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Predefined Logics Based Anesthesia Delivery Module with Vital Monitoring

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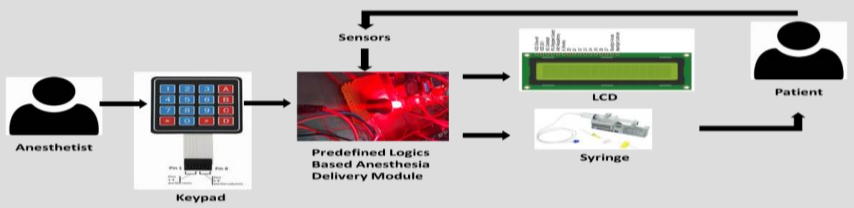
Abstract: Anesthesia management is crucial during surgeries and in the intensive care unit to keep the patient unconscious and pain-free. The inaccurate dose may lead the patient to a critical condition and subsequently to a lifelong unconsciousness. Unlike manual system for anesthesia delivery, the automatic mechanism of drug administration may reduce the occurrence of human error greatly. Additionally, the use of vital sign monitoring during drug delivery may serve a crucial role in patient care during certain medical procedures. The anesthetist delivers the drug in milliliters over a specific time period precisely and this may lead to human error. Therefore, this work focuses on the design and development of an automatic anesthesia regularization system using microcontroller allowing vital sign monitoring to control the infusion speed of the medicine based on the patient's state. Different sensors are used to monitor heart rate, oxygen saturation, and temperature of the patient continuously and an alarm system is incorporated to go off in case of emergency. The drug dose must be known beforehand and is used as the predefined amount to configure and control data. The prototype has 4 pre-defined logics for easy operation and dose selection. When the logics are applied the device behaves accordingly, the system is driven by the stored logics and delivers the dose timely and precisely. In case of abnormal vitals, the device stops further delivery of the drug until the condition of the patient becomes stable again. The prototype successfully meets the demand of the algorithm by satisfying the conditions whilst the automation is useful in providing ease to anesthetists and comfort to patients during medical procedures. The result of this prototype extracted by comparing this model with commercially available MMED portable patient monitor and it has been observed that the system accuracy is around 95-98% as it's a prototype that's why initial findings are reported in this paper.

Graphical Abstract:



Keywords: Automation, Drug delivery, Feedback, Anesthesia, Vital signs, Monitoring, Patient care.

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1. Introduction

Anesthesia is a controlled state to keep the patient unconscious and pain-free during certain medical procedures and its management is crucial during surgeries and in the intensive care unit. The excess dose may get the patient in a critical condition leading to lifelong unconsciousness. Therefore, there is a need to develop an automated path of anesthesia based on the patient's clinical condition and history to reduce potential side effects [1]. Modern medical innovations have given rise to the possibility of an integrated regularization system for anesthesia accompanied by a module for vital signs monitoring. One important feature, heart monitoring, remains a problem that modern methods still need to solve entirely. Anesthesiologists have always kept a close eye on anesthetic distribution. Their knowledge guarantees that the agents delivered are safe and effective. However, with the fast advancement of automation in medical sciences, there is a growing interest in automating the anesthetic delivery process. An automated anesthetic depth control system for isoflurane concentration was suggested by Mehr et al. in 2022, however, it did not sufficiently solve issues with heart monitoring [2]. Since anesthetic medications vitally alter heart rate and rhythm, this restriction may pose dangers. Anesthetist uses manual system for the control of anesthesia drug leading to potential human error[3] and giving rise to complexities in dosage and administration of the drug for the duration of the specified period [4]. These errors may lead to possible discomfort disturbance, getting conscious during procedure and developing undesirable side effects[5].

One of the most challenging aspects of anesthetist's work is to correctly evaluate the quantity of the drug to be administered and monitoring the amount of medication given to maintain the required level of unconsciousness. The automatic mechanism of drug administration reduces may the occurrence of human error greatly[5] and a microcontroller based system can automatically regulates the Anesthesia regularization system based on clinical data. It analyzes several clinical characteristics received through the sensors that are attached to the human body. Vitals monitored according to the normal ranges as shown in Table 1**.** The plunger of the syringe moves in and out because of the rotational direction of the DC motor and the anesthetic is administered into the patient through syringe[6]. Drug dose and post-operative recovery are anticipated to reduce with closed-loop monitoring, improving patient safety and reducing the anesthesiologist's burden. Del Vecchio et al. suggested the possibility of using artificial intelligence and nanotechnology in postoperative patient care [7]. This paradigm change emphasizes that future research must make use of cutting-edge technology that can give real-time feedback mechanisms, notably regarding heart monitoring, in order to establish a genuinely complete anesthetic administration module with vital monitoring.

The primary goal of anesthesia is to keep the patient asleep and pain-free throughout operation. Therefore, the aim of this work is to provide anesthetist with an aid during procedures and to eliminate human errors in injecting precise amount of anesthesia drug to the patient. This may allow them to perform the other tasks more efficiently that includes; controlling the medication infusion speed contingent to the patient's state and to provide the precise amount of drug in given time span which will omit the complications during surgery like vital imbalance early awake of patient or over dosage. This will also reduce the workload of anesthesiologists by leaving them more time to maintain the hemodynamics of the patient in addition to ventilation[6].

Table 1 Vital Signs and its Normal ranges

Vital Signs	**Normal Ranges**
Pulse Rate	60-100 beats/ minute
Oxygen Saturation	93-100 %
Temperature	36-38 ^{o}C

2. Background and Literature Review

Intravenous drug administration is aimed at compensating for unfavorable changes in the patient's condition and anticipating painful surgical stimuli. Medications administered via IV are typically given on an as-needed basis. The most essential element that has led to the growing popularity of IV infusion anesthesia is IV Anesthetic delivery system[8].

In manual Intravenous insertion, there is a possibility of human mistake. There would be a risk in intravenous medication because of their complications and so many steps are required in the preparation and administration. When compared to other adverse events, intravenous drug delivery mistakes had a higher rate of serious patient outcomes. In the United Kingdom, intravenous injections were involved in 62% of publicly reported occurrences that ended in death or severe patient damage. Little research has focused exclusively on intravenous drug delivery mistakes. According to research from the United States, intravenous medication mistakes have a much greater risk of related fatalities than other pharmaceutical errors [9].

The most common and most likely to be classified as severe mistake was incorrect intravenous rate. Because IV treatment is an intrusive technique, substantial problems can develop if the improper quantity of IV fluids or medicine is administered. Almost 70% of all IV medicines provided had at least one clinical mistake that might have resulted in long-term suffering to patients [9]. The anesthesia medicines used on the patients have significant adverse effects on their systems, such as cardiorespiratory suppression. Because anesthesiologists and ICU staff are unaware of the agony, drugs are provided manually. As a result, closed-loop drug administration systems have acquired recognition over open loop or manual drug delivery systems. Due to benefits such as appropriate time and range of administered anesthesia, reduced burden of low-level tasks on anesthesiologists, enhanced patient safety, and enhanced standard of care for patients by decreasing fluctuations in the medical use of the drug [10].

There will be rises and reductions in the quantity of medication through manual insertion, which will result in fatalities, and the patient's vitals, such as blood pressure and oxygen level, will also decline. Initially in controller pumps, a controller infusion device controls the rate of flow induced by gravity. The flow rate can be changed by varying the radius of the IV tubing while knowing the volume of each drop (60 drops/ml for a typical micro drip set) and the drip rate. However, this procedure is time-consuming and relatively inaccurate, and it provides no feedback on the amount of drug administered. The feedback report of the clinical effect must be used to continually adjust the anesthetic medication concentration in order to optimize drug delivery to the user and raise safety [11].

Furthermore, the rate of administration of such an infusion apparatus is highly dependent on the flow rate of the main intravenous line, which is frequently adjusted during the operative course and may be under pressure at times during rapid fluid administration. This would be especially problematic when injecting viscous medications like Propofol. As a result, such delivery systems are generally not thought to be suitable for controlling the infusion rates of powerful intravenous anesthetic drugs. A safety system for the patient's plasma, target site concentrations, and blood pressure within the safety limits during closed-loop anesthesia delivery was presented by Yousef M [12]. The works cited to show that the closed-loop control of anesthesia administration has been an active research area.

3. Research Methodology

A microcontroller-based embedded system is designed to inject the drug into the patients' body to safely regulate the given amount of anesthesia. The dosage of anesthesia that has to be delivered to the patient must be known earlier, as the predefined amount is configured and set up by the anesthesia professional. The precise dose of anesthesia is calculated based on blood oxygen saturation, heart rate and patient body temperature. The microcontroller is programmed using an integrated device to monitor the dose delivery of the anesthetic drug.
Max30100 Sensor- measurement is used to monitor the blood oxygen saturation and heart rate [Maxim Integrated] [13] [14] whilst Lm35 is being utilized as a temperature sensor for the measurement of body temperature [Texas Instruments] [15]. To control the overall operation, Micro-Controller ATmega 2560/ Uno [Arduino] [16] [17] is used and Stepper Motor Nema17 [Schneider Electronics] [18] [19] along with Motor driver - A4988 [Allegro micro systems] [20] is being used to move the syringe as per command. In order to set the time and dosage of the drug a keypad is used to enter the data [21] and Liquid Crystal Display is added to the prototype to display the readings of the sensors [22]

3.1 General Algorithm

This Anesthesia regularization system (ARS) performs the task by getting signals from the corresponding sensors to display the vitals and conveys these signals to the microcontroller. Anesthetist sets the dose by selecting any of the four predefined logics, as shown in **Figure 1**, to deliver that drug as per the condition of patient;

- **Logic 1-** 5 ml in 1 minute with a delay of 2 minutes
- **Logic 2-** 5 ml in 5 minutes with a delay of 2 minutes
- **Logic 3-** 5 ml in 2.5 minutes with a delay of 2 minutes
- **Logic 4-** 5 ml in 1.5 minutes with a delay of 2 minutes

Logic 1- 5ml in 1 mints with a delay of 2 minutes

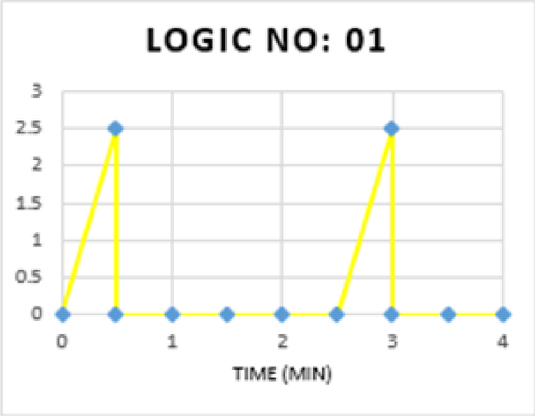

Fig 5.1: graph showing drug delivered w.r.t time by using logic 1

Logic 2- 5ml in 5 mints with a delay of 2 minutes

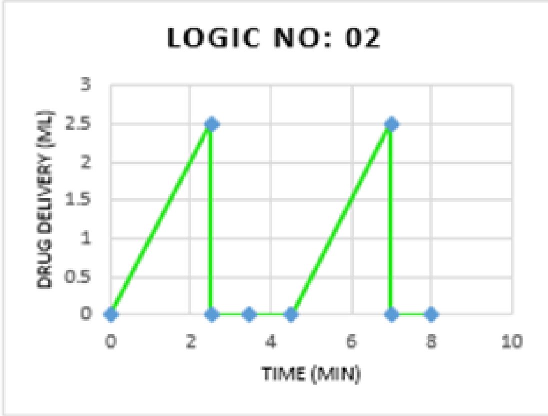

Fig 5.2: graph showing drug delivered w.r.t time by using logic 2

Logic 3- 5ml in 2.5 mints with a delay of 2 minutes

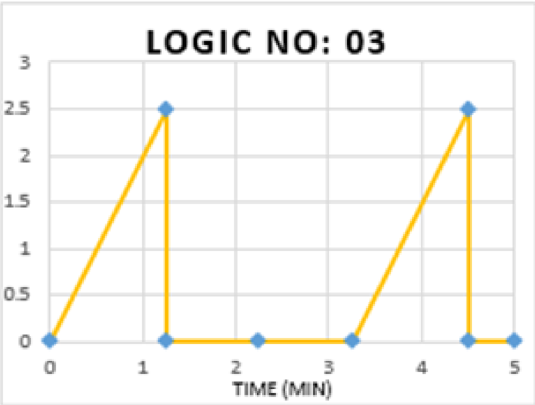

Fig 5.3: graph showing drug delivered w.r.t time by using logic 3

Logic 4- 5ml in 1.5 mints with a delay of 2 minutes

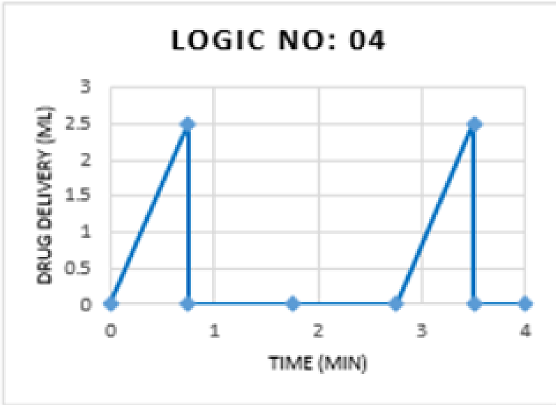

Fig 5.4: graph showing drug delivered w.r.t time by using logic 4

Fig. 1 - **Graph showing pre-defined logics**

The operator is provided with an option to select any of the given logic with the required delay by using the push buttons. Furthermore, the real time clock module updates the time with the correct time zone to maintain the check on the drug dosage with the specified time delay and displays it on LCD. Microcontroller as a main processor takes signals from multiple sources at a time, integrate them and send them towards the Arduino Uno to transform these signals into the rotations of the stepper motor. These rotations cause the plunger of the syringe to move in specified direction and release the drug from the syringe.

The system checks the vitals initially and allows to proceed forward only in case of vitals being in normal range. The plunger is controlled and moved to administer the first half of the dose, as shown in **Figure 2**. The system then waits for the specified delay time, checks the vitals again and then release the remaining dose to ensure that the drug dose is not causing any adverse reactions to the patient.

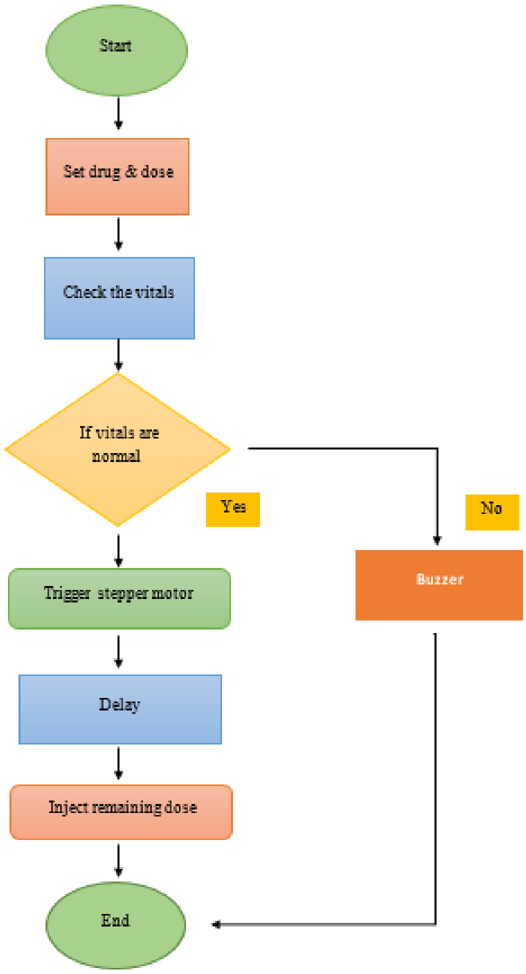

Fig. 2 - Process Flow Chart

4. Results and Discussion

The study included 25 participants whose vitals are monitored and compared with the vitals obtained from MMED portable patient monitor and the accuracy of oxygen saturation, heart rate and temperature values are found to be 98%, 95% and 96% respectively. The vitals obtained from the designed prototype are successfully shown on the display LCD as shown in Figure 3.

Fig. 3 - Prototype display showing the results of the vital signs.

Analysis also revealed no significant differences between the actual values and the measured values of the dose delivered. The performance of the designed anesthesia machine prototype shows promising results in terms of accuracy between the actual and measured values as shown in Figure 4.

This anesthesia regularization system delivers the dose as per the defined logics in the specified period with the delay of 2 minutes; the system checks the vitals within the delay time and then deliver the remaining dose successfully. The device meets the demand of the algorithm by satisfying the conditions that is shown in Table 1

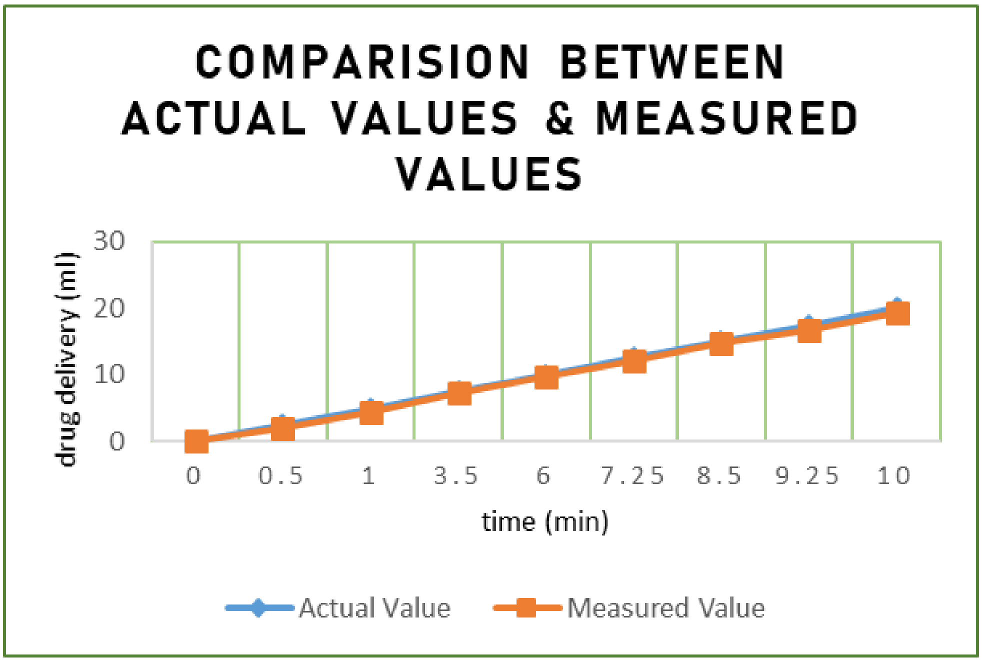

Fig. 4 - Graph of difference between actual values and measured values

These results suggest that the prototype of the anesthesia machine performs well in delivering anesthetic during the experimental procedures as per predefined logics. However, further research is needed to confirm these findings and evaluate the performance of the machine in settings other than the predefined logics. No adverse events related to anesthesia delivery were observed in any of the experiments. This prototype is effectively work on both domains one is vital monitoring and other is anesthesia drug delivery with precise calculation of dose according to the data input. The findings of this prototype shows that this system will provide the accurate and precise delivery of anesthesia without causing any problem in dose delivery time.

5. Conclusion

This Prototype specifically focuses on the Automation of the anesthesia delivery system and the motive of this research is to bring changes in the anesthesia delivery systems. The programming algorithm of this prototype is successfully satisfying the problem statement presented above and it has achieved the delivery of precise amount of anesthesia along with vital signs monitoring throughout the procedure. The major focus of existing work is on drug delivery some of them lacking the real time vital monitoring and dosage delivery as per feedback of vitals. This project focuses on the vital monitoring and drug delivery to the patient, with an added emergency stop function in case of vitals unitability. It has shown to effectively contribute towards a better and precise drug delivery, which would be very helpful, particularly in deciding the dose of anesthesia using continuous vital monitoring.

Reference

[1] S. Krishnakumar, J. Bethanney Janney, W. Antony Josephine Snowfy, S. Joshin Sharon, and S. Vinodh Kumar, "Automatic anesthesia regularization system (AARS) with patient monitoring modules," *Int. J. Eng. Technol.*, vol. 7, no. 2, pp. 48–52, 2018.

[2] M. M. Mehr, A., Shah, S. I. A., Shaban, M., Shahid, M., & Awais, "Automatic Anesthesia Depth Control System For Isoflurane Concentration. In 2022 19th International Bhurban Conference on Applied Sciences and Technology (IBCAST) (pp. 476-489). IEEE."

[3] M. Haché *et al.*, "Outcomes from wake up safe, the pediatric anesthesia quality improvement initiative," *Paediatr. Anaesth.*, vol. 30, no. 12, pp. 1348–1354, 2020.

[4] J. A. Méndez, A. Marrero, J. A. Reboso, and A. León, "Adaptive fuzzy predictive controller for anesthesia delivery," *Control Eng. Pract.*, vol. 46, pp. 1–9, 2016.

[5] L. Pasin *et al.*, "Closed-loop delivery systems versus manually controlled administration of total IV Anesthesia: A meta-analysis of randomized clinical trials," *Anesth. Analg.*, vol. 124, no. 2, pp. 456–464, 2017.

[6] S. L. Salim, A. Thomas, M. Akshay, A. K. Alias, and M. I. E. K, "Microcontroller based Anesthesia Injector," no. June, pp. 826–829, 2019.

[7] D. Del Vecchio, M. J. Stein, E. Dayan, J. Marte, and S. Theodorou, "Nanotechnology and Artificial Intelligence: An Emerging Paradigm for Postoperative Patient Care," *Aesthetic Surg. J.*, vol. 43, no. 7, pp. 748–757, 2023.

[8] G. R. Doyle and J. A. McCutcheon, "Clinical Procedures for Safer Patient Care," in *British Columbia Institute of Technology*, 2015, pp. 479–487.

[9] J. I. Westbrook, M. I. Rob, A. Woods, and D. Parry, "Errors in the administration of intravenous medications in hospital and the role of correct procedures and nurse experience," *BMJ Qual. Saf.*, vol. 20, no. 12, pp. 1027–1034, 2011.

[10] K. Van Heusden, J. M. Ansermino, and G. A. Dumont, "Closed-loop instrumental variable identification of propofol anesthesia," *1st Annu. IEEE Conf. Control Technol. Appl. CCTA 2017*, vol. 2017-Janua, pp. 1165–1170, 2017.

[11] N. West *et al.*, "Design and evaluation of a closed-loop anesthesia system with robust control and safety system," *Anesth. Analg.*, vol. 127, no. 4, pp. 883–894, 2018.

[12] M. Yousefi, K. van Heusden, N. West, I. M. Mitchell, J. M. Ansermino, and G. A. Dumont, "A formalized safety system for closed-loop anesthesia with pharmacokinetic and pharmacodynamic constraints," *Control Eng. Pract.*, vol. 84, pp. 23–31, 2019.

[13] Maxim Integrated, "Pulse Oximeter and Heart-Rate Sensor IC for Wearable Health," *Maxim Integrated*, 2014. [Online]. Available: www.maximintegrated.com.

[14] "MAX30100 - Heart Rate Oxygen Pulse Sensor." [Online]. Available: https://components101.com/sensors/max30100-heart-rate-oxygen-pulse-sensor-pinout-features-datasheet.

[15] Texas Instruments, "LM35 Precision Centigrade Temperature Sensors."

[16] Shawn, "ATmega2560 - Features, Comparisons, and Arduino Mega Review - Lastest Open Tech From Seeed," *Lastest Open Tech From Seeed*, 2019. [Online]. Available: https://www.seeedstudio.com/blog/2019/11/13/atmega2560-features-comparisons-and-arduino-mega-review.

[17] "Top 5 Arduino integrated development environments (IDE)." [Online]. Available: https://codeandunicorns.com/top-5-arduino-integrated-development-environments-ide/.

[18] Ooznest.co.uk, "Nema 17 stepper motor," *Ooznest.Co.Uk*, 2014. [Online]. Available: http://ooznest.co.uk/3D-Printer-Electronic-Parts/NEMA-17-Stepper-Motor.

[19] Q. Reference, "Nema17-phase stepper motor," no. mm, pp. 1–2, 2010.

[20] Allegro MicroSystems, "a4988 [Datasheet]," pp. 1–22, 2014.

[21] Parallax, "4x4 Matrix Membrane Keypad (# 27899)," *4x4 Matrix Membr. Keypad*, no. 916, pp. 1–5, 2011.

[22] "20×4 Character LCD Display Blue Backlight Module HD44780." [Online]. Available: https://www.mytechnocare.com/product/20x4-lcd-display-blue/.