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Development of Drug delivery Unit for Closed Loop Anaesthesia System

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Abstract Drug Delivery Unit for Closed Loop Anaesthesia System developed to optimized drug administration during anaesthesia and sedation.The main goals of general anaesthesia are adequate hypnosis, analgesia and maintenance of vital functions. Closed-loop systems are able to make decision on their own and try to reach and maintain a preset target .With the help of patients electrode EEG,ECG and GSR these biosignals taken from patient ,processed and analysed in microcontroller then index values obtained from the patient parameters. Then microcontroller compared index & target values & accordingly intravenous infusion rates of the hypnotic drug propofol and analgesic drug Fentanyl is adjusted to maintain the target range and with the help of syringe mechanical assembly drugs were delivered to the patient.

The use of closed-loop systems in anesthesia can improve the quality of drug delivery. It will decrease the drug dosage and facilitate post-operative recovery while increasing patient safety and decreasing the workload of the anaesthesiologist.

Index Terms— Analgesia,Anaesthesia, closed loop system, EEG, ECG,GSR,Hypnosis,Fentanyl ,Propofol, Syringe mechanical assembly.

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1 INTRODUCTION

Anaesthesia is a reversible and temporary state consisting of unconciosness,loss of memory,lack of pain & muscle relaxation in patients undergoing surgery without pain. The main functional components of anaesthsia are as follows-

- Hypnosis
- Analgesia
- Immobility

Hypnosis, referred to as depth of anesthesia, is a general term indicating the unconsciousness and absence of post-operative recall of events that occurred during surgery. The electroencephalogram, which is the only non-invasive measure of central nervous system activity while the patient is unconscious, is considered as the major source of information to assess the level of hypnosis [1]. Analgesia is linked with pain relief. The electrocardiogram and response to nerve muscle stimulation is related to the extent of pain relief in the patient. An effort has been made to develop a closed-loop system that will automatically deliver hypnotic and analgesic drugs to the patient based on the EEG, ECG and galvanic skin response.

In this project, To maintain the level of hypnosis and analgesia patient parameters such as EEG,ECG,GSR were acquired from the patient through electrode assembly.Then this biosignals processed, analysed in microcontroller and index values obtained from these parameters. EEG index value(AI) indicates hypnosis level where as analgoscore and galvanic skin response indicates level of pain. For drug delivery we designed the syringe mechanical assembly,which has two syringe for delivering the two anaesthetic drugs propofol and fentanyl to maintained the adequate level of anaesthesia. After infusing the drugs to the patient again patient parameters were measured .By observing the variations in the patient parameters & comparing resulting index values with the target values further drug delivery will take place. So in this way this drug delivery unit will be formed for closed loop anaesthesia system. The use of closed-loop systems in anesthesia can improve the quality of drug delivery.

Closed-loop control can minimize individual operator variability in titration of anesthetic dose. A closed-loop system senses the level of output, feedbacks this information, compares it to a set point that defines the desired output level and uses the difference to push the output towards the set point. Such systems are referred to as feedback control systems. Because of more frequent sampling of the control variable and more frequent changes to the rate of drug delivery than with manually delivered anaesthesia, the stability of the control variable may be greater. At the same time, the dose delivered is customized to meet the exact requirements of each patient, thereby overcoming the problems of inter-individual differences and differing levels of surgical stimulation[2] Reduced variability has been suggested as a key goal in quality and safety improvement The potentials of closed-loop controlled anesthesia is that it is expected to decrease drug dosage and facilitate post-operative recovery while increasing patient safety and decreasing the workload of the anesthesiologist. The advantage of closed-loop anaesthesia delivery system is that the control is continuous and responsive that may improve the quality of care as compared with intermittent control practiced routinely. Recovery times and the risk of inadvertent awareness may thereby be decreased. [5]

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2 METHODOLOGY

Drug Delivery unit for closed loop anaessthesia system was implemented as shown in figure below.

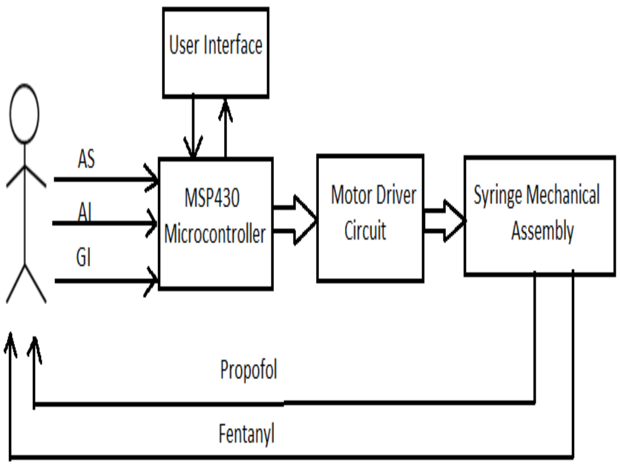

Fig:Block diagram

The fig: shown above is explained as follows:
EEG Index (AI) is a parameter derived from EEG which is used to measure the depth of hypnosis. Depth of analgesia is determined by AnalgoScore (AS), which is derived from ECG and GSR Index (GI). The EEG Index algorithm derives the AI by applying FFT on the EEG signal,we get different range of frequency then power of each frequency band is obtained in that maximum power of frequency display as EEG Index value(AI). Power of different frequency range from 0 to 50 in that 0-6 indicate adequate anaesthesia level,7-12awake and resting,13-25 mental activity and 25-50 indicate tension and intense mental activity.The AnalgoScore (AS) is derived from the ECG. This is an index which ranges from -9 to +9. A value between -3 and +3 represents adequate analgesia. The Galvanic Skin Response (GSR) also indicates the extent of pain or pain relief of the patient. The GI is a value 0 represents pain and 1 represents no pain. Controller The various inputs are given to the controller which calculates the appropriate doses of anesthetic drugs to be given to the patient.
These index values (AS,AI,GI) and age ,weight of the patient will be given to the MSP430 microcontroller. Then microcontroller compared input values with target values and it will give pulses at particular frequency to the motor driver circuit to drive the syringe mechanical assembly.

MSP430 MICROCONTROLLER

The Texas Instruments MSP430 family of ultralow-power microcontrollersThe architecture, combined with five low-power modes, is optimized to achieve extended battery life in portable measurement applications. The device features a powerful 16-bit RISC CPU, 16-bit registers, and constant generators that contribute to maximum code efficiency[6]. The function of microcontroller to processed,analysed input variable obtained an index values.from index values and age, weght of the patient controller calculates drug dose amount.and according to that it gives particular pulses to motor driver circuit to drive the syringe mechanical assembly.

MOTOR DRIVER CIRCUIT

A stepper motor is an electro mechanical device, which con verts electrical pulses into discrete mechanical movements.
The stepper motor cannot be directly driven using the microcotroller I/O pins as the microcontroller can not supply the required current to drive the Stepper Motor. Also, the Stepper Motor will cause a Back EMF in the circuit while it is accelerating or decelerating. This can cause to controller to be damaged. Hence we use a Driver circuit which isolates the Stepper Motor circuit from the microcontroller circuit.

when the microcontroller is giving pulses with particular frequency to ULN2803, the motor is rotated in clockwise or anticlockwise.stepper motor is used to achieve precise positioning via digital control. The motor operates by accurately synchronizing with the pulse signal output from the controller to the driver.

SYRINGE MECHANICAL ASSEMBLY

Syringe mechanical assembly consists of two syringe which infuses anaesthetic drug propofol and fentanyl for hypnosis and pain relief respectly. Stepper motors are used for movement of the syringe Mechanical assembly is made of Aluminium sheet. Nut-Screw mechanism is used, which convert circular motion of the motor into linear movement. When motor rotate in clockwise direction ,The plunger of syringe pump is move in forward direction and when motor rotate in anticlockwise direction the plunger of syringe pump is move backward direction. In this way we can control the movement of syringe pump by programming through controller.

DRUG DOSE CALCULATION

The microcontroller calculates the amount of each drug to be administered based on the age and weight of the patient. The doses differ for paediatric and adult patients. The dose during the induction phase is to be injected by the anaesthesiologist. The system here is designed for the maintenance of anesthesia during the surgery. During the maintenance period, fentanyl is infused at a rate of 0.1µg/kg/min and propofol is infused at a rate of 0.5mg/kg/min.[9]
The dose is calculated using the following equation,

Volume to be administered =

(Dose ordered/Dose Available) X Volume Available

Using this equation, the volume of drug to be administered is calculated to be 0.002ml/kg/min for 50µg/ml solution of remifentanil and 0.05ml/kg/min for 10mg/ml solution of propofol during the maintenance phase. [9]

4 RESULT

The Drug delivery unit for closed loop anaesthesia system designed here was tested for its accuracy. The amount of each drug varies according to the input given by the user. The system was tested by inputting different values of age and weight. Also, each time, the AI, AS and GI values were changed to observe the output of the system. The observations were as follows.

Table 1

Sr. No.	*Age*	*Weight (Kg)*	*AI*	*AS*	*GI*	*Dose delivered(ml)*	
						Fentanyl	Propofol
1	30	55	05	+5	0	0.11	0.00
2	30	55	08	+6	0	0.11	2.75
3	30	55	11	+3	1	0.00	2.75
4	55	85	12	+6	0	0.17	4.25
5	55	85	06	+3	1	0.00	0.00

5 CONCLUSION

The aim of the designed system is to delivered proper amount of anaesthetic drugs propofol and fentanyl to maintained the hypnosis and analgesia state of the patient. The system continuous monitored the patient parameters and administeres the drug when required.It will helps to anaesthesiologist and decreases the workload of his job.This drug delivery unit will avoid an excessive dose to the patient thus it will increase patient safety,the cost of the drugs will be reduced and shorter time will be spent in the postoperative care unit.

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