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Risk Analysis of SIP Monitoring and Control System User Interface

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As technology level increases, modern medicine becomes inconceivable without complex electronic devices and their systems, and these become more and more reliable and sophisticated. Modern electronic devices are reliable, they rarely brake down, and the risk of electric shock or any other injury for the patient is vanishingly small.

On the other hand, the problem of personnel working with electronic equipment becomes relevant. All the devices have their individual indicators and personnel have to look after different devices, showing different information and located in different places. Complex monitoring and controlling consumes a lot of time. The overall process, which includes walking from bed to bed, manually collecting data and transcribing parameters into the patient records takes 2 to 3 minutes per device, 10 to 20 times each day. The result is 12,000 to 36,000 nursing hours per year for a 50 bed unit [1]. Also the controlling of the devices problem occurs – personnel needs high qualification, special, non-medical knowledge. From 50 to 90 percent mistakes in such systems are made by humans [2].

It mostly depends on the electronic device interface how it will affect human work as well how human will affect the work of the device.

That is why medical device systems are created, which makes control of the devices simpler. It saves time and gives an opportunity to keep logs. Syringe infusion pumps (SIP) control system, which allows using one controller for different SIP's, infusing different medicine, is an example of such systems.

SIP control system has a graphic user interface, handles SIP parameter setting, controlling, work information registering and handling, enables information input with bar code scanner.

Graphic user interface allows to:

- Improve control of the infusion by showing graphical and digital SIP parameter information;
- Easy SIP controlling with the usage of active display, mouse, keyboard or manipulator;
- Input patient and personnel data.

SIP control systems allows to:

- Keep automatic centralized monitoring of connected SIPs;
- Register infusion process parameters to permanent memory (event logs);
- Keep, process and provide stored data in various forms;
- Use a pre-created drug library;
- Actualize drug infusion profiles;
- Identify SIP's;
- Identify drugs;
- Identify syringes programmed in SIP's;
- Identify drug infusion profiles;
- Modify capacity and speed during infusion;
- Automate event sequences;
- Detect parameter and work mode deviation.

Bar code scanner allows to:

- Insert SIP's identification data;
- Identify drugs;
- Identify syringes;
- Identify drug infusion profiles;
- Identify patient;
- Identify personnel.

It is hard to determine what level of risk should be considered as acceptable in designing medical systems, especially because analogical systems are just being created and there is no statistical data about them. The quantitive evaluation of medical systems is much more complicated and safety requirements are much stricter than in industry. Designers have to frequently search for an optimum level of risk – the system must not only be safe, but also easy to use and of competitive price. We offer such concept of SIP Monitoring and Control System patient risk evaluation model:

- The prototype of the system, connecting n SIPs, is the same number of separate SIP's, separately infusing medicine for one patient, here: n = (1…32);
- The system is designed to handle infusion for one patient;
- To ease the calculation, the model of the system is divided into separate functional blocks;

• The risk level of each such functional block is analyzed by the reasons of possible safety hazards. This helps to find effective risk management measures;

• The risk level of prototype is analyzed considering possible reasons of safety hazards and evaluating the opportunity to decrease these risks and understand at what level it can possibly be achieved;

• Primary and secondary risk management measures are evaluated and implemented to the system;

• The risk level change is calculated because of the additional device usage;

The decrease of risk level by using the system is compared to the risk level of using separate pumps. Unfortunately, risk evaluation of even a known parameter is sometimes hard or impossible. While running a risk analysis it emerged that the probability of separate faults or errors can differ up to 10^4 times. Their influence to patient's safety has even bigger deviation. So further on we will base our analysis only to that part of the risk, which can influence patient's safety.

The object of analysis is the currently designed SIP Monitoring and Control System, designed to control few SIP's, mechanically connected on one docking station. The system consists of such parts: (Fig. 1):

- N syringe infusion pumps, including software, n= (1...32);
- SIP docking station;
- Concentrator, including firmware;
- Controller, including software;
- Bar code scanner;
- Other (e.g.: connections, UPS, monitor, keyboard, mouse, etc.).

To evaluate risk, it is necessary to decide what the basic level of risk is. In our case, it is several (n) autonomic SIP's, infusing different drugs to one patient. Their basic level of risk is considered acceptable and reasonable, because they have been successfully used in medical practice for a few years. They work independently; each one is controlled separately, with its own keyboard.

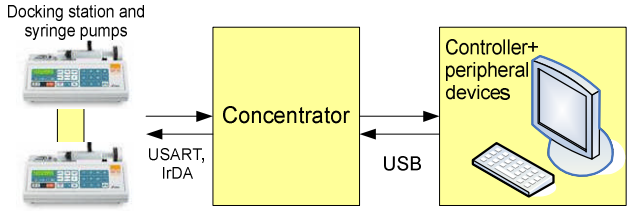

Fig. 1. Data transfer scheme in SIP monitoring and control system

Main reasons of safety hazards for the patient, caused by the prototype:

• operator (patient) mistakes;

• harmful effect (for example, synergetic, antagonistic or allergenic) of infused drugs;

• random fault;

• manufacturing error;

• design errors.

Operator mistakes can be divided to:

• mistakes prescribing drugs;

• mistakes infusing drugs;

• SIP's control mistakes;

• other mistakes.

According to [3] probability of operator error, caused by the mentioned reasons, which might cause safety hazard to the patient, infusing medicine with one pump is P_P = (0,1 – 0,01), depending on circumstances. For the basic calculations it is accurate enough to presume that harmful effect of the medicine is already evaluated in this number, because a reasonable amount of such effects are due to human error in prescribing or infusing drugs.

According to SIP safety concept, a random individual fault must not provide safety hazard to the patient, and probability of error in certificated mass production devices is decreased to minimum. Fault intensity of SIP, declared by the manufacturer is λ_H =0,00001/h. Fig. 2 shows the tree of probabilities of safety hazards to the patient using n syringe pumps for the infusion. Here: P_{1S} – the probability of one successful (without causing safety hazards to the patient) infusion using one SIP; $(1 – P_P)$ – probability that personnel will not cause error while preparing and performing infusion with one SIP; $(1 - P_H)$ – probability that one SIP will remain unbroken during infusion. These events are inconsistent, so probabilities can be summed.

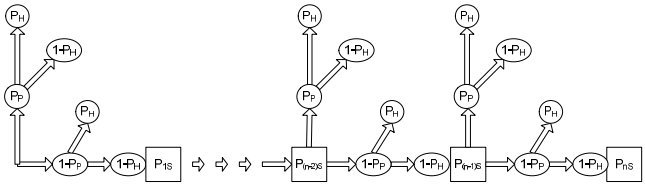

Fig. 2. The tree of probabilities of safety hazards for one patient using n SIP's for the infusion

Presuming that the intensity of faults during the infusion time *t* remains constant, the probability of faults can be described exponentially. Then the probability P_F of safety hazard to one patient handling infusion with one SIP, lasting t hours, can be calculated:

$$P_F = P_p \cdot (1 - e^{-\int_0^t \lambda(\tau)d\tau}) + P_p \cdot e^{-\int_0^t \lambda(\tau)d\tau} + (1 - e^{-\int_0^t \lambda(\tau)d\tau}) \cdot (1 - P_p). \quad (1)$$

Probability P_S of one successful infusion with single SIP (no safety hazards for the patient):

$$P_S = (1 - P_p) \cdot e^{-\int_0^t \lambda(\tau)d\tau}. \quad (2)$$

Probability P_{nS} of successful infusion (no safety hazards for the patient) using *n* alike SIP's:

$$P_{nS} = \prod_{i=1}^{n} [1 - (P_p \cdot (1 - e^{-\int_0^t \lambda(\tau)d\tau}) + P_p \cdot e^{-\int_0^t \lambda(\tau)d\tau} + (1 - e^{-\int_0^t \lambda(\tau)d\tau}) \cdot (1 - P_p))]. \quad (3)$$

Fig. 3 shows variation of probability P_{nS} of safe infusion, calculated by equation (3), depending on the number n of independent (not connected to the system) SIP's, used for one patient in two cases:

- when the probability of personnel error is P_P =0,1 (personnel working under inauspicious circumstances, e. g. stress, weariness, rush, distraction, etc.);
- and when P_P = 0,01 (normal working conditions).

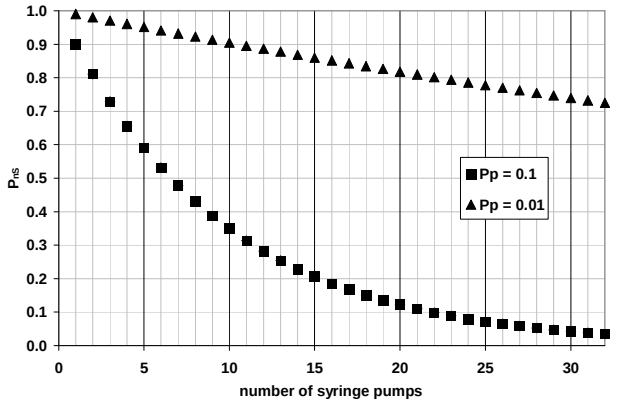

Fig. 3. Reliance between infusion reliability and number of pumps

The designed system eases and simplifies SIP control, automates infusion data logging. Because of larger memory it can also audit decisions that are being performed and alarm the personnel about possible hazards. In comparison with separate SIP's, system has these advantages and all of them reduce the probability of personnel error (Table 1).

Table 1. Advantages of SIP system

Operator + n SIP	Operator + System with n SIP	Comments
n small grayscale monitors.	1 big color display	Mistakes are easier to notice, when one can see all SIP parameters and/or working charts in one screen. Colors are useful for emphasizing alarms, alerts and other important information.
Display size 6-12 cm. (1 – 4 lines are seen at once)	Display size (0,3 – 1,2)m. (50 lines and graphic information can be seen at once)	The system can show summarized SIP parameters, system alerts and tips, so it is easier to manage infusion using one big screen
Smaller font size and contrast	Bigger font size and contrast	Bigger and brighter font is easier to read and notice mistakes
Event log disabled	Event log enabled	All prescribed drugs can be monitored: their infusion parameters, system alerts on dosage and interaction
Infusion parameters registered by personnel	Infusion parameters registered by system	SIP parameters and event logs are registered periodically by the system. It can then audit medicine, group data
Sound alarms are hard to distinguish	The sound alarms in the system are doubled with text and visual messages	The alarms in system are easier to identify and understand

Table 1 (continued)

Operator + n SIP	Operator + System with n SIP	Comments
Each SIP is programmed separately	Standard or specialized keyboard can be used	While programming a SIP, the same combinations of buttons are repeated each time manually. The system allows to program common parameters to all SIP's, less time is consumed.
Manual data input	Data input from a drop-down menu	System allows inserting prepared and revised data sets
Manual data input	Data input using bar code scanner.	Using bar code scanner saves time
No additional comments	Additional comments, alerts	Systems stores information about drugs, patient allergies and can give alerts when prescribing drugs

From the lack of statistical data, we cannot accurately evaluate how much the system with n SIP's reduces the risk to the patient in comparison with separate SIP's. But with the method provided, we can calculate, how much would the risk to the patient be reduced, depending on the amount of mistakes, detected by the system.

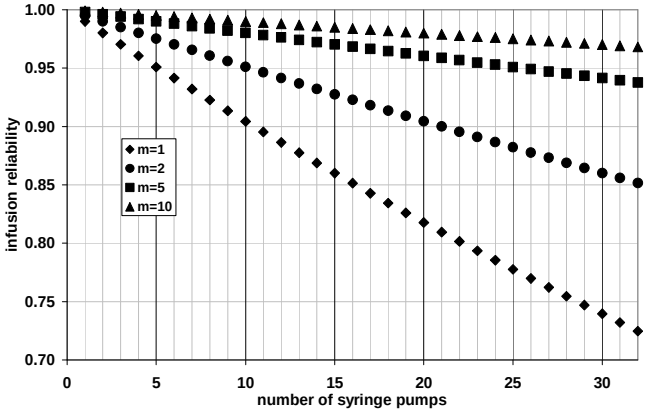

Fig. 4. Reliance between infusion reliability and the number of pumps, when personnel error probability is P_P = 0,01

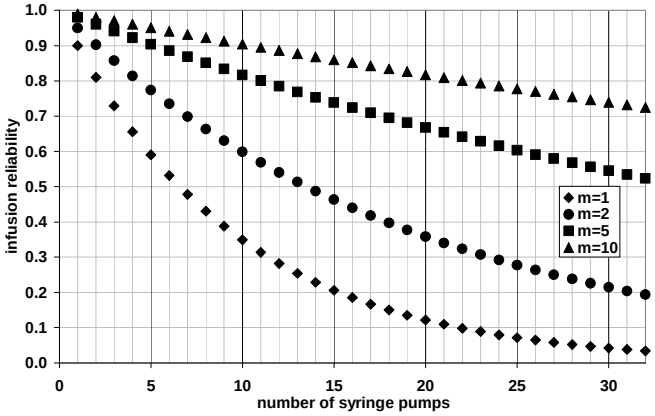

Fig. 5. Reliance between infusion reliability and the number of pumps, when personnel error probability is P_P = 0,1

Fig. 4 and Fig. 5 show calculated (predicted) reliance between probability of safe infusion and the number of used SIP's and personnel error probability if the system reduces personnel error quantity m times.

Chart in Fig. 6 shows predicted increase of reliability (patient safety) of infusion with n syringe pumps , if the system reduces personnel error quantity m times.

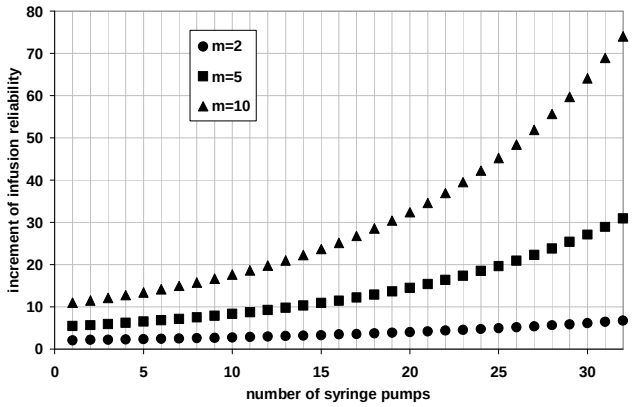

Fig. 6. Predicted increase of reliability (patient safety) of infusion with n syringe pumps, if the system reduces personnel error quantity m times

Chart (Fig. 6) shows that the effectiveness of system usage increases when the number of SIP's is increased, used for the infusion.

Conclusions

The main advantage of such system in comparison with separate SIP's usage is the reduction of operator error probability.

The main purpose of SIP Monitoring and Control System user interface is to increase infusion process control and monitoring quality and reliability, automating data input and infusion process visualization.

SIP Monitoring and Control System cannot increase the reliability of SIP's; its purpose is to increase patient safety by increasing reliability and efficiency of personnel work.

Using SIP Monitoring and Control System risk for the patient is reduced, more possibilities of data visualizing and processing emerge. Documentation is more accurate and takes less time. The possibility of integration to clinical information system emerges, data storage opportunities are practically unlimited.

System allows to reduce personnel errors and increases infusion reliability by 3–24 times (in case of 16 SIP's). Finally, appliance efficiency of the system increases, if more pumps are used.

References

1. **Valinevičius A., Markevičius V., Navikas D., Jonynas V, Dubauskienė N.** Syringe Pumps System Risk Management Aspects // Proceedings of international conference on Communications, Electromagnetism and Medical Applications (CEMA'07), Sofia, Bulgaria, 25th-27th October, 2007 / Technical University of Sofia, Bulgaria; National Technical University of Athens, Greece. Sofia: Technical University of Sofia, 2007. ISBN 978-954-9518-44-3. p. 81-87.
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3. **Markevičius V., Navikas D.** Syringe pumps integration influence to infusion process efficiency // ITI 2007: proceedings of the 29th international conference on Information Technology Interfaces, June 25-28, 2007, Dubrovnik, Croatia / University of Zagreb. University Computing Centre. – Zagreb: University of Zagreb, 2007. ISBN 978-953-7138-09-7. p. 257-262.

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There are analyzed properties of syringe infusion pumps (SIP) control system user interface that allows reducing patient risk during the infusion. Also there are analysed main reasons of SIP security problems for the patient. Patient risk variation evaluation method according to statistical SIP reliability and personel human mistake factor during the work is presented. Infusion for one patient using n single syringe infusion pumps reliability and infusion for one patient using SIPCS with n syringe infusion pumps reliability calculation example results are shown. Ill. 6, bibl. 3 (in English; summaries in English, Russian and Lithuanian).

В. Маркявичюс, Д. Навикас. В. Ионинас, Н. Дубаускене. Анализ риска пользовательского интерфейса управления системой шприцевых насосов // Электроника и электротехника. – Каунас: Технология, 2008 – № 7(87). – С. 85–88.

Исследуются свойства пользовательского интерфейса управления системой шприцевых насосов инфузии (СУ ШНИ), позволяющего уменьшить риск опасности пациенту во время инфузии. Определены основные причины возникновения опасности пациенту, которую могут создать ШНИ. Предложен метод оценки изменения риска пациенту из-за объединения ШНИ в систему по статистическим данным надежности ШНИ и ошибкам персонала (человеческий фактор). Представлены результаты расчетов и образцы сравнения вероятностей успешного выполнения инфузии одному пациенту при использовании n ШНИ, объединенных в СУ. Ил. 6, библ. 3 (на английском языке; рефераты на английском, русском и литовском яз.).

V. Markevičius, D. Navikas, V. Jonynas, N. Dubauskienė. Švirkštinių infuzinių siurblių valdymo sistemos vartotojo sąsajos rizikos analizė // Electronics and Electrical Engineering. – Kaunas: Technologija, 2008 – No. 7(87) – P. 85–88.

Nagrinėjamos švirkštinių infuzinių siurblių valdymo sistemos (ŠIS VS) vartotojo sąsajos savybės, leidžiančios sumažinti paciento riziką infuzijos metu. Analizuojamos pagrindinės pacientui ŠIS keliamo pavojaus priežastys. Pasiūlytas būdas paciento rizikos pokyčiui dėl ŠIS sujungimo į sistemą įvertinti pagal statistinius ŠIS patikimumo ir personalo daromų klaidų dėl žmogiškojo faktoriaus duomenis. Pateiktas infuzijos, vienam pacientui naudojant n pavienių švirkštinių infuzinių siurblių, patikimumo ir infuzijos, vienam pacientui naudojant ŠIS VS su n švirkštinių infuzinių siurblių patikimumo skaičiavimo ir palyginimo pavyzdys. Il. 6, bibl. 3 (anglų kalba; santraukos anglų, rusų ir lietuvių k.).