

# User feedback on the Flowtron<sup>®</sup> ACS900 pump and Tri Pulse garment range



Authors: **Jonathan Busby**, MSc, BSc (Hons) RN, Global Senior Clinical Manager; **Kristina Holst**, MSc, Senior Clinical Trial Manager; **Kristina Hansson**, BSc, Senior Clinical Affairs Manager

## Introduction & clinical context

Venous Thromboembolism (VTE), (a blood clot in the leg or lung) is a largely preventable condition associated with a high rate of mortality and morbidity if left untreated. VTE formation although complex consists of three primary risk factors collectively referred to as Virchow's Triad, namely: **Venous Stasis, Hypercoagulation** and **Vessel injury** (Figure 1)<sup>1</sup>.

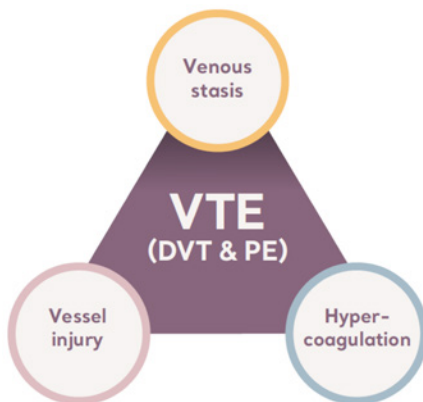


Figure 1: Virchow's Triad

## Executive summary

118 users of the Flowtron ACS900 and Tri Pulse system participated in this survey that included users at 32 hospitals in Australia, France, UK and USA.

The survey gained user feed back and demonstrated the clinical application of the Flowtron ACS900 and Tri Pulse garment range.

The majority of users who took part provided positive feedback e.g.:

- 97.5% of the users responded that they experience patients in general to comply with Flowtron ACS900 and Tri Pulse therapy
- 98.3% of the users thought that the Tri Pulse garment design allows for good anatomical fit to the patients' limbs
- 99.2% of the users thought that the Flowtron ACS900 pump is easy to use in general

Patients admitted to hospital (medical or surgical), are particularly at risk of VTE and the problem continues after discharge<sup>2</sup>. Without adequate prophylaxis the incidence of VTE is high<sup>3</sup>. There are approximately 10 million VTE cases reported worldwide each year<sup>4</sup> and these are associated with high economic and humanitarian cost<sup>5</sup>. VTE is considered the most common preventable form of hospital death<sup>6</sup>.

In clinical practice, routine systematic patient risk assessment has become an inherent aspect of effective VTE prevention programmes.

Prevention strategies commonly incorporate the use of pharmacological prophylaxis and mechanical methods including intermittent pneumatic compression (IPC). These can be used as stand-alone therapies, or for the highest risk patients, a combination of methods may be used concurrently to enhance benefit<sup>7</sup>.

IPC devices involve the use of inflatable garments wrapped around either the foot, calf or thigh of the patient, intermittently inflated by an electrically operated pump. This intermittent inflation and deflation enhances venous return. Venous stasis is prevented and the action of the inflation and deflation stimulates the release of chemical substances in the blood, that both inhibit clot formation and promote fibrinolysis<sup>8</sup>. IPC addresses two of the principle causes of DVT formation: **Venous stasis** and **Hypercoagulation**.

The use of IPC in VTE prevention is a very well-established, generic, intervention with few side effects. It is indicated for use across a wide range of patients including those for whom anticoagulation is contraindicated. Many configurations of IPC devices are available to clinicians, with different garment types, compression profiles and cycle times. Whilst there has been considerable debate over many years about the relative merits of these, clinical studies have consistently shown no significant difference in VTE outcome, even where there are small differences in type of garment, compression profile, and cycle time<sup>1,9,10,11,12</sup>. This can often make the clinical decision making process problematic and hence the need for user feedback and evaluation data is important.

This paper reports the results of a user survey conducted with end users in order to gain post market feedback on the use and clinical application of the Flowtron ACS900 pump and Tri Pulse sequential compression garment range manufactured by Arjo.

### The Flowtron ACS900 & Tri Pulse garment range

The Flowtron ACS900 system offers both uniform and sequential compression therapy modes in one easy-to-use pump (Figure 2) and is designed to be used in conjunction with an extensive range of garment types and sizes, ensuring effective and comfortable therapy for all patients.



Figure 2: Flowtron ACS900 & Tri Pulse Garment Range

Arjo's patented SmartSense garment detection technology automatically sets the correct pressure and compression cycle depending on the type of garment connected to the tubaset, without the need for any additional user intervention. The system allows for a combination of different garment types to be used simultaneously.

The Tri Pulse garment range provides a graduated sequential intermittent compression profile, designed for optimal anatomical fit and enhanced patient comfort. The range consists of calf and calf-and-thigh garments available in a variety of sizes including a bariatric version.

### Study description

The objective of this user survey was to collect user data on Tri Pulse and Flowtron ACS900 by interviewing caregivers (=users) in the USA, United Kingdom (UK), Australia and France. The purpose was to understand user perception of Tri Pulse and Flowtron ACS900, and how it is used in the clinical environment.

User data from caregivers was collected in the following areas:

- Patient compliance
- Patient comfort
- Ease of use
- Safety

Users were contacted by Arjo representatives and face-to-face interviews were performed in the UK, Australia and France. In the US, users were contacted by an Arjo representative who sent a link to the questionnaire that was completed online. All data was collected in Google Forms. No personal data on caregivers and no patient data was collected. For any questions related to the patient, e.g. on patient comfort, only user's perceptions were collected.

Facilities that had used Tri Pulse for at least six (6) months were included in the survey.

The interview consisted of open and multiple choice questions on user information, patient compliance, fit and comfort of the Tri Pulse garment, ease of use, safety and a summary. Users were asked to add comments for each question. The selectable ratings of the multiple choice-questions were: **strongly disagree, disagree, agree and strongly agree.**

### Results

A total of 118 users of the Flowtron ACS900 and Tri Pulse system participated in the user survey that included users at 32 hospitals in Australia (6), France (15), UK (7) and USA (4) (Figure 3). The users were nurses, caregivers, clinical educators and healthcare assistants.

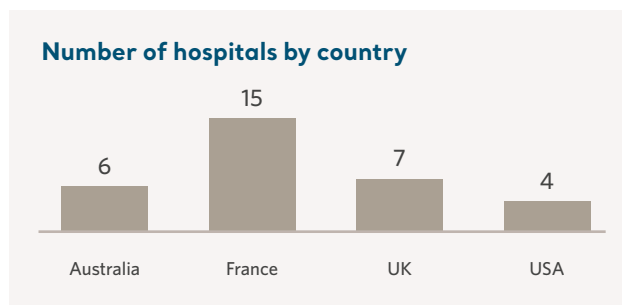


Figure 3

### User information and demographics

The majority of the responding users were nurses (63%). The remaining 37% were mainly caregivers, clinical educators and healthcare assistants. Most users worked in surgical wards (48%), intensive care (21%), acute stroke wards (5%), medical wards (7%) or general wards (6%).

The most common responsibilities with Flowtron ACS900 and Tri Pulse system were

- To set up equipment; e.g., connecting garments to the pump (36%)
- Various logistics; e.g., maintaining correct working conditions (32%)
- Monitoring therapy (31%)
- 1% responded "other", e.g., ordering, training

A majority of the responders had worked for more than one year with the Flowtron ACS900 and Tri Pulse system.

### Patient compliance

**A majority of the users responded that they experience patients in general to comply with Flowtron ACS900 and Tri Pulse therapy (97.5%)** (Figure 4) and that patients wear the garments as prescribed by the doctor (88.8%). In addition, 79% of the users experienced that patients do not complain about discomfort or any inconvenience during therapy and that the system allows for patients' rest and recovery (81%).

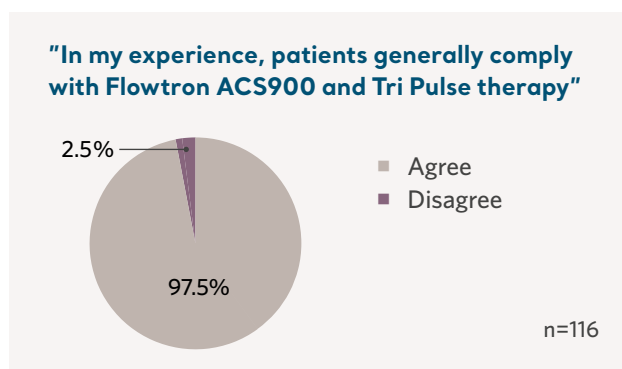


Figure 4: Patient Compliance

Caregivers commented that if they explain the device and treatment to patients, patients comply with therapy. Most patients found the garments comfortable and wore them as prescribed.

### Fit and comfort of the Tri Pulse garment

Users were overall very positive about fit and comfort (Figure 5) and a majority of users considered the garment to be comfortable for the patients (96.5%). Once the garment is fitted onto the patient's limb it doesn't need to be adjusted (93.2%). A few users commented that they may need to adjust the garment if the patient moves a lot. Most users thought that the Velcro® fastens appropriately and keeps the Tri Pulse garment in place on the limb (96.6%) and that the **Tri Pulse garment design allows for good anatomical fit to the patients' limbs (98.3%)**.

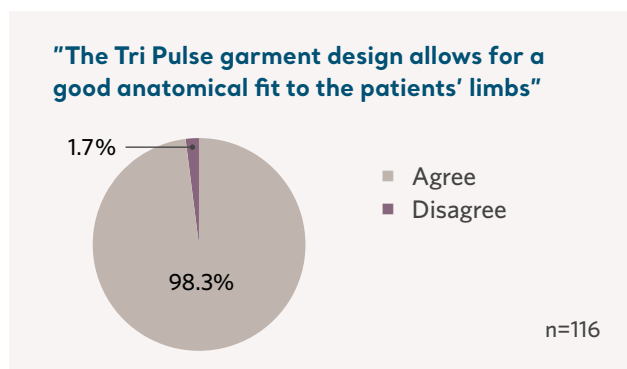


Figure 5

The majority of users were happy with the range of sizes on the Tri Pulse garment.

### Ease of use

Most users found the Flowtron ACS900 and Tri Pulse easy to use.

**99.2% of the users thought that the Flowtron ACS900 pump is easy to use in general (figure 6)**, easy to operate and that it facilitates ease of use. The plug-and-play system is considered to free up time to care for patients by most users (95%) as it reduces time spent on non-patient related activities.

Users reported that the Flowtron ACS900 pump was easy to clean.

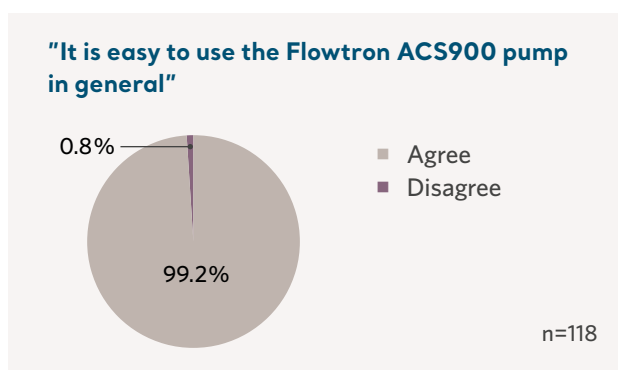


Figure 6

**Most users (99.1%) liked the placement of the tube/garment connector on the Tri Pulse garment and felt that this could help in reducing the risk of pressure injuries whilst wearing the garments.** The tubeset being fixed to the pump to eliminate the risk of losing it was also valued by users.

All users appreciated that one pump covers all VTE prevention IPC therapy needs, as it facilitates ease of use and training.

### Safety

The majority of users (94%) considered the safety features to limit risk of operator error and to facilitate troubleshooting when using the Flowtron ACS900 and Tri Pulse system.

### Miscellaneous

Almost all users (97.5%) who took part in this survey indicated that they would recommend the Flowtron ACS900 with Tri Pulse garments to other facilities and caregivers.

### Discussion and conclusion

A VTE represents a serious, potentially life-threatening complication which is largely preventable. The use of IPC provides one aspect of a prevention strategy that can be used either as a standalone therapy, or combined with other methods of prophylaxis. It is a well-established therapy with many configurations of IPC device available.

This survey has gained user feedback with end users of the device and demonstrated the clinical application of the Flowtron ACS900 and Tri Pulse garment range in the clinical environment. The majority of users who took part provided positive feedback in terms of patient compliance, ease of use and safety of the Flowtron ACS900 device. In addition users were very positive with regards to the overall fit and comfort of the Tri Pulse garment and with the range of garment sizes available. Compliance with therapy was considered to be high in general which is an important aspect in VTE prevention practices requiring the patient to adhere to prescribed therapy.

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Arjo AB • Hans Michelsensgatan 10 • 211 20 Malmö • Sweden • +46 10 335 4500

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