WORKING PRINCIPLE AND INTELLIGENCE OF SMART INFUSION PUMP

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ABSTRACT: There is a tremendous demand on the critical care resources due to the extensive spread of the ongoing coronavirus pandemic and the large number of patients requiring critical care. The efficacy of a device directly influences how long a patient lives since patients are often receiving critical care. Smart infusion pump is a medical device that can drip fluids into the patient's body. This device is considered as one of the most safety-critical medical devices due to the way it functions and the risks it presents. The main objective of this work is to develop an affordable infusion pump using embedded technology. The main tactic is to develop equipment that can identify air bubbles in infusion pump tubing since even a little one might obstruct blood flow and result in mortality. This method may provide consumers an accurate result, making it the greatest method for identifying bubbles and saving lives.

Keywords: smart, infusion, pump, patient, medical

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INTRODUCTION

Since they were first created in the late 1960s, infusion pumps have undergone changes without the knowledge of the caretakers, evolving from simple volumetric rate devices primarily used for nutrition and cardiovascular medications to more complicated, therapy-specific systems. (Nivas & Singh, 1988) Fluids or medications are slowly infused into a patient's body using an infusion pump. Infusion pumps come in a wide variety of designs and are used in a variety of settings. By occasionally finishing a certain solution transfer procedure, this innovation is often utilised in medicine to intermittently transfer a solution while injecting a medicinal solution into the patient's body. A 200 kg adult patient's dose range for an ICU pump today is 10,000, and it may be adjusted to provide as little as a drop or two over the course of an hour or as much as 1 litre or more. Large or small quantities of fluids, nutrients, medications like insulin or other hormones, antibiotics, chemotherapeutic treatments, and painkillers are often administered using infusion pumps. In certain circumstances, a patient's bedside infusion pump may be used. Others include wearable or portable ambulatory infusion pumps. (Batliner et al., 2019) The FDA has just been made aware of the significant safety hazards associated with infusion pumps. These issues might put the security of using external infusion pumps in jeopardy and result in over- or under-infusion, missed treatments, or delayed medicines. The FDA received about 56,000 complaints about harmful side effects of infusion pumps between 2005 and 2009, including a number of accidents and deaths. In order to increase the security of infusion pumps, the FDA launched three efforts namely increasing user awareness, aggressive support for device modifications, and submit revised sector ideas.

The main aim of this paper is to describe the operation of a sophisticated device that helps patients get their medications. By using compact and dependable parts, we expect the prototype to be strong and manageable, allowing it to be lifted with only one hand. Other pumps have been designed to handle a variety of infusion modalities, while other smart pumps have evolved into network devices that link to wireless networks in hospitals and clinics. Since we're trying to keep it affordable and portable, it wouldn't happen often.

Background: Medical device design has advanced because of significant technical improvements. Sensors and actuators are examples of physical equipment with remote access to the cyber environment, other devices, and the whole system. Almost all stand-alone medical devices only include a communication interface for use with patients, carers, and healthcare providers. (Weiss et al., 2000) Most medical devices can now connect remotely with other devices, medical workers, and carers thanks to modern technology. Operational effectiveness has enhanced communication with medical devices. For the purposes of this research, the medical pump—such as an infusion pump—is taken into consideration. Infusion pumps, a unique medical device, may communicate with patients or healthcare professionals. These gadgets now wirelessly connect to different systems, networks, and other tools inside the Healthcare Delivery Organization (HDO) and eventually medical assistance, contributing to
MCPS as a result of technology advancements aimed at improving patient care. Devices based on MCPS have an emphasis on physical system design, cyberspace communication, and security measures. (Lim et al., 2018) Collaboration between medical professionals and technology improves accuracy and efficacy. Ingenious machines with computerised controls are infusion pumps of today. The ecosystem of wireless infusion pumps is susceptible to dangers such as unauthorised access to protected health information, variations in the cost of prescription medications, and interference from the pumps. Because delivering the drug to the patient is so crucial, the infusion pump's components must be meticulously managed and observed. (Govindaraj, 2019)

**Literature Review:** Intravenous (IV) drug mistakes are frequent and may be quite dangerous in hospitals. The FDA has been informed of several hundred IV pump-related occurrences over the last 20 years, some of which have resulted in patient fatalities. The kinds, frequency, and severity of pharmaceutical mistakes related to IV pumps were identified by Husch (2005). They assess if using a smart pump instead of a link to other systems would have averted problems. Researchers prospectively compared the drug, dose, and infusion rate on the IV pump to the prescribed medicine, doses, and rate in the patient's medical file using a point prevalence technique. An extensive analysis of the currently available technologies served as the foundation for the deployment of smart pump technology to demonstrate preventability. With IV pumps, medication mistakes are common, epidemiologically varied, and perhaps deadly. Intelligent pumps are a need for a complete, secure medical system. However, unless smart pumps can connect with other systems like the electronic medical record, computerised prescriber order input, bar-coded medicine delivery systems, and pharmacy information systems, they won't be able to substantially increase patient safety. The efficiency of new technology in avoiding latent and active flaws as well as brand-new sorts of error that any technology may bring should be the main topic of future study.

To avoid harmful drug errors, use intelligent infusion pumps with dosage error reduction software. Kuittinen et al. (2022) created simulation-style test scenarios utilising medication error reports to build and evaluate appropriate dose limits in a neonatal critical care unit's smart infusion pump drug library. They used both qualitative and quantitative techniques in their mixed-methods research. Improper infusion rates were involved in 3.5% of all drug mistakes that were recorded in the newborn critical care unit. To evaluate the sufficiency of dose restrictions within the newborn critical care unit’s medication library, simulation-style test scenarios may be employed. To create test cases and get a thorough knowledge of the factors producing improper infusion rate mistakes, it is advised that hospital medication error data be integrated with other prospective data gathering techniques. It is crucial to review the alert log data and medication library compliance once the medication library has been installed to make sure the dose limitations are appropriate.

Inpatient therapy requires intravenous medicines. Adverse drug events may occur when intravenous infusion pumps are used incorrectly to provide drugs to critically sick patients. Rothschild et al. (2005) evaluated how smart pumps with built-in decision support software affect the quantity and kind of medication mistakes and adverse drug events. The main medication mistake rate was compared between the intervention and control periods in a prospective, randomised time-series study. Near calls and avoidable adverse drug events were both categorised as major pharmaceutical mistakes. To identifying possible problems, the pump software generated log data. Doctors were given events to assess for event kind, preventability, and severity. Smart pumps may be able to identify adverse drug events and intravenous medication mistakes, both of which were common. There was no discernable reduction in the high medication mistake rate, which was probably caused in part by poor compliance. Smart pumps have a lot of potential, but there must be certain technical and behavioural issues with nurses before they can entirely boost drug safety.

The detection of programming faults in medication administrations in a paediatric critical care unit is influenced by smart infusion pumps. To determine the advantages of using smart pump technology for patient safety, Manrique-Rodríguez et al. (2013) carried out a prospective observational intervention research in the PICU of a hospital in Madrid, Spain. 78% of users in total cooperated with the safety software during the course of the 17-month research. By allowing the interception of infusion programming mistakes that presented a significant risk of harm to paediatric patients, the adoption of smart pumps in a PICU enhanced patient safety.

Giving patients the fluids and drugs, they need to survive at a consistent and predictable pace is a challenging duty that falls to the large-volume infusion pump, a piece of medical equipment. The frequency with which infusion treatments are delivered increases the risk of adverse consequences brought on by improper administration. Smith & Gray (2020) committed to a thorough usability engineering effort that involved more than 400 hours of user testing in order to create a safer infusion pump. In order to protect against possible usage mistakes, the pump's design includes risk controls that are absent from conventional pumps. The result was the selection of the Stanley Caplan User-Centred Design Award winner for 2019.
In order to provide evidence-based guidance on how to reduce workarounds and encourage adherence to patient safety criteria, Dunford et al. (2017) looked into nurses’ impressions of smart infusion drug pumps. To address the problem, they specifically conducted a detailed investigation of nurses in three American healthcare systems. They classified the open-ended replies to questions on the causes of workarounds using qualitative research techniques. The nurses enjoyed the innovative infusion pumps in general. They did, however, highlight several organisational, cultural, and psychological causes for the presence of smart pump workarounds. By addressing the non-technical reasons of workarounds, giving greater leadership, and offering organised training for resolving smart pump-related issues, hospitals may greatly increase adherence to smart pump safety requirements.

There is enough data to draw the conclusion that patients are susceptible to drug mistakes. This danger is greatest in an intensive care unit environment and is worse when drugs are given through an infusion pump. When medicine delivery data is entered, standard pumps won't notify or stop mistakes in drug calculation, drug unit, button pushing, or multiples of ten. Research, however, indicates that smart pump limitations might considerably reduce medication mistakes at the distribution site. By using an infusion pump device, Murdoch & Cameron (2008) eliminate medication delivery mistakes right away using these pumps.

Smart infusion pumps are now often employed in hospitals. An infusion is a method of giving a patient fluids or drugs through intravenous, subcutaneous, epidural, or enteral channels while utilising an infusion device. Precision dosing is essential for pharmaceutical delivery systems used in healthcare. Using intelligent pumps may help prevent errors made while programming pumps as well as issues with ordering providers' dosage, dose rate, or solution concentration. Even when programming is carried out using intelligent alerts, precise motor control flow must be taken into account. Alamelu & Mythili (2021) discusses a framework for the best motor control to carry out a precise medication flow to the patient utilising an infusion device. A mathematical model of the infusion pump and the electric motor it is connected to makes up the framework. The aforementioned methods are used to contrast the stability and temporal response analysis needs. To ensure prompt infusion and further minimise lag time and delay in the medication infusion's flow rate, the infusion device's motor should have a short rise time.

**Materials:** The kind of fluid to use and how soon it must be provided depend on whether there are fluid losses in the body or if there is a chance that there will be fluid losses. The underlying disease must be identified and addressed before the therapy may be employed as a treatment. Following is a brief description of all components:

**Stepper motors:** Stepper motors are used in the pump mechanism to provide a precise flow rate. The motor loading changes as the machine rotates. The fluid viscosity, flow rate, and placement of the pump mechanism all have an impact on the motor load.

**Drip:** They may be used to administer medicine, supply nourishment, prevent dehydration, and maintain blood pressure when a patient is unable to eat.
Fixible tubes: An intravenous fluid, IV, or cannula are other names for a drip. It is a plastic tube that is just the right length. In order to allow fluids and drugs to directly enter the bloodstream, a doctor will implant the drip using a needle and leave the plastic tube in place.

Motor dosing head: A metering pump is used to precisely add tiny quantities of a liquid to other fluid streams or containers.

Human Machine Interface (HMI): It is an interactive display that provides details about facts, figures, and situational measures of a specific system to a human operator via the HMI panel.

Controller: The proper amount of fluid may be distributed by managing the gravity flow. In order to control the flow so that a certain number of droplets reach the drip chamber each minute, squeeze the tube.

Power supply: By providing the other devices' components with the required power, this device makes it possible for the system to work.

Solenoid valve: Regardless of whether it is open or closed, a solenoid valve controls the movement of gases or liquids. They are often used to replace manual valves or to provide remote control. An opening in the valve body may be opened or closed to allow or deactivate flow via a solenoid valve.
Bubble detector sensor: In fluid-filled tubes, bubble detector sensors are used to check for the presence of bubbles. They are crucial to many industries, including petroleum, process control, pharmaceuticals, and medical technology. Two piezoelectric ultrasonic transducers serve as the transmitter and receiver in a standard non-invasive ultrasonic bubble sensor. Based on the significant acoustic impedance mismatch between the fluid or tube wall and the air, a technique is employed to detect air in flowing fluid. Ultrasonic and capacitor-based sensors are the two types that are most often employed. Most bubble sensors are constructed in a way that allows them to work without the need of grease or other acoustic coupling agents via the tube walls. Ultrasonic bubble sensors have a variety of uses outside of only medical equipment, including in the semiconductor, chemical, food and beverage, oil and gas, and other industries.

Arduino MEGA: The Arduino Mega 2560 is a microcontroller board based on the ATmega2560. Four UARTs, sixteen analogue inputs, fifty-four digital I/O pins, an ICSP header, a reset button, a USB port, a power connection, and a power connector are all included on the gadget. It also has a 16 MHz crystal oscillator.

The following are some additional components (switches):
- **Drip Mode Indicator**: Drop mode on the digital display unit, in contrast to other modes, shows a light to indicate the current infusion data unit.
- **Menu & Return Button**: Hit the return key after selecting the menu programme.
- **Button of Confirmation (Selection)**: Launch the programme of your choice, then adjust the parameters using one of its many interfaces.

Methodology: Our research aims to develop a tool that can identify air bubbles in infusion pump tubing since even a little one might stop blood flow and result in mortality. When a bubble is found, the machine will immediately stop pumping and sound a warning so the nurse can fix it. We shall construct both the detecting system and the infusion pump. To notify the motor to stop, the detector, which consists of a transistor and a receiver, will communicate when there is a change in the medium's density.

The same source provides power to the CPU, HMI, and pump. Infusion pumps are monitored and controlled via sensors. They sometimes also experience the warmth of the IV fluid. Their functions include occlusion detection, fluid flow monitoring, motor control feedback, and others. Since the micro-collector was previously set up to instruct the infusion pump motor to stop and encourage it to repair the problem, the microcontroller recognises the change in the reflected signal as soon as an air bubble appears.

Software faults, poor user interface design, battery issues, and alarm failures are a few potential issues. An example of a straightforward issue for which the imbuenment direct fails to provide an aural warning is an air bubble that causes an obstruction. When at least one air bubble fills a vein or other passageway, an air embolism occurs. An air bubble entering a blood artery causes a blood vessel air embolism, while an air bubble entering a vein causes a venous air embolism. Heart attacks, strokes, or respiratory failure may result from these air pockets getting into the brain, the heart, or the lungs. The schematic diagram in appendix 1 highlight the methodology used in the process.

RESULTS

The smart pump prototype we developed is identical to the kind of infusion pump that is already available on the market. Our objective is to make an infusion pump portable enough for anybody to operate. We provide the controller instructions via the HMI. It regulates the fluid flow rate through the body as well as
the stepper through the stepper motor. According to the
time shown on the HMI, the controller will send fluid.
The bubble detector we included into our gadget is its
most important feature since it ensures that no one will be
hurt or inconvenienced by bubbles entering their bodies.
A bubble entering the body might cause heart failure or
clothing. The main goal of our project's bubble detector is
to, wherever possible, have any found bubbles flow back
via the solenoid.

When a bubble is found, the drip's settings are
reset to their default values, moving fluid flow from the
solenoid, which is under relay control, to the drip. Our
senior year project, titled "Bubble Remover (Infusion
Pump)," took home the special category award at the
sixth All Pakistan DUHS-DICE Health Innovation
Exhibition in 2021. The event was organised by the
Office of Research, Innovation & Commercialization
(ORIC), and it was held on December 30, 2021, at DUHS
(Ojha Campus), Karachi. That prospect may become a
reality with the aid of the Health Innovation Prize.

Maintenance: While cleaning the pump on a regular
basis, we used a clean, moist towel and a suitable amount
of detergent. After drying the surface with a clean, dry
cloth and setting the pump on a dry shelf, we repeated the
process. When the battery was low, the pump ceased to
function and sound an audible and visual alert; to
continue servicing, we switched the device off right once
or connected it into an AC power source. When the
battery was low, the pump may sometimes sound a
warning; in order to keep using the pump, we rapidly charged it or connected it to an AC power source. When the
AC electrical indicator lamp went off and the pump began charging, we connected the pump to an AC power
source when it is not in use.

Safety Precautions

- The pump won't accept the solution if it is injected
  outside of the blood artery so we inspected the
  puncture site carefully and kept a close check on the
  patient's health.
- Free flow happened when the tubing clamp was
  opened when the pump is connected to a patient, so
  we examined the pump's stability by mounting it on
  a pole stand.
- Training-equipped medical personnel provided
  instructions on how to utilise the pump and use the
  parts that are provided or advised, such as the power
cable.

Patient Safety: These two guiding principles—
improving patient safety from both an objective and a
subjective standpoint—were taken into consideration
while developing infusion pumps. It is abundantly
obvious that infusion pumps greatly reduce drug
mistakes. The screen can be seen from a distance, which
is very helpful in settings like the intensive care unit
(ICU), where multiple infusion pumps are frequently
running simultaneously, in operating rooms where the
surgical and anaesthesia teams can quickly gather
accurate information, and in locations where diagnostic
tests are conducted where there may be low lighting due
to the requirements of the tests themselves. (Smith &
Gray, 2020)

There are limits on how much medicine may be
supplied at drug libraries. Limitations may be divided
into two categories: "soft limits" that can be manually
exceeded and "hard limits" that cannot be surpassed due
to the significant harm they bring to the patient. Target
controlled infusion techniques are often used in complete
intravenous anaesthesia. They save the anaesthetist from
having to do time-consuming computations to figure out
the delivered medication's tissue concentrations.
Physicians just need to input the patient's biometric
information; the pump will do all computations
automatically. Furthermore, wireless connectivity
between pumps enables patient data to be transferred
between pumps without the need for re-entry, lowering the
risk of mistake. The link to the hospital's PDMS
enables both central pump monitoring and bidirectional
communication between the pumps. (Weiss et al., 2000)

DISCUSSION

There are numerous projects where people utilise
other kinds of sensors, including is sensors and
occlusion sensors, but for our project, we are employing
bubble detector sensors since they are affordable, tiny,
and accurate, particularly at close distances, while other
sensors may be inaccurate. The gadget has to be
enhanced for bubble detection using bubble detector,
which can be accurate because we need a little one and it
can be reasonably priced.

Conclusion: Fluid therapy is an essential part of
treatment since it is dependable, manageable, and simple
to use. An infusion pump or drip-feeding pump is a
popular name for a piece of medical equipment. Infusion
pumps are a kind of medical equipment that can provide
patients massive quantities of fluids, medications, and
nutrients intravenously as needed. We developed a smart
infusion pump with a bubble sensor and a solenoid valve
to address a potentially deadly problem that arises during
intravenous fluid treatment. The solenoid valve opens
when the sensor detects a bubble instead of shutting,
allowing fluid to enter the output jar instead of the
patient's body through a tube. Until the device is
completely bubble-free, the fluid will start to flow back
into the patient's body via them, serving as a conduit for
the fluid to return to the drip. The gadget also comes with
a customizable touch panel that can be used to control it
and show data that is essential for correct functioning,
like fluid flow rate among other things. The well-
designed electric circuit and pre-programmed system make the device easier for the nurse and patients to grasp. The user may get an accurate result using this method, making it the greatest method for detecting bubbles and saving lives.

REFERENCES


APPENDIX 1

Figure 8: Schematic diagram of methodology used