Port.
8. A small air bubble may remain within the Elastomeric Reservoir and is a normal occurrence. Do not attempt to remove the bubble.
9. Using Rate Adjustment Tool, change setting on pacemark to lowest labeled rate to initiate priming.
10. Prime the MULTIRATE INFUSOR system by removing the Winged Luer Cap. Retain the Winged Luer Cap for later use.
11. The MULTIRATE INFUSOR system will prime slowly.
12. Ensure that all air has been purged from the tubing.
13. If air bubbles are present in the tubing, allow the device to flow until all air has been removed.
14. If medication is not flowing at all to the Distal End Luer Lock, force prime to remove. First, attach a Luer adapter (not included) to the Distal End Luer Lock. Second, attach a syringe (10 ml preferred) to the Luer adapter (or disposing and pull back the syringe plunger to apply continuous suction until fluid is observed in the syringe. Third, disconnect the syringe and Luer adapter (or disposable from the Distal End Luer Lock.
15. Using Rate Adjustment Tool, change rate to middle labeled rate to continue priming.
16. Using Rate Adjustment Tool, change rate to highest labeled rate to continue priming.
17. Visually confirm that the product is primed by observing two consecutive drops of medication from the tip of the Distal End Luer Lock.
18. Replace the Winged Luer Cap onto the Distal End Luer Lock. Ensure that the Winged Luer Cap is securely connected after filling and priming. Over-tightening may cause the Winged Luer Cap to be difficult to remove.
19. Using the Rate Adjustment Tool, adjust MULTIRATE INFUSOR Control Module to prescribed flow rate, then replace or remove Rate Adjustment Tool as prescribed by the healthcare provider.
20. Label the MULTIRATE INFUSOR system in accordance with applicable regulations and local institutional policy.
21. Place the filled MULTIRATE INFUSOR system in its pouch for transport to the patient.

Directions for Administration:

Refer to the Information for Patients and Healthcare Provider section.

Warning: Use aseptic technique throughout entire procedure.

1. To start the infusion, remove the Winged Luer Cap from the Distal End Luer Lock. Visually confirm that medication is flowing by observing two consecutive drops of medication from the tip of the Distal End Luer Lock before use.
2. For convenient administration, securely connect the Distal End Luer Lock to the catheter hub. Do not over-tighten.
3. To achieve the desired medication temperature, ensure that the MULTIRATE INFUSOR Control Module is **secured to the skin**.
4. Ensure that the Fill Port and Distal End Luer Lock are positioned at **approximately the same height** during the infusion. Use of a carrying bag or case may assist with positioning of the device.

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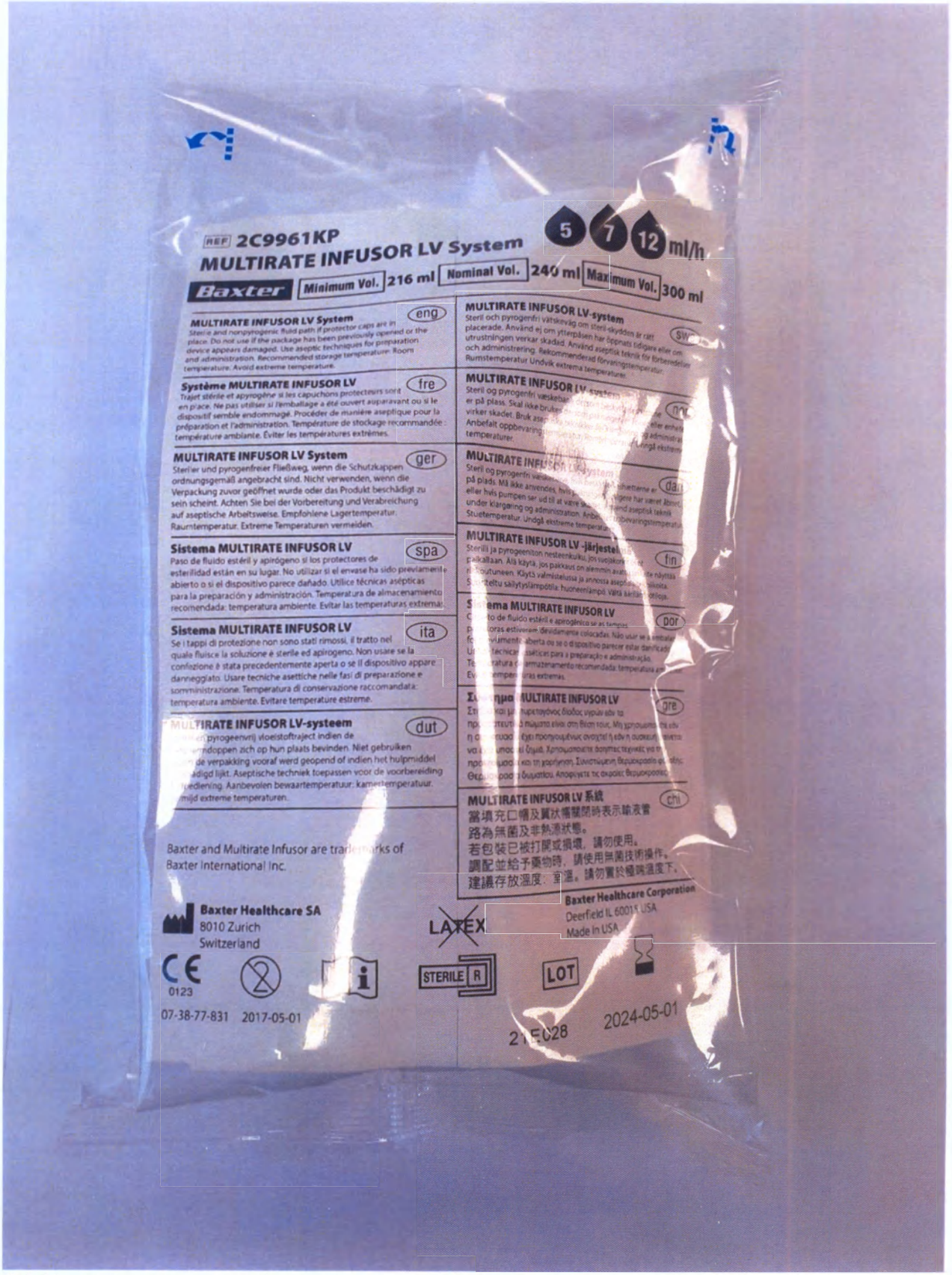
4.8. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 2-4-6 мл/ч; Оригинальная инструкция

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

5. Помпа медицинская инфузионная эластомерная одноразовая стерильная

Infusor LV 5-7-12 мл/ч

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



5.1. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 5-7-12 мл/ч; Индивидуальная упаковка, лицевой сторона, с оригинальной маркировкой

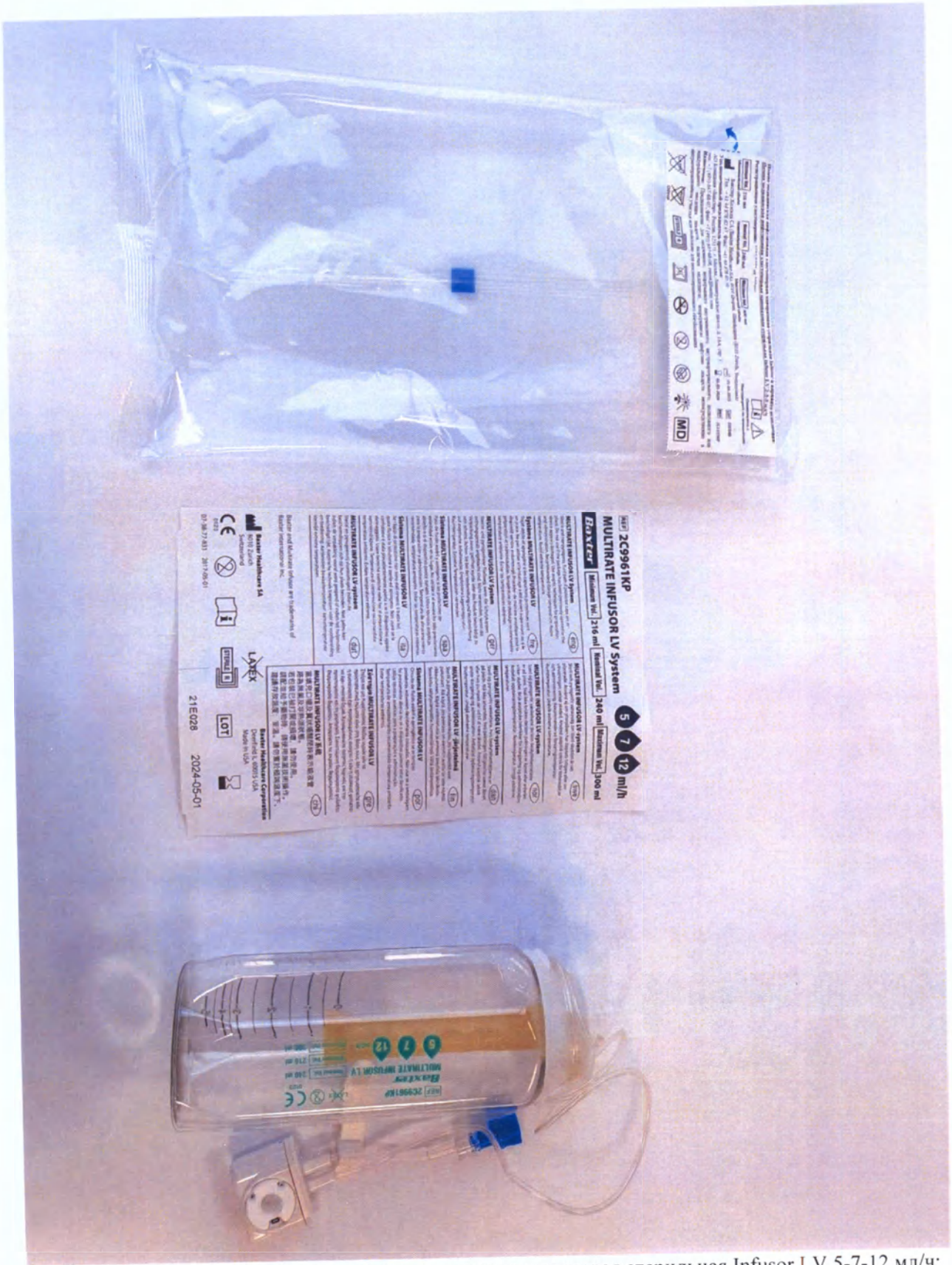
ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

5.2. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 5-7-12 мл/ч; Индивидуальная упаковка, оборотная сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

5.3. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 5-7-12 мл/ч; Индивидуальная упаковка, лицевая сторона, с нанесенной маркировкой на русском языке

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



5.4. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 5-7-12 мл/ч; Комплект поставки

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

5.5. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 5-7-12 мл/ч; Помпа, лицевая сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

5.6. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 5-7-12 мл/ч; Помпа, сторона со шкалой инфузии

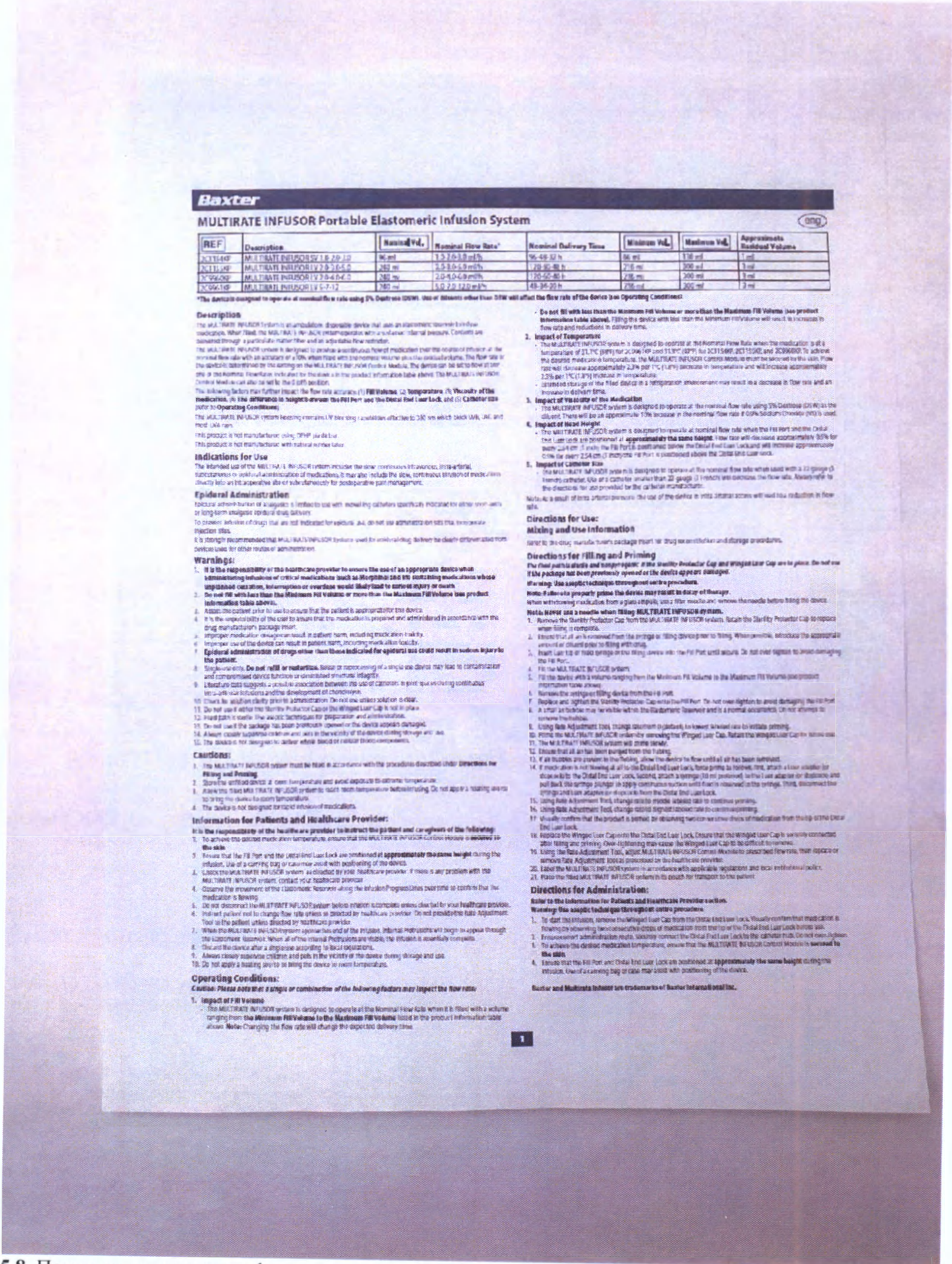
ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

5.7. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 5-7-12 мл/ч; Помпа, вид сверху

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

5.7. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 5-7-12 мл/ч; Помпа, вид сверху

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



REF	Description	Nominal Vol.	Nominal Flow Rate*	Nominal Delivery Time	Minimum Vol.	Maximum Vol.	Approximate Residual Volume
2C1164KP	MULTIRATE INFUSOR SV 1.0-2.0-3.0	96 ml	1.0-2.0-3.0 ml/h	96-48-32 h	66 ml	118 ml	1 ml
2C1162KP	MULTIRATE INFUSOR LV 2.0-3.0-5.0	240 ml	2.0-3.0-5.0 ml/h	120-80-48 h	216 ml	300 ml	1 ml
2C9960KP	MULTIRATE INFUSOR LV 2.0-4.0-6.0	240 ml	2.0-4.0-6.0 ml/h	120-60-40 h	216 ml	300 ml	1 ml
2C9961KP	MULTIRATE INFUSOR LV 5-7-12	240 ml	5.0-7.0-12.0 ml/h	48-34-20 h	216 ml	300 ml	3 ml

*The device is designed to operate at nominal flow rate using 5% Dextrose (D5W). Use of diluents other than D5W will affect the flow rate of the device (see Operating Conditions)

Description

[illegible]

This product is not manufactured using DEHP plasticizer.
This product is not manufactured with natural rubber latex.

Indications for Use

[illegible]

Epidural Administration

[illegible]

Warnings:

[illegible]

Cautions:

[illegible]

Information for Patients and Healthcare Provider:

[illegible]

Operating Conditions:

Caution: Please note that a single or combination of the following factors may impact the flow rate:

1. **Impact of Fill Volume**
2. **Impact of Temperature**
3. **Impact of Viscosity of the Medication**
4. **Impact of Head Height**
5. **Impact of Catheter Size**

Directions for Use:

Mixing and Use Information

[illegible]

Directions for Filling and Priming

[illegible]

Directions for Administration:

Refer to the Information for Patients and Healthcare Provider section.

[illegible]

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5.8. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor LV 5-7-12 мл/ч; Оригинальная инструкция

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

6. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor XLV 8 мл/ч

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

6.1. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor XLV 8 мл/ч; Индивидуальная упаковка, лицевой сторона, с оригинальной маркировкой

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

6.2. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor XLV 8 мл/ч; Индивидуальная упаковка, оборотная сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

6.3. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor XLV 8 мл/ч; Индивидуальная упаковка, лицевая сторона, с нанесенной маркировкой на русском языке

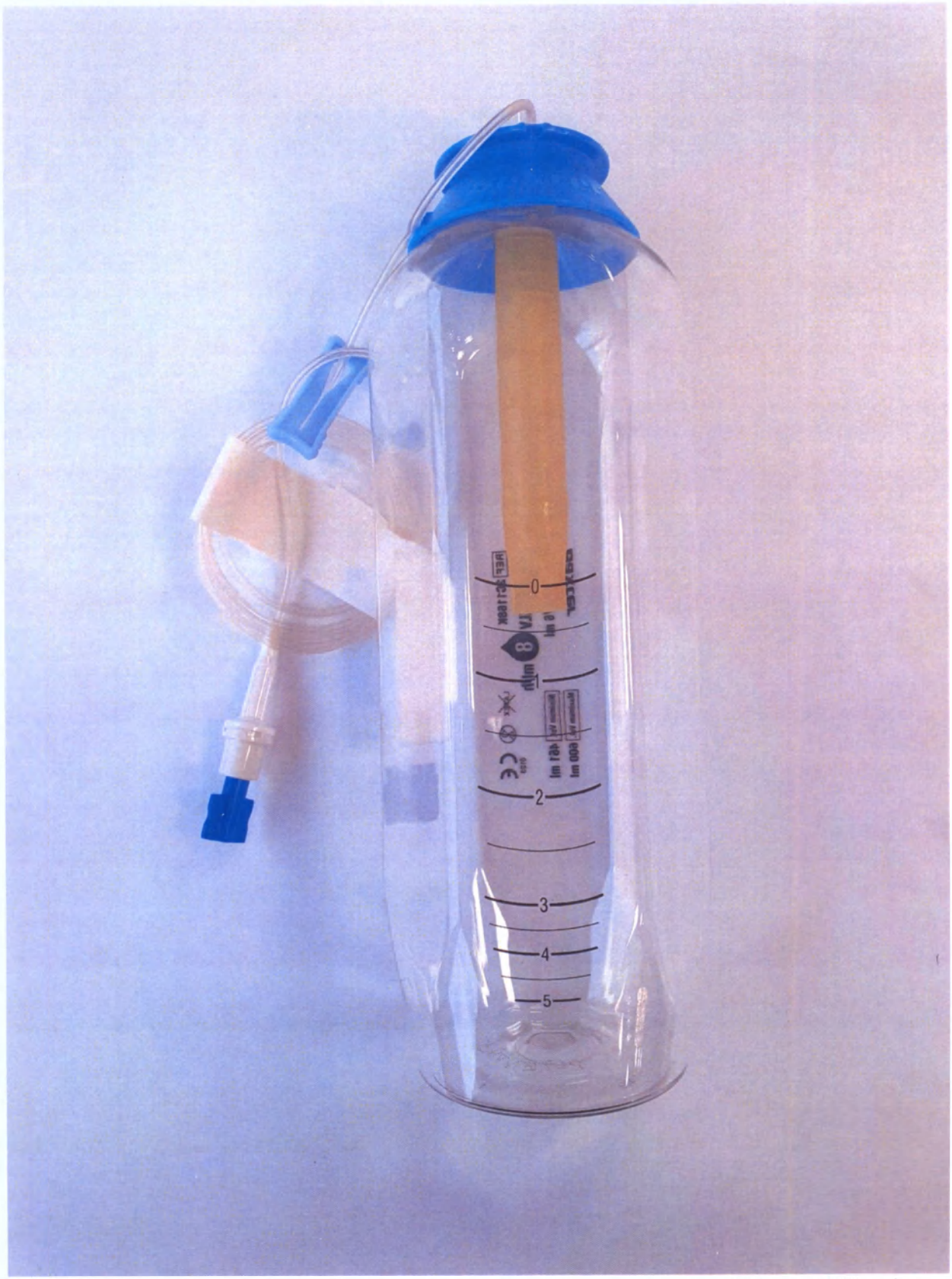
ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

6.4. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor XLV 8 мл/ч; Комплект поставки

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

6.5. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor XLV 8 мл/ч; Помпа, лицевая сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



6.6. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor XLV 8 мл/ч; Помпа, сторона со шкалой инфузии

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

6.7. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor XLV 8 мл/ч; Помпа, вид сверху

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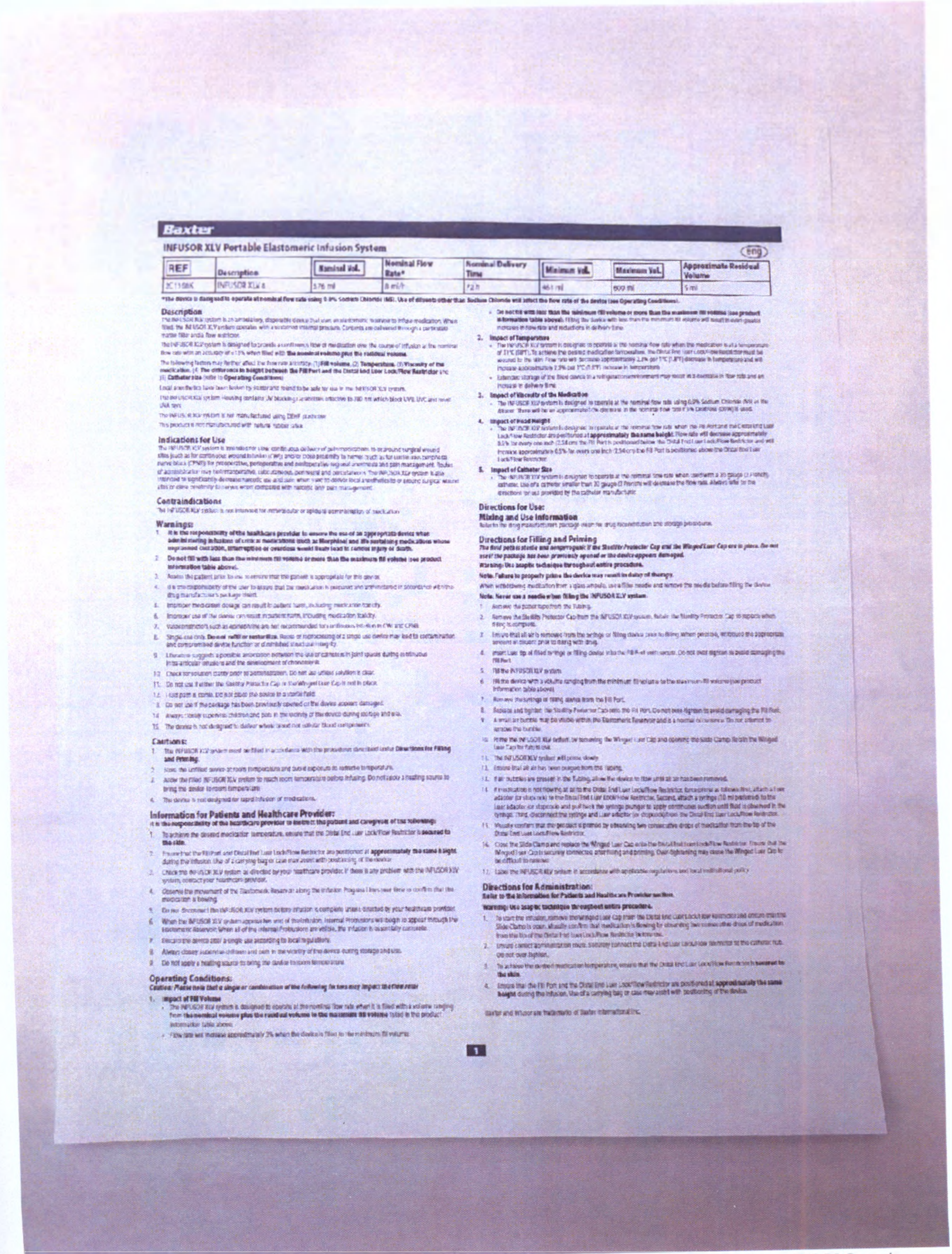

Baxter

INFUSOR XLV Portable Elastomeric Infusion System

eng

REF	Description	Nominal Vol.	Nominal Flow Rate*	Nominal Delivery Time	Minimum Vol.	Maximum Vol.	Approximate Residual Volume
2C1108K	INFUSOR XLV 8	576 ml	8 ml/h	72 h	461 ml	609 ml	5 ml

*The device is designed to operate at nominal flow rate using 0.9% Sodium Chloride (NS). Use of diluents other than Sodium Chloride will affect the flow rate of the device (see Operating Conditions).

Description

[illegible]

Indications for Use

[illegible]

Contraindications

[illegible]

Warnings:

1. **It is the responsibility of the healthcare provider to ensure the use of an appropriate device when administering infusions of critical medications (such as Morphine) and life sustaining medications whose unplanned cessation, interruption or overdose would likely lead to serious injury or death.**
2. **Do not fill with less than the minimum fill volume or more than the maximum fill volume (see product information table above).**

[illegible]

Cautions:

[illegible]

Information for Patients and Healthcare Provider:

[illegible]

Operating Conditions:

[illegible]

Directions for Use:

Mixing and Use Information

[illegible]

Directions for Filling and Priming

[illegible]

Directions for Administration:

[illegible]

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6.8. Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor XLV 8 мл/ч; Оригинальная инструкция

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

7. Модуль контроля скоростью потока (у вариантов исполнения № 1 – 5)

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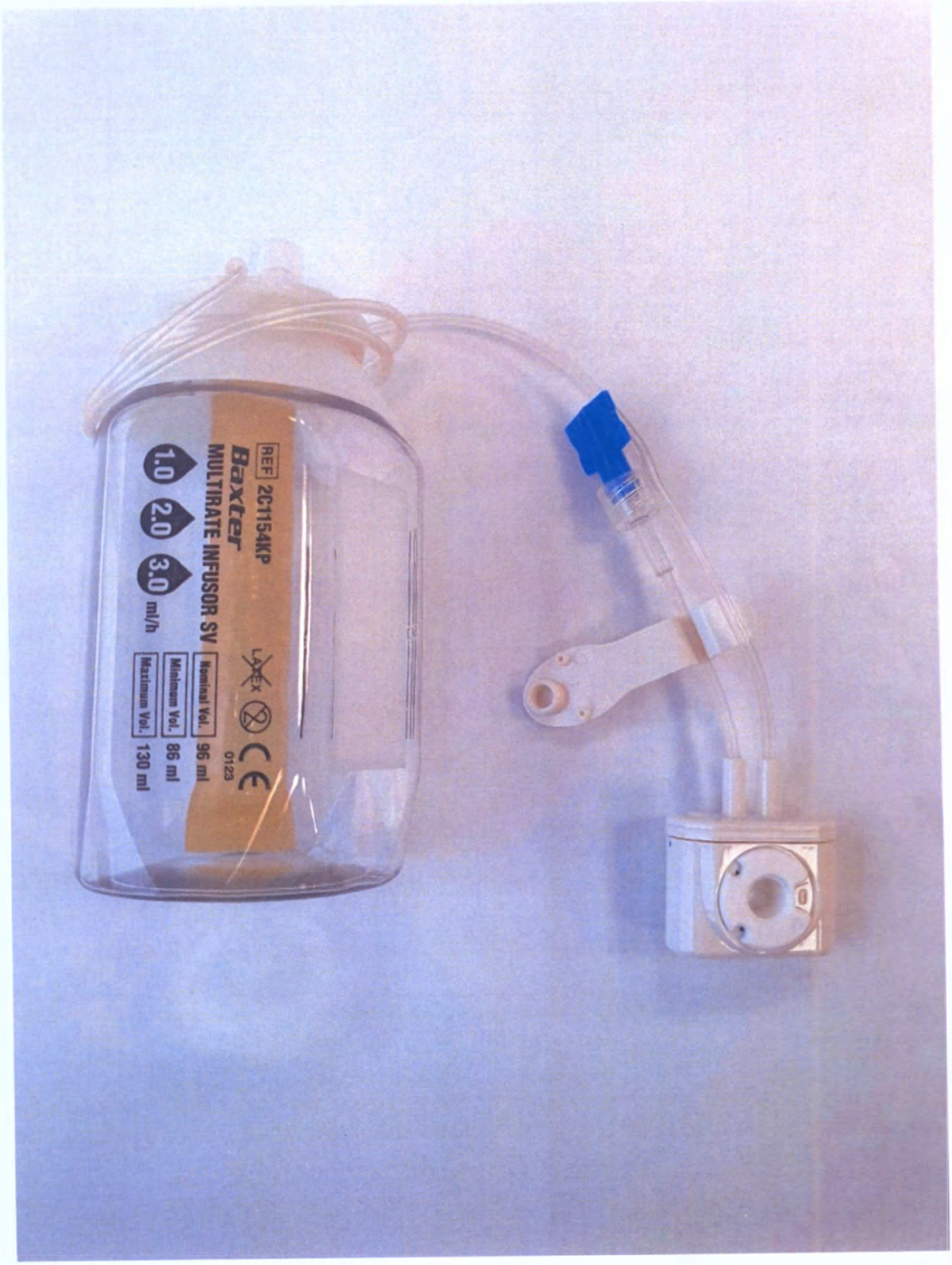
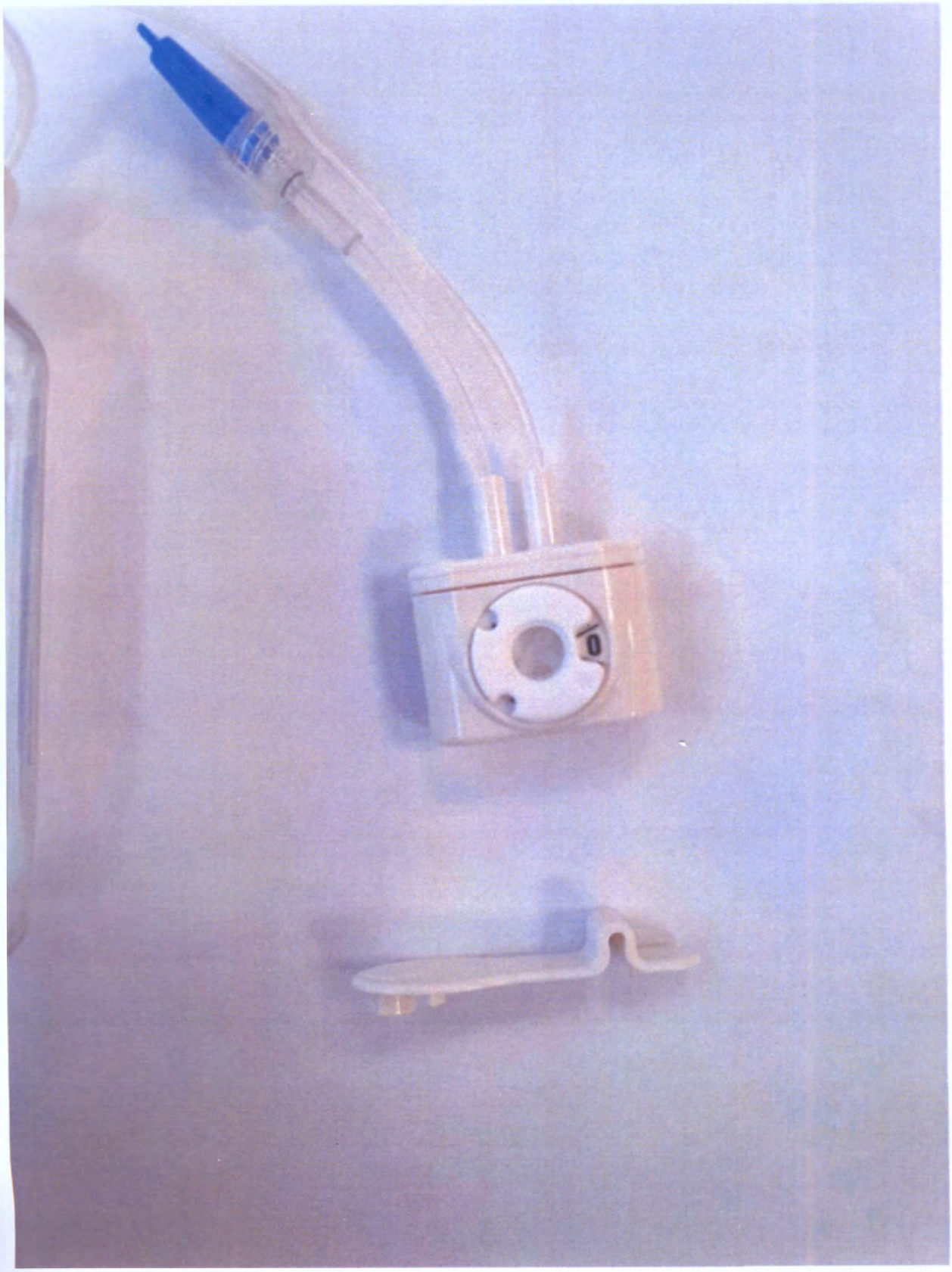


7.2. Модуль контроля скоростью потока;
Оборотная сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU



7.3. Модуль контроля скоростью потока;
Инструмент для переключения скорости потока, вид сбоку

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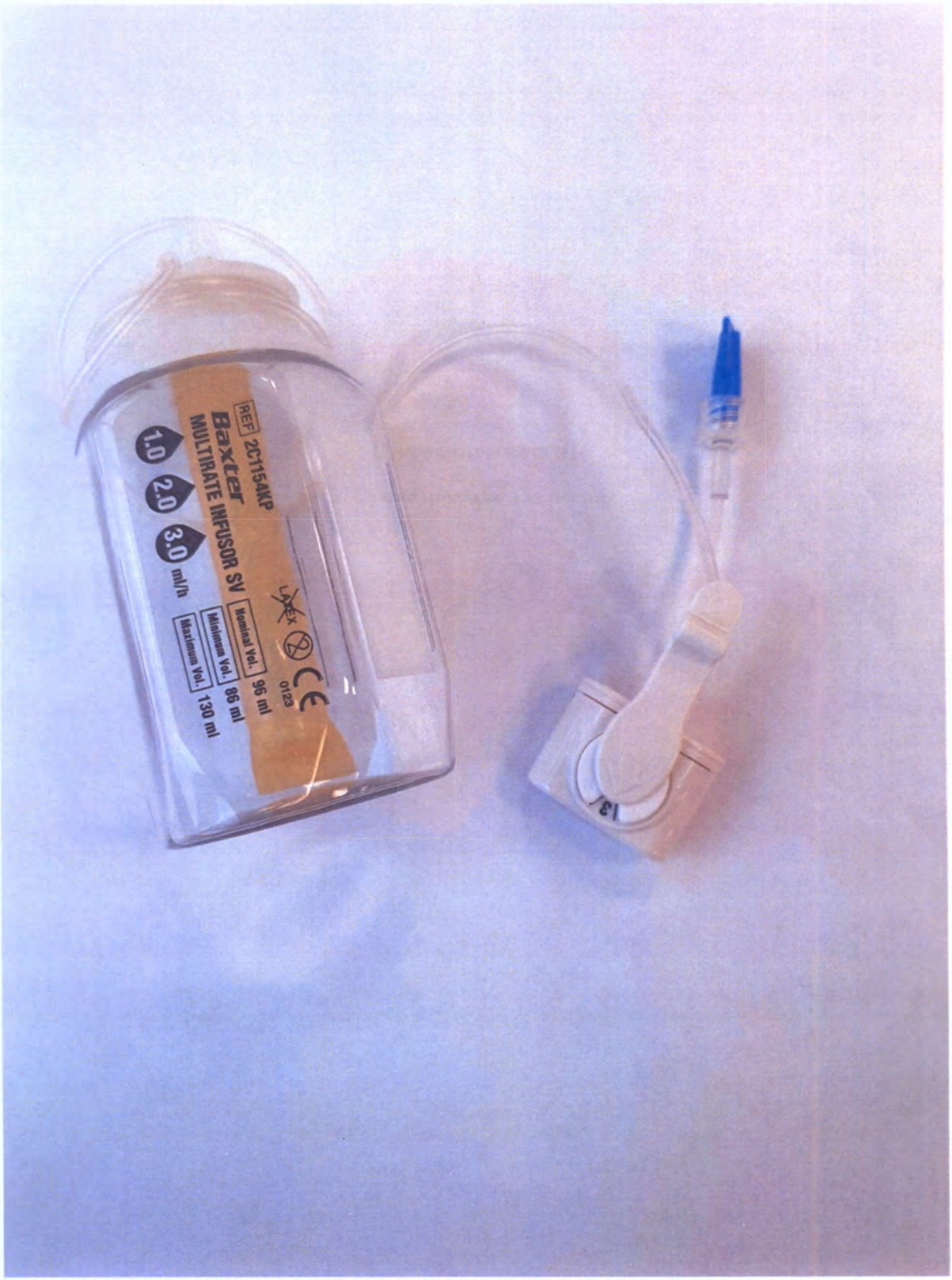

7.4. Модуль контроля скоростью потока;
Размещение инструмента на модуле, для переключения скорости

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Принадлежности:

8. Сумка поясная для помпы

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

8.1. Сумка поясная для помпы;
Индивидуальная упаковка, с нанесенной маркировкой на русском языке

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

8.2. Сумка поясная для помпы;
Лицевая сторона

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

8.3. Сумка поясная для помпы;
Оборотная сторона с крючком крепления к ремню

ООО ЦИРМИ INFO@CIRMI.RU WWW.GOSZDRAVNADZOR.RU

8.4. Сумка поясная для помпы;
Вид сбоку

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8.5. Сумка поясная для помпы;
Крепление сумки

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8.6. Сумка поясная для помпы;
Внутри сумки хранится ремень для сумки

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8.7. Сумка поясная для помпы;
Сумка и ремень

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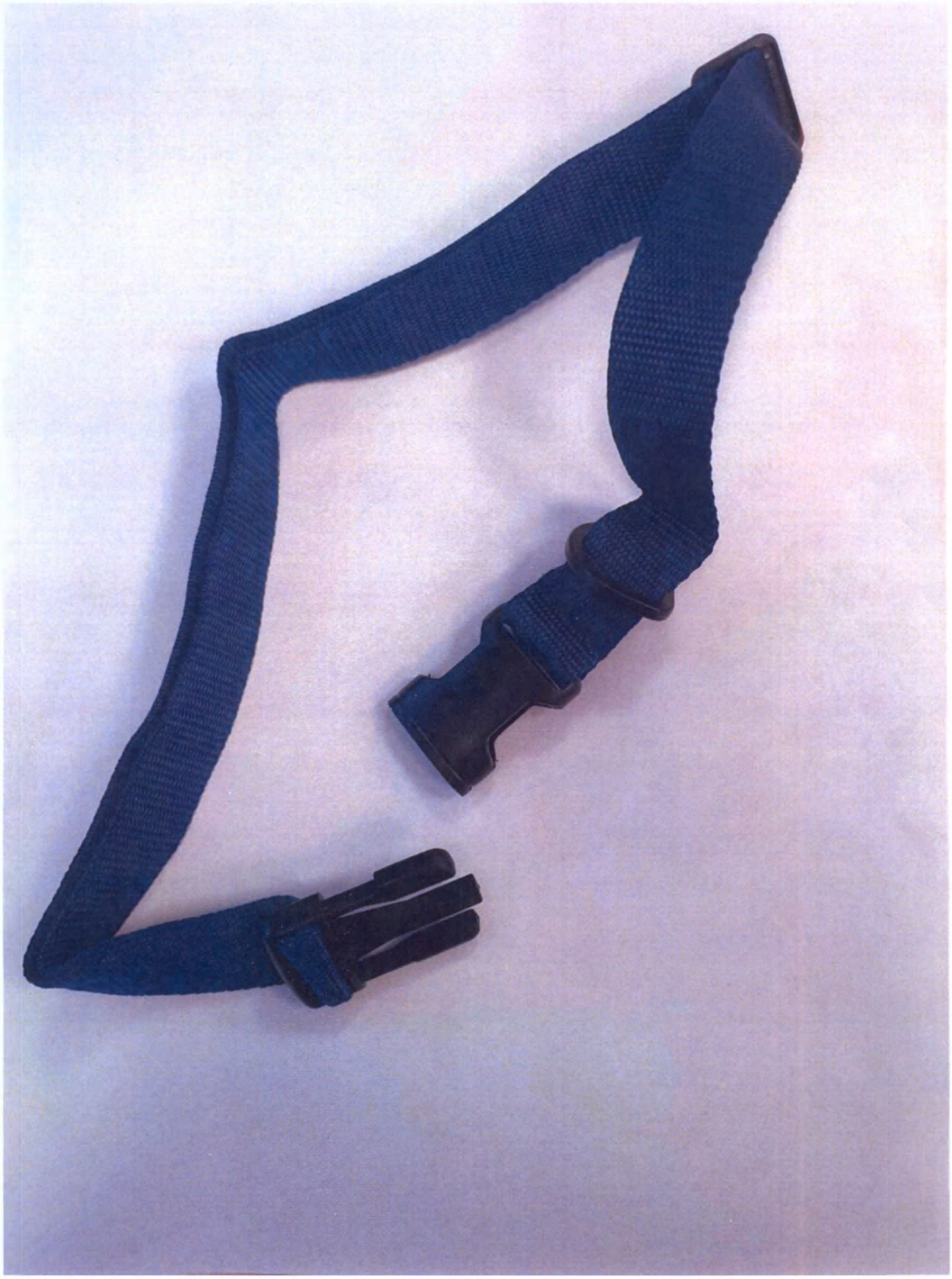

8.8. Сумка поясная для помпы;
Ремень

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8.9. Сумка поясная для помпы;
Вид сверху, сумка раскрыта

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8.10. Сумка поясная для помпы;
Сумка, пристегнутая к ремню, помпа внутри

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8.11. Сумка поясная для помпы;
Сумка с помпой внутри, вид сверху

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Пример маркировки на русском языке:

Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor в варианте исполнения:
Помпа медицинская инфузионная эластомерная одноразовая стерильная Infusor болюсом, 5-7-12 мл/ч

Регистрационное удостоверение: ****/**** от ******

Ознакомьтесь с Инструкцией по применению

Minimum Vol. 216 мл
Минимальный объём

Nominal Vol. 240 мл
Номинальный объём

Maximum Vol. 300 мл
Максимальный объём

Бакстер Хелскеа СА (Baxter Healthcare SA), 8010 Zürich, Switzerland (Швейцария)
Тел.: + 41 44 878 62 47; Факс: +41 44 878 63 50.

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тел. +7 (495) 647-68-07, факс +7 (495) 647-68-08, russia@baxter.com

14-07-2020 LOT 20G003
01-07-2023 REF 2C1811K

Назначение: Предназначена для медленного, непрерывного внутривенного, внутриартериального, подкожного или эпидурального введения лекарств, включая медленную, непрерывную инфузию лекарств непосредственно в интраоперационном участке или подкожно для послеоперационного обезболивания.

LATEX PHT DEHP STERILE R MD

Принадлежности:
Сумка поясная для помпы

Регистрационное удостоверение: ****/**** от ******

Ознакомьтесь с Инструкцией по применению

Бакстер Хелскеа СА (Baxter Healthcare SA), 8010 Zürich, Switzerland (Швейцария)
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26-02-2020 LOT 20B048
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_____Гусев М.В.
«14» декабря 2021 г.

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