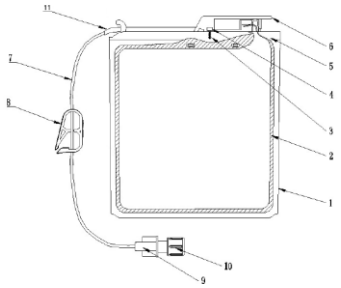
MEDCAPTAIN LIFE SCIENCE CO., LTD.
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Medication Cassette Reservoir Instructions for Use

1. Device description

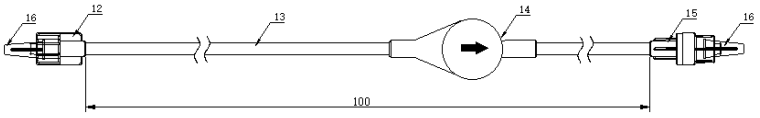
1.1 Device structure

Medication Cassette Reservoir consists of cassette assembly and extension set assembly. As shown in Figure 1, the cassette assembly consists of cassette shell, medicine bag, spring, liquid stop clamp, pressure plate, stopper, infusion tube, Robert clamp, female connector (Luer or NRFit), screw cap with hole and extruded tube, and as shown in Figure 2, the extension set assembly consists of male connector (Luer or NRFit), infusion tube, filter (5μm), check valve Luer or (check valve Luer and Luer to NRFit connector) and protective cap.



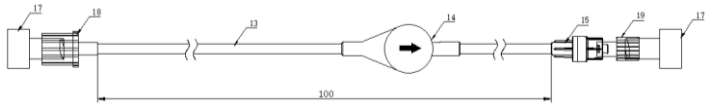
1. Cassette Shell 2.Medicine Bag 3.Spring 4.Liquid Stop Clamp 5.Pressure Plate 6.Stopper 7.Infusion Tube 8.Robert Clamp 9.Female Connector (Luer or NRFit) 10.Screw Cap with Hole 11.Extruded Tube

Figure 1, Schematic diagram of cassette assembly



12. Male Luer Connector 13.Infusion Tube 14.Filter (5μm) 15.Check Valve Luer 16. Protective Cap

Figure 2, Schematic diagram of extension set assembly (Luer Type)



17. Male NRFit Connector Protective Cap 18. Male NRFit Connector 13. Infusion Tube 14. Filter (5μm) 15. Check Valve Luer 19. Luer to NRFit Connector

Figure 3, Schematic diagram of extension set assembly (NRFit Type)

1.2 Device models

There are 20 models of Medication Cassette Reservoir according to the volume, type of connector and whether contain extension set. The detail is showed in Table 1.

Table 1, Medication Cassette Reservoir

No.	Model	Volume (ml)	Type of Connector	Extension set
1	AR1L-050	50	Luer	Exclude
2	AR1L-100	100	Luer	
3	AR1L-150	150	Luer	
4	AR1L-300	300	Luer	
5	AR1L-500	500	Luer	

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6	AR1N-050	50	NRFit	
7	AR1N-100	100	NRFit	
8	AR1N-150	150	NRFit	
9	AR1N-300	300	NRFit	
10	AR1N-500	500	NRFit	
11	AR1L-050E	50	Luer	Include
12	AR1L-100E	100	Luer	
13	AR1L-150E	150	Luer	
14	AR1L-300E	300	Luer	
15	AR1L-500E	500	Luer	
16	AR1N-050E	50	NRFit	
17	AR1N-100E	100	NRFit	
18	AR1N-150E	150	NRFit	
19	AR1N-300E	300	NRFit	
20	AR1N-500E	500	NRFit	

1.3 Device features

The features of the products see below:

1) EO sterilization and sterile.
2) Non pyrogenic.
3) Does not contain natural rubber latex.
4) Contain PVC (DEHP plasticizer).
5) Bubbles in the solution can be observed through the shell of the medication reservoir cassette.

1.4 Device materials

The materials used to make Medication Cassette Reservoir contains: ABS, TPU, PVC (contains DEHP plasticizer), PC, POM, and stainless steel.

2. Intended use, Contraindications, Patient target group and Intended users

Intended Use: The Medication Cassette Reservoirs is specially used with Ambulatory Infusion Pump (model: ELFensor P2、ELFensor P3、ELFensor P5、ELFensor P6、ELFensor P8、ELFensor P9) made by Medcaptain Medical Technology Co., Ltd. for medication delivery.

Contraindications: No absolute contraindication.

Patient Target Group: Adults.

Intended Users: Professional medical personnel or persons who received professional training.

3. Instructions for use

1) Use aseptic technique.
2) Fill the syringe with the desired volume of medication and/or diluent.
3) Remove screw cap from tubing.
4) Attach filled syringe to Luer (or NRfit) connector and fill medicine bag until about half full.
5) Make the liquid outlet of the medicine bag face up, turn or shake the bag gather all the bubbles and aspiration.
6) Turn the syringe upside down, grasp the end of the syringe and inject the remaining liquid into the medicine bag.
7) Repeat steps 5-6 until no bubbles are visible. After injection all fluid, close the clamp. Make sure the medicine and diluent are properly mixed.
8) If an extension set is required, disconnect the Luer (or NRFit) connector from the attached syringe, connect to the

extension set and pre-fill the tube.

9) Install the medication cassette reservoir to the infusion pump according to the infusion pump operation manual. (Before fixing the medication cassette reservoir to the infusion pump, the stopper should be removed. Removing the stopper will close the line to prevent accidental gravity flow.)

To temporarily open fluid path once Stopper is removed:

- Close Robert clamp
- Disconnect from patient access site
- Open Robert clamp
- Press and hold liquid stop clamp

4. Precautions and warnings

1) The accuracy of MEDCAPTAIN Ambulatory Infusion Pump (model: ELFensor P2、ELFensor P3、ELFensor P5、ELFensor P6、ELFensor P8、ELFensor P9) is ±5%. To make sure patient does not run out of medication sooner than expected, consider this 5% accuracy when filing the Medication cassette reservoir and/or programming the pump.
2) Inspect package and contents. Do not use this product if it appears damaged, or stopper is not in place.
3) This product is for single use only, do not re-use.
4) Do not use if the product is expired.
5) This product is not opaque, so there is no ultraviolet protection of light-sensitive medicines.
6) Do not overfill or pressurize medication bag inside medication cassette reservoir or it may cause medication bag to rupture or leak.
7) Note that if a leak is observed during filling or the infusion, the product and medicine should not be used. The medicine should not be re-used or removed and placed into another product as this carries a risk of introducing infection.
8) If the filled medication cassette reservoir is to be frozen, it must be thawed only at room temperature. Do not thaw in a microwave oven.
9) With the stopper in place, fluid path is open to allow for filling.
10) Do not use with substances that are incompatible with fluid path materials. The medication bag and infusion tube inside the medication cassette reservoir are made of PVC. To determine compatibility contact the drug/fluid manufacturer.
11) Do not use this product for infusion of medicines incompatible with PVC.
12) This product is not intended for the delivery of fat-soluble liquids and drugs. It is recommended to use this product under the guidance of doctors when infusing other medicines.
13) Ensure fluid path is free of air before connecting to patient.
14) Please read the instructions for use carefully before use. Failure to do so, could result in death or serious injury to the patient.
15) The maximum use time of this product shall not exceed 7 days.
16) The extension tube with check valve of our company must be used, otherwise the infusion accuracy may be affected.
17) This product contains DEHP, and clinicians should be aware of its possible toxicity in high-risk groups (newborns, prepubescent males, breastfeeding women during pregnancy).

5. Storage and transportation

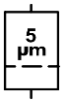
1) The product should be stored in a dry, cool and ventilated environment, avoiding sunlight, rain and high temperature.
2) Prevent weight pressure, direct sunlight and rain immersion during transportation.
3) Please dispose this product according to local laws and regulations or hospital regulations.

6. Notice to the user and/or patient

If there is any serious incident that has occurred in relation to the device, please report to the manufacturer and the

competent authority of the Member State in which the user and/or patient is established.

7. Definition of symbols

Symbol	Description	Symbol	Description
	Caution		Consult instructions for use
	Sterilized using ethylene oxide		Do not re-use
	Does not contain LATEX		Do not use if package is damaged and consult instructions for use
	Manufacturer		Authorized representative in the European Community
	Use-by date		Date of manufacture
	Catalogue number		Batch code
	This way up		Model number
	Keep dry		Fragile, handle with care
	Keep away from sunlight		Contains DEHP
	Non-pyrogenic		ISO8536-8-IS-P
	Single sterile barrier system		Unique device identifier
	Liquid filter with pore size	**Qty**	Quantity
	Medical device		

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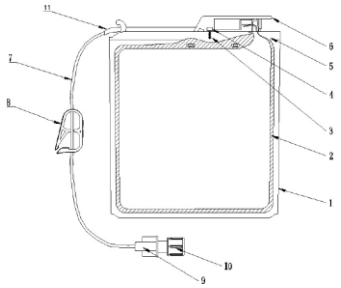
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Medication Cassette Reservoir Instructions for Use

1. Device description

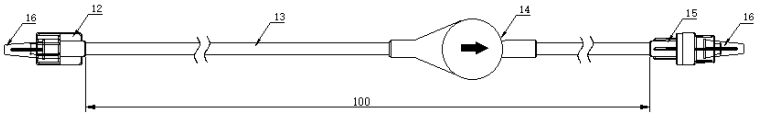
1.1 Device structure

Medication Cassette Reservoir consists of cassette assembly and extension set assembly. As shown in Figure 1, the cassette assembly consists of cassette shell, medicine bag, spring, liquid stop clamp, pressure plate, stopper, infusion tube, Robert clamp, female connector (Luer or NRFit), screw cap with hole and extruded tube, and as shown in Figure 2, the extension set assembly consists of male connector (Luer or NRFit), infusion tube, filter (5μm), check valve Luer or (check valve Luer and Luer to NRFit connector) and protective cap.



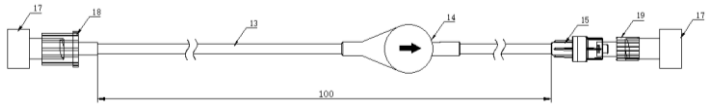
1. Cassette Shell 2.Medicine Bag 3.Spring 4.Liquid Stop Clamp 5.Pressure Plate 6.Stopper 7.Infusion Tube 8.Robert Clamp 9.Female Connector (Luer or NRFit) 10.Screw Cap with Hole 11.Extruded Tube

Figure 1, Schematic diagram of cassette assembly



12. Male Luer Connector 13.Infusion Tube 14.Filter (5μm) 15.Check Valve Luer 16. Protective Cap

Figure 2, Schematic diagram of extension set assembly (Luer Type)



17. Male NRFit Connector Protective Cap 18. Male NRFit Connector 13. Infusion Tube 14. Filter (5μm) 15. Check Valve Luer 19. Luer to NRFit Connector

Figure 3, Schematic diagram of extension set assembly (NRFit Type)

1.2 Device models

There are 20 models of Medication Cassette Reservoir according to the volume, type of connector and whether contain extension set. The detail is showed in Table 1.

Table 1, Medication Cassette Reservoir

No.	Model	Volume (ml)	Type of Connector	Extension set
1	AR2L-050	50	Luer	Exclude
2	AR2L-100	100	Luer	
3	AR2L-150	150	Luer	
4	AR2L-300	300	Luer	
5	AR2L-500	500	Luer	

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6	AR2N-050	50	NRFit	
7	AR2N-100	100	NRFit	
8	AR2N-150	150	NRFit	
9	AR2N-300	300	NRFit	
10	AR2N-500	500	NRFit	
11	AR2L-050E	50	Luer	Include
12	AR2L-100E	100	Luer	
13	AR2L-150E	150	Luer	
14	AR2L-300E	300	Luer	
15	AR2L-500E	500	Luer	
16	AR2N-050E	50	NRFit	
17	AR2N-100E	100	NRFit	
18	AR2N-150E	150	NRFit	
19	AR2N-300E	300	NRFit	
20	AR2N-500E	500	NRFit	

1.3 Device features

The features of the products see below:

1) EO sterilization and sterile.
2) Non pyrogenic.
3) Does not contain natural rubber latex.
4) Contain PVC (TOTM plasticizer).
5) Bubbles in the solution can be observed through the shell of the medication reservoir cassette.

1.4 Device materials

The materials used to make Medication Cassette Reservoir contains: ABS, TPU, PVC (contains TOTM plasticizer), PC, POM, and stainless steel.

2. Intended use, Contraindications, Patient target group and Intended users

Intended Use: The Medication Cassette Reservoirs is specially used with Ambulatory Infusion Pump (model: ELFensor P2、ELFensor P3、ELFensor P5、ELFensor P6、ELFensor P8、ELFensor P9) made by Medcaptain Medical Technology Co., Ltd. for medication delivery.

Contraindications: No absolute contraindication.

Patient Target Group: Adults and pediatrics.

Intended Users: Professional medical personnel or persons who received professional training.

3. Instructions for use

1) Use aseptic technique.
2) Fill the syringe with the desired volume of medication and/or diluent.
3) Remove screw cap from tubing.
4) Attach filled syringe to Luer (or NRfit) connector and fill medicine bag until about half full.
5) Make the liquid outlet of the medicine bag face up, turn or shake the bag gather all the bubbles and aspiration.
6) Turn the syringe upside down, grasp the end of the syringe and inject the remaining liquid into the medicine bag.
7) Repeat steps 4-5 until no bubbles are visible. After injection all fluid, close the clamp. Make sure the medicine and diluent are properly mixed.
8) If an extension set is required, disconnect the Luer (or NRFit) connector from the attached syringe, connect to the

extension set and pre-fill the tube.

9) Install the medication cassette reservoir to the infusion pump according to the infusion pump operation manual. (Before fixing the medication cassette reservoir to the infusion pump, the stopper should be removed. Removing the stopper will close the line to prevent accidental gravity flow.)

To temporarily open fluid path once Stopper is removed:

- Close Robert clamp
- Disconnect from patient access site
- Open Robert clamp
- Press and hold liquid stop clamp

4. Precautions and warnings

1) The accuracy of MEDCAPTAIN Ambulatory Infusion Pump (model: ELFensor P2、ELFensor P3、ELFensor P5、ELFensor P6、ELFensor P8、ELFensor P9) is ±5%. To make sure patient does not run out of medication sooner than expected, consider this 5% accuracy when filing the Medication cassette reservoir and/or programming the pump.
2) Inspect package and contents. Do not use this product if it appears damaged, or stopper is not in place.
3) This product is for single use only, do not re-use.
4) Do not use if the product is expired.
5) This product is not opaque, so there is no ultraviolet protection of light-sensitive medicines.
6) Do not overfill or pressurize medication bag inside medication cassette reservoir or it may cause medication bag to rupture or leak.
7) Note that if a leak is observed during filling or the infusion, the product and medicine should not be used. The medicine should not be re-used or removed and placed into another product as this carries a risk of introducing infection.
8) If the filled medication cassette reservoir is to be frozen, it must be thawed only at room temperature. Do not thaw in a microwave oven.
9) With the stopper in place, fluid path is open to allow for filling.
10) Do not use with substances that are incompatible with fluid path materials. The medication bag and infusion tube inside the medication cassette reservoir are made of PVC. To determine compatibility contact the drug/fluid manufacturer.
11) Do not use this product for infusion of medicines incompatible with PVC.
12) The compatibility of the medicines studied in this product include: Dexmedetomidine Hydrochloride, Flurbiprofen Axetil, Lansoprazole, Fat Emulsion. It is recommended to use this product under the guidance of doctors when infusing other medicines.
13) Ensure fluid path is free of air before connecting to patient.
14) Please read the instructions for use carefully before use. Failure to do so, could result in death or serious injury to the patient.
15) The maximum use time of this product shall not exceed 7 days.
16) The extension tube with check valve of our company must be used, otherwise the infusion accuracy may be affected.

5. Storage and transportation

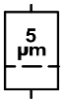
1) The product should be stored in a dry, cool and ventilated environment, avoiding sunlight, rain and high temperature.
2) Prevent weight pressure, direct sunlight and rain immersion during transportation.
3) Please dispose this product according to local laws and regulations or hospital regulations.

6. Notice to the user and/or patient

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7. Definition of symbols

Symbol	Description	Symbol	Description
	Caution		Consult instructions for use
	Sterilized using ethylene oxide		Do not re-use
	Does not contain LATEX		Do not use if package is damaged and consult instructions for use
	Manufacturer		Authorized representative in the European Community
	Use-by date		Date of manufacture
	Catalogue number		Batch code
	This way up		Model number
	Keep dry		Fragile, handle with care
	Keep away from sunlight		Does not contain DEHP
	Non-pyrogenic		ISO8536-8-IS-P
	Single sterile barrier system		Unique device identifier
	Liquid filter with pore size	**Qty**	Quantity
	Medical device		

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