Infusion pumps that sense the drug flow – and even your heartbeat in it

Sensor technology takes infusion pumps to the next level by making failure detection reliable, even for infiltration.

Everyday millions of patients worldwide receive intravenous infusion therapy, many times assisted by a smart infusion pump. Smart infusion pumps provide well-controlled drug delivery over a prolonged period of time and are of tremendous help for hospital staff. However, they fall short when it comes to reliable failure detection. Today’s infusion pumps lack the technology to directly measure the flow rate of the drug inside the tubing which results in two main problems: First, there are failures that remain undetected and, second, over-sensitive pumps generate a high number of false alarms. The ECRI Institute named alarm fatigue and infusion pump medication errors as number one and two on their list of top 10 health technology hazards for 2014.

Typical failures during infusion therapy include occlusion, air-in-line, free flow, cross-flow in multi-infusion settings, and infiltration or extravasation. While all of the above failure modes are very well known to hospital staff, today’s infusion pumps can at best only detect the first three. Sensirion’s liquid flow sensing technology enables smart infusion pumps to detect not only these failures, but also reverse flow, cross-flow and even infiltration errors reliably.

Sensirion’s Sensor Technology

Sensirion’s sensor technology for medical devices is based on more than ten years of experience in measuring very low flow rates using advanced CMOSens® components that combine MEMS and CMOS portions on a single monolithic silicon chip. By integrating this tiny flow sensor chip into a variety of packages, Sensirion has successfully improved diagnostics, automation, and semiconductor industry processes around the world. The same proven technology can be applied to infusion applications and medical devices to increase patient safety and significantly support hospital staff during their daily work.

The measurement method is based on a micro-thermal principle by which a microscopic heating element introduces a negligible amount of heat into the bypassing liquid. The shape of this “heat cloud” is monitored by two temperature sensors and is directly related to the flow rate inside the fluidic channel. By using this principle, Sensirion’s liquid flow sensors can reliably and constantly measure the low flow rates which are typical for medical applications. Every sensor is fully calibrated and provides a linearized, digital output to ensure the highest accuracy. CMOSens® technology is highly scalable and allows sensor solutions to be technically as well as economically feasible. The sensor chip is packaged into a plastic housing which features all mechanical, electrical, and fluidic connections needed to smoothly integrate it into e.g. an infusion set.

Integrated into an infusion set, Sensirion’s disposable liquid flow sensor communicates the flow rate inside the tubing in real-time allowing an unprecedented reliability and safety for infusion therapies. Occlusion for example can be detected within a few seconds by noticing a decrease in the flow rate even in ultra-low flow ranges. No more waiting for 45 minutes before an alarm is triggered by an infusion pump. Drops in primary infusions due to cross-flow errors from secondary lines can be detected quickly so that corrections can be made without impacting patient therapy. The sensor also features bubble detection to identify air inside the infusion tubing. Sensirion’s liquid flow sensor is fast, precise, and smart. Besides, it is sensitive enough to detect the smallest changes in the flow rate. For instance, it is so sensitive that it can detect the regular peaks in the infusion flow rate produced by the oscillating back pressure of the patient’s venous pulse – the sensor can feel the patient’s heartbeat (see Fig. 1).
Detecting the heartbeat on the flow rate is a direct indication of an intact connection of the infusion cannula to the vein of the patient, absence of the pulsation on the contrary indicates an interrupted connection. Possible causes may include e.g. kinked, disconnected or, ruptured tubing or a dislodged infusion cannula which may in turn lead to infiltration. By evaluating the sensor signal, Sensirion’s sensor solution offers a unique possibility of detecting infiltration quickly and preventing harmful consequences to the patient.

**Infiltration and Extravasation**

Infiltration and extravasation describe the leaking of IV fluid into the tissue surrounding the vein (see Fig. 2). With infiltration, the IV fluid is a so-called non-vesicant agent leading to irritations while extravasation describes the efflux of vesicant agents that can cause damage to the tissue. Potent drugs, used in chemotherapy for example are such vesicant agents. The damage can extend to involve nerves, tendons, and joints and can continue for months after the initial incident. If treatment is delayed, surgical debridement, skin grafting, and even amputation may be the unfortunate consequences. Potentially severe consequences strengthen the need to include disposable liquid flow sensors for enhanced reliability and safety in infusion therapy. The frequency of complications caused by extravasation is hard to establish clearly, varying heavily between different hospitals and tending to be generally underreported. However, the estimated incidence rate published in literature is between 0.1 % and 6 % for patients receiving chemotherapy. Extravasation causes harm to patients and inflicts heavy costs on the healthcare system, while both of them could be prevented. The costs following an extravasation injury can be enormous including extended therapy, a longer hospital stay as well as legal costs.

**Cause of Extravasation**

The leakage of IV fluid into the surrounding tissue can be caused by many reasons including damage to the vein’s backside during catheter insertion. However, one of the most common reasons is the puncture of the vein wall by mechanical friction of the catheter needle. This is typically preceded by an occlusion. With a traditional infusion pump, the occlusion may remain undetected until the pressure in the tubing reaches a certain threshold level, triggering the alarm through a pressure sensor many minutes and sometimes close to an hour later. Detecting the occlusion quickly and reliably and consequently stopping the infusion pump can prevent the rupture of the vein and the subsequent leakage.

**Plenty of Benefits from Integrating a Liquid Flow Sensor**

Most medical device manufacturers - familiar with the art of infusion therapies - are aware of the challenges inherent to the technology of smart infusion pumps. Integrating a liquid flow sensor into infusion tube sets will take the infusion therapies a great step forward and allow for a controlled drug delivery on a much broader scale than today. Failures that go by completely unnoticed today can be detected or even prevented. This will lead to an increase in patient safety and well-being, a reduced workload and less stress for hospital staff as well as overall savings in the healthcare system.

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