Achieving Noise Reduction With a Novel Lower Limb External Mechanical Compression System

By Karen Giuliano & Rachel Pozzar

FEATURE AT A GLANCE:
Hospitals are one of the noisiest public environments in the United States, and hospital noise is associated with disrupted sleep. This study provides insights into the noise levels produced by three commonly used medical devices for mechanical deep vein thrombosis prophylaxis: the VenaFlow Elite System, the Kendall SCD Compression System, and the ArjoHuntleigh Flowtron. Noise levels produced were compared with a novel device, the RF Health MAC™ system, which was designed to provide improved comfort and noise reduction. Results suggest that future innovation in mechanical deep vein thrombosis prophylaxis should include efforts to reduce noise during operation.

KEYWORDS:
health systems, medical/health products, product design methods, product development, fatigue, usability, design strategies

The hospital setting is one of the noisiest public environments in the United States, and research indicates that hospital noise levels have risen consistently since the 1960s (Busch-Vishniac et al., 2005). Excessive hospital noise is associated with disrupted sleep (Jones & Dawson, 2012; Xie et al., 2009), which has been linked to a myriad of adverse health effects, including impaired immune function and increased mortality (Pope et al., 2013).

Despite the detrimental effects of lost sleep, research indicates that hospital noise levels consistently exceed the maximum limit recommended by the World Health Organization (WHO) and the Environmental Protection Agency (EPA; Darbyshire & Young, 2013; Xie & Kang, 2012). Prior research on this topic is primarily focused on sound levels in patient rooms and the nurses' station but does not specifically address the extent to which medical equipment contributes to hospital noise.

The goal of this study was to evaluate the noise contribution of a commonly used type of medical equipment – intermittent pneumatic compression (IPC). These devices require continuous use to be effective in preventing deep vein thrombosis but have high rates of nonadherence to prescribed use due to a number of factors, including noise and sleep disruption (Craigie et al., 2015).

THE PROBLEM OF NOISE IN THE HOSPITAL SETTING

The human ear is capable of hearing sound at frequencies ranging from 20 to 20,000 hertz (Hz). Sound intensity is measured in decibels (dB), while A-weighted decibels (dBA) represent the intensity of sound as it is perceived by the human ear (Chepesiuk, 2005). The A-weighted measurement is used to account for the decreased sensitivity of the human ear at lower frequencies, such as those below 1,000 Hz, as compared with higher frequencies. Thus, dBA approximate the human perception of loudness. A quiet room registers at approximately 30 dBA, normal conversation at 55 dBA, an electric shaver at 75 dBA, an average motorcycle at 90 dBA, and an average rock concert at 140 dBA (Chepesiuk, 2005). The WHO recommends a maximum of 40 dBA in patients' hospital rooms at night, while the EPA recommends a maximum of 40 dBA in hospitals overall. Unfortunately, research supports that hospital noise levels consistently exceed the recommended limits (Darbyshire & Young, 2013; Xie & Kang, 2012).

The major sources of noise in the hospital setting include bedside equipment such as ventilators, nebulizers, and infusion pumps; equipment alarms, such as those from ventilators, heart monitors, and infusion pumps; doors and drawers closing; telephones and pagers ringing; and staff conversation (Elliott et al., 2010; Halm, 2016; Pope, 2010; Xie et al., 2009). In a population-based study of patient perceptions of hospital care quality in the United States, noise in patient rooms was identified as the quality of care factor that needed the most improvement (Jha et al., 2008).

Several authors have sought to quantify sound intensity in the hospital environment. In their study of sound levels in an Australian adult general intensive care unit (ICU), Elliott et al. (2010) found that the

background noise in the ICU ranged from 43.5 to 50.2 dBA, while peak noises consistently reached up to 85 dBA. In a study of decibel levels on four medical–surgical nursing units in the Pacific Northwest of the United States, Pope (2010) found that the average sound intensity at nurses' stations ranged from 62 to 65 dBA, while the average sound intensity in patient rooms ranged from 48 to 79 dBA. Peak noise levels frequently exceeded 100 dBA on all of the units under study. In their study of nocturnal sound intensity in one English ICU, Xie and Kang (2012) found that the average sound level was between 51.7 and 53.1 dBA, while the average maximum nocturnal sound intensity ranged from 79.3 to 82.3 dBA. The study authors also observed that overnight sound levels on the unit under study were dominantly at the middle frequencies (Xie & Kang, 2012). Darbyshire and Young (2013) studied five ICUs in the Thames Valley region of England and found that average sound intensity always exceeded 45 dBA and exceeded between 52 and 59 dBA at least 50% of the time. Finally, in a study of 29 inpatient ward rooms at a university hospital in Korea, Park et al. (2014) found that the mean continuous noise level for a 24-hour time period was 63.5 dBA. A more recent study has confirmed findings from prior research (Scquizzato, et al, 2020). The results of these studies confirm that sound intensity in the hospital environment was unacceptably high, consistently exceeding the recommended WHO and EPA thresholds.

Implications of Hospital Noise

The consequences of a noisy hospital environment are significant. A healthy sleep period consists of four to six 90- to 100-minute cycles during which an individual experiences different stages of sleep. Healthy, restorative sleep includes several sleep stages. Stage N1, also known as light sleep, should comprise 2% to 5% of total sleep time; Stage N2 should comprise 45% to 55% of total sleep time; Stage N3, also known as deep sleep, should comprise 15% to 20% of the total sleep time; and rapid eye movement (REM) sleep should comprise 20% to 25% of total sleep time (Kamdar et al., 2012). In contrast, research using polysomnography has demonstrated that hospitalized patients experience a predominance of Stages N1 and N2 sleep with a lack or almost total absence of Stage N3 and REM sleep (Kamdar et al., 2012; Weinhouse et al., 2009). This is concerning given that Stage N3 and REM sleep are associated with both restorative cognitive processes and regulation of the thermoregulatory, respiratory, cardiovascular, gastrointestinal, and endocrine systems (Kamdar et al., 2012). Disturbed sleep has been associated with impaired immune function (Palmblad et al., 1979), impaired mentation (Kamdar et al., 2012; Salas & Gamaldo, 2008), and increased risk of delirium (Aaron et al., 1996; Weinhouse et al., 2009).

Although sleep disruption can be attributed to several factors (Pellatt, 2007), a number of studies have found noise to be the most significant cause of sleep disruption in the hospital setting (Jones & Dawson, 2012; Xie et al., 2009; Marn Joon et al., 2014). In a study conducted by Park et al. (2014), 86% of the participants experienced disturbed sleep, and increased noise was a significant predictor of sleep disturbance even after adjusting for several potential confounders. Likewise, in a study of sleep in the ICU, Boyko et al. (2017) used polysomnography to assess sleep patterns among critically ill mechanically ventilated patients. The authors found that only 53% of the patients had any identifiable characteristics of normal sleep, while 47% showed only pathologic patterns. Similarly, a qualitative study of the medical ICU at night found that staff and patients alike perceived the nighttime hospital environment as noisy with frequent disturbances in patient rooms (Ding et al., 2017). In a study of the relationship between hospital noise and patient well-being, Cunha and Silva found that 28.6% of the participants reported that they were unable to sleep or rest as a result of hospital noise. Using an Apple Watch, sleep disturbances due to noise has been recently found in ICU patients, further supporting findings from previous research (Simons, et al, 2018).

Interventions Aimed at Addressing Hospital Noise

A variety of interventions to reduce noise and promote rest among hospitalized individuals have been reported in the literature. These interventions can broadly be described in four categories: earplugs, behavioral modification, sound masking, and acoustic absorption. In a review of the effectiveness of noise reduction strategies in the ICU, Xie et al. (2009) reported that the use of earplugs and earmuffs was found to improve sleep by 10% to 39%. In the same review, behavior modification was found to decrease noise by 1.9 to 3 dBA and to improve sleep by 13.8% to 18.3%. Sound masking was found to improve sleep by 22.9% to 67.6%, and the use of acoustic material for sound absorption was found to decrease noise by 3.3 to 4 dBA. Jones and Dawson (2012) found that although participants reported sleeping for longer periods using earplugs and eye masks, participants did not perceive an improvement in sleep quality. Conversely, Hu et al. (2010) found that the use of earplugs and eye masks were associated with more REM sleep and improved subjective sleep quality.

Findings describing the effects of behavior modification interventions are similarly mixed. Gardner et al. (2009) reported that a "quiet time" intervention on an acute care unit resulted in significant differences in the mean decibel level and number of patients awake and asleep. However, implementation of "sleep rounds," consisting of sleep-promoting practices enacted by staff, improved patient perceptions of the sleep experience but did not measurably improve sleep or mitigate sleep-disrupting factors (Thomas et al., 2012). Boyko et al. (2017) also implemented a "quiet routine" in the ICU and found that the effect of the intervention on noise reduction was not significant. After implementing a noise reduction protocol in the medical ICU, van de Pol et al. (2017) found that although sleep quality was unaffected by the intervention, the

intervention group used significantly less sleep-inducing medication, and the nocturnal noise rating improved after the intervention. These interventions were primarily focused on human noise rather than noise from medical devices, which may be why the effectiveness has mixed results. As previously discussed, noise from staff conversations is just one source of hospital noise. Noise from bedside equipment and the various alarms is a significant source of noise that has yet to be fully explored.

External Mechanical Compression

In the acute care setting, mechanical compression of the lower extremities is used commonly for the prevention of venous thromboembolism from deep vein thrombosis.

Venous thrombosis affects 350,000 to 900,000 patients annually with an estimated 60,000 to 100,000 deaths. Furthermore, venous thromboembolism is considered to be largely preventable, yet remains a common hospital-associated complication and the most common cause of preventable death within hospitals (Cohen et al., 2008; Mejilla et al., 2017).

IPC is currently the most widely used therapy to provide external mechanical compression for the prevention of venous thromboembolism in hospitalized patients. IPC promotes blood flow in the legs to reduce venous stasis, a major contributor to the development of venous thromboembolism (Kahn et al., 2013). In U.S. health care, IPC is most commonly achieved through the use of sequential compression devices. These devices are composed of sleeves that wrap around either the patient's calf or the patient's calf and thigh and are connected to a pneumatic motorized pump. The pump sequentially inflates the air chambers in each sleeve starting distally and moving up the leg, with the goal of helping to move venous blood toward the more central circulation. As the air chambers deflate, the pressure exerted by the sleeves is reduced, allowing the venous system to refill. The complete cycle of inflation, compression, and deflation occurs once per minute, with a total cycle duration that varies from 30 to 40 seconds. Throughout the cycle, noise is generated by the sound of the motorized pump during inflation and compression and the sound of the air movement into and out of the air chambers throughout all three phases of the cycle.

The effectiveness of IPC requires near-continuous 24-hour per day use, including use during sleep. Unfortunately, there are numerous issues associated with the currently available external mechanical compression devices, which result in decreased adherence to recommended use and diminish the therapeutic value of IPC (Elpern et al., 2013; Gould et al., 2012; Muramoto, 2017). A meta-analysis by Craigie et al. (2015) found the mean external mechanical compression device use among postoperative patients at only 75% of the recommended use time. The most commonly reported reasons for patient nonadherence included lack of comfort, excessive noise during operation, sleep disturbances, and poor usability design (Craigie et al., 2015).

Despite the widespread use of external mechanical compression by IPC in acute care, little is known regarding the extent to which these devices contribute to the overall sound intensity in the hospital environment. The purpose of this study was to measure and compare the sound intensity generated by three commonly used IPC devices – the VenaFlow Elite System, the Kendall SCD Compression System, and the ArjoHuntleigh Flowtron, to the RF Health Movement and Compressions (MAC) System. The RF Health MAC is a novel system that was designed to provide external mechanical compression of the lower limbs more effectively and with less noise than the currently available IPC devices.

The RF Health MAC works by providing intermittent compressive forces to the legs, increasing the blood flow in the veins, moving blood toward the direction of the heart, and reducing the risk of clot formation. To perform intermittent compression for deep venous thrombosis prophylaxis, a single-patient use disposable fabric moisture wicking strap (MAC Strap) is wrapped around a patient's calf muscle just below the knee. The controller is then attached to the strap. Inside the controller is a small DC motor that controls the mechanical actions to contract and retract the strap. When the strap is contracted, compression is applied to the patient's calf muscle. When the strap is retracted, compression force is released to the patient's calf muscle. This provides the blood flow "pumping" action once per minute that prevents blood clots from forming (Labropoulos et al., 2021).

Based on this mode of action, the MAC System uses mechanical force to provide intermittent compression, not pneumatic force. The system does not require a powered air supply, so the risk of aerosolization of potential contaminants or germs is mitigated as there is no blowing air. Also, the device components are either disposable (the MAC Strap) or the surfaces are easily disinfected (MAC Controller and Charging Hub) allowing for ease of cleaning and mitigation of cross-contamination. There are no air connections or pneumatic pumps to clean between patients.

METHOD

Acoustic testing of all devices was conducted by engineers at the independent testing firm Indy Acoustic Research, LLC, in Indianapolis, Indiana. During the acoustic testing, the sleeves of the model being tested were placed on the center of a 30-inch × 60-inch tabletop. The powered pumps were placed on top of a foam block at one end of the tabletop to simulate the typical placement (at the foot of the bed) for each of these devices and device components during actual clinical use. A microphone was placed at the other end of the tabletop to simulate the head of the bed. Room noise, equipment noise, and sound frequency were measured using a Brüel and Kjaer 4190 laboratory measurement microphone positioned at 30 cm × 40 cm × 50 cm from the end of the tabletop. A series of three measurements were taken on each device.

Testing was performed in three rounds (Table 1), with the first round completed on October 18, 2018. In that first round,

Table 1. Attributable Sound Intensity by Device

Test Run	Attributable Sound Intensity (dBA)
VenaFlow Elite: October 18, 2018	
Run 1	48.1
Run 2	48.5
Run 3	48.2
M	48.3
SD	0.21
Kendall SCD: October 18, 2018	
Run 1	44.8
Run 2	43.8
Run 3	43.9
M	44.2
SD	0.55
RF Health MAC System: February 13, 2019	
Run 1	32.6
Run 2	37.8
Run 3	31.1
M	33.8
SD	3.5
ArjoHuntleigh System: June 18, 2020	
Run 1	40.2
Run 2	43.7
Run 3	37.3
M	40.5
SD	3.1
RF Health MAC System: June 18, 2020	
Run 1	23.3
Run 2	23.7
Run 3	22.5
M	23.2
SD	0.62

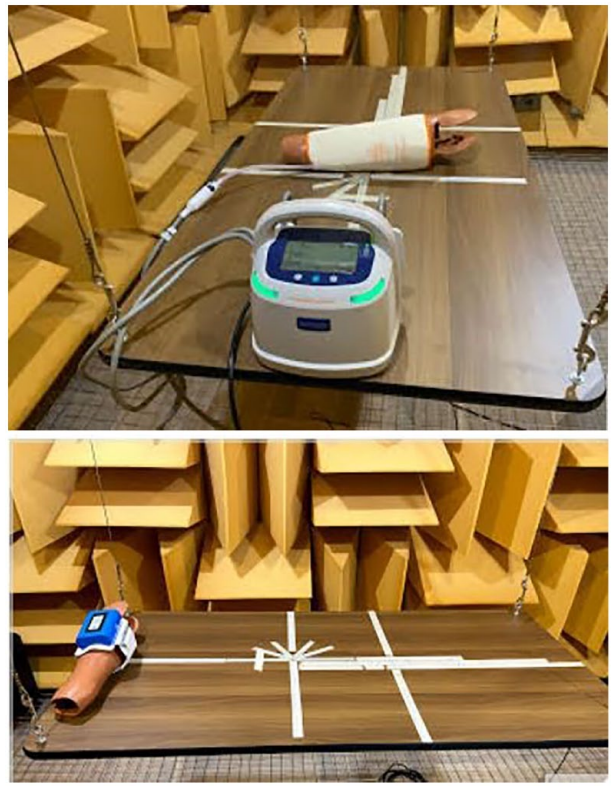

Figure 1. Photos of the lab setup of devices during testing.

the VenaFlow Elite System and the Kendall SCD Compression System were tested. The second round of testing was completed on February 13, 2019, using a functional prototype of the RF Health MAC System, which was not available when the first round of testing was performed. The same testing protocol was used, but since the MAC System has a strap integrated with a motor – instead of separate sleeves and a pump like the other devices – the whole system was placed at the end of the tabletop (Figure 1). A third round of testing was completed on June 18, 2020, which included the ArjoHuntleigh Flowtron and an updated version of the RF Health MAC System, which had undergone further design changes for additional operational noise reduction. A final test was performed on June 30, 2020, to measure noise duration per minute with each device included in the study.

RESULTS AND DISCUSSION

The A-weighted room noise varied slightly across the three testing days, measuring 24.1 dBA on October 18, 2018, 24.3 dBA on February 13, 2019, and 21.5 on June 18, 2020. Accounting for the room noise on each testing day, the mean sound intensities directly attributable to each device are summarized in Table 1. The results of follow-up testing on the duration of sound performed on June 30, 2020, are shown in Table 2. Because most external mechanical compression devices employ asynchronous inflation of the right and left

Table 2. Maximum Sound Duration by Device

Inflation Time (Seconds)		Compression Time (Seconds)		Deflation Time (Seconds)		Total Cycle Time (Seconds)	Sound Duration per Day (Maximum)
Left	**Right**	**Left**	**Right**	**Left**	**Right**	**Total**	**Total**
VenaFlow Elite							
1	1	6	6	8	8	30	12 hours
Kendall SCD							
11	11	0	0	11	11	44	17.6 hours
ArjoHuntleigh System							
6	6	8	8	6	6	40	16 hours
Compression Time (Seconds)		**Hold Time (Seconds)**		**Compression Release Time (Seconds)**		**Total Cycle Time per Minute (Seconds)**	**Sound Duration per Day (Maximum)**
Left	**Right**	**Left**	**Right**	**Left**	**Right**	**Total**	**Total**
RF Health MAC System							
1	1	1	1	2	2	8	3.2 hours

legs, the sound duration for each leg is presented, and the total maximum sound duration assumes asynchronous operation.

These findings provide insight into the noise levels produced by three commonly used IPC device and the RF Health MAC System. For the three commonly used IPC devices tested, operational noise levels exceeded the recommended 40 dBA threshold. The RF Health MAC System was the only external mechanical compression system that achieved a total noise level that did not exceed the recommended WHO and EPA hospital noise thresholds.

With regard to the sound duration summarized in Table 2, the total sound duration of the three commonly used devices ranged from 12 to 17.6 hours per 24 hours, as compared with the RF Health MAC, at 3.2 hours per 24 hours. Given the American College of Chest Physician Guidelines for mechanical compression for deep venous thrombosis prevention of 18 to 22 hours/day, the differences in both sound intensity and sound duration between the devices are a likely factor in adherence to prescribed use.

CONCLUSION

This study builds on the body of research on hospital noise in at least three ways. First, it quantifies the noise levels of a medical device that is commonly used in U.S. acute care. Second, it provides data to show how certain aspects of device performance may contribute to nonadherence to prescribed use. Third, this study provides a clear example of how improvements in medical device design have the potential to significantly reduce noise in the hospital environment. Thus, these findings provide foundational data that can be used to inform how device makers approach future designs to broadly meet patient care needs. As noise reduction is an important component of sleep promotion for hospitalized patients, further research is needed to explore associations between medical device types/models, impact of noise levels with recovery/patient satisfaction, and total duration of sleep disturbance during an inpatient hospital care. In addition, noise impact on clinician function and concentration is another potential area for further study.

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