Equipment Packet: Infusion Pump

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Equipment Packet Contents:

This packet contains information about the operation, maintenance, and repair of infusion pumps.

Part I: External From the Packet:

1. **An Introduction to Infusion Pumps:** PowerPoint

Part II: Included in this Packet:

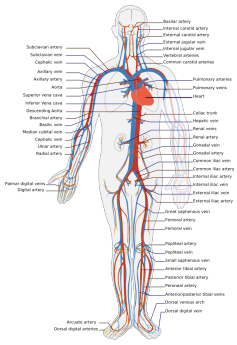
1. Operation and Use of Infusion Pumps

Featured in this Section:

Wikipedia. “Circulatory System.” *Wikipedia*, p. 1-9. Retrieved from: https://en.wikipedia.org/wiki/Circulatory_system

Wikipedia. “Infusion Pump.” *Wikipedia*, p. 1-4. Retrieved from: https://en.wikipedia.org/wiki/Infusion_pump

Circulatory system

Circulatory system

The human circulatory system. Red indicates oxygenated blood, blue indicates deoxygenated.
Latin | *systema cardiovasculare*

The **circulatory system** is an organ system that passes nutrients (such as amino acids and electrolytes), gases, hormones, blood cells, etc. to and from cells in the body to help fight diseases and help stabilize body temperature and pH to maintain homeostasis.

This system may be seen strictly as a blood distribution network, but some consider the circulatory system as composed of the **cardiovascular system**, which distributes blood,[1] and the **lymphatic system**,[2] which distributes lymph. While humans, as well as other vertebrates, have a closed cardiovascular system (meaning that the blood never leaves the network of arteries, veins and capillaries), some invertebrate groups have an open cardiovascular system. The most primitive animal phyla lack circulatory systems. The lymphatic system, on the other hand, is an open system.

Two types of fluids move through the circulatory system: blood and lymph. The blood, heart, and blood vessels form the cardiovascular system. The lymph, lymph nodes, and lymph vessels form the lymphatic system. The cardiovascular system and the lymphatic system collectively make up the circulatory system.

Human cardiovascular system

The main components of the human cardiovascular system are the heart and the blood vessels.[3] It includes: the pulmonary circulation, a "loop" through the lungs where blood is oxygenated; and the systemic circulation, a "loop" through the rest of the body to provide oxygenated blood. An average adult contains five to six quarts (roughly 4.7 to 5.7 liters) of blood, which consists of plasma, red blood cells, white blood cells, and platelets. Also, the digestive system works with the circulatory system to provide the nutrients the system needs to keep the heart pumping.

Pulmonary circulation

The Pulmonary circulation is the portion of the cardiovascular system which transports oxygen-depleted blood away from the heart, to the lungs, and returns oxygenated blood back to the heart.

Oxygen deprived blood from the vena cava enters the right atrium of the heart and flows through the tricuspid valve into the right ventricle, from which it is pumped through the pulmonary semilunar valve into the pulmonary arteries which go to the lungs. Pulmonary veins return the now oxygen-rich blood to the heart, where it enters the left atrium before flowing through the mitral valve into the left ventricle. Then, oxygen-rich blood from the left ventricle is pumped out via the aorta, and on to the rest of the body.

Systemic circulation

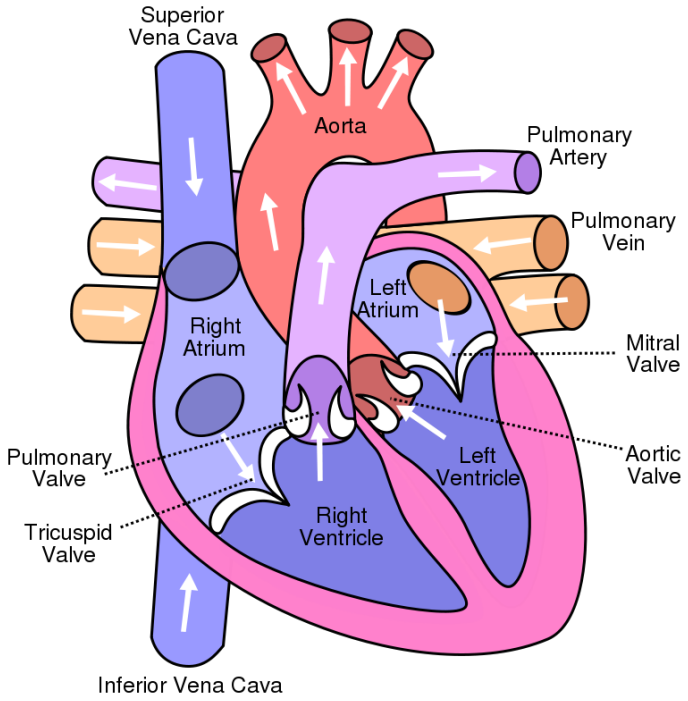
Systemic circulation is the portion of the cardiovascular system which transports oxygenated blood away from the heart, to the rest of the body, and returns oxygen-depleted blood back to the heart. Systemic circulation is, distance-wise, much longer than pulmonary circulation, transporting blood to every part of the body.

Coronary circulation

The coronary circulatory system provides a blood supply to the heart. As it provides oxygenated blood to the heart, it is by definition a part of the systemic circulatory system.

Heart

The heart pumps oxygenated blood to the body and deoxygenated blood to the lungs. In the human heart there is one atrium and one ventricle for each circulation, and with both a systemic and a pulmonary circulation there are four chambers in total: left atrium, left ventricle, right atrium and right ventricle. The right atrium is the upper chamber of the right side of the heart. The blood that is returned to the right atrium is deoxygenated (poor in oxygen) and passed into the right ventricle to be pumped through the pulmonary artery to the lungs for re-oxygenation and removal of carbon dioxide. The left atrium receives newly oxygenated blood from the lungs as well as the pulmonary vein which is passed into the strong left ventricle to be pumped through the aorta to the different organs of the body.



View from the front, which means the right side of the heart is on the left of the diagram (and vice-versa)

Closed cardiovascular system

The cardiovascular systems of humans are closed, meaning that the blood never leaves the network of blood vessels. In contrast, oxygen and nutrients diffuse across the blood vessel layers and enters interstitial fluid, which carries oxygen and nutrients to the target cells, and carbon dioxide and wastes in the opposite direction. The other component of the circulatory system, the lymphatic system, is not closed. The heart is located in the center of the body between the two lungs. The reason that the heart beat is felt on the left side is because the left ventricle, on the left, is pumping.

Measurement techniques

- Electrocardiogram—for cardiac electrophysiology
- Sphygmomanometer and stethoscope—for blood pressure
- Pulse meter—for cardiac function (heart rate, rhythm, dropped beats)
- Pulse—commonly used to determine the heart rate in absence of certain cardiac pathologies
- Heart rate variability -- used to measure variations of time intervals between heart beats
- Nail bed blanching test—test for perfusion
- Vessel cannula or catheter pressure measurement—pulmonary wedge pressure or in older animal experiments.

Oxygen transportation

About 98.5% of the oxygen in a sample of arterial blood in a healthy human breathing air at sea-level pressure is chemically combined with haemoglobin molecules. About 1.5% is physically dissolved in the other blood liquids and not connected to Hgb. The haemoglobin molecule is the primary transporter of oxygen in mammals and many other species.

Nonhuman

Other vertebrates

The circulatory systems of all vertebrates, as well as of annelids (for example, earthworms) and cephalopods (squid and octopus) are *closed*, just as in humans. Still, the systems of fish, amphibians, reptiles, and birds show various stages of the evolution of the circulatory system.

In fish, the system has only one circuit, with the blood being pumped through the capillaries of the gills and on to the capillaries of the body tissues. This is known as *single cycle* circulation. The heart of fish is therefore only a single pump (consisting of two chambers).

In amphibians and most reptiles, a double circulatory system is used, but the heart is not always completely separated into two pumps. Amphibians have a three-chambered heart.

In reptiles, the ventricular septum of the heart is incomplete and the pulmonary artery is equipped with a sphincter muscle. This allows a second possible route of blood flow. Instead of blood flowing through the pulmonary artery to the lungs, the sphincter may be contracted to divert this blood flow through the incomplete ventricular septum into the left ventricle and out through the aorta. This means the blood flows from the capillaries to the heart and back to the capillaries instead of to the lungs. This process is useful to ectothermic (cold-blooded) animals in the regulation of their body temperature.

Birds and mammals show complete separation of the heart into two pumps, for a total of four heart chambers; it is thought that the four-chambered heart of birds evolved independently from that of mammals.

Open circulatory system

The Open Circulatory System is a system in which fluid (called hemolymph) in a cavity called the hemocoel bathes the organs directly with oxygen and nutrients and there is no distinction between blood and interstitial fluid; this combined fluid is called hemolymph or haemolymph. Muscular movements by the animal during locomotion can facilitate hemolymph movement, but diverting flow from one area to another is limited. When the heart relaxes, blood is drawn back toward the heart through open-ended pores (ostia).

Hemolymph fills all of the interior hemocoel of the body and surrounds all cells. Hemolymph is composed of water, inorganic salts (mostly Na^+, Cl^-, K^+, Mg^{2+}, and Ca^{2+}), and organic compounds (mostly carbohydrates, proteins, and lipids). The primary oxygen transporter molecule is hemocyanin.

See also

- Microcirculation
- Cardiology
- Lymphatic system
- Blood vessels
- Innate heat
- Cardiac muscle
- Major systems of the human body
- Heart
- Amato Lusitano
- William Harvey

External links

- The Circulatory System Article [11]
- The Circulatory System [12], a comprehensive overview
- NCP Cardiovascular Medicine [13] A Journal Covering Clinical Cardiovascular Medicine

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Infusion pump

An **infusion pump** infuses fluids, medication or nutrients into a patient's circulatory system. It is generally used intravenously, although subcutaneous, arterial and epidural infusions are occasionally used.

Infusion pumps can administer fluids in ways that would be impractically expensive or unreliable if performed manually by nursing staff. For example, they can administer as little as 0.1 mL per hour injections (too small for a drip), injections every minute, injections with repeated boluses requested by the patient, up to maximum number per hour (e.g. in patient-controlled analgesia), or fluids whose volumes vary by the time of day.

Because they can also produce quite high but controlled pressures, they can inject controlled amounts of fluids subcutaneously (beneath the skin), or epidurally (just within the surface of the central nervous system- a very popular local spinal anesthesia for childbirth).

A type of infusion pump, manufactured by Fresenius.

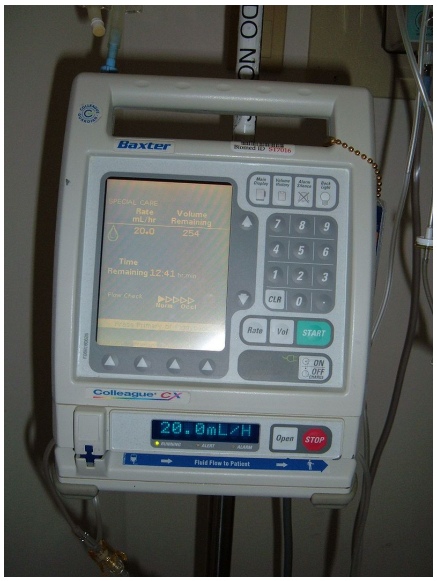
Types of infusion

The user interface of pumps usually requests details on the type of infusion from the technician or nurse that sets them up:

- *Continuous infusion* usually consists of small pulses of infusion, usually between 500 nanoliters and 10000 microliters, depending on the pump's design, with the rate of these pulses depending on the programmed infusion speed.
- *Intermittent infusion* has a "high" infusion rate, alternating with a low programmable infusion rate to keep the cannula open. The timings are programmable. This mode is often used to administer antibiotics, or other drugs that can irritate a blood vessel.
- *Patient-controlled* is infusion on-demand, usually with a preprogrammed ceiling to avoid intoxication. The rate is controlled by a pressure pad or button that can be activated by the patient. It is the method of choice for patient-controlled analgesia (PCA), in which repeated small doses of opioid analgesics are delivered, with the device coded to stop administration before a dose that may cause hazardous respiratory depression is reached.
- *Total parenteral nutrition* usually requires an infusion curve similar to normal mealtimes.

Some pumps offer modes in which the amounts can be scaled or controlled based on the time of day. This allows for circadian cycles which may be required for certain types of medication.

Types of pump



A Baxter International Colleague CX infusion pump

There are two basic classes of pumps. Large volume pumps can pump nutrient solutions large enough to feed a patient. Small-volume pumps infuse hormones, such as insulin, or other medicines, such as opiates.

Within these classes, some pumps are designed to be portable, others are designed to be used in a hospital, and there are special systems for charity and battlefield use.

Large-volume pumps usually use some form of peristaltic pump. Classically, they use computer-controlled rollers compressing a silicone-rubber tube through which the medicine flows. Another common form is a set of fingers that press on the tube in sequence.

Small-volume pumps usually use a computer-controlled motor turning a screw that pushes the plunger on a syringe.

The classic medical improvisation for an infusion pump is to place a blood pressure cuff around a bag of fluid. The battlefield equivalent is to place the bag under the patient. The pressure on the bag sets the infusion pressure. The pressure can actually be read-out at the cuff's indicator. The problem is that the flow varies dramatically with the patient's blood pressure (or weight), and the needed pressure varies with the administration route, making this quite risky for use by an untrained person. Pressures into a vein are usually less than 8 lbf/in² (55 kPa. Epidural and subcutaneous pressures are usually less than 18 lbf/in² (125 kPa).

Places that must provide the least-expensive care often use pressurized infusion systems. One common system has a purpose-designed plastic "pressure bottle" pressurized with a large disposable plastic syringe. A combined flow restrictor, air filter and drip chamber helps a nurse set the flow. The parts are reusable, mass-produced sterile plastic, and can be produced by the same machines that make plastic soft-drink bottles and caps. A pressure bottle, restrictor and chamber requires more nursing attention than electronically-controlled pumps. In the areas where these are used, nurses are often volunteers, or very inexpensive.

The restrictor and high pressure helps control the flow better than the improvised schemes because the high pressure through the small restrictor orifice reduces the variation of flow caused by patients' blood pressures.

An air filter is an essential safety device in a pressure infusor, to keep air out of the patients' veins: doctors estimate that 0.55 cm³ of air per kilogram of body weight is enough to kill (200–300 cm³ for adults) by filling the patient's heart. Small bubbles could cause harm in arteries, but in the veins they pass through the heart and leave in the patients' lungs. The air filter is just a membrane that passes gas but not fluid or pathogens. When a large air bubble reaches it, it bleeds off.

Some of the smallest infusion pumps use osmotic power. Basically, a bag of salt solution absorbs water through a membrane, swelling its volume. The bag presses medicine out. The rate is precisely controlled by the salt concentrations and pump volume. Osmotic pumps are usually recharged with a syringe.

Spring-powered clockwork infusion pumps have been developed, and are sometimes still used in veterinary work and for ambulatory small-volume pumps. They generally have one spring to power the infusion, and another for the alarm bell when the infusion completes.

Battlefields often have a need to perfuse large amounts of fluid quickly, with dramatically changing blood pressures and patient condition. Specialized infusion pumps have been designed for this purpose, although they have not been deployed.

Many infusion pumps are controlled by a small embedded system. They are carefully designed so that no single cause of failure can harm the patient. For example, most have batteries in case the wall-socket power fails. Additional hazards are uncontrolled flow causing an overdose, uncontrolled lack of flow, causing an underdose, reverse flow, which can siphon blood from a patient, and air in the line, which can starve a patient's tissues of oxygen if it floats to some part of a patient's body.

Safety features available on some pumps

The range of safety features varies widely with the age and make of the pump. A state of the art pump in 2003 may have the following safety features:

- Certified to have no single point of failure. That is, no single cause of failure should cause the pump to silently fail to operate correctly. It should at least stop pumping and make at least an audible error indication. This is a minimum requirement on all human-rated infusion pumps of whatever age. It is not required for veterinary infusion pumps.
- Batteries, so the pump can operate if the power fails or is unplugged.
- Anti-free-flow devices prevent blood from draining from the patient, or infusate from freely entering the patient, when the infusion pump is being set-up.
- A "down pressure" sensor will detect when the patient's vein is blocked, or the line to the patient is kinked. This may be configurable for high (subcutaneous and epidural) or low (venous) applications.
- An "air-in-line" detector. A typical detector will use an ultrasonic transmitter and receiver to detect when air is being pumped. Some pumps actually measure the volume, and may even have configurable volumes, from 0.1 to 2 ml of air. None of these amounts can cause harm, but sometimes the air can interfere with the infusion of a low-dose medicine.
- An "up pressure" sensor can detect when the bag or syringe is empty, or even if the bag or syringe is being squeezed.
- A drug library with customizable programmable limits for individual drugs that that helps to avoid medication errors.
- Mechanisms to avoid uncontrolled flow of drugs in large volume pumps (often in combination with a giving st based free flow clamp) and increasingly also in syringe pumps (piston-brake)
- Many pumps include an internal electronic log of the last several thousand therapy events. These are usually tagged with the time and date from the pump's clock. Usually, erasing the log is a feature protected by a security code, specifically to detect staff abuse of the pump or patient.
- Many makes of infusion pump can be configured to display only a small subset of features while they are operating, in order to prevent tampering by patients, untrained staff and visitors.

See also

- Intravenous drip
- Pharmacy informatics
- Syringe driver
- Research Syringe Pump
- Total parenteral nutrition

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Overview of the Risks of Intravenous Therapy

Risks of intravenous therapy

Infection

Any break in the skin carries a risk of infection. Although IV insertion is an aseptic procedure, skin-dwelling organisms such as *Coagulase-negative staphylococcus* or *Candida albicans* may enter through the insertion site around the catheter, or bacteria may be accidentally introduced inside the catheter from contaminated equipment. Moisture introduced to unprotected IV sites through washing or bathing substantially increases the infection risks.

Infection of IV sites is usually local, causing easily visible swelling, redness, and fever. If bacteria do not remain in one area but spread through the bloodstream, the infection is called septicemia and can be rapid and life-threatening. An infected central IV poses a higher risk of septicemia, as it can deliver bacteria directly into the central circulation.

Phlebitis

Phlebitis is inflammation of a vein that may be caused by infection, the mere presence of a foreign body (the IV catheter) or the fluids or medication being given. Symptoms are warmth, swelling, pain, and redness around the vein. The IV device must be removed and if necessary re-inserted into another extremity.

Due to frequent injections and recurring phlebitis, scar tissue can build up along the vein. The peripheral veins of intravenous drug addicts, and of cancer patients undergoing chemotherapy, become sclerotic and difficult to access over time, sometimes forming a hard “venous cord”.

Infiltration

Infiltration occurs when an IV fluid accidentally enters the surrounding tissue rather than the vein. It is characterized by coolness and pallor to the skin as well as localized swelling or edema. It is usually not painful. It is treated by removing the intravenous access device and elevating the affected limb so that the collected fluids can drain away. Infiltration is one of the most common adverse effects of IV therapy and is usually not serious unless the infiltrated fluid is a medication damaging to the surrounding tissue, in which case the incident is known as extravasation.

Fluid overload

This occurs when fluids are given at a higher rate or in a larger volume than the system can absorb or excrete. Possible consequences include hypertension, heart failure, and pulmonary edema.

Electrolyte imbalance

Administering a too-dilute or too-concentrated solution can disrupt the patient's balance of sodium, potassium, magnesium, and other electrolytes. Hospital patients usually receive blood tests to monitor these levels.

Embolism

A blood clot or other solid mass, as well as an air bubble, can be delivered into the circulation through an IV and end up blocking a vessel; this is called embolism. Peripheral IVs have a low risk of embolism, since large solid masses cannot travel through a narrow catheter, and it is nearly impossible to inject air through a peripheral IV at a dangerous rate. The risk is greater with a central IV.

Air bubbles of less than 30 milliliters are thought to dissolve into the circulation harmlessly. Small volumes do not result in readily detectable symptoms, but ongoing studies hypothesize that these "micro-bubbles" may have some adverse effects. A larger amount of air, if delivered all at once, can cause life-threatening damage to pulmonary circulation, or, if extremely large (3-8 milliliters per kilogram of body weight), can stop the heart.

One reason veins are preferred over arteries for intravascular administration is because the flow will pass through the lungs before passing through the body. Air bubbles can leave the blood through the lungs. A patient with a heart

defect causing a right-to-left shunt is vulnerable to embolism from smaller amounts of air. Fatality by air embolism is vanishingly rare, in part because it is also difficult to diagnose.

Extravasation

Extravasation is the accidental administration of IV infused medicinal drugs into the surrounding tissue which are caustic to these tissues, either by leakage (e.g. because of brittle veins in very elderly patients), or directly (e.g. because the needle has punctured the vein and the infusion goes directly into the arm tissue). This occurs more frequently with chemotherapeutic agents and people who have tuberculosis.

See also

- Life support
- Blood transfusion
- Blood substitutes
- Oral rehydration therapy
- Bolus (medicine)
- Dialysis
- Saline flush
- Hypodermic needle

External links

- Wyeth v. Levine, 06-1249 [3] opinion of US supreme Court - No limit in lawsuits as the result of an injury by IV-push injection resulting in gangrene and consequent amputation. Gangrene is likely if the injection accidentally hits an artery — precisely what happened to Levine.
- IVTEAM.com [4]
- Otsuka co [5]
- IV-Therapy.net [6]
- UWash [7]
- Venous Air Embolism by Dr. Andrew G Wittenberg, MD, MPH [8]
- Nursing-Resource, Drip Rate Formulas [9]

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Infusion Pump Operation and Use Tips

Table 2 Action required by infusion pump users

When?	Action
Before use	• Check that leads, administration sets, bags and cassettes or syringes are in good working order and properly assembled/loaded. • Carry out relevant functional and calibration checks (start-up checks). • Note results. • Check control settings. • Check that correct flow rate has been set.
A problem occurs	• Stop the infusion. Make sure that all clamps on the giving sets are closed. • Seek technical advice. • Record problems and action taken. • If necessary, withdraw the device from service.
At specified intervals	• Check that the observed flow rate corresponds to the rate displayed on the infusion pump. • Inspect infusion site. • Note results. • If checks fail, withdraw the device from service if necessary.
After use	• Clean as recommended by the manufacturer. • Safely dispose of single-use devices and other accessories that cannot be reused.
When sending an infusion system to be repaired or serviced	• Include all the leads and accessories needed to operate the device. • Enclose a full account of any problems and faults. • Decontaminate. • Fill in decontamination form.
When an infusion device has undergone service	• Carry out all standard pre-use inspections. • Check the set-up of protocols and programs, as these may have been altered during servicing.
When an adverse incident has occurred (see section 3.4 for what should be reported to the MHRA)	First take steps necessary for the well being of the patient and/or staff, then: • Do not alter settings or remove administration sets. • Leave any fluids in the infusion system if possible. • Note details of all medical equipment attached to the patient. • Note details of device: type, make, model and serial number. • Retain packaging for details of consumables. • Note setting of controls and limits of alarms. • Note the content volume remaining in the bag, container, set or syringe. • If relevant, record the contents of computer memory logs of the infusion pump. Seek the assistance of the electrical biomedical engineering (EBME) department if necessary. • If possible, contact the MHRA before moving or dismantling the equipment.

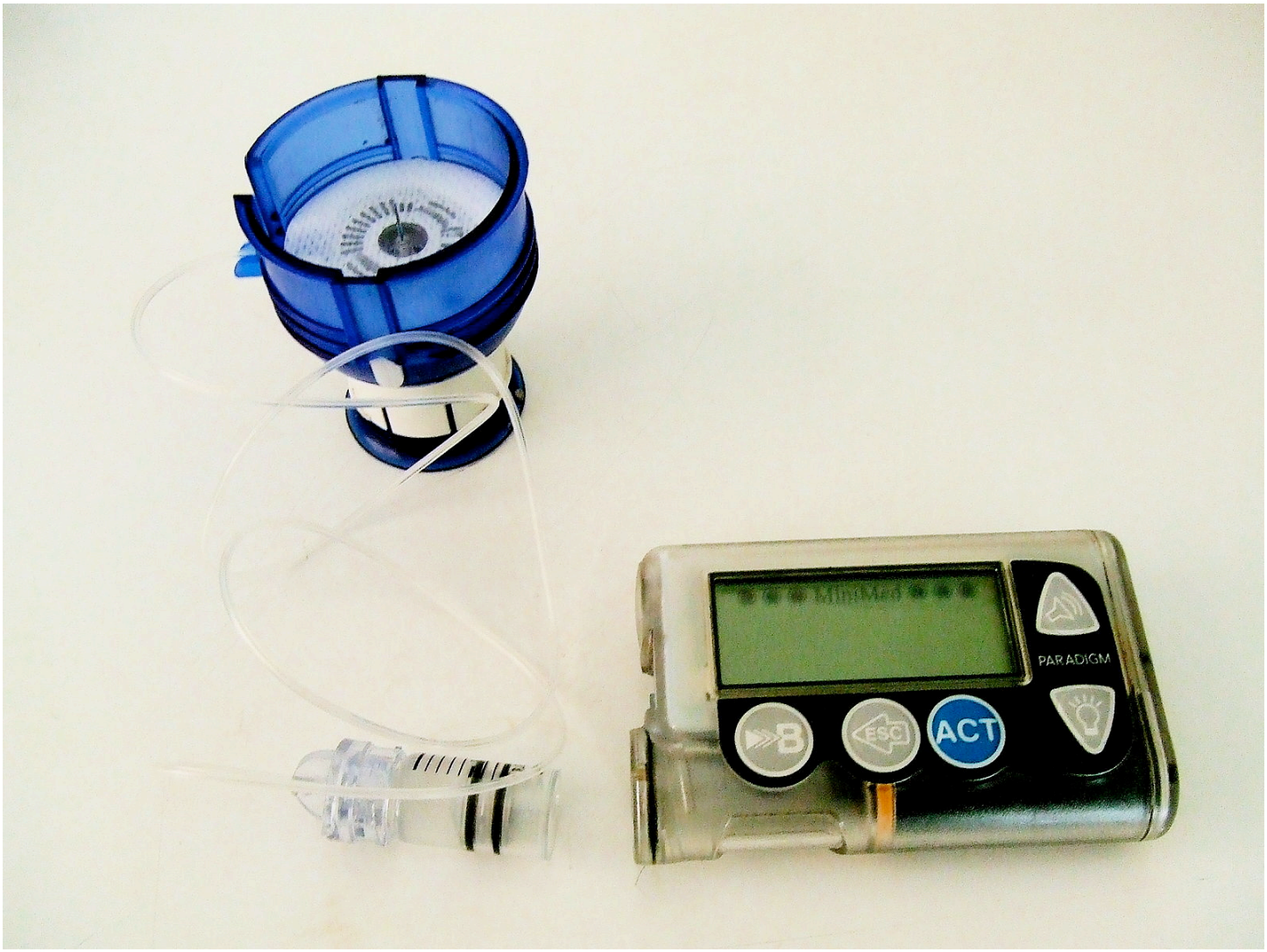
Department of Health, Social Services and Public Safety. "Device Bulletin: Infusion Systems DB, v2.0." Vol. DB2003, No. 2. Department of Health, Social Services and Public Safety, 2010, p. 1-56.

2. Diagrams and Schematics of Infusion Pumps

Featured in this Section:

Wikimedia. “Insulin Pump and Infusion Set.” *Wikimedia Commons*. Posted July 22, 2007. Retrieved from: https://commons.wikimedia.org/wiki/File:Insulin_pump_and_infusion_set.JPG

Figure 1: Infusion Pump Set for Insulin



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3. Preventative Maintenance and Safety of Infusion Pumps

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Preventative Maintenance of Infusion Pumps

EQUIPMENT

Infusion Pump Preventative Maintenance

Preventive Maintenance Checklist

Syringe (IV) pumps:

1. Examine plug and line cord.
2. Examine internal cables and connectors.
3. Verify software and menu settings are appropriate for clinical application.
4. Examine controls and switches for proper function.
5. Verify battery chargers and indicators are working
6. Check replacement date for battery. Replace battery if necessary.
7. Confirm lights, indicators, and displays are working.
8. Verify flow stops when device is turned off.
9. If device requires the IV set to be closed before it is disconnected, verify this mechanism is operating.
10. Calibrate machine for flow rate.
11. Check for unusual noise or vibration.
12. Run self-test, if equipped.
13. Lubricate lead screw, gears, and other moving parts as required.
14. Measure chassis leakage current
15. Measure ground resistance.
16. Test audible and visual alarms and indicators.

Feeding pumps:

1. Clean machine and chassis of any enteral solution residue.
2. Examine plug and line cord.
3. Examine internal cables and connectors.
4. Verify software and menu settings.
5. Examine controls and switches for proper function.
6. Verify battery chargers and indicators are working.
7. Check replacement date for the battery. Replace battery if necessary.
8. Confirm lights, indicators, and displays are working.
9. Verify flow stops when device is turned off.
10. Calibrate machine for flow rate.
11. Check for unusual noise or vibration.
12. Check rollers and tubing to see if replacement is necessary.
13. Run self-test, if equipped.
14. Lubricate any rollers or actuators as necessary.
15. Measure chassis leakage current.
16. Measure ground resistance
17. Test audible and visual alarms and indicators.

Cooper, Justin and Alex Dahinten for EWH. "Infusion Pump Preventative Maintenance." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

Infusion Pump Safety Checklist

Infusion Pumps- Safety & Performance

[ ] Inspect exterior of equipment for damage or missing hardware.
[ ] Inspect the power cord, strain relief and plug/s for any signs of damage.
[ ] Turn unit off, open user-accessible covers and inspect unit for damage.
[ ] Clean unit interior components and exterior with vacuum or compressed air.
[ ] Inspect interior for signs of corrosion or missing hardware. Repair as required.
[ ] Inspect electrical components for signs of excessive heat or deterioration.
[ ] Perform battery operation test.
[ ] Test instrument service/test mode.
[ ] Verify pressure calibration.
[ ] Perform auto pinch-off test.
[ ] Verify rate accuracy.
[ ] Verify correct operation of all buttons, controls, displays and/or indicators.
[ ] Verify correct operation of unit in all functional modalities.

Examples of Incidents Involving Infusion Pumps

Table 1 Examples of types of incidents involving infusion pumps

Category of incident	Examples of incidents
Storage / packaging	● Flat battery due to not charging the pump. ● Set packaging damaged – set contaminated.
Maintenance	● Loss of battery capacity because battery not maintained according to manufacturer's instructions. ● Incorrectly replaced seal resulting in fluid ingress. ● Free-flow from volumetric pump because the door contacts were not checked during the pump's annual maintenance.
Contamination	● Fluid ingress into infusion pump. ● Dried infusate on syringe size sensor resulting in incorrect syringe size being displayed by the pump.
Degradation	● Set worn out – inaccurate infusion. ● Worn pumping mechanism leading to inaccurate infusion.
Damage	Pumping mechanism became loose because the pump was dropped. The loose mechanism could not hold the set against the door sufficiently to control the flow.
Performance	Infusion pump not performing to specification because the manufacturer had incorrectly set the pumping mechanism.
Design and labelling	A reprint of the user instructions specified a zero instead of the number one to set the KVO. Users following the new instructions could not set the pump to KVO.
Quality assurance (QA)	Spare components for detecting when the infusion was near its end were undersize. If fitted the pump would not signal 'near end of infusion'.
User errors	● Misloading administration set. ● Misloading the syringe. ● Setting the wrong rate. ● Confusing primary and secondary rates. ● Not confirming the set rate. ● Not confirming the syringe size. ● Confusing the pump type. ● Not stopping the infusion correctly. ● Not confirming the pump mode. ● Not confirming the configuration of the pump.

Department of Health, Social Services and Public Safety. "Device Bulletin: Infusion Systems DB, v2.0." Vol. DB2003, No. 2. Department of Health, Social Services and Public Safety, 2010, p. 1-56.

4. Troubleshooting and Repair of Infusion Pumps

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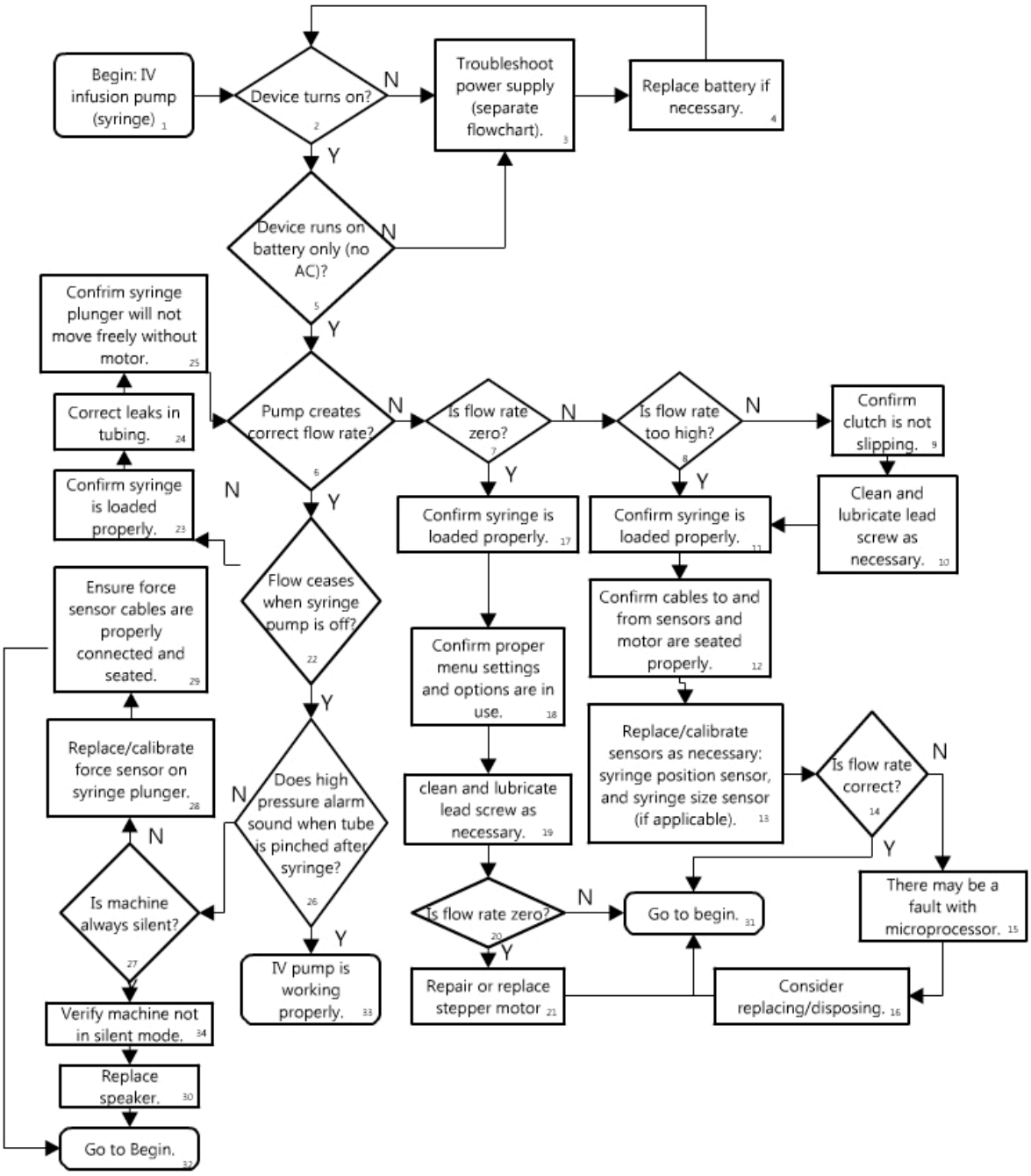
EQUIPMENT

Infusion Pump Troubleshooting

Diagnostic flowchart (Syringe Pumps)

Syringe pumps use a syringe driven by a lead screw to deliver precise amounts of liquid medication intravenously.



Cooper, Justin and Alex Dahinten for EWH. "Infusion Pump Troubleshooting Flowchart." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

#	Text box	Explanation or Comment
1	Begin: IV infusion pump (syringe)	Start the diagnostic process.
2	Device turns on?	Displays, lights, and sounds indicate the machine has turned on.
3	Troubleshoot power supply (separate flowchart).	Syringe pumps generally have an AC-DC power supply.
4	Replace battery if necessary.	Old batteries are a common problem with syringe pump batteries.
5	Device runs on battery only (no AC)?	Check if the machine will run on battery when power is unplugged. This is a safety feature on many syringe pumps.
6	Pump creates correct flow rate?	Measure the flow rate using a container of known-volume to collect the fluid and a stopwatch. For small flow rates, it may be necessary to use a precision scale to measure the fluid output. Flow rate is volume divided by time.
7	Is flow rate zero?	Check if the machine will generate any output of fluid.
8	Is flow rate too high?	Compare the measured flow rate to the amount programmed in the machine.
9	Confirm clutch is not slipping.	Low flow can be caused by a clutch slipping on the lead screw. Repair if necessary.
10	Clean and lubricate lead screw as necessary.	See BTA skills on cleaning and lubrication.
11	Confirm syringe is loaded properly.	Incorrect flow rate can be caused by improperly loaded syringe.
12	Confirm cables to and from sensors and motor are seated properly.	See BTA skills on electric connections and connectors.
13	Replace/calibrate sensors as necessary: syringe position sensor, and syringe size sensor (if applicable).	Faulty sensors can cause faults in controlling the flow rate.
14	Is flow rate correct?	Measure the flow rate using a container of known-volume to collect the fluid and a stopwatch. For small flow rates, it may be necessary to use a precision scale to measure the fluid output.
15	There may be a fault with microprocessor.	Possible problem with the microprocessor or computing software.

Cooper, Justin and Alex Dahinten for EWH. "Infusion Pump Troubleshooting Flowchart." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

16	Consider replacing/disposing.	If the problem lies with the microprocessor, the machine may need to be disposed and replaced.
17	Confirm syringe is loaded properly.	Incorrect flow rate can be caused by improperly loaded syringe.
18	Confirm proper menu settings and options are in use.	User error may be a problem if machine is reported for lack of flow.
19	Clean and lubricate lead screw as necessary.	See BTA skills on cleaning and lubrication.
20	Is flow rate zero?	Check if the machine will generate any output of fluid.
21	Repair or replace stepper motor.	If corrective measures don't start fluid output, there may be a problem with the motor that drives the syringe.
22	Flow ceases when syringe pump is off?	Verify that the flow ends when the pump is turned off or the control panel is used to end the flow.
23	Confirm syringe is loaded properly.	An incorrectly loaded syringe could leak fluid when flow is turned off by controls.
24	Correct leaks in tubing.	See BTA skills on plumbing leaks.
25	Confirm syringe plunger will not move freely without motor.	If plunger moves independently of machine controls, check mechanical connections.
26	Does high pressure alarm sound when tube is pinched after syringe?	If the output tube is occluded, the machine should emit a high pressure alarm.
27	Is machine always silent?	Investigate if machine makes noises due to any other inputs or alarms.
28	Replace/calibrate force sensor on syringe plunger.	High pressure alarm is not sounding. Check the force sensor that measures the force applied to the syringe plunger.
29	Ensure force sensor cables are properly connected and seated.	See BTA skills on electric connections and connectors.
30	Replace speaker.	Machine is not in silent mode, but it does not make noise. Replace the speaker.
31	Go to begin.	Restart the diagnostic process to see if the corrective measures have repaired the machine.
32	Go to begin.	Restart the diagnostic process to see if the corrective measures have repaired the machine.
33	IV pump is working properly.	Return the machine to service via the appropriate clinical personnel.
34	Verify machine not in silent mode.	Silent mode may be preventing the alarm. Turn off silent mode and check alarm again.

Cooper, Justin and Alex Dahinten for EWH. "Infusion Pump Troubleshooting Flowchart." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

31	Go to begin.	Restart the diagnostic process to see if the corrective measures have repaired the machine.
32	Feeding pump is working properly.	Return the machine to service via the appropriate clinical personnel.
33	Check if machine is in silent mode.	Silent mode may be preventing the alarm. Turn off silent mode and check alarm again.

Cooper, Justin and Alex Dahinten for EWH. "Infusion Pump Troubleshooting Flowchart." From the publication: Medical Equipment Troubleshooting Flowchart Handbook. Durham, NC: Engineering World Health, 2013.

5. Syringe Pumps

Featured in this Section:

WHO. “Syringe Pump.” From the publication: “WHO Technical Specifications for 61 Medical Devices. *WHO*. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Wikipedia. “Syringe Driver.” *Wikipedia*, p. 1-2. Retrieved from: http://en.wikipedia.org/wiki/Syringe_driver

Syringe driver

A syringe pump for laboratory use. World Precision Instruments (WPI) SP120PZ.

A **syringe driver** or **syringe pump** is a small infusion pump (some include infuse and withdraw capability), used to gradually administer small amounts of fluid (with or without medication) to a patient or for use in chemical and biomedical research.

The most popular use of syringe drivers is in palliative care, to continuously administer analgesics (painkillers), antiemetics (medication to suppress nausea and vomiting) and other drugs. This prevents periods during which medication levels in the blood are too high or too low, and avoids the use of multiple tablets (especially in people who have difficulty swallowing). As the medication is administered subcutaneously, the area for administration is practically limitless, although edema may interfere with the action of some drugs.

Syringe drivers are also useful for delivering IV medications over several minutes. In the case of a medication which should be slowly pushed in over the course of several minutes, this device saves staff time and reduces errors.

Syringe pumps are also useful in microfluidic applications, such as microreactor design and testing, and also in chemistry for slow incorporation of a fixed volume of fluid into a solution. In enzyme kinetics syringe drivers can be used to observe rapid kinetics as part of a stopped-flow apparatus.[1]

External links

- Picture of syringe driver in use [2]

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[2] http://www.mja.com.au/public/issues/178_10_190503/rey10533_fm-1.jpg

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Figure 2: WHO Syringe Pump Specification

NAME, CATEGORY AND CODING		
1	*WHO Category / Code*	(under development)
2	Generic name	Syringe Pump
3	Specific type or variation (optional)	N/A
4	GMDN name	Syringe pump
5	GMDN code	13217
6	GMDN category	02 Anaesthetic and respiratory devices 04 Electro mechanical medical devices 11 Assistive products for persons with disability
7	UMDNS name	Infusion Pumps, Syringe
8	UMDNS code	13217
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Syringe Drivers; Driver, syringe; Infusion pump, syringe
11	Alternative code/s (optional)	S 18092; S 46419
12	Keywords (optional)	analgesia, analgesia, drug, syringe driver
13	GMDN/UMDNS definition (optional)	A device designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency. Because of the lower flow settings and flow resolution, it is especially appropriate for neonatal, infant, and critical care applications in which small volumes of concentrated drugs are to be delivered over an extended period. It can also be used to administer epidural analgesia.
PURPOSE OF USE		
14	Clinical or other purpose	Designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency.
15	Level of use (if relevant)	Health centre, district hospital, provincial hospital, specialized hospital
16	Clinical department/ward(if relevant)	Intensive care unit (ICU), radiology department, emergencies, operating theatres ...
17	Overview of functional requirements	A syringe containing medication is securely mounted on the drive arm. The drive arm infuses the medication at a steady, programmed rate. Alarms indicate if any error situations occur.
TECHNICAL CHARACTERISTICS		
18	Detailed requirements	1. Infusion pump with one channel. 2. Capable of accept any kind of fluids (as solutions and medicines). 3. Must work on commonly available 20, 50 and 60 ml syringes. 4. Control panel. 5. Accuracy of ±2% or better. 6. Maximum pressure generated ≤ 20 psi. 7. Automatic detection of syringe size and proper fixing. 8. Must provide alarm for wrong loading of syringe. 9. Anti-bolus system to reduce pressure on sudden release of occlusion. 10. Pause infusion facility required. 11. Self-check carried out on powering on. 12. Events stored system. 13. Battery with operating time at least 6 hours.
19	Displayed parameters	Comprehensive alarm package required including: occlusion alarm, plunger disengaged, syringe loading error, flow error, syringe unlocked, infusion complete, near end of infusion pre-alarm and alarm, volume limit pre-alarm and alarm, low battery pre-alarm and alarm, AC power failure, maintenance required.

WHO. "Syringe Pump." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

20	User adjustable settings	1. Flow rate programmable range at least from 0.1 to 200 ml/hr, in steps of 0.1 ml/hr; and at least from 100 to 1200 ml/hr in steps of 1 ml/hr. 2. Flow rate or volume limit to administer from 0.1 to 999.9 ml. 3. Saves last infusion rate even when the AC power is switched off. 4. Bolus rate should be programmable to approx. 500 ml, with infused volume display. 5. Selectable occlusion pressure trigger levels selectable from 300, 500 and 900 mmHg.
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components(if relevant)	N/A
22	Mobility, portability(if relevant)	Portable, Securely mountable on table-top, IV stand or bed fitting
23	Raw Materials(if relevant)	Tamper-resistant case made of impact resistant material
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	1. Power input to be ******* fitted with ******* compatible mains plug. 2. Internal rechargeable battery having at least 5 hours backup for 10ml/hr flow rate with 50ml syringe. 3. Battery powered alarm for power failure or disconnection.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Clamp for mounting pump on IV stand
26	Sterilization process for accessories (if relevant)	Autoclavable temperature sensor
27	Consumables / reagents (if relevant)	Disposable syringes of different kind of volumes.
28	Spare parts (if relevant)	Medical units select them according to their needs, ensuring compatibility with the brand and model of the equipment.
29	Other components (if relevant)	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	N/A
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	N/A
33	Labelling (if relevant)	N/A
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	1. Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. 2. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements(if relevant)	Supplier to perform installation, safety and operation checks before handover.
36	Requirements for commissioning (if relevant)	Local clinical staff to affirm completion of installation
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided
38	User care(if relevant)	Enclosure to protect against water ingress. Capable of cleaning with alcohol or chlorine wipes.
WARRANTY AND MAINTENANCE		
39	Warranty	2 years
40	Maintenance tasks	Preventive/periodic maintenance requirements to be listed.

41	Type of service contract	N/A
42	Spare parts availability post-warranty	N/A
43	Software / Hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	1. Advanced maintenance and calibration tasks required shall be documented. 2. User, technical and maintenance manuals to be supplied in (***** language). 3. List to be provided of equipment and procedures required for local calibration and routine maintenance. 4. List to be provided of important spares and accessories, with their part numbers and cost. 5. Certificate of calibration and inspection to be provided.
DECOMMISSIONING		
45	Estimated Life Span	8 to 10 years.
SAFETY AND STANDARDS		
46	Risk Classification	Class C (GHTF Rule 11-1); Class II (USA); Class II a (EU and Australia); Class III (Japan and Canada)
47	Regulatory Approval / Certification	FDA approval (USA); CE mark (EU)
48	International standards	ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU) ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-2-24 Ed. 2.0:2012 (b) Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers ISO 7886-2:1996 Sterile hypodermic syringes for single use -- Part 2: Syringes for use with power-driven syringe pumps ISO 8536-8:2004 Infusion equipment for medical use -- Part 8: Infusion equipment for use with pressure infusion apparatus ISO 8536-9:2004 Infusion equipment for medical use -- Part 9: Fluid lines for use with pressure infusion equipment ISO 8536-10:2004 Infusion equipment for medical use -- Part 10: Accessories for fluid lines for use with pressure infusion equipment ISO 8536-11:2004 Infusion equipment for medical use -- Part 11: Infusion filters for use with pressure infusion equipment ISO 8536-12:2007 Infusion equipment for medical use -- Part 12: Check valves ISO 9626:1991 Stainless steel needle tubing for the manufacture of medical devices ISO 23908:2011 Sharps injury protection -- Requirements and test methods -- Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling ISO 26825:2008 Anaesthetic and respiratory equipment -- User-applied labels for syringes containing drugs used during anaesthesia -- Colours, design and performance
49	Reginal / Local Standards	**EU standards** EN 60601-2-24:1998 Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers

50	Regulations	**US regulations** 21 CFR part 820 21CFR section 880.5725 pump, infusion **EU regulations** Council Directive 93/42/EEC Directive 93/68/EEC (CE Marking) Directive 98/79/EC Directive 2001/104/EC Directive 2007/47/EC **Japan regulations** MHLW Ordinance No.169 13217000 Syringe infusion pump

WHO. "Syringe Pump." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

6. Resources for More Information about Infusion Pumps

Featured in this Section:

Malkin, Robert. “Fluid Pump: Use and Operation.” *Medical Instrumentation in the Developing World*. Engineering World Health, 2006.

Resources for More Information:

Internal Resources at library.ewh.org: For More Information about Infusion pumps, please see this resource in the BMET Library!

1. Malkin, Robert. "Fluid Pump: Use and Operation." *Medical Instrumentation in the Developing World*. Engineering World Health, 2006.

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Wikipedia. "Syringe Driver." *Wikipedia*, p. 1-2. Retrieved from: http://en.wikipedia.org/wiki/Syringe_driver

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