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## Design and production of a demountable modular infusion pump

**Zehra Gok Metin** \*\*, Department of Internal Medicine Nursing, Faculty of Health Sciences, Hacettepe University, 06000, Ankara, Turkey.

**Leyla Ozdemir** <sup>b</sup>, Department of Nursing, Faculty of Nursing, Hacettepe University, 06000, Ankara, Turkey.

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### Abstract

The study aimed to produce a new pump with different and improved features and included three phases. In phase one, we collected the views of 40 nurses on pumps available in the market. In phase two, a pump was designed and a prototype was produced. In phase three, 10 nurses used and evaluated the prototype. The prototype combined three intravenous infusion pumps and one enteral pump in a single machine. Nurses assessed the prototype in a practice laboratory. All nurses found prototype very adequate with respect to carrying and installing. 90% of nurses found the prototype very adequate and practical in general. Moreover, the majority (80%) stated that the prototype produced less noise than the available pumps in the market.

Keywords: Nurse; design; infusion pump; enteral nutrition; patient safety.

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\* ADDRESS FOR CORRESPONDENCE: **Zehra Gok Metin**, Department of Internal Medicine Nursing, Faculty of Health Sciences, Hacettepe University, 06000, Ankara, Turkey.

E-mail address: [zehra.gok@hacettepe.edu.tr](mailto:zehra.gok@hacettepe.edu.tr) / Tel.: +90 312 324 20 13

## 1. Introduction

Medical infusion pumps currently available in the health sector deliver medicine or nutrition to patients within a certain time and quantity by means of programmes and sensors (Gupta, Taneja, Thariyan & Kumar, 2005). While intravenous (IV) infusion pumps are applied to deliver drugs, fluids and total parenteral nutrition solutions, enteral pumps are employed to infuse nutritional products via nasogastric/orogastric, gastrostomy or ileostomy tubes (Ersoy, Iskit & Abbasoglu, 2010; Hebuterne et al., 2003). Infusion systems include drop counters, volumetric infusion pumps, infusion pumps with injectors and patient-controlled analgesia devices. Intravenous infusion systems aim to ensure IV drug administration and to control the drug delivery rate. Each IV infusion pump has some features, including a distinctive barcode, drug library, approximate or precise dose calculation and manual programming (Saladow, 2007). The pumps can be employed in emergency settings, inpatient clinics, operating rooms, outpatient clinics and houses; however, they are particularly applied in intensive care units (ICUs) (O'Shea, 2013; Peterfreund & Philip, 2013; Woo, Sutton & Stephens, 2007; Yentur, 2008).

When designing an infusion pump, it is important to remember that any device must prevent medical errors and infusion risks and must ensure patient safety (Bowcutt et al., 2008; Cho, Chung & Hong, 2013; O'Shea, 2013). Medical errors related to infusion pumps are very common and can be fatal. Reasons for medical errors related to infusion pumps include the complexities of design, software error messages, user errors, broken components, battery or alarm failure and over or under infusion. The Food and Drug Administration (FDA) received over 56.000 medical error reports regarding the use of infusion pumps from 2005 to 2009, which included death (1%), serious injury (34%) and malfunction (62%) (Food & Administration, 2010). In ICU, drug errors are the most prevalent medical errors (78%). Furthermore, the ratio of medical errors related to the administration of IV medications in ICU has been reported to be between 61% and 78% (Fahimi et al., 2008; Rothschild et al., 2005). The factors associated with errors in this setting include continuous infusions with high-risk drugs, complex orders, poor communication and repeated treatment interruptions (Herout & Erstad, 2004; Summa-Sorgini et al., 2012).

Some problems have been encountered through hardware specifications during infusion pump use. These problems are associated with the motor and sensor type, the heaviness of equipment, its transportation, difficulties reading the screen, overly complicated menu items and the need for a continuous power supply (Food & Administration, 2010). One of the most important hardware components of infusion the pump systems is pump-operating mechanism (Food & Administration, 2010). Because a big deviation exists in the flow velocity depending on the type of the pump used. To ensure delivery of the correct amount of an agent (i.e. drug or fluid) to the patients, an appropriate and optimal pump motor should be selected correctly.

Patients treated with infusion pumps in clinics or at home often need to remain mobile. Thus, an infusion pump must also be designed for portability. When considering such a requirement, hardware components must be lightweight and have smaller features, and battery motors can be utilised owing to their lightweight and compact designs. Despite their high prices, we considered battery motors to be most suitable when developing the infusion pump prototype.

### 1.1. Pumps available in clinics and related issues

Pumps available in the market can only transfer IV solutions or enteral nutrition. With the pumps currently available in the market, it is only possible to infuse two IV solutions with one IV pump or to infuse a single enteral solution with an enteral pump. However, depending on their clinical condition, patients in ICU often require more than one fluid or drug simultaneously in addition to enteral feeding. Furthermore, pumps currently produce excess noise that can disturb patients, cause overcrowded cable sets, often limit the available workspace and obstruct access to control alarms and pumps. Consequently, these pumps may limit the treatment of patients who require more than two IV solutions and the other undesired conditions may adversely affect patient care. In particular, patients

may have sensory overload or deprivation, and health professionals can experience stress and loss of time (Chambrin, 2001).

This study aimed to design a pump that was capable of delivering four infusions simultaneously, e.g. three IV infusions and one enteral infusion, within a single machine. We specifically aimed for the device to have the following novel features: lightweight, long battery life, demountable pump units, dose calculation, visual and audial alarms, patient data recording function and the ability to initiate the infusion at a programmed time to delay the infusion. In addition, we aimed to provide evidence in support of a patent application for the demountable feature of the pump unit.

## **2. Method**

### **2.1. Study design and sample**

This descriptive and innovative study was conducted to produce a new pump with improved features over currently available pumps. This research was completed in three phases from 2011 to 2013. In phase one, we sought the views of 40 nurses on pumps available in the market to identify the clinical requirements. In phase two, we designed and produced a prototype pump in accordance with the preferred technical specifications obtained from phase one. In phase three, 10 nurses were asked to use the prototype and provide feedback. In addition, an expert engineer examined the technical competence of the prototype. This research was performed by a team of mechanical engineers, electrical electronics engineers, computer engineers, industrial engineers and clinical nurses.

### **2.2. Ethical approval**

Ethical approval with numbered 2013/10 LUT 13/43 was obtained from the Non-Interventional Clinical Trials Ethics Committee of Hacettepe University. In addition, nurses and engineers provided informed consent.

### **2.3. Data collection and analysis**

The data collection forms were prepared by the researchers. Nurses' opinions on the available pumps in the clinics were evaluated using a 'Pump Evaluation Form' that included likert-type questions regarding the technical specifications, alarm parameters and desired features of the new pump design. Each technical specification item was ranked as less adequate (negative response) and adequate or very adequate (positive responses). Nurses' opinions on the prototype were again measured using the 'Pump Evaluation Form' in phase three. The expert engineer then evaluated the prototype using an 'Expert Evaluation Form' that required yes/no answers to questions about the weight and installation of the pump, battery lifetime, patient data recording functions, drug dose calculation functions, alarm parameters, intelligibility of screen warnings, keypad ergonomics and its ability to manage multiple infusions. The SPSS 16.0 software package was used to assess the data. Descriptive statistical analysis (percentage) was applied on the data.

## **3. Results**

### **3.1. Phase one: Nurses' opinions of pumps available in clinics**

We wanted to determine whether the available pumps met the requirements of nurses and patients. The study nurses found few IV pumps 'very adequate', and most were particularly negative about transporting (67.5%), mounting (52.5%) and battery durability (57.5%). However, nurses felt that certain pump characteristics were 'adequate', including ease of IV infusion set insertion (60.0%), screen legibility (60.0%), intelligibility of screen symbols (57.5%), keypad comfort (72.5%) and level of alarm sound (75.0%). Nurses stated that the average alarm resolving time was 3 min for IV infusion pumps. The requirements of an IV infusion pump were a longer battery life, easier drug dose calculation functions, greater portability, lighter weight, compactness, and ease of mounting (Table 1).

The nurses also expressed negative opinions about enteral pumps, particularly battery durability (52.5%), mounting (32.5%) and the intelligibility of screen symbols (32.5%). However, the level of alarm sound (82.5%), screen legibility (65.0%), ease of IV infusion set insertion (62.5%), display lighting (62.5%), keypad comfort (62.5%), intelligibility of screen symbols (57.5%) and transporting (50.0%) were reported as 'adequate'. Nurses stated that the average alarm resolving time was 2 min for enteral pumps. The requirements of an enteral pump were ease of insertion and de-airing the IV infusion set, the ability to wash the set rapidly flush and automatically, and a longer battery life of the pump (Table 1).

**Table 1. Nurses' opinions on available pumps and produced prototype**

Assessment Criteria	Partially Adequate (%) Pump			Adequate (%) Pump			Very Adequate (%) Pump		
	Intravenous Infusion (n = 40)	Enteral (n = 40)	Prototype (n = 10)	Intravenous Infusion (n = 40)	Enteral (n = 40)	Prototype (n = 10)	Intravenous Infusion (n = 40)	Enteral (n = 40)	Prototype (n = 10)
Alarm of air in infusion set	17.5	17.5	0.0	45.0	55.0	0.0	37.5	27.5	100.0
Alarm of battery low	17.5	17.5	0.0	52.0	62.5	30.0	30.0	20.0	70.0
Alarm of completion of infusion	7.5	20.0	0.0	55.0	52.5	0.0	37.5	27.5	100.0
Alarm of occlusion	12.5	22.5	0.0	47.5	50.0	0.0	40.0	27.5	100.0
Alarm sounds' level	5.0	2.5	0.0	75.0	82.5	30.0	20.0	15.0	70.0
Clarity of icons on the screen	20.0	25.0	0.0	57.5	57.5	60.0	22.5	17.0	40.0
Comfort of the keypad	7.5	15.0	0.0	72.5	62.5	80.0	20.0	22.5	20.0
Comprehensibility of the pump menu	22.5	32.5	0.0	47.5	45.0	40.0	30.0	22.5	60.0
Display backlight	27.5	17.5	0.0	45.0	62.5	20.0	27.5	20.0	80.0
Easy carrying	67.5	25.0	0.0	27.5	50.0	40.0	5.0	25.0	60.0
Easy mounting	52.5	32.5	0.0	42.5	42.5	20.0	5.0	25.0	80.0
Easy to insert infusion set	12.5	17.5	0.0	60.0	62.5	30.0	27.5	20.0	70.0
Lifetime of the battery	57.5	52.5	0.0	37.5	40.0	20.0	5.0	7.5	80.0
Readability of screen	10.0	17.5	0.0	60.0	65.0	30.0	30.0	17.5	70.0

### 3.2. Phase two: System design

The crucial design process was performed by a multidisciplinary team that consisted of four engineer specialties and a team of nurses. Members of the nursing team all had experience in the use of infusion pumps and provided direction and opinion to the engineers during the design process. The industrial engineers suggested the potential benefit of combining two pumps within a single system at the beginning of the research. The electronics engineers integrated circuit elements, selected battery motors and developed the software programme. A computer engineer completed the software

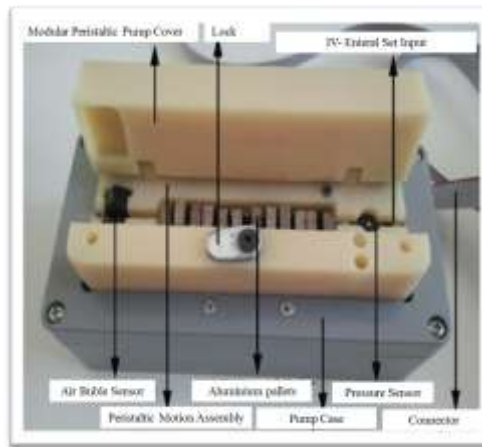
programme for the pump. Finally, a mechanical engineer designed the peristaltic pump body and examined the patent files.

All infrastructure works were completed after investigating the requirements of motors, sensors, screen types, moulding materials, medical consumable materials, operating manuals and technical specifications for IV and enteral infusion pumps in national and international certification systems. The pump system was designed with a pump mechanism and power supply as well as power management, user interface, screen, keypad, alarm, time counter, system monitor and self-test features. The research team installed four battery motors in each peristaltic pump unit. Light sensors were placed at the front and back of each peristaltic movement body to calculate the sensitivity of the liquid volume. When the engine made a tour, the number of peristaltic pump motions was measured by light sensors. We are unable to find any other record of this combination of IV infusion and enteral pump systems in a single pump body in any published literature, and we believe that this is the first report of such a device in the world.

### **3.2.1. Hardware**

The infusion pump had air bubble and pressure sensors, and to ensure patient safety, the sensor sensitivity was rigorously tested. The air bubble sensor was activated when air entered the infusion set, and the pressure sensor was triggered in response to vascular obstruction or folding of the infusion set. Following this, we tested different motor types for measurement of flow rate sensitivity and found that the motor type changed the flow rate and the engine volume affected the size of the design. Therefore, we opted to use battery motors because of their small engines and ability to infuse liquids at accurate rates.

The peristaltic pump body that adjusted the fluid volume by the time was crucial to the design process (Figure 1). The main purpose of the peristaltic pump body was the provision of liquid at a consistent rate and with minimum deviation. The length, width and height of the pump prototype body were 90 mm, 16 mm and 20 mm, respectively, and the pump weight was 1.5 kg (Figure 2). To maintain the lightweight pump design, Aluminium Pallets were used in the production of the peristaltic pump body, and the final prototype was lighter than pumps available in the market. The design was also able to pump three fluids and one nutrition solution with independent velocities synchronously or consecutively and could do so for 12 h because of the inclusion of a long-life rechargeable lithium-ion battery. In the final design phase, the project team decided that the pump should be demountable.



**Figure 1. Peristaltic pump body**



**Figure 2. Designed infusion and feeding pump**

### **3.2.2. Software**

Based on the nurses' remarks, the software program included the following functions: drug dose calculation, patient data storage, ability to perform multiple infusions simultaneously and a separate status display for the infusion. The prototype contained two different software programs that allowed all circuit elements to work in an integrated manner. The mainboard software was in the body, and the slave software operated the peristaltic pump body. The mainboard software was specifically responsible for implementing the information by slave card software. Moreover, the commands, power system, battery, keypad and screen were under the control of mainboard software. The master card provided data entry from the user interface and operated the slave card to perform this accurately. The mainboard software also determined the data shown in the screen (drug dose, quantity of fluid, duration of therapy, fluid–drug quantity by hour, active peristaltic motion assemblies and battery). Slave software was responsible for operating and controlling the pressure sensor, air bubble sensor, motor, reductor, on/off mechanism and peristaltic motion on the basis of the commands received from the mainboard (Figure 3). The IV infusion and feeding software requested the patient's name and the drug name dose and time/rate of treatment, which were entered by

keypad and checked on screen by the user. The infusion could be safely started after ensuring the accuracy of the data.

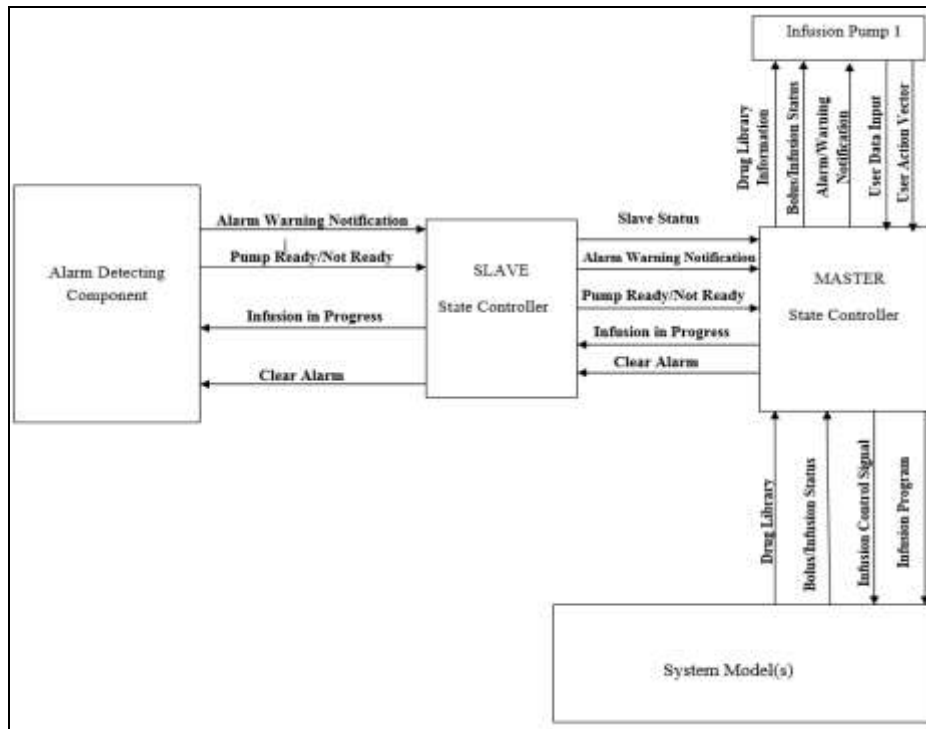


Figure 3. Software Diagram

### 3.3. Phase three: Prototype assessment by nurses and an expert engineer

In phase three, 10 nurses assessed the prototype in a practice laboratory. All nurses found the prototype very adequate with respect to carrying and installing. All nurses indicated that air, occlusion and infusion alarms were very adequate. Almost all nurses (90%) found the prototype to be very adequate and practical to use. Moreover, the majority (70%) stated that the prototype produced less noise than the pumps available in the market. Only 10% nurses (n = 1) indicated that the drug entry screen was too complicated (Table 1). None of the nurses reported that any aspect of the prototype was inadequate, and most found the prototype to be practical. To assess the technical specifications of the pump, we received an expert opinion from a consultant engineer. The engineer gave positive feedback on the demountable units, weight, screen and symbols, alarm types, battery life, noise level and min/max infusion volumes (Table 2).

**Table 2. Opinion of an expert engineer regarding the pump prototype (N = 1)**

Test Parameters	Yes	No
Is the device 1.5 kg?		
Is the device working without noise?		
Is the device mounted easily?		
Is the device giving battery low alarm?		
Is the device giving alarm when the power supply is interrupted?		
Is the device giving alarm 'the same/different patient' when it is first opened?		
Are daily infusions registered in the device memory?		
Is the device screen read in dim, darkness and bright places?		
Are the screen icons displaying wait for/active status?		
Are infusion-related properties shown separately while the pump is running?		
Are the timer and volume calculations observed on the screen consistently?		
Is accurate volume calculation done for the liquid–drug–nutrition solution?		
Is the device delivering intravenous and enteral solutions simultaneously?		
Is the device infusing maximum of 500 ml/h?		
Is the device sending 1 ml maximum in an hour intravenously to remain on the patient?		

#### 4. Discussion

Infusion pumps are used worldwide in hospital clinics, other healthcare settings and home. Infusion pumps have contributed to significant improvements in patient care; however, they are associated with some problems that have led the FDA to emphasise on the need of designing pumps with new features to reduce those associated risks.<sup>11</sup> In this study, a pump prototype was produced that combined IV infusion and enteral pump systems in a single pump body. Thus, the prototype eliminated the need to use two separate devices at the bedside.

The use of infusion pumps increases the ease of daily nursing care and decreases the likelihood of making IV medication errors (Rosenkoetter, Bowcutt, Khasanshina, Chernecky & Wall, 2008). The pump prototype provided labour and time saving to the nurses because of its novel and purpose-designed software and hardware features. The pump software program included a multi-step drug calculation algorithm. Importantly, the commands input by nurses were verified at each step by the pump menu, thereby ensuring patient safety, correct drug dose calculations and reduced medical errors. The pump prototype reduced the likelihood of situations that could threaten patient safety.

We were unable to find a study or a patent that combined IV infusion and enteral pumps in a single system. Infusion pumps currently available in the market are separately used for supporting either enteral or IV requirements. Patients monitored in ICU have variable clinical conditions and variable liquid/drug/enteral solution requirements with more than one IV drug. The many pumps that are



subsequently required create a crowded appearance and lead to unnecessary alarms. The pump prototype can reduce this bedside crowding.

Close cardiac and haemodynamic monitoring and supportive respiratory procedures create noise in ICU. In addition, using two or more infusion pumps increases the level of sound. The pump prototype made less noise than existing pumps, offering an important benefit in this regard. Because the prototype has both audible and visual alarms, the health worker can further reduce patient disruption by selecting visual alarms only. This could have important impacts on sleep patterns and agitation levels.

Alarms, visual icons and the infusion rate/volume information can be monitored from a single screen on the pump, allowing nurses to intervene via four different pumps without losing time, thereby reducing the alarm resolving time. Thus, the time allotted to solve alarm could be transferred to patient care.

Nurse experience and individual ability can affect the use of infusion pump technology. One nurse did find difficulty in calculating drug doses. They were accustomed to using the available pumps in the market and had no experience with the pump prototype (Carayon, Hundt, & Wetterneck, 2010; Gupta et al., 2005).

This study aimed to produce a new pump with improved features over currently available pumps. Clinical nurses were included in the design process and shared their experiences and views with engineers, indicating specific problems with the available pumps and identifying the features required of a new pump design. A multidisciplinary team then designed the infusion pump prototype over a period of 2 years.

The main issues encountered by nurses are reported to be transportation difficulties, fixing problems, the limited ability to infuse a maximum of two IV liquids because of the cassette mechanism, the short battery lifetime (5–8 h) and the inability to demount the pump body (Lee, Thompson, & Thimbleby, 2012).

By integrating clinical nursing requirements and engineering experience, we developed a final prototype that combined one enteral nutrition and three IV infusion pumps in a single machine. The novel design characteristics of the prototype are as follows: it is lightweight, has a long battery life, has demountable pump units, has both visual and audial alarms and has facilities for dose calculation, patient data recording and programming the start time and duration of an infusion. Moreover, the prototype can perform both IV and enteral infusions simultaneously, while meeting both nurse and patient needs for effectiveness, practicality and safety. An international patent application was made for the demountable pump unit design.

The prototype was designed in accordance with the experiences and perspectives of clinical nurses. Nurses can carry the produced prototype pump easily, and its advanced software features allow infusions to be performed safely. Crucially, nurses can also follow both enteral and IV infusions from a single pump screen. Another important issue is that nurses and patients are less likely to be disturbed by the noise produced by the pump prototype.

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#### **Conflict of interest**

The authors have no conflicts of interest to declare.

## References

- Bowcutt, M., Rosenkoetter, M. M., Chernecky, C. C., Wall, J., Wynn, D. & Serrano, C. (2008). Implementation of an intravenous medication infusion pump system: Implications for nursing. *Journal of Nursing Management*, 16(2), 188-197.
- Carayon, P., Hundt, A. S. & Wetterneck, T. B. (2010). Nurses' acceptance of Smart IV pump technology. *International Journal of Medical Informatics*, 79(6), 401-411.
- Chambrin, M. C. (2001). Alarms in the intensive care unit: how can the number of false alarms be reduced? *Critical Care*, 5(4), 184.
- Cho, J., Chung, H. S. & Hong, S. H. (2013). Improving the safety of continuously infused fluids in the emergency department. *International Journal of Nursing Practice*, 19(1), 95-100.
- Ersoy, E., Iskit, A. & Abbasoglu, O. (2010). Parenteral nutrisyon. *Ic Hastaliklari Dergisi*, 17, 209-216.
- Fahimi, F., Ariapanah, P., Faizi, M., Shafaghi, B., Namdar, R. & Ardakani, M. T. (2008). Errors in preparation and administration of intravenous medications in the intensive care unit of a teaching hospital: An observational study. *Australian Critical Care*, 21(2), 110-116.
- Food, U. & Administration, D. (2010). Guidance for industry and FDA Staff-Total Product Life Cycle: Infusion Pump-Premarket Notification [510 (k)] Submissions. *Issued April*, 23, 1-10.
- Gupta, R., Taneja, S., Thariyan, K. & Kumar, S. (2005). Design and implementation of controlled drug infusion system. *Journal of Scientific and Industrial Research*, 64(10), 761-766.
- Hébuterne, X., Bozzetti, F., Villares, J. M., Pertkiewicz, M., Shaffer, J., Staun, M. & Van Gossum, A. (2003). Home enteral nutrition in adults: A European multicentre survey. *Clinical Nutrition*, 22(3), 261-266.
- Herout, P. M. & Erstad, B. L. (2004). Medication errors involving continuously infused medications in a surgical intensive care unit. *Critical Care Medicine*, 32(2), 428-432.
- Lee, P., Thompson, F. & Thimbleby, H. (2012). Analysis of infusion pump error logs and their significance for health care. *British Journal of Nursing*, 21(8), 12-22.
- O'Shea, K. (2013). Infusion management: Working smarter, not harder. *Hospital Pharmacy*, 48(3), 1-4.
- Peterfreund, R. A. & Philip, J. H. (2013). Critical parameters in drug delivery by intravenous infusion. *Expert Opinion on Drug Delivery*, 10(8), 1095-1108.
- Rosenkoetter, M. M., Bowcutt, M., Khasanshina, E. V., Chernecky, C. C. & Wall, J. (2008). Perceptions of the impact of "smart pumps" on nurses and nursing care provided. *Journal of the Association for Vascular Access*, 13(2), 60-69.
- Rothschild, J. M., Landrigan, C. P., Cronin, J. W., Kaushal, R., Lockley, S. W., Burdick, E. & Czeisler, C. A. (2005). The critical care safety study: The incidence and nature of adverse events and serious medical errors in intensive care. *Critical Care Medicine*, 33(8), 1694-1700.
- Saladow, J. (2007). Ambulatory infusion pump technologies new developments and how they might affect alternate site care. *Infusion-Alexandria*, 13(4), 17-22.
- Summa-Sorgini, C., Fernandes, V., Lubchansky, S., Mehta, S., Hallett, D., Bailie, T. & Burry, L. (2012). Errors associated with IV infusions in critical care. *The Canadian Journal of Hospital Pharmacy*, 65(1), 19-26.
- Woo, A., Sutton, H. & Stephens, R. (2007). An introduction to fluid therapy. *British Journal of Hospital Medicine* 68(4), 62-64.
- Yentur, E. (2008). Evde enteral ve parenteral beslenme. *Turk Yogun Bakim Dernegi Dergisi*, 6(4), 28-33.