Chapter 23

INFUSION DEVICES

OBJECTIVES

- State the applications of IV infusion.
- Describe the setup and identify the components of a typical gravity flow manual infusion system.
- List the common problems encountered in manual gravity flow infusion.
- Differentiate between infusion pumps and infusion controllers.
- Analyze the pumping mechanisms of common infusion pumps.
- Evaluate the safety and convenient features of modern infusion pumps.
- Draw a functional block diagram of an infusion pump and describe its operation.
- Review performance verification procedures of infusion pumps.
- Identify factors affecting the accuracy of infusion pumps.

CHAPTER CONTENTS

INTRODUCTION

Infusion devices are used to administer fluid into the body either through intravenous (IV) or epidural routes. Infusion devices for IV administration are commonly referred to as IV devices. As the venous pressure is below 50 mmHg (about 0.6 mH_2O), a 1-meter water column is sufficient to allow gravity to overcome the venous blood pressure and drive the solution into the blood vessel. Manual gravity flow IV infusion is used extensively in health care facilities for general-purpose infusion. To allow more controlled and accurate fluid delivery, more sophisticated devices have been developed. A number of infusion devices are available for different applications. This chapter studies the principles and applications of a few of these devices.

PURPOSE OF IV INFUSION

In general, four types of solutions are administered intravenously.

1. Water—Usually in the form of saline or dextrose, to prevent patient dehydration.
2. Medications and electrolytes—IV administration of drugs and electrolytes produces precise and fast-acting effects as it sends the drug directly into the bloodstream without going through the process of digestion and absorption. Examples include IV cardiovascular drugs, chemotherapy drugs, et cetera.
3. Nutrition—Although parenteral nutrition can be delivered through enteral feeding, total or partial parenteral nutrition is administered by IV infusion to patients when their normal diet cannot be ingested, absorbed, or tolerated for a significant period of time.
4. Blood—Blood infusion may be performed by an IV infusion device. However, some may require special infusion sets to avoid problems associated with the relatively high viscosity of blood and potential hemolysis of blood cells.

IV infusion is a procedure commonly performed in health care facilities. Infusion devices can be found in most parts of a hospital, including the emergency department, medical imaging areas, operating rooms, and so forth.

TYPES OF INFUSION DEVICES

Many different types of infusion devices are available in the market. Each has its own characteristics and serves some special applications. In general, infusion devices can be divided into two main groups: gravity flow infusion devices and infusion pumps. A gravity flow infusion device relies on the gravitational force exerted by a liquid column to push the fluid via a venous access into the patient's bloodstream, whereas an infusion pump has a motorized pumping mechanism to generate the positive pressure. Within the gravitation group are the manual gravity flow sets and the infusion controllers. There are two types of pumps in the infusion pump group: volumetric and syringe. Within the volumetric pump group are three different pumping mechanisms: piston cylinder, diaphragm, and peristaltic pumping mechanisms. Figure 23-1 shows the different types of infusion devices.

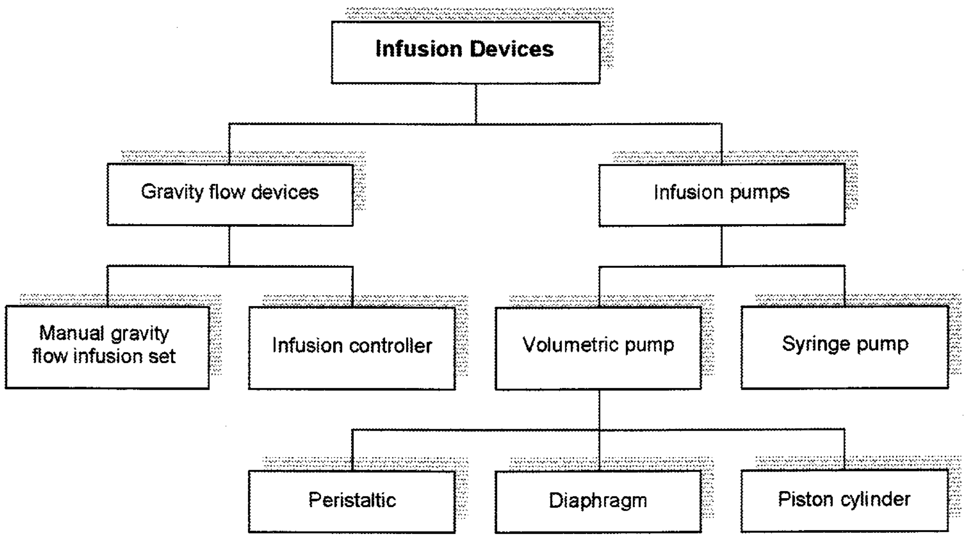

Figure 23-1. Types of Infusion Devices.

MANUAL GRAVITY FLOW INFUSION

The simplest infusion device is the manual gravity flow infusion set. Figure 23-2 shows a typical gravity flow infusion set. It consists of a long flexible PVC tubing with a solution bag spike at one end and a luer lock connector at the other end. The following sections describe the functional components of a gravity flow infusion setup.

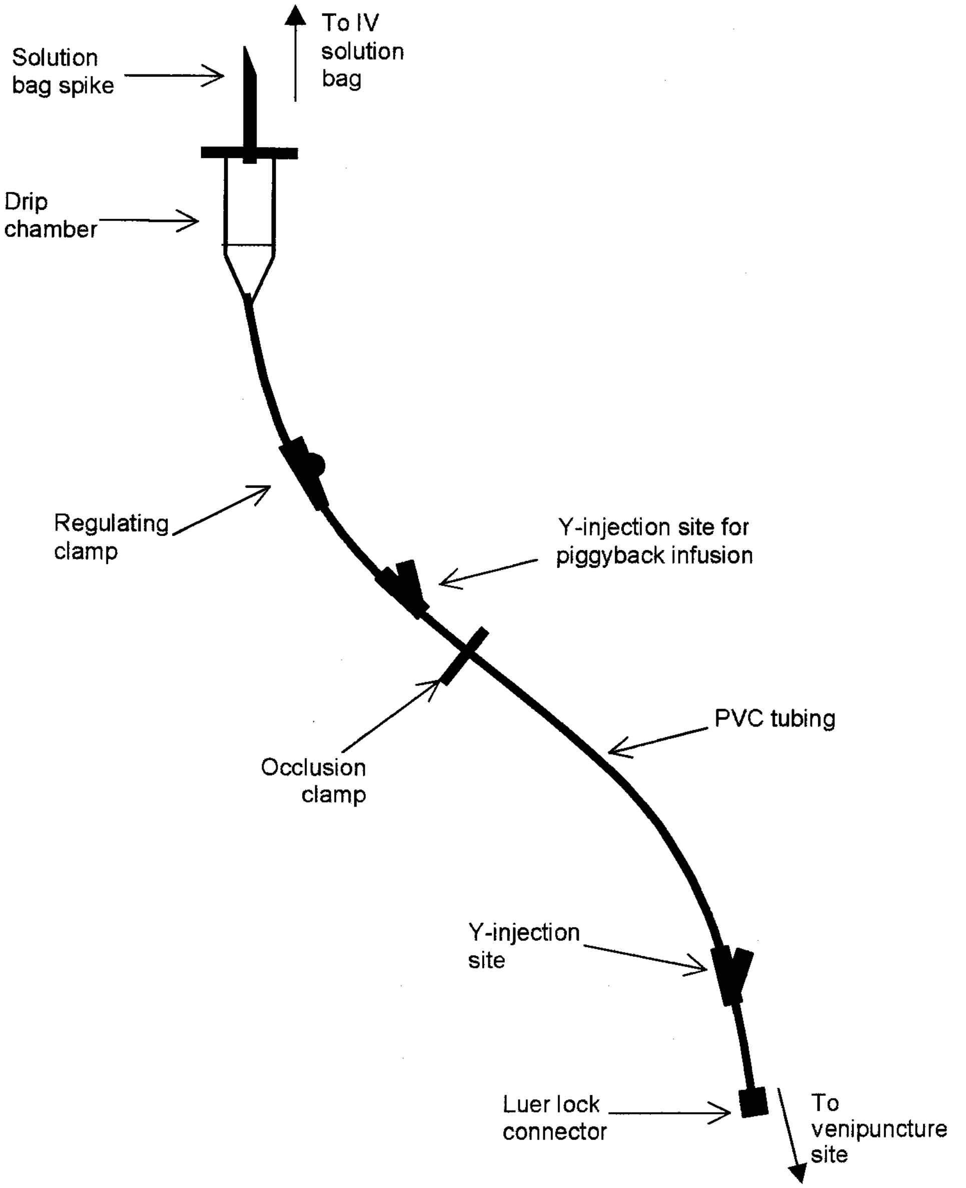

Figure 23-2. Gravity Flow Intravenous Infusion Set.

IV Solution Bag

The solution bag contains the IV solution and comes in different sizes (e.g., 500 cc, 1 liter, etc.). The bag is usually hung on an IV pole about 1.5 m above the infusion site to create enough pressure to overcome the venous pressure to cause infusion. Solution-filled glass bottles instead of disposable bags are used in some developing countries.

Solution Bag Spike

The solution bag spike is a sharp-ended tubing connecting the set to the IV solution bag. This sharp spike is pushed through the seal of the solution bag to allow solution to flow from the bag into the line.

Drip Chamber

The drip chamber is a clear compartment that permits the clinician to see the solution drops coming down from the solution bag. The size of the drop nozzle is designed so that each drop of solution is 1/20 ml (or 1/60 ml for slow flow rate sets). By counting the number of drops within a known time interval, a nurse can calculate the volume flow rate of the infusion.

Regulating Clamp

The regulating clamp is used to control the volume flow rate of infusion. It is also known as a roller clamp. By squeezing the roller over the flexible PVC tubing, it changes the cross-sectional area of the lumen, thereby controlling the infusion flow rate.

Yinjection Site

The Y-injection site provides a point of access into the infusion line. Drugs or other solutions can be injected into the infusion fluid by puncturing the injection port with a needle. To infuse a second solution when an infusion line has already been established (e.g., medication, blood plasma, etc.), a setup called piggyback infusion is used (Figure 23-3a). In this setup, since the secondary solution bag is located at a higher level than the primary solution bag, only the solution from the second bag will flow downstream through the Y-injection site. Flow of the primary solution will resume automatically when the secondary solution bag becomes emptied.

Occlusion Clamp

An occlusion clamp is used to totally occlude or shut down the infusion flow. Unlike the roller clamp, an occlusion clamp either fully opens the infu-

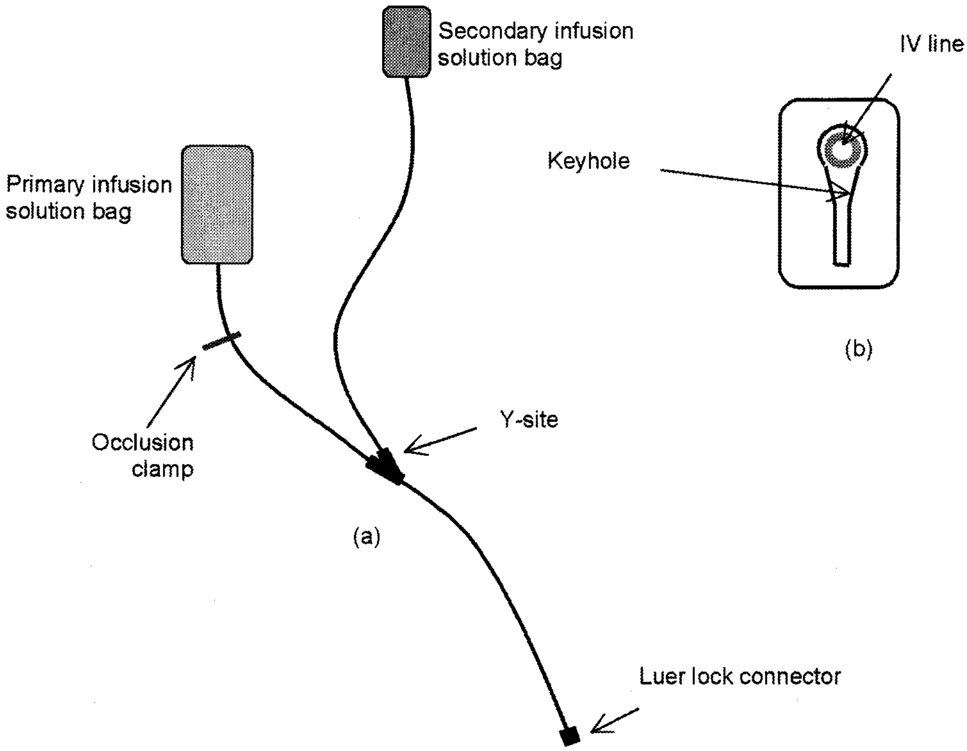

Figure 23-3. (a) Piggyback Infusion Setup, (b) Occlusion Clamp.

sion line or totally occludes the line. It is constructed from a piece of thick plastic with the infusion line threaded through a keyhole-shaped opening in the middle (Figure 23-3b). The line is fully open when the PVC tubing is at the larger opening of the keyhole. If the line is pushed to the narrow end, the clamp will occlude the tubing and shut off the flow.

Luer Lock Connector

A luer lock connector is a special twist lock mechanism to ensure a secure connection. To set up an IV infusion, a catheter is inserted into a vein; the other end of the catheter is a male luer lock connector. After the IV line is primed, it is connected to the catheter using the luer lock connector.

The procedure to prime the IV line is:

- Suspend the IV solution bag on the IV pole.
- Open the bag containing the IV line following sterile supplies handling procedure.
- Insert the solution bag spike of the line into the IV bag.

- Open the roller clamp and the occlusion clamp to allow the solution to flush all the air from the line.
- Remove air bubbles trapped in the Y-injection site by inverting and gently tapping it with a finger.
- Close the roller clamp and connect the luer lock at the end of the line to the luer lock at the catheter.
- Squeeze and release the drip chamber compartment to fill about one-third of the chamber with the IV solution.
- Slowly open the roller clamp to set up the desired solution flow rate (by counting the drops using a stopwatch).

Example

A nurse is observing the drop rate in the drip chamber to set the infusion flow rate on a manual gravity flow infusion set. How many drops per minute should be counted in the drip chamber if an infusion flow rate of 60 ml/hr is required? Assume that a 20 drops/ml nozzle is used in the drip chamber.

Solution

At a flow of 60 ml/hr, 60 X 20 drops will come down from the nozzle in 1 hour. Therefore, there will be 60 X 20/60 = 20 drops from the nozzle in 1 minute.

As the fluid to be infused flows directly into the bloodstream, infusion sets are sterilized inside their packages and are single-use disposable devices. With proper handling, infusion fluid from the solution bag flows only inside the infusion line, thereby maintaining the sterility of the system. A major drawback of manual gravity flow infusion is the low flow rate accuracy. As the mechanism to regulate the infusion flow rate (roller clamp) relies on compressing the PVC tubing of the infusion set, the rate of infusion cannot be precisely controlled. Figure 23-4 shows the change in flow rate after initial setup when there is no user intervention. This decrease in flow is due primarily to the nonperfect elastic nature of the material of the infusion line. The flow rate also changes with the level of fluid in the solution bag (the height of the liquid column). Experiments have shown that the flow rate can drop by about 40% within a couple of hours after initial setup. To overcome such a problem, as a normal practice, a nurse must recheck the flow rate after initial setup and adjust the regulating clamp to reestablish the desired flow rate.

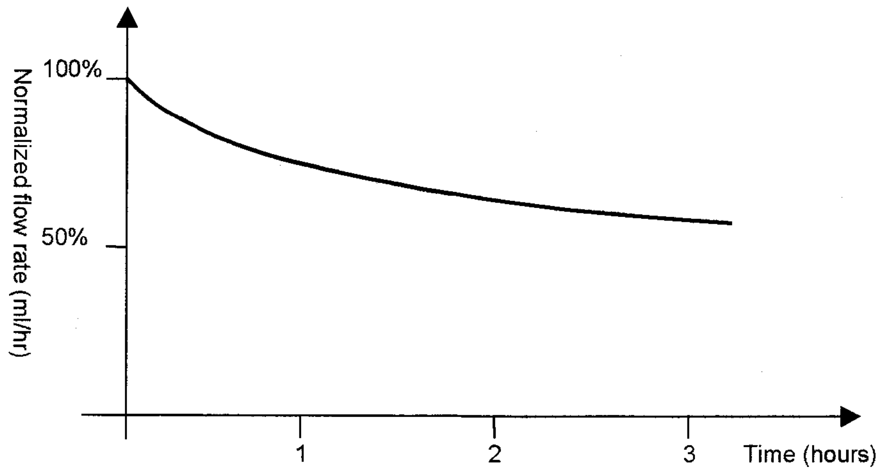

Figure 23-4. Flow Rate Change in Gravity Infusion.

INFUSION CONTROLLERS

An infusion controller overcomes the problem of flow rate variation by automatically adjusting the regulating clamp. Figure 23-5 shows the setup of an infusion controller. An infusion controller monitors the flow rate by counting the drops in the drip chamber. A typical drop sensor consists of an infrared light-emitting diode (LED) and an infrared light-sensitive transistor, each located on the opposite side of the drip chamber. A fluid drop from the solution bag interrupts the optical path and produces an electrical pulse. The flow rate is computed from the drop rate and the drop size. The calculated flow rate is then compared to the setting. If it is lower than the setting, the pinching force of the pinch mechanism will be released to allow more fluid to flow through. If it is higher, it will increase the pinching force to reduce the flow. Such a feedback mechanism maintains a constant flow rate equal to the setting. Although it automatically regulates the fluid flow rate, an infusion controller still relies on gravitational force to generate the infusion. If there is some restriction in the infusion line, the gravity pressure created by the liquid column may not be sufficient to produce the desired flow rate.

INFUSION PUMPS AND PUMPING MECHANISMS

An infusion pump contains a motor-driven pumping mechanism to produce a net positive pressure on the fluid inside the infusion line. With the

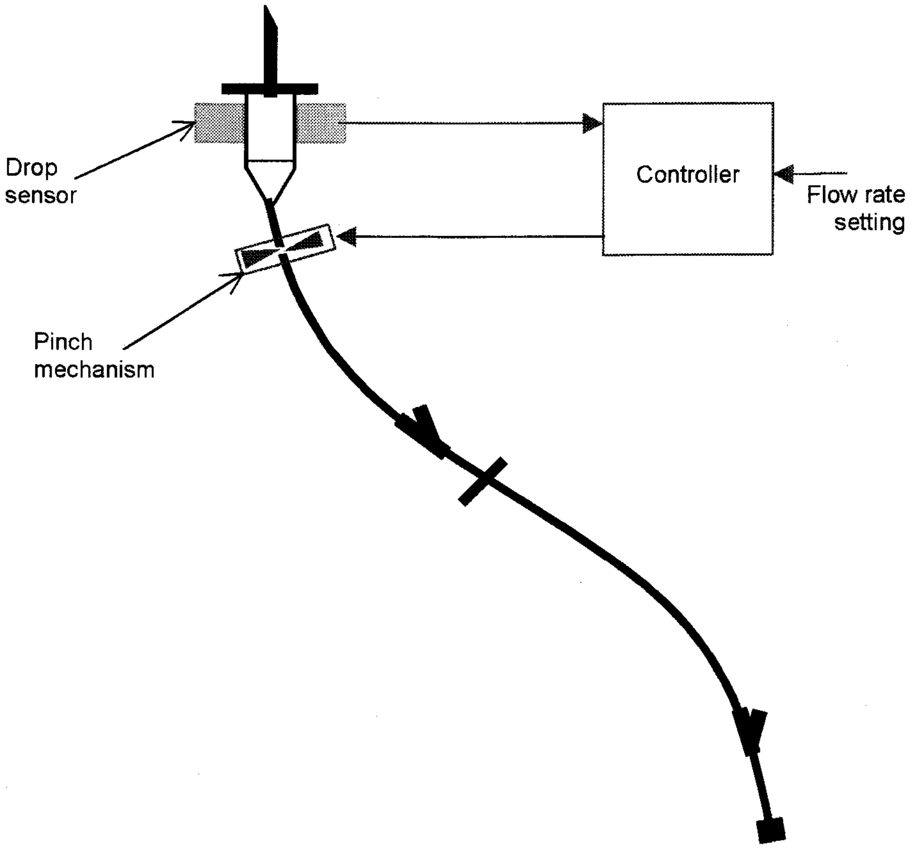

Figure 23-5. Infusion Controller.

pumping mechanism, infusion pumps produce a more controlled and consistent flow than infusion controllers. Infusion pumps can be divided into two types: volumetric pumps and syringe pumps.

Three common pumping mechanisms are used in volumetric infusion pumps. They are piston cylinder, diaphragm, and peristaltic. A syringe pump uses a screw and nut mechanism to drive the plunger of a syringe; it is also called a screw pump. The following sections describe these pumping mechanisms.

Piston Cylinder Pumps

The pumping mechanism of a piston cylinder pump consists of a cylinder, a piston, and valves that are mechanically linked to the piston motion. A stepper motor drives a cam to move the piston in and out of the cylinder in a reciprocal motion. Figure 23-6a shows that when the piston is moving downward, it creates a negative pressure inside the cylinder. The valve, which is linked to the cam, will be in such a position that the input port to the cylinder is opened and the output port is closed. Fluid from the IV bag will therefore be drawn into the cylinder. When the piston is moving upward (Figure 23-6b), the valve will close the input port and open the output port, allowing IV solution in the cylinder to exit through the output port. The stroke distance and the diameter of the piston determine the stroke volume, and the infusion flow rate is equal to the stroke volume times the cam's rotational speed.

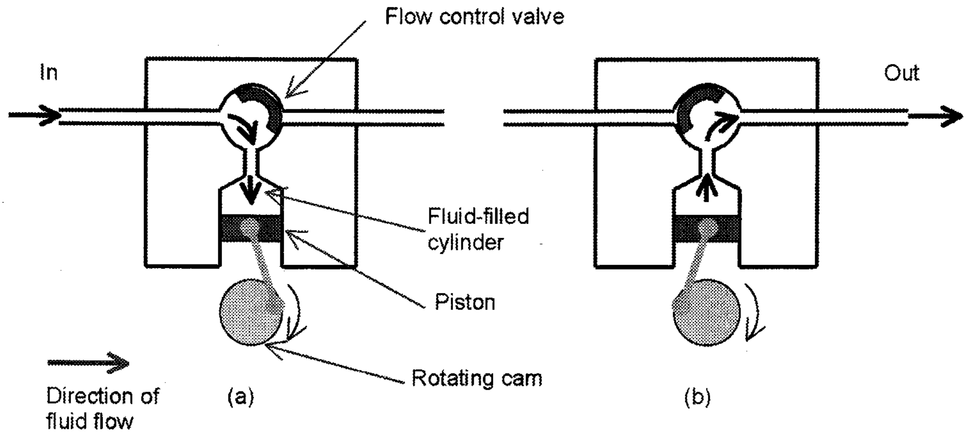

Figure 23-6. Piston Cylinder Infusion Mechanism.

Diaphragm Pumps

The pumping mechanism of a diaphragm pump is similar to that of a piston cylinder pump except that the stroke motion is replaced by a moveable diaphragm. In the illustration shown (Figure 23-7), when the diaphragm moves to the left, the intake valve is open to allow fluid to enter the fluid chamber. When it moves to the right, fluid is forced out of the chamber. Repeating the action provides a continuous flow of fluid.

Peristaltic Pumps

A peristaltic pump employs a protruding finger mechanism to occlude the flexible IV tubing. Its pumping action is similar to one using the thumb and index finger to squeeze on a plastic tubing filled with fluid and then running the fingers along the tube. This action will force the fluid to move along

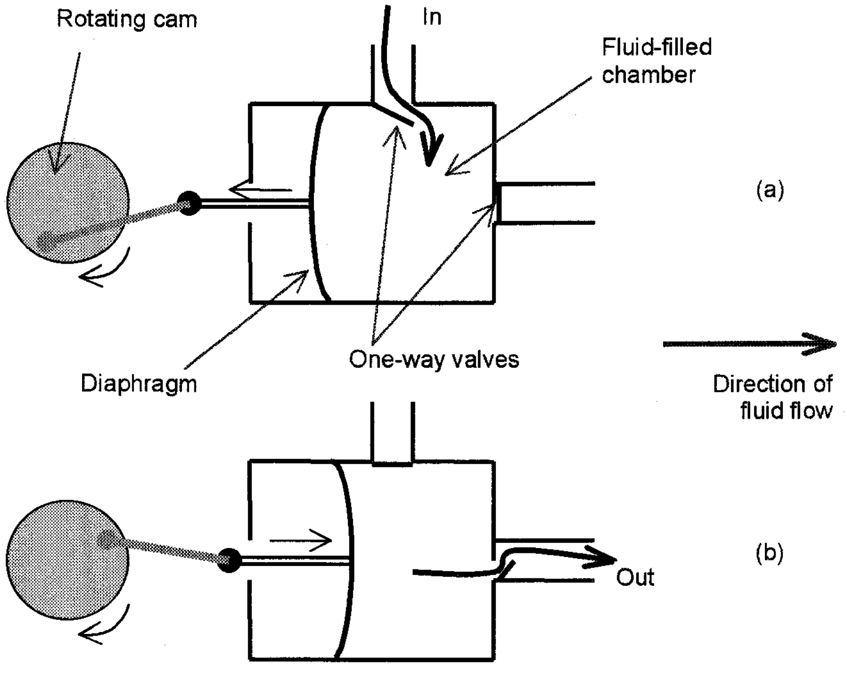

Figure 23-7. Piston Diaphragm Infusion Mechanism.

the direction of the finger motion. Repeating this action will produce a continuous fluid flow.

Figure 23-8a shows the pumping mechanism of a rotary peristaltic infusion pump. In a rotary peristaltic pump (or roller pump), the rotor has several protruding rollers. The flexible IV tubing is placed inside a groove on the pumping mechanism housing with one side open to the rotor. The rollers on the rotating rotor push the tubing against the wall of the groove. The protruding rollers, while occluding the tubing, move in one direction along the IV tubing, creating a continuous fluid flow in the direction of motion of the rollers.

Instead of rotating the protruding rollers over the IV tubing, the protruding fingers in the linear peristaltic infusion pump sequentially occlude the IV tubing. Figure 23-8b shows the positions of the protruding fingers of a linear peristaltic pump at three sequential time instances. These coordinated motions of the protruding fingers produce a continuous flow of fluid in the direction shown. The driving mechanism of a linear peristaltic pump is shown in Figure 23-9. To create a linear peristaltic motion, cams with eccentric axes are attached to a rotating cam shaft (Figure 23-10a) such that when a shaft rotates, it moves the protruding finger up or down according to its eccentric angle of rotation (Figure 23-10b).

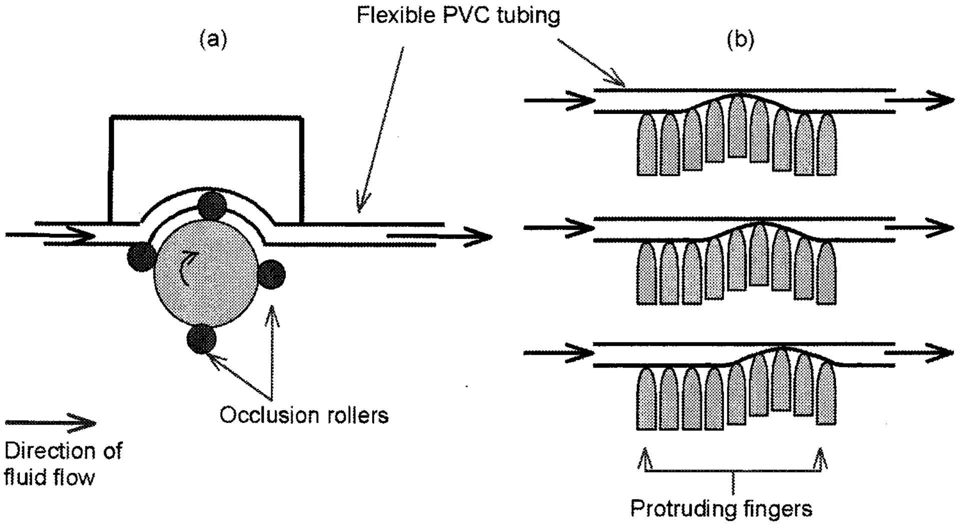

Figure 23-8. Peristaltic Infusion Mechanism. (a) Rotary Peristaltic; (b) Linear Peristaltic.

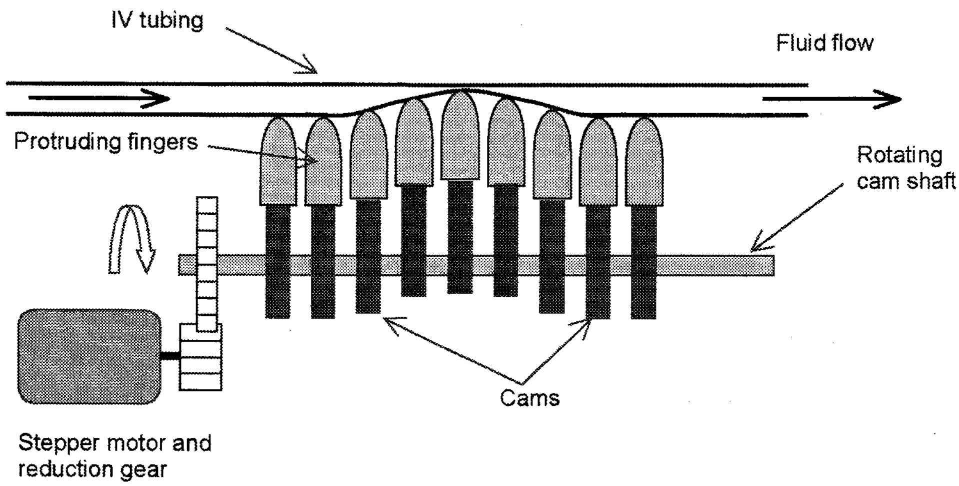

Figure 23-9. Linear Peristaltic Pump Driving Mechanism.

Syringe Pumps

A syringe pump has a long screw mounted on the pump support. The screw is rotated by a stepper motor and gear combination. The screw is supported by two bearings to allow smooth operation. As the screw rotates, it moves a nut threaded onto the screw in the horizontal direction (Figure 23-11). The nut is attached to a pusher connecting to the plunger of a

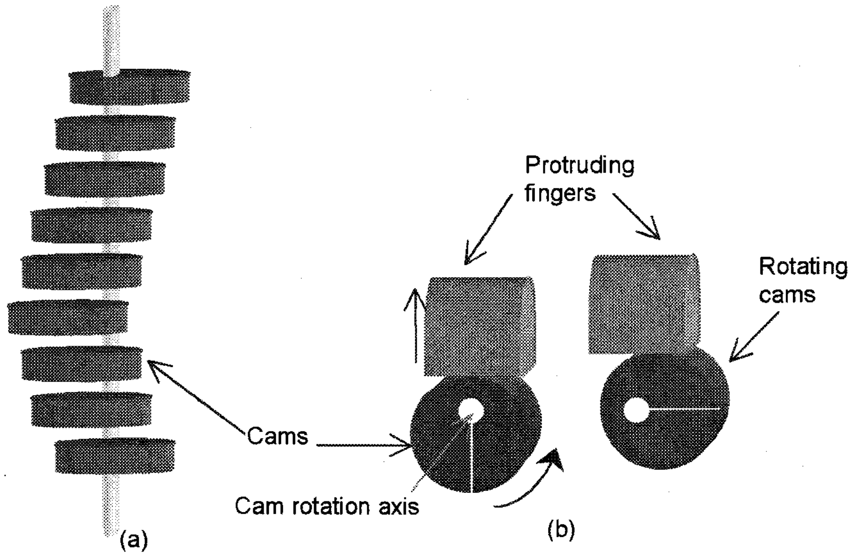

Figure 23-10. Linear Peristaltic Plunger Driving Mechanism.

syringe, which is loaded with the solution to be infused. The flow rate of the fluid coming out of the syringe depends on the rotational speed of the screw and the cross sectional area of the syringe body. In mathematical terms, the volume flow rate of a syringe pump is:

$$F = R \times t \times A,$$

where:

F = volume flow rate in cubic centimeters per minute,

R = rotational speed of the screw in revolutions per minute,
t = screw pitch in cm, and

A = cross-sectional area of the syringe plunger in cm^2.

Syringe pumps are often used in high-accuracy, low-flow rate applications (e.g., 0.5 to 10 ml/hr) and when more uniform flow pattern is required. It is also used to infuse thicker feeding solutions. A patient-controlled analgesic (P CA) pump is a special syringe pump designed to allow patients to self-administer boluses of narcotic analgesic for pain relief.

In general, piston cylinder infusion pumps and syringe pumps produce a more accurate and consistent flow output. However, during low flow rate settings, piston pumps (both piston cylinder and diaphragm) produce boluses of infusion rather than a smooth flow pattern. Figure 23-12a shows the flow pattern of a piston cylinder pump at a low flow rate setting (e.g., 10 ml/hr); a bolus in the diagram corresponds to the flow of one stroke of the piston. A bolus type of infusion may not be suitable for some applications such as

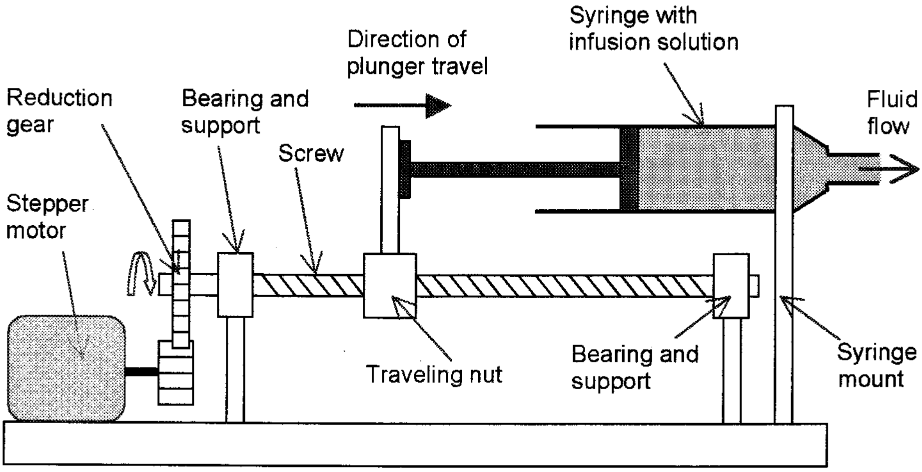

Figure 23-11. Syringe Pump.

administering medications to small infants. Under ideal conditions, a syringe pump will produce a uniform flow with little fluctuation. A peristaltic pump, with its multiple protruding finger pumping action, produces a flow pattern with less fluctuation than piston pumps as shown in Figure 23-12b.

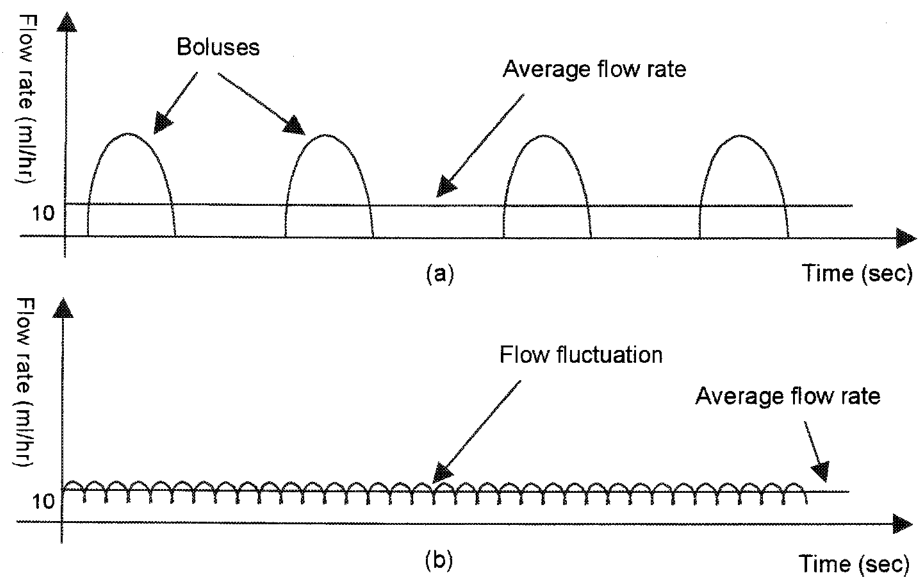

Figure 23-12. Low Flow Rate Infusion Flow Pattern.

COMMON FEATURES

Some common features found in general-purpose infusion pumps are described in the following sections. Depending on the design application, an infusion pump may have other additional features.

Flow Rates

The flow rate of a general-purpose infusion pump can be set within a range from 1 to 999 ml/hr with an accuracy of ±5 to 10%. For neonatal pumps, the range is 0.1 to 99 m/hr with an accuracy of ± 2%.

Volume To Be Infused (VTBI)

A VTBI of 1 to 9,999 ml can be programmed such that the pump will stop after this volume has been delivered. Usually, when VTBI is reached, an audible tone will sound to alert the clinician. The pump will switch to its KVO rate.

Keep Vein Open (KVO)

When infusion has stopped, in order to prevent blood clot at the venipuncture site, a slow infusion rate of about 1 to 5 ml/hr is maintained to flush the catheter to prevent blood clotting.

Occlusion Pressure Alarm

A pressure sensor inside the pump monitors the pressure of infusion. A high pressure indicates occlusion downstream of the pump. An alarm is set to notify the clinician to check the IV line. Downstream occlusion may be due to clot IV catheter or pinching of the IV line (e.g., by the patient rolling over the line). In some infusion pumps, the occlusion pressure alarm may be adjusted to activate between 1 and 20 psi.

Fluid Depletion (or Upstream Occlusion) Alarm

When the IV bag is empty, a negative pressure will develop upstream of the pump. An alarm to indicate such a condition can prevent air from entering the IV line and being infused into the patient.

Infusion Runaway (or Free Flow) Prevention

Most modern pumps have a built-in mechanism to prevent free flow of solution into the patient. Free flow can occur when the IV line is removed from the pump while the occlusion clamp and roller clamp are both open. When the pump is used to administer a potent drug to a patient, free flow can impose serious risk to the patient if a large dose of such medication is infused into the patient. A mechanical interlock on the IV line to shut off the line when it is pulled out from the pump will prevent this.

Air-in-Line Detection

To prevent air embolism in patients, air-in-line detectors are built into infusion pumps to detect air bubbles in the IV lines. Infusion will stop and an alarm will sound when a large air bubble is detected during infusion.

Dose Error Reduction System

This is a software algorithm that checks programmed doses against preset limits specific to certain drugs and clinical location profiles. It alerts clinicians if the programmed dose exceeded the preset limits. For example, drug X used in area A has a dose limit of 20 mcg/kg/hr. If the dose, based on the programmed flow rate and drug concentration, exceeds 20 mcg/kg/hr, infusion will not start and an alarm will sound.

Battery Operation

Most pumps are powered by internal rechargeable batteries so that the pump may be moved around with the patient during use. A battery low detector circuit will alert the user if the battery is running low and must be recharged.

FUNCTIONAL BLOCK DIAGRAM

Figure 23-13 shows a functional block diagram of a volumetric infusion pump. The user input/output interfaces are shown on the left-hand side of the diagram. User selectable inputs include:

- Infusion flow rate
- Volume to be infused (VTBI)

- Keep vein open (KVO) enable selection
- Pump start/stop control

The CPU, based on the input settings, controls the speed of the stepper motor driving the pumping mechanism to deliver the set infusion rate. The rotational speed of the pump driver is monitored by a LED/optical transistor slit detector. Based on this rotational speed, the volume of infusion is computed and compared to the VTBI setting. If KVO is enabled, the motor speed will be reduced to the KVO rate when VTBI has been reached.

The pressure in the IV line is monitored by a pressure sensor pressing on the IV tube inside the pump. When the pressure exceeds the occlusion pressure, the CPU will shut down the pump and sound an alarm.

Air bubbles in the IV line are detected by an ultrasound transmitter and receiver pair. The attenuation of ultrasound in air is higher than that in water.

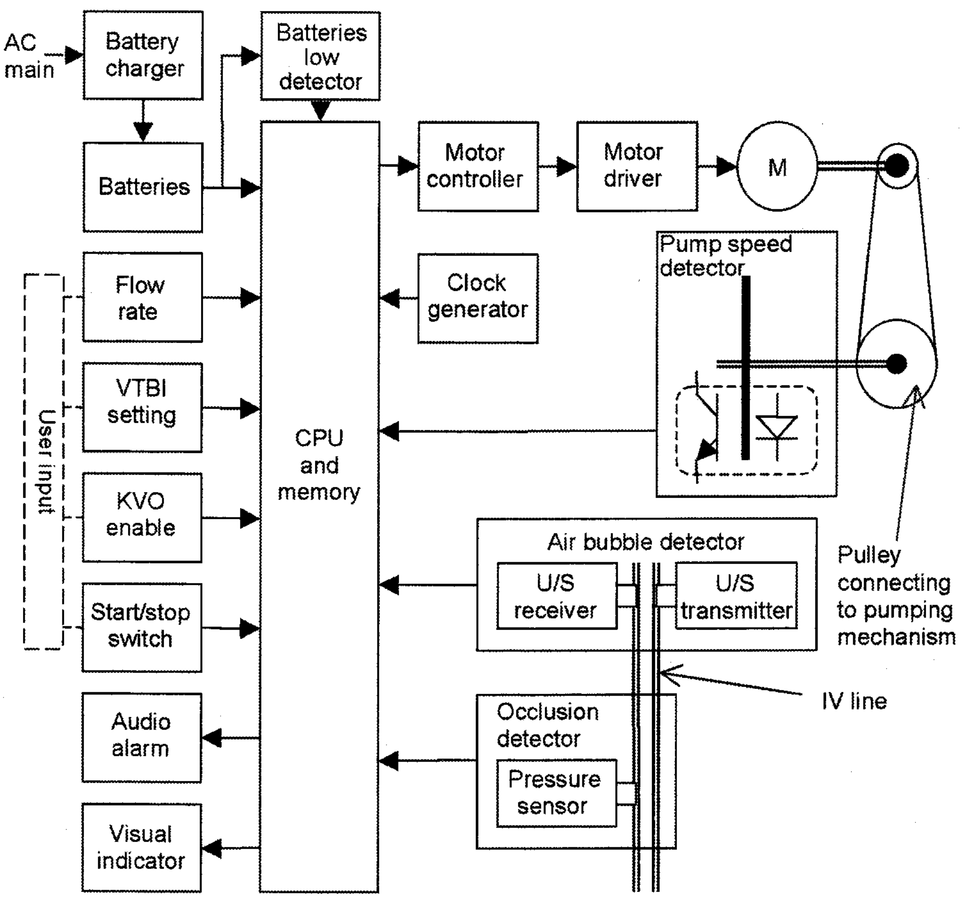

Figure 23-13. Functional Block Diagram of Volumetric Infusion Pump.

When an air bubble passes through the detector, the intensity of ultrasound detected by the receiver will decrease. The duration of this decreased signal corresponds to the size of the air bubble in the line. The CPU will stop infusion and sound an alarm if a large air bubble is detected.

PERFORMANCE EVALUATION

An important performance parameter of an infusion device is its flow rate accuracy. The flow rate of an infusion pump can be calculated by measuring the volume of solution delivered over a period of time. For example, a measuring cylinder can be used to collect the fluid infused over a period of, say, 5 minutes at a certain flow rate setting. Such a method is generally acceptable for most general-purpose infusion devices. However, this method will not be appropriate to measure the accuracy of very low flow rate settings due to the fact that it will take a very long time to collect enough solution to obtain an accurate volume measurement (e.g., it takes 2 hours to collect 10 ml of solution at 5 ml/hr setting). Evaporation of fluid in the collection container will also affect the accuracy of such low volume long duration measurement. In addition, this measure gives only the average flow rate over a period of time. No information regarding the flow pattern is obtained (flow fluctuation, bolus effect, etc.).

Another parameter to be measured is the occlusion alarm pressure. This pressure is measured by connecting the IV line to a pressure meter and then starting the infusion. The pressure inside the line will quickly build up until it reaches the occlusion pressure alarm limit. It is important to leave an air buffer between the liquid line and the pressure meter should the meter not be able to measure wet pressure.

Example

A measuring cylinder is used to collect fluid from an infusion pump during a flow rate performance evaluation test. During the test, 9.6 mL of fluid is collected over a period of 5 minutes. If the flow rate setting of the infusion pump is 120 ml/hr, what is the accuracy of the pump?

Solution

From the test, 9.6 ml of fluid is infused in 5 minutes. Therefore, the calculated pump flow rate is 9.6 m1/5 min = 1.9 ml/min = 115 ml/hr. Therefore, the percentage error of the infusion pump is $\frac{120-115}{120} X\ 100\% =$ $+4.2\%$.

FACTORS AFFECTING FLOW ACCURACY

Other than electronic component failures and mechanical wear and tear, the following common factors affect the flow accuracy of infusion pumps.

Too high backpressure in the IV line can reduce the flow rate. Normal backpressure depends on the flow rate, the diameter and length of the IV tubing, and the viscosity of the IV fluid. The smaller the inside lumen and the longer the tubing, the higher the backpressure. Backpressure increases with increase flow and fluid viscosity. Backpressure may also be created when the IV tube is kinked. When the backpressure is too high, the pumping mechanism may not be able to overcome such pressure. For example, during high backpressure, if the occlusion pressure created by the protruding fingers on the IV tubing is not high enough, fluid may leak backwards at the location of occlusion.

Another potential problem associated with high backpressure is bolus infusion. As the flexible IV tubing is slightly elastic, its diameter will increase under high backpressure. Upon clearing the occlusion, the IV tubing will recoil to its original diameter thereby releasing the stored fluid along the length of the tubing. Therefore, a large bolus of fluid may be infused into the patient.

For IV pumps using the peristaltic pumping mechanism, as the flow rate depends on the inner diameter of the IV tubing, variation of the inner diameter will change the rate of infusion. It is therefore important to ensure that the inner diameter dimension of IV lines used with peristaltic infusion pumps are manufactured within acceptable tolerance. In addition, as the section of IV tubing under the protruding fingers is being compressed for a period of time with prolonged use, the shape and therefore the inner diameter of the tubing will change. In order to avoid inaccuracy, manufacturers often recommend that users move a different section of tubing under the pumping mechanism every several hours.

Theoretically, a syringe pump should produce an accurate and uniform flow pattern. In practice, however, under very low flow rate applications, the plunger may stick to the side of the cylinder until the pusher delivers enough force to overcome the static friction. Once the plunger is free, it will advance rapidly and stop, thereby pushing a bolus of solution into the patient. This sudden start and stop movement can repeat itself during low flow rate infusion.

In general, among different pumping mechanisms of volumetric infusion pumps, the piston cylinder pump is the most accurate but most expensive due to the special infusion set with the piston cassette. The linear peristaltic pump is very commonly used in general IV infusion since it has a fairly accurate infusion rate. In addition, most peristaltic pumps can use ordinary gravity infusion sets and are therefore less expensive to operate than those that require dedicated infusion sets.