SMARTeZ™ Pump

Portable single-use elastomeric infusion pump
Manufactured under 21 CFR 820 QS Reg. and EN ISO 13485: 2016 compliant quality management systems.

DESCRIPTION

The SMARTeZ™ Pump has a specially designed multi-layered balloon-like reservoir to be filled with the drug or fluid intended for infusion. It exerts a mechanical pressure, thereby administering the contents through an orifice tube at a predetermined flow rate. The entire unit is sterile and is intended for single-use only. When filled at the nominal volume, flow accuracy is within +/- 15% of the nominal (label) flow rate (at 99% confidence level).
Flow rate is affected by temperature and viscosity of the drug or fluid (see MIXING AND USE INFORMATION) and the actual fill volume.
Expected flow profile of a pump filled at nominal volume is shown in Figure 1. Flow rate profiles of long infusion time and short infusion time are similar as shown in Figure 2.

Figure 1: Expected flow profile of a pump filled at nominal volume

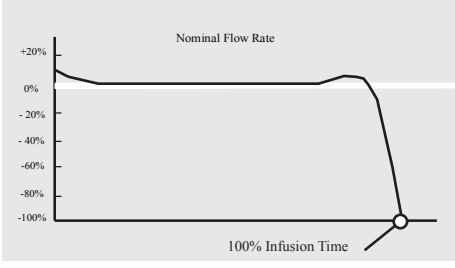


Table 1: Residual volumes

Nominal Volume	Residual Volume
50 - 125 mL	2.0 mL
200 - 300 mL	3.5 mL
400 - 500 mL	5.0 mL

INDICATIONS FOR USE STATEMENTS

The SMARTeZ™ Pump (Long infusion time article) is intended for continuous infusion of medications for general infusion use including pain management.
- Routes of administration: intravenous and subcutaneous.

The SMARTeZ™ Pump (Short infusion time article) is intended for continuous infusion of medications for general infusion use including antibiotic delivery.
- Route of administration: intravenous.

The SMARTeZ™ Pump (Chemotherapy article) is intended for continuous infusion of medications for chemotherapy.
- Routes of administration: intravenous and intra-arterial.

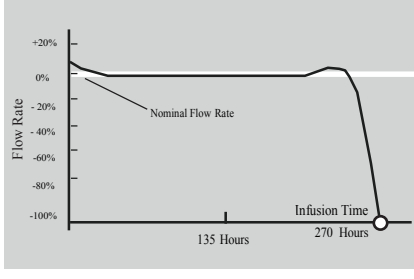
WARNINGS

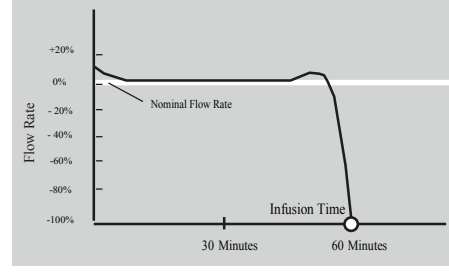
- Do not use in infusion regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapies or who are not under the care of responsible individuals. This warning includes paediatrics as they are not capable of using the devices by themselves.
- Do not use if packaging or product is damaged or opened.
- Do not immerse the pump in water. Prevent the filter from getting wet.
- Do not use with pressure infusion device.
- When administering through the intra-arterial and subcutaneous routes where back pressures are expected, flow rates will decrease.
- Do not exert pressure or play with filled device and take caution when used with immobilized patients and to avoid device being slept on. Applied pressure may result in rupture or breakage and will result in increased flow rate. In case of spillage of medication, see drug MSDS for appropriate actions.
- Do not re-sterilize. Strictly for single-use and pump must be discarded in accordance with local regulations.
- Store under general warehouse conditions at 68°F to 77°F (20°C to 25°C). Protect from light sources and heat. Keep dry.
- Drug products should be stored in their approved containers and closures.
- Do not store in freezer.

CONTRAINDICATIONS

- Infusion of insulin, blood or blood products, TPN, lipids or fat emulsions.
- Infusion of any solutions that are not compatible. Consult the pharmaceutical manufacturer's precautions and guidelines to ensure that the medications used will not interact with the device that may possibly cause damage, leakage or precipitation.
- Intra-articular infusion of local anesthesia.
- Infusion of anesthetics in neonates, infants and children below 5 years of age.

Figure 2 : Flow rate profiles of long infusion time and short infusion time pumps are similar.

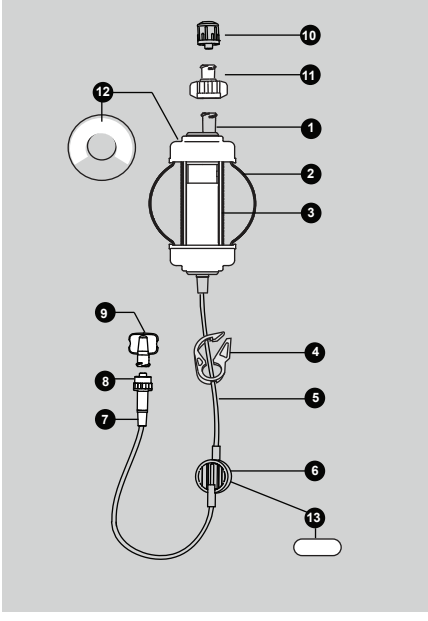




SMARTeZ™ Pump

Portable single use elastomeric infusion pump

1. Fill Port
2. Outer soft cover
3. Multi-layered elastomeric membrane
4. ON-OFF Clamp
5. Non DEHP PVC administration tubing
6. Air and particulate eliminating filter
7. Flow restrictor
8. Patient connector
9. Patient end cap
10. Sterile color-coded fill port cap
11. Disposable protective fill port cap
12. Labeling – Fill volume & infusion duration
13. Labeling - Flowrate



OPERATING CONDITIONS AND SAFETY

Actual infusion time may vary due to the following:

- Filling the device less than the nominal volume generally results in slower flow rate.
- Filling the device more than the nominal volume generally results in faster flow rate.
- To achieve claimed flow rate accuracy infusion should be started one (1) hour after filling the device.
- The safety of the device is validated based on infusion time and an additional 8 hour drug/device contact time.
- Temperature affects viscosity. Higher temperature lowers viscosity resulting in shorter delivery times , while lower temperature increases viscosity resulting in longer delivery times.
- The device flow restrictor should be close to or in contact with the skin (31 deg C / 88 deg F) and the tubing and pump should be under the patients clothing (25 deg C/ 77 deg F). For an increase of every one (1) deg C, the flow rate may increase by 2.5% and conversely for every one (1) deg C reduction flow rate may decrease by 2.5%.
- The nominal flow rates are based on sodium chloride (0.9%, 31 deg C / 88 deg F) as reference. Use of 5% dextrose will result in 10% slower flow rate or correspondingly 10% longer delivery times.
- Avoid getting alcohol or detergents on the filter which may cause leakage from the air eliminating filter.

MIXING AND USE INFORMATION

- See the drug manufacturer's package insert for drug reconstitution / dilution and storage procedures. Drugs tested for stability and compatibility, representing each route of infusion, include Ceftriaxone, Deferoxamine, Floxuridine, and Vancomycin. Also see drug package insert for drug compatibility with ABS, silicone elastomer, PVC not made from phthalate (DEHP), acrylic, cellulose acetate or e-PFTE and for use suitability with an in-line 1.2µm filter.
- Calculate the fill volume by multiplying the desired infusion time (hours) by the nominal flow rate (mL/h) and adding the residual volume. Alteration of dosage is achieved by adjusting the drug concentration - the flow rate is fixed.

INSTRUCTIONS FOR FILLING

- Use Aseptic Technique

1. Unscrew the disposable protective fill port cap with the sterile color-coded fill port cap connected.
2. SMARTeZ™ Pump can be filled with a syringe or automated filling device. Remove trapped air from the filling device and attach it securely to the fill port.
3. Close the ON-OFF clamp and fill the SMARTeZ™ Pump with no more than the maximum recommended volume. When using a syringe to fill, push the plunger to dispense the fluid. Do not push the barrel onto the fill port as the syringe tip or fill port may break. Repeat as necessary.
4. Remove filling device from the fill port. Remove disposable protective fill port cap from the sterile color-coded fill port cap. Attach the sterile color-coded fill port cap to the filled SMARTeZ pump fill port.
5. Label with appropriate pharmaceutical and patient information.

PRIMING THE ADMINISTRATION TUBING

- Use Aseptic Technique

1. Open the ON-OFF clamp.
2. Loosen the patient end cap. Medication will start to flow and fill the tubing. When all air is expelled, tighten the patient end cap.
3. Close the ON-OFF clamp.

PRIMING TECHNIQUE FOR DRUGS

- (for drugs prone to precipitation)

1. Fill SMARTeZ™ Pump with 10 mL of diluent first.
2. Using the above priming method, prime the tubing.
3. Fill the remaining volume with diluent and medication. At completion, the diluent will fill the entire tubing, protecting it from precipitation, while the pump reservoir will contain medication.

STARTING INFUSION

- Use Aseptic Technique

1. Allow SMARTeZ™ Pump to warm to room temperature before use, especially when infusate has been refrigerated.
2. Infusion should preferably be started 1 hour after filling.
3. Verify that the ON-OFF clamp is close.
4. Clean patient access site as directed by the hospital or healthcare provider. Attach the patient connector to the injection site.
5. Begin infusion by opening the ON-OFF clamp.

SINGLE USE ONLY

SMARTeZ™ Pump is designed for optimal performance, effectiveness and safety as a single-use device and not for reuse. Performance, effectiveness and safety may be compromised if the device is reused.

CAUTION : Federal (USA) Law restricts this device to be sold by or on the order of a physician.

Distributed by : Progressive Medical Inc., St. Louis, MO.
800-969-6331.

LIST OF ARTICLES / MODEL NUMBERS - SMARTeZ™ PUMPS

Type	REF No. (Article/ Model)	Nominal Fill Volume (mL)	Nominal Flow Rate (mL/h)	Nominal Time (Hr)	Approx. Nominal Time (Day)	Qty Per Carton
Long infusion time	480151	65 mL	0.5 mL/h	130 Hr	5.5 Days	12
	480181	100 mL	0.5 mL/h	200 Hr	8 Days	12
	480191	270 mL	1 mL/h	270 Hr	11 Days	12
	480121	100 mL	1.5 mL/h	67 Hr	3 Days	12
	480051	60 mL	2 mL/h	30 Hr	1 Day	12
	480081	100 mL	2 mL/h	50 Hr	2 Days	12
	480101	120 mL	2 mL/h	60 Hr	2.5 Days	12
	480161	270 mL	2 mL/h	135 Hr	5.5 Days	12
	480171	300 mL	2 mL/h	150 Hr	6 Days	12
	480061	120 mL	4 mL/h	30 Hr	1 Day	12
	480131	270 mL	4 mL/h	68 Hr	3 Days	12
	480141	400 mL	4 mL/h	100 Hr	4 Days	12
	480011	60 mL	5 mL/h	12 Hr	0.5 Day	12
	480021	80 mL	5 mL/h	16 Hr	0.5 Day	12
	480031	125 mL	5 mL/h	25 Hr	1 Day	12
	480091	270 mL	5 mL/h	54 Hr	2 Days	12
	480111	400 mL	5 mL/h	80 Hr	3 Days	12
	480041	270 mL	10 mL/h	27 Hr	1 Day	12
	480071	400 mL	10 mL/h	40 Hr	1.5 Days	12
Type	REF No. (Article/ Model)	Nominal Fill Volume (mL)	Nominal Flow Rate (mL/h)	Nominal Time (Min)	Approx. Nominal Time (Hr)	Qty Per Carton
Short infusion time	481032	50 mL	50 mL/h	60 Min	1 Hr	24
	481092	100 mL	50 mL/h	120 Min	2 Hrs	24
	481152	250 mL	50 mL/h	300 Min	5 Hrs	24
	481042	100 mL	100 mL/h	60 Min	1 Hr	24
	481112	200 mL	100 mL/h	120 Min	2 Hrs	24
	481122	250 mL	100 mL/h	150 Min	2.5 Hrs	24
	481101	400 mL	100 mL/h	240 Min	4 Hrs	12
	481132	250 mL	125 mL/h	120 Min	2 Hrs	24
	481062	250 mL	175 mL/h	90 Min	1.5 Hrs	24
	481012	100 mL	200 mL/h	30 Min	0.5 Hr	24
	481142	200 mL	200 mL/h	60 Min	1 Hr	24
	481071	400 mL	200 mL/h	120 Min	2 Hrs	12
	481052	250 mL	250 mL/h	60 Min	1 Hr	24
	481081	500 mL	250 mL/h	120 Min	2 Hrs	12
	481022	250 mL	500 mL/h	30 Min	0.5 Hr	24
Chemotherapy	484011	100 mL	2 mL/h	50 Hr	2 Days	12
	484021	270 mL	2 mL/h	135 Hr	5.5 Days	12
	484031	120 mL	4 mL/h	30 Hr	1 Day	12
	484041	270 mL	5 mL/h	54 Hr	2 Days	12
	484051	270 mL	10 mL/h	27 Hr	1 Day	12

Table 3: Definitions of symbols

QTY	QuanTitY	EA	EAch
	Use by YYYY-MM-DD		Manufactured on YYYY-MM-DD
	Batch code	REF	Article number/ model number
	Authorized representative in the European Union and EFTA		Manufacturer
	Sterilized using ethyleneoxide	CE 0086	CE Marking of Conformity, Certification by BSi
	Single-use only, do not reuse		Consult instructions for use
	Do not use if package is damaged		Keep dry
	Keep away from sunlight		Packaging is able to be recycled
	Not made with natural rubber latex		Not made with phthalate(DEHP)
Rx only	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician		