Novel Negative-Pressure Wound Therapy System Provides Accurate Pressure Delivery and Exceptional Fluid Handling Capability

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Negative-pressure wound therapy (NPWT) is a widely accepted modality in the treatment of complex wounds.[1] However, there are fundamental requirements[2] not incorporated in all current NPWT systems that must be met in order to realize its full clinical benefits, which include (1) accurately delivering a set level of negative pressure to the wound bed, (2) creating a pressure gradient between the wound bed and the waste canister to efficiently remove fluid and prevent stagnation in the tubing, and (3) maintaining a sealed wound environment. The objective of this investigation[3] was to use a simulated wound model to compare the ability of two NPWT systems (System A, Invia® Liberty™ [Medela AG] and System B, V.A.C.ULTA™ [3M+KCI]) to deliver set levels of NPWT and simultaneously manage volumes of simulated wound exudate.*

TEST METHOD 1: ACCURATE PRESSURE DELIVERY TO THE WOUND BED

This test assessed the ability of System A and System B to accurately deliver set pressure to the wound at three different heights with respect to the wound model and was repeated at two different pressure settings. Data were recorded three times at each height and pressure setting (Figure 1).

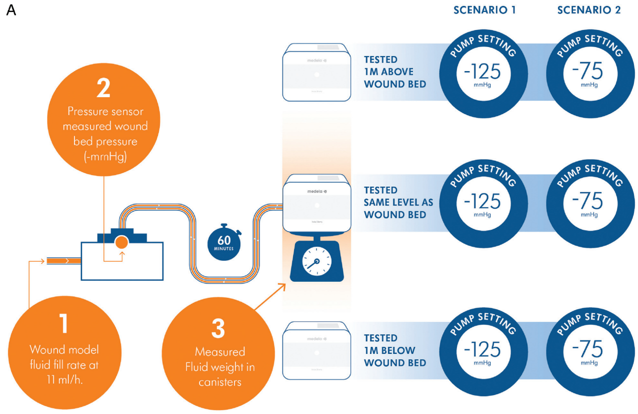
Results. Both System A and System B accurately and precisely delivered the set level of negative pressure regardless of their position relative to the wound model without pressure loss. (Figure 1).

TEST METHOD 2: EFFICIENT EXUDATE REMOVAL

System A and System B were compared to assess their ability to efficiently remove simulated wound fluid at a pressure setting of −125 mmHg. The test was repeated three times per system. Wound models were dressed with the respective black foam dressing kits specific to each NPWT system, and the systems were set up to simulate the delivery of therapy with the wound and at the same height. 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 bed of −125 mmHg. After this, 150 ml of simulated wound fluid was introduced into the wound model. Measurements of airflow cycles, pressure at the wound bed, and fluid weight in the canister were continuously recorded (Figure 2). This test method simulated a bolus fluid challenge and measured each NPWT system's distinct ability to efficiently react and manage wound fluid. (The results shown here represent a set pressure of 125 mmHg with the device at the same level as the wound model; similar observations

Figure 1. TEST METHODOLOGY FOR 1 M ABOVE, SAME LEVEL, AND 1 M BELOW

A



B

	-125 mmHg			-75 mmHg		
	1m below	same level	1m above	1m below	same level	1m above
System A	124.7	124.4	123.3	74.7	75	74.5
System B	123.5	121	122.9	71.1	70.8	72.5

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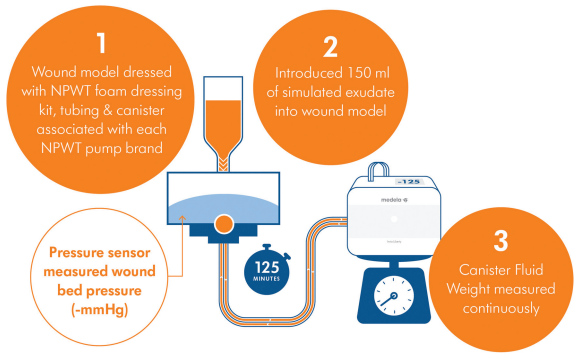
*Testing was conducted at an independent third-party laboratory using a test protocol designed by Medela AG. Outcomes may not be indicative of clinical performance.

Figure 2. TEST METHOD AT THE SAME LEVEL



were made at a set pressure of –75 mmHg [data not shown].)

Results. System A removed simulated wound fluid more efficiently than System B, evacuating 89% of the fluid from the simulated wound into the canister in less than 20 minutes after introduction of the fluid. System B did not attain 89% fluid removal throughout the 125-minute duration of the experiment (Figure 3).

In less than 20 minutes, System A was able to reestablish a set pressure of –125 mmHg, returning patency and delivering consistent levels of therapy at the wound bed. System B fluctuated widely from the set pressure (–125 mmHg) throughout the test method. In addition, System B had frequent excursions that exceeded +/–10 mmHg of the set pressure, directly impacting its ability to maintain set pressure at the wound bed (Figure 4).

Figure 3. COMPARISON OF EXUDATE REMOVAL RATES

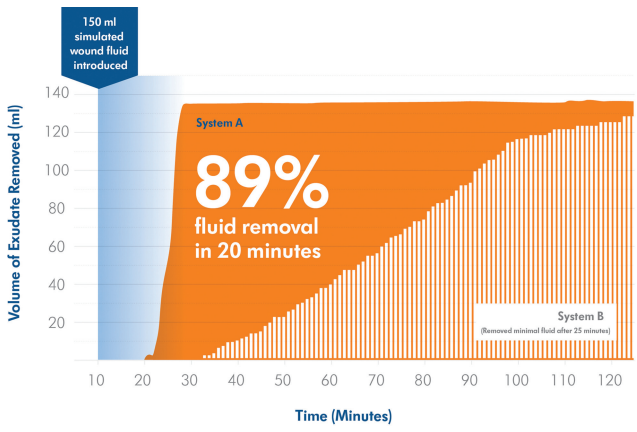
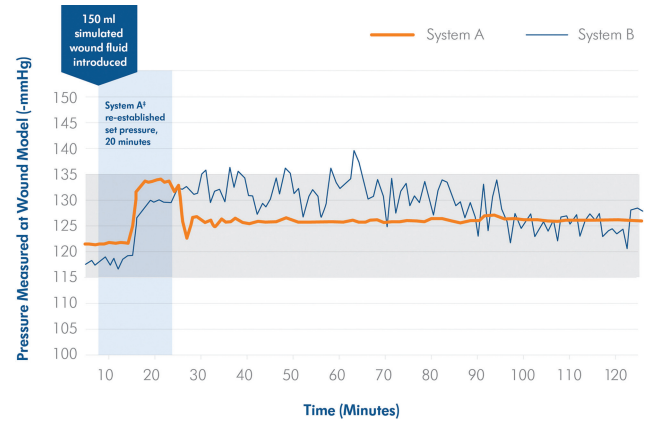


Figure 4. COMPARISON OF PRESSURE DELIVERY AT THE WOUND BED



CONCLUSIONS

This study demonstrated the Intelligent Pressure Control™ and Dynamic Exudate Removal™ technologies provided by System A; it improved fluid management and helped reduce the risk of tubing blockages from simulated exudate while maintaining a set pressure at the wound bed. The results confirm the Intelligent Pressure Control™ feature illustrated by System A meets the standard of care. Further, the results of the bolus fluid challenge illustrate that the Dynamic Exudate Removal™ (unique to 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. Accordingly, System A innovates the standard of care. ●

REFERENCES

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3. Paglinawan R, Schwab P, Bechert K. Negative pressure wound therapy system innovates standard of care via Intelligent Pressure Control and Dynamic Exudate Removal. Wounds 2020;32(10):S1-8.