

## Negative Pressure Wound Therapy System Innovates Standard of Care via Intelligent Pressure Control and Dynamic Exudate Removal

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## Objectives

- Review the mode of action of negative pressure wound therapy (NPWT).
- Discuss the fundamental requirements of NPWT systems to deliver clinical benefits.
- Compare the ability of Invia Liberty NPWT System (Medela AG) and V.A.C.ULTA Therapy System (3M + KCI) to deliver set levels of NPWT and manage fluid volumes in a simulated wound model.

## Introduction

### Historical recap

Negative pressure wound therapy (NPWT) has become the cornerstone modality in the treatment of complex acute, chronic, and postsurgical wounds since its inception in the 1990s. Negative pressure wound therapy has been widely accepted as the standard treatment to promote healing in wounds with a variety of etiologies and is applied extensively across the continuum of care in both inpatient and outpatient settings.

While there have been many important developments with NPWT, there has been little, if any, innovation to the way NPWT is delivered and controlled at the wound bed and the manner in which fluid removal is managed.

### NPWT standard

In 2017, the European Wound Management Association (EWMA) published interdisciplinary guidelines with the intention of highlighting the key principles of NPWT and educating clinicians to the standard tenets that must be incorporated

in a NPWT system to effectively deliver therapy.<sup>1</sup> A key to the success of NPWT is whether the chosen system can manage changes in fluid volume and viscosity as they occur.<sup>2</sup> The most reliable systems are able to prevent stagnation in the tubing when the direction of fluid removal is against gravity (eg, the NPWT pump is placed above the wound) and effectively manage large fluid volumes.

### Investigation

The objective of this investigation was to compare the ability of Invia Liberty NPWT System (Medela AG; System A) and V.A.C.ULTA Therapy System (3M + KCI; System B) to meet and exceed the standard of NPWT care. A simulated wound model system was utilized to measure each system's ability to deliver set levels of NPWT and simultaneously manage volumes of simulated wound exudate. Testing was conducted at an independent third party laboratory using a test protocol designed by the manufacturer of System A.

### Mechanisms of action

Previous studies have established that NPWT improves wound healing through 6 discrete mechanisms of action (MOA)<sup>3,4</sup>:

1. Promotes perfusion<sup>5,6</sup>
  - The constant stimulation between the cells and the wound filler, due to a vacuum, causes a microvascular response and can thus affect blood flow perfusion on the wound surface.
2. Draws wound edges together (macrodeformation)<sup>4</sup>
  - The contraction of the wound filler along with the obvious reduction in the size of the wound can be seen when NPWT is applied to most wounds; this leads to tissue remodeling and wound healing.
3. Promotes granulation tissue formation (microdeformation)<sup>5</sup>
  - NPWT has been shown to

enhance granulation tissue formation. Porcine wound studies have demonstrated a significant increase in granulation formation compared to conventional dressings.

4. Removes fluid and reduces edema<sup>5,7</sup>
  - NPWT facilitates the removal of excess interstitial fluid and edema. This may positively affect perfusion to the wound.
  - NPWT removes fluid/material directly from the wound bed.
5. Removes potentially infectious materials<sup>6,8</sup>
  - Removing stagnant wound fluid may help reduce the bacterial load of the wound.
  - A diminished wound bioburden has been shown in

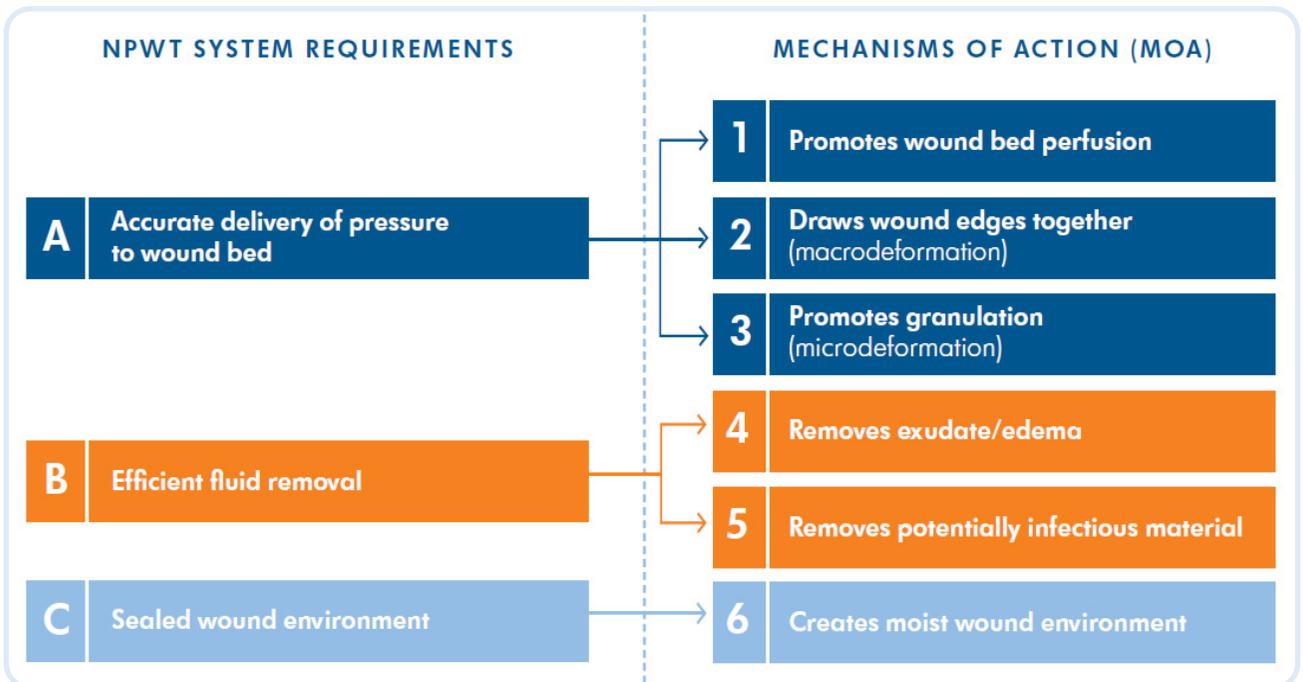
6. Creates a moist wound environment<sup>1,6,7,9</sup>
  - The seal created by the wound filler and transparent film provides a moist wound healing environment and reduces the risk of external contamination.

NPWT has fundamental requirements so that clinical benefits can be realized: (1) the set level of negative pressure must be accurately delivered to the wound bed; (2) NPWT must create a pressure gradient between the wound bed and the waste canister for efficient fluid removal; and (3) NPWT must maintain a sealed wound environment. Each of the 3 fundamental requirements for effective NPWT is associated with 1 or more of the 6 direct mechanisms through which NPWT promotes efficient wound healing (**Figure 1**). In the context of these

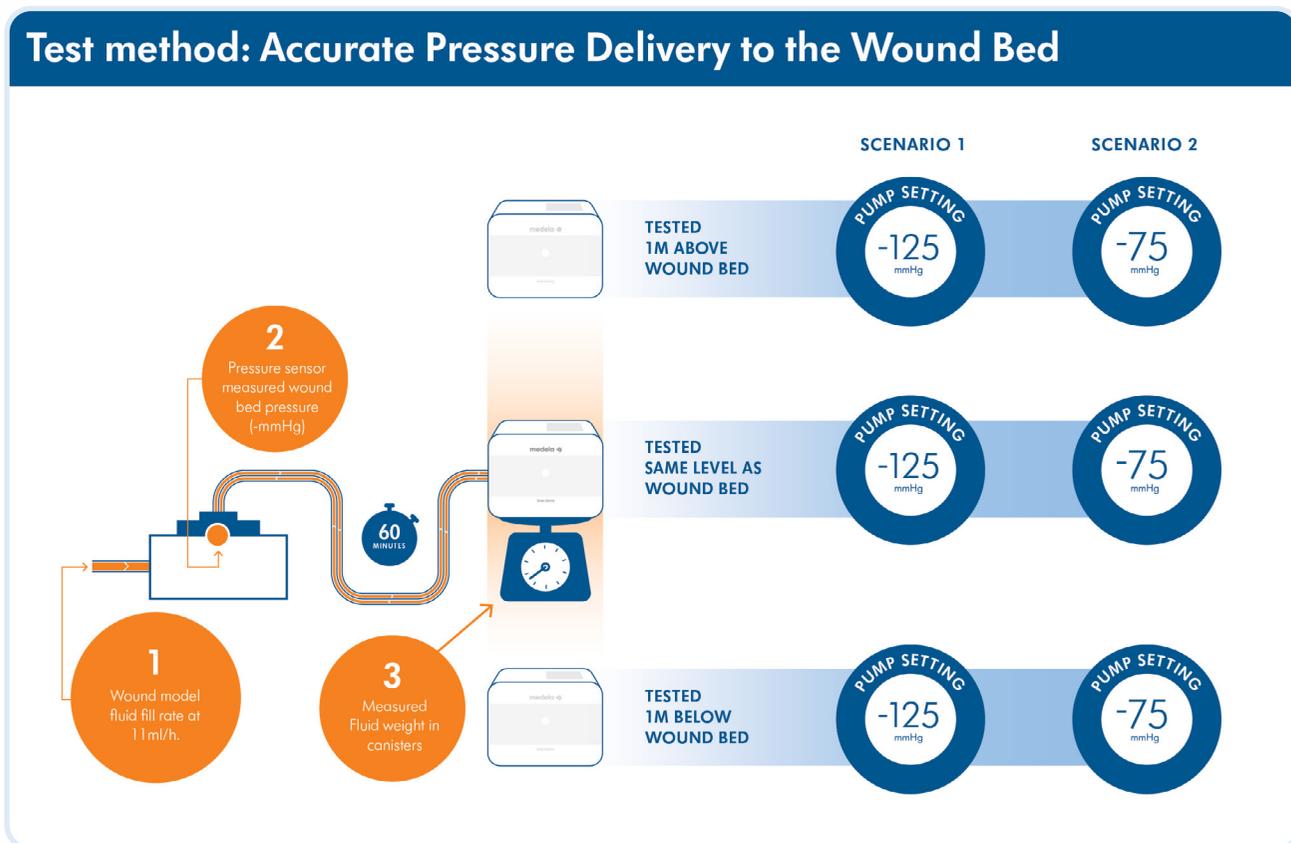
requirements and the MOA, it becomes apparent that not all NPWT systems are created equal and even fewer satisfy the technical standards to effectively and reliably meet the needs of an ever-changing wound environment.<sup>1,2</sup>

**Requirements necessary for effective delivery of NPWT**

*Accurate delivery of pressure to the wound bed.* International recommendations for NPWT set by EWMA state that NPWT systems “use an electronically controlled feedback system that ensures the maintenance of the selected pressure level (for example, -50 mm Hg to -200 mm Hg) even in the presence of small air leaks, guaranteeing the effectiveness of NPWT. The electronically controlled feedback system, not implemented in all mechanical systems, ensures the maintenance of the selected pressure level giving the patient higher safety.”<sup>11</sup> This requirement is necessary



**Figure 1.** Negative pressure wound therapy (NPWT) system requirements and mechanisms of action.



**Figure 2.** Test methodology for 1m above, same level, and 1m below.

to ensure accurate delivery of the prescribed NPWT to the wound bed and is the standard of care for NPWT systems presently. Systems that do not provide an electronically controlled feedback system cannot consistently or accurately deliver NPWT to the wound bed.

*Efficient fluid removal.* Fluid volumes and viscosities can vary greatly. Effective wound management requires a system that can dynamically manage changes in fluid volume and/or viscosity as they occur.<sup>2</sup> Gravity further complicates a NPWT system's ability to effectively remove fluid from the wound bed; this effect cannot be overlooked. An electronically controlled feedback system also plays a crucial role in clearing wound fluid away from the tubing and preventing blockages. Select

NPWT systems use an electronically controlled feedback system to manage airflow cycles through a combination of control and removal lumens. In this system, the control lumen is responsible for ensuring the patency of the tubing, while the removal lumen simultaneously provides a pressure gradient to transport fluid from the wound to the canister. At the time of this report, there are only 2 NPWT systems commercially available with US Food and Drug Administration clearance: (1) System A with FitPad offering Intelligent Pressure Control and Dynamic Exudate Removal (Medela AG) and (2) System B with SensaT.R.A.C Technology (3M + KCI). Standard NPWT systems generally remove fluid through the use of static airflow cycles,

which are defined by unchanging time periods between air cycles that render the system unable to react to changes in wound fluid volume or viscosity. In order to remove wound fluid more efficiently and truly innovate the standard of care, NPWT systems must be able to sense changes in wound fluid volume and viscosity and dynamically adjust airflow cycles.

*Sealed wound environment.* Negative pressure wound therapy dressing systems must contain an adhesive film dressing to seal the wound and maintain a moist wound environment.<sup>1,6,7</sup> According to Apelqvist et al, "a moist environment is vital in wound healing as it facilitates the re-epithelialization process. However, in an overly moist wound, exudate may cause infection

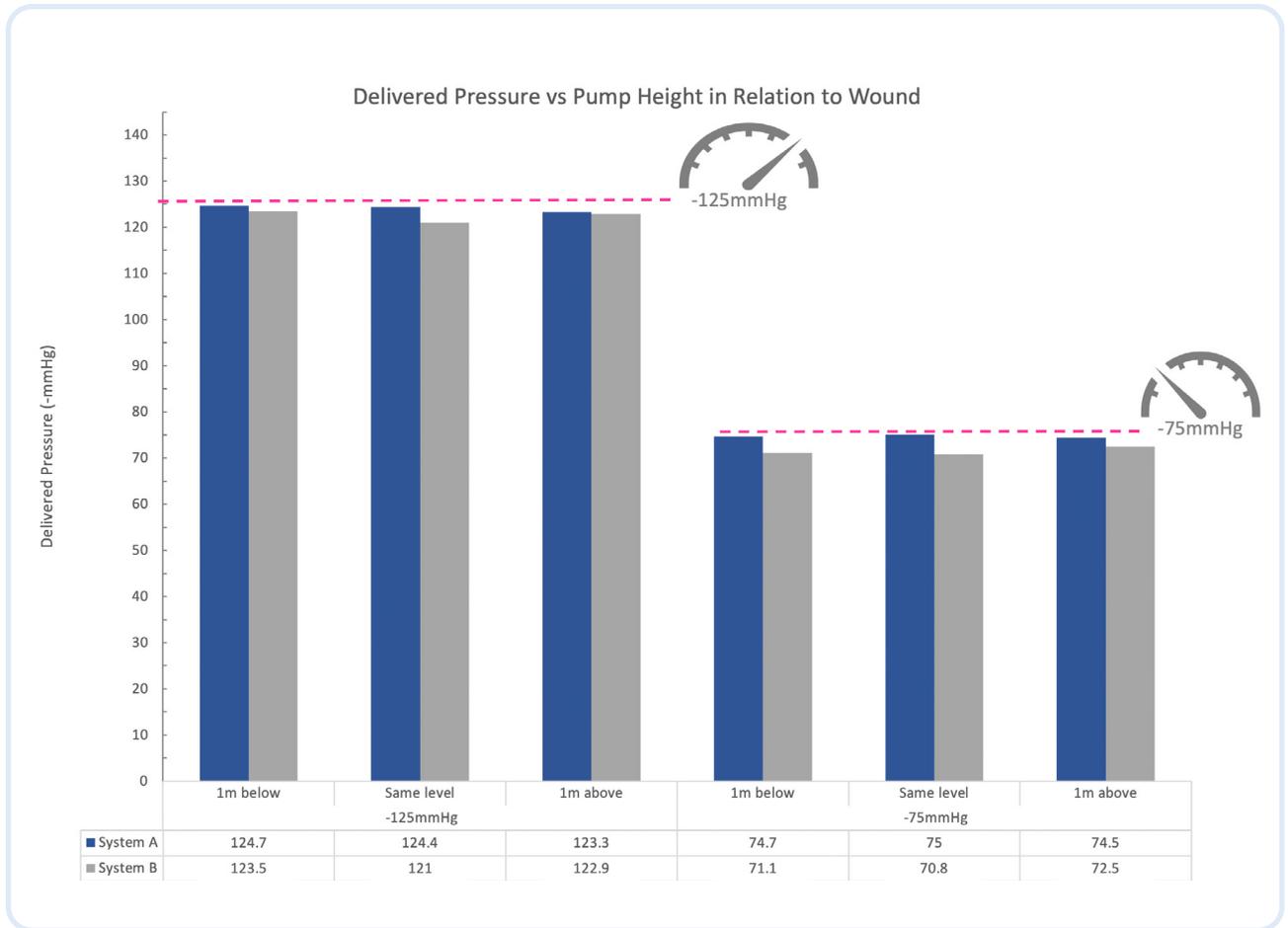


Figure 3. Delivered pressure versus pump height in relation to the wound for both System A and System B.

and maceration, which may damage the wound edge. Efficient removal of exudate is important to prevent the accumulation of necrotic tissue and slough that tend to continually accumulate in wounds and alter the biochemical and cellular environment. Stagnant wound fluid may also increase the risk of abscess formation.”<sup>11</sup> Commercially available systems designed with a constant *airleak* in the drain or film intended to create a constant pressure gradient may assist fluid removal, but will adversely affect the ability to consistently and accurately maintain prescribed pressures in the wound bed. Additionally, a continu-

ous *airleak* inherently creates a steady airflow throughout the NPWT system and across the wound bed, which may have an adverse effect on maintaining a sealed, moist wound environment.<sup>10</sup>

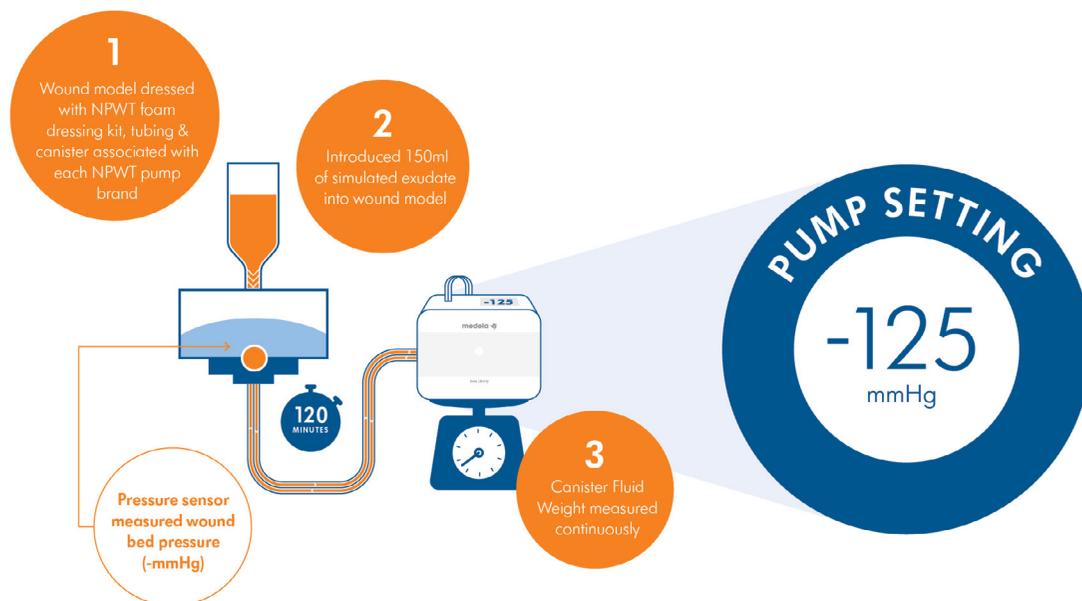
The objectives of this investigation were to compare the ability of a NPWT system (System A) with a common NPWT system (System B) to (1) deliver set levels of negative pressure regardless of position relative to the wound and (2) efficiently manage volumes of fluid introduced during a bolus fluid challenge. The authors hypothesize that while both systems provide consistent pressure at the wound bed, only System A dynamically responds to fluctuations

in fluid amounts and viscosity due to its Dynamic Exudate Removal technology, thereby improving upon the management of complex wounds and elevating the standard of care.

### Materials and Methods & Results

The 2 NPWT systems were compared at 3 different heights with respect to the mock wound (1 meter above; same level; and 1 meter below), and the experiment was repeated at 2 different pressure settings and in triplicates (n = 3) in order to assess the ability of each NPWT system to accurately deliver the set pressure to the wound bed (Figure 2).

## Test method: Efficient Exudate Removal



**Figure 4.** Test method at the same level. NPWT: negative pressure wound therapy

System A accurately and precisely delivered the set level of negative pressure regardless of its position relative to the wound model. This can be attributed to the Intelligent Pressure Control feature, which ensures the prescribed pressure is delivered to the wound site. When the pump was positioned 1 meter above the wound model, presenting the greatest challenge for fluid to travel ver-

tically against gravity, the System A's excellent fluid handling ensured that the delivered pressure was maintained within defined limits of the set pressure; the System B performed comparably (**Figure 3**).

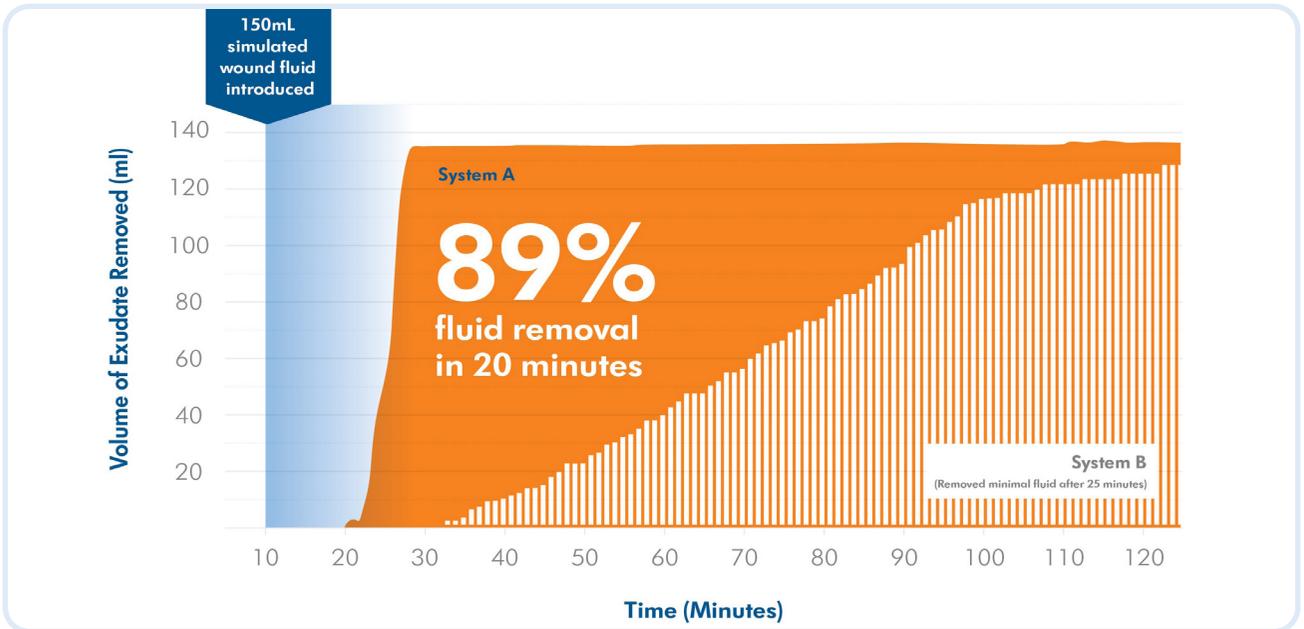
### Efficient fluid removal

In the second portion of the investigation, System A and System B were compared to assess their ability to ef-

ficiently remove simulated wound fluid. The experiment was performed at 2 different pressure settings (-125 mm Hg and -75 mm Hg) and in triplicates ( $n = 3$ ). For this portion, data from the -125 mm Hg setting is shown in this paper. Wound models were dressed with the respective black foam dressing kits specific to each NPWT system, and the system was set up to simulate the delivery of therapy with the wound and pump at similar heights (**Figure 4**). After each system's wound dressing was applied, therapy was initiated and allowed to reach a steady state (~10 minutes) and pressure sensors confirmed pressure at the wound site of -125 mm Hg. After a steady state was achieved, 150 mL of simulated wound fluid was introduced into the wound model.

### Key Point

Intelligent Pressure Control delivered by the System A ensures reliable and accurate delivery of set pressure to the wound bed. Both NPWT systems meet the standard of NPWT, as recommended by EWMA.<sup>1</sup> Each manufacturer has implemented different versions of an electronically controlled feedback system, which are intended to consistently and accurately maintain the therapy settings at the wound bed.



**Figure 5.** Comparison of exudate removal rates between both System A and System B. NPWT: negative pressure wound therapy

Measurements were continuously recorded for airflow cycles, pressure at the wound bed, and fluid weight in the canister. This test method simulates a bolus fluid challenge and measures each NPWT system’s distinct ability to efficiently react and manage wound fluid.

System A removed simulated wound fluid more efficiently than System B by evacuating 89% of the fluid from the mock wound into the canister in under 20 minutes after introduction of the fluid. Conversely, System B made minimal progress towards removing the fluid after 25 minutes.

System B did not attain 89% fluid removal throughout the duration of the experiment (125 minutes long). The results shown here represent a set pressure of -125 mm Hg, with the device at the same level as the wound model; similar observations were made at a set pressure of -75 mm Hg (data not shown).

System A rapidly cleared the fluid due to the Dynamic Exudate Removal

technology, which automatically increases the rate of airflow cycles until the fluid is cleared. The airflow cycles from System B were observed to be static in this investigation and did not initiate a dynamic response to the fluid present in the wound model or tubing (**Figure 5**).

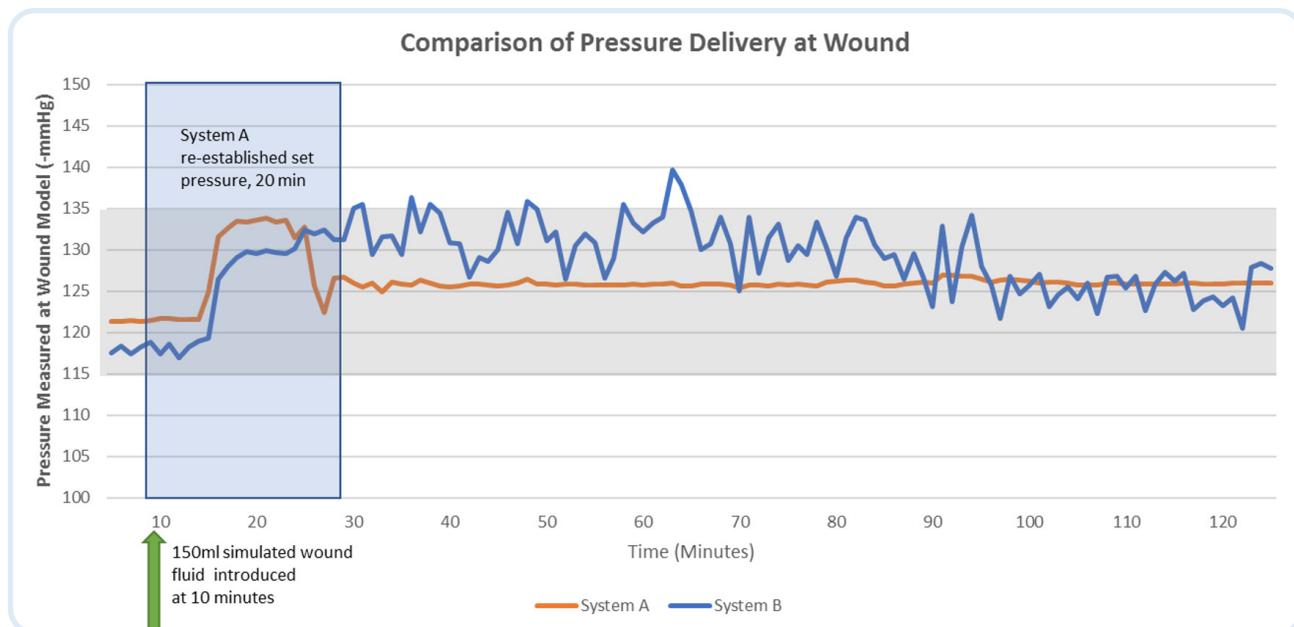
Not all electronically controlled feedback systems with airflow cycles are equal. When System A senses changes to fluid volume and/or viscosity in the tubing, a dynamic airflow cycle is initiated until the tubing is clear of fluid. The manufacturer of System A has the only NPWT devices that optimize fluid removal by dynam-

ically adapting airflow cycles to fluctuating fluid volume and viscosity in the manner previously described.

In less than 20 minutes, System A was able to re-establish a set pressure of -125 mm Hg while simultaneously clearing 89% of the fluid. This accelerated performance is due to the Dynamic Exudate Removal technology working in tandem with Intelligent Pressure Control in order to consistently maintain a set pressure (-125 mm Hg). Excursions from set pressure (-125 mm Hg) were frequent with System B and data points exceeded plus or minus 10%. The pressure data fluctuated widely from the pressure setting on System B

**Key Point**

The electronically controlled feedback system to ensure pressure level maintenance and help give the patient higher safety is not implemented equally in all mechanical NPWT systems. The manufacturer of System A’s devices are the only NPWT devices that optimize fluid removal by dynamically adapting airflow cycles to fluctuating fluid volume and viscosity in the manner described.



**Figure 6.** Comparison of pressure delivery at the wound for both System A and System B. NPWT: negative pressure wound therapy; min: minute

(-125 mm Hg) and was not maintained as closely to the set pressure as System A (Figure 6).

## Discussion

The results from this investigation confirm the Intelligent Pressure Control feature illustrated by System A meets the standard of care defined by EWMA recommendations for an electronically controlled feedback system to maintain the therapy prescribed by the physician. The data show System A performed as efficiently as System B without pressure loss, whether the pump was 1 meter above, 1 meter below, or at the same level as the wound model.

The EWMA standard requiring NPWT systems to deliver accurate pressure to the wound site is integral to ensure the system can deliver the following MOA: wound bed perfusion, drawing wound edges together (macrodeformation), and granulation tissue formation (microdeformation). The constant stimulation between the

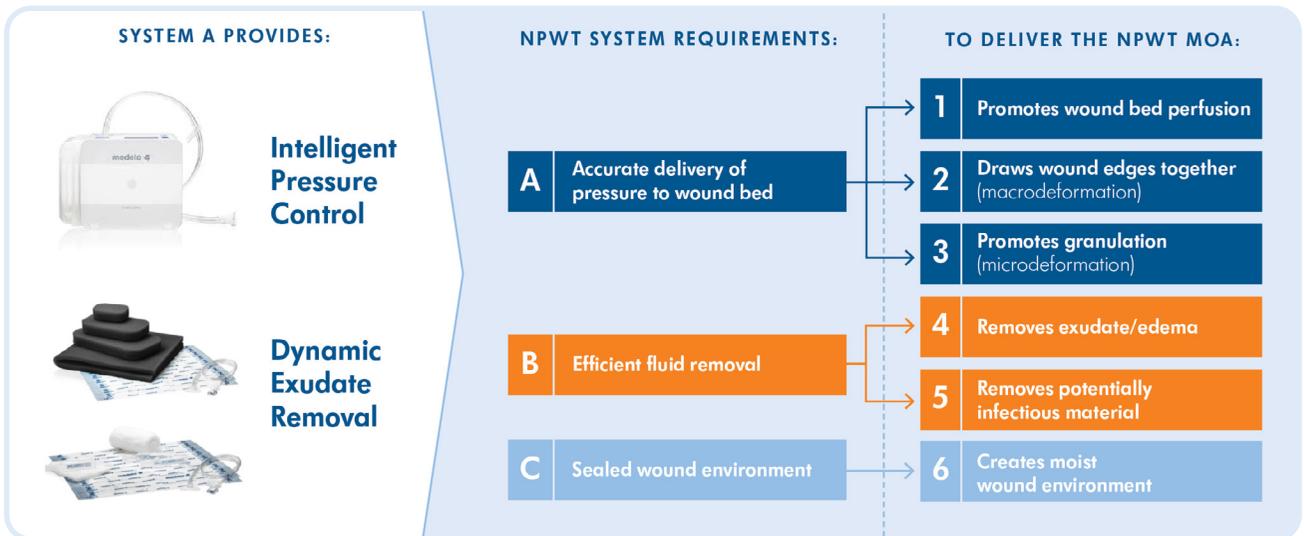
cells and the wound filler, due to a negative pressure, causes a microvascular response and promotes perfusion. The contraction of the wound filler along with the obvious reduction in the size of the wound can be seen when NPWT is applied to most wounds, leading to tissue remodeling and wound healing. There is a more rapid and robust response with granulation tissue formation when NPWT is applied, compared with conventional dressings.<sup>1</sup>

Furthermore, the results of the bolus fluid challenge illustrate that the Dynamic Exudate Removal (unique to Medela NPWT Systems [System A]) allowed for faster and more efficient removal of fluid volumes while maintaining set pressure at the wound bed when compared with System B. This NPWT system efficiently removed 89% of the simulated wound fluid in under 20 minutes, whereas no fluid was removed by the System B unit in the same timeframe.

The EWMA<sup>1</sup> and WUWHS<sup>2</sup> requirements for NPWT systems to efficiently remove fluid is critical, because this property relates directly back to the MOA for NPWT. The effective removal of excess interstitial fluid and edema correlates with improved wound perfusion. Negative pressure wound therapy removes excess fluid and likely infectious materials directly from the wound bed. Efficient removal of stagnant wound fluid supports the reduction of the bacterial load in the wound. The results of this study demonstrate that System A was more efficient in removing wound fluid than System B, likely due to System A's ability to dynamically sense and respond to changing wound conditions with dynamic modification of airflow cycles.

## Conclusions

The MOA, which directly drives the 3 fundamental system requirements of NPWT, are imperative to successfully manage the challenges associated with



**Figure 7.** System A is illustrated here. NPWT: negative pressure wound therapy; MOA: mechanism of action

changing wound conditions. It is important that NPWT systems are able to dynamically sense and respond to fluid volumes and viscosities as wound conditions change. Maintaining tubing that is patent and clear of fluid is essential for NPWT systems to effectively deliver therapy to the wound bed and provide the MOA that are critical to successful wound healing through NPWT. If the set pressure is not delivered to the wound bed, or if fluid is not efficiently removed from the tubing, then the full benefits of NPWT's unique MOA cannot be realized.

This study showed the Intelligent Pressure Control and Dynamic Exudate Removal technologies provided by System A (Invia Liberty NPWT System; Medela AG) improved fluid management and helped reduce the risk of tubing blockages from simulated exudate, while maintaining a set pressure at the wound bed as compared with System B (V.A.C.ULTA Therapy System; 3M + KCI). Thus, System A (Invia Liberty NPWT System) innovates the standard of care (**Figure 7**).

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