

## **Infusion & Syringe Pumps**

Open Source Medical Supplies opensourcemedical Supplies.org

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# **DOCUMENT IN PROGRESS**

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### The Problem

Medication administration is the process of giving medication to a patient orally, through injection, or intravenously (through a vein). The supplies and devices used in medication administration vary depending on the type of medication being given. Oral medications can be dispensed via a pill bottle, injections are given via a syringe and needle, while intravenous medications are given via an IV bag through IV



tubing and sometimes with the use of an infusion pump to control the volume and rate of administration.

#### **Current Global Resources**

<u>The latest coronavirus shortage: hospital infusion pumps</u> Global- "With much attention focused on shortages of ventilators and PPE, Niemeier says the healthcare system must take a "comprehensive look" at what it needs to care for the surge in COVID-19 patients, especially those on ventilator assistance who require IV support." 2020/04/14

<u>Chip shortage puts crimp in Baxter's pump production</u> US- "Baxter International makes tens of thousands of infusion pump systems a year at its plant in Medina, devices which deliver fluids and medicines to hospital patients. But a shortage of semiconductor chips used in the pumps has hampered Baxter's production, and the problem continues to overshadow its manufacturing." 2022/08/11

## **Engineering Requirements For Syringe Pumps**

- The infusion pump system should include fluid infusion set for the complete fluid pathway from, and including, the drug reservoir or fluid source container (e.g. bag, cassette, vial, syringe), infusion set, extension sets, filters and valves, clamps, up to and including the patient connection.
- Components and accessories (e.g. power cord, wireless controller).
- Network (i.e. any device or system physically or wirelessly connected to the infusion pump). Patient; environment of use (e.g. clinical setting, temperature, humidity). User (e.g. health care provider, lay user, biomedical technicians).
- Requirements include the following:
- Size
- Battery Life
- Rate Mode
- Interval Mode
- Demand Dose
- Syringe Capacity
- Alarms
- Power Source

### Assembly/Fabrication Requirements

No additional information at this time.

#### Resources

- Open Syringe Pump
- Infusion Pumps Total Product Life Cycle Guidance for Industry and FDA Staff
- <u>51 0(k) Submission: ICU WillCare Infusion Pump 510(k) Summary Name of Device:</u> Trade name: WillCare GW-1020 Common name: Infusion
- Combination Products

### Links to Projects

This section is for designs (links to instructions or downloadable packages) that have been submitted for inclusion into our documents\*. Any design within this list will include the (approximate) date of addition, the group or organization that reviewed it (when appropriate), and any additional notes. Designs intended for use in clinical settings are being used by clinicians and others and they have been critiqued by, or developed in partnership with, medical professionals (as indicated). Designs intended for use in the Community are not subject to regulatory requirements.

\*Designs must be manufactured as described. The linked designs have not been cleared, certified, or otherwise approved by the Food and Drug Administration (FDA) or the National Institute for Occupational Safety and Health (NIOSH). OSMS does not offer any warranty or assume any liability for the use of the included designs. Individuals or organizations that manufacture products utilizing these designs and specifications are responsible for any federal or state regulatory requirements that apply to the manufacture of products intended for medical use. These designs should only be used during the declared COVID-19 public health emergency if FDA cleared or approved products are unavailable.

1. Project Name: MOST Syringe Pump

Project Link

• Date Added: 2021/11/18

- Notes: 3DP, CAD and Raspberry Pi supported syringe pump which was developed, tested, and published by Michigan Tech's Open Sustainability Technology Lab. This design is intended for use in research labs, reducing potentially prohibitive cost and time delays compared to commercially available products.
- 2. Project Name: 3DP Accessible Pill Bottle

Project Link
Insert for pharmacy pill bottles
Video instructable for insert

Date Added: 2022/08/11

- In early 2021, a Parkinson Pill Bottle design appeared on TikTok and took the 3D printing world by storm. Since then, the bottle has undergone many modifications and improvements, resulting in version 5 linked here. The insert version can be used in a commercial pharmacy bottle. Both designs are still undergoing changes based on user feedback, so be sure to check project comments for relevant updates. The pill bottle allows easier access and dispensing for small pills, which are often a challenge for tremor-affected patients to self-administer.
- 3. Project Name: 3DP NG Tube Clip

Project Link
12 French size

• Date Added: 2022/08/11

- Nasogastric (NG) tubes are often placed for extended use outside the hospital, creating
  a tubing management problem for patient clothing and variable ambient temperatures.
  This clip is available in 8, 10, and 12 French (FR) sizes, allowing the NG tube to be
  securely and discreetly fastened to clothing or headwear, such as a riding helmet or
  baseball cap. Printing in PETG or ABS ensures stability during ambient heat exposure.
- 4. Project Name: Western University Auto-Injector

Project Link

Date Added: 2023/09/15

•	Notes: Peer reviewed publication presenting design, testing, and regulatory discussion of a 3DP Auto-Injector, a Class II device. Component cost is less than CAD\$10 and print time is just over 12 hours.