Novel NPWT System‡ Provides Accurate Negative 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 included in all currently available NPWT systems, that must be met in order to realize its full clinical benefits which include: (A) the set level of negative pressure must be accurately delivered to the wound bed; (B) NPWT must create a pressure gradient between the wound bed and the waste canister to efficiently remove fluid and prevent stagnation in the tubing; and (C) NPWT must maintain a sealed wound environment. The objective of this investigation[3] was to use a simulated wound model to compare the ability of System A‡ and System B^ to measure each system's ability 1) to deliver set levels of NPWT and 2) simultaneously manage volumes of simulated wound exudate.*

* 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.

‡ System A = Invia® Liberty™ (Medela AG)

^ System B = V.A.C.ULTA™ (3M+KCI)

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2. Apelqvist J, Willy C, Fagerdahl AM, et al. EWMA document: negative pressure wound therapy – overview, challenges and perspectives. J Wound Care. 2017;26(Suppl 3):S1–S113.
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-S8.

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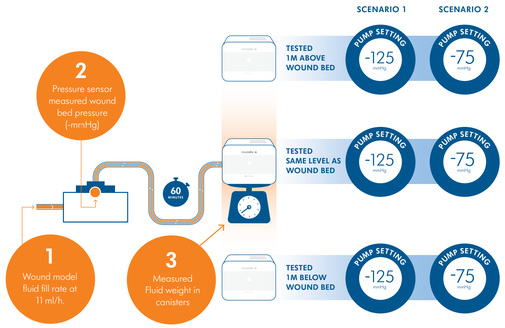
TEST METHOD #1:
Accurate Pressure Delivery to the Wound Bed

This test assessed the ability of System A‡ and System B^ to accurately deliver set pressure to the wound at 3 different heights with respect to the wound model and repeated at 2 different pressure settings.

Data was recorded 3 times at each height and pressure setting (Figure 1).



	-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

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

RESULTS

System A‡ accurately and precisely delivered the set level of negative pressure regardless of its position relative to the wound model as efficiently as System B^ 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 at pressure setting -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 system was set up to simulate the delivery of therapy with the wound and pump at similar heights. 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 mmHg. After a steady state was achieved, 150 ml of simulated wound fluid was introduced into the wound model. Measurements were continuously recorded for airflow cycles, pressure at the wound bed, and fluid weight in the canister (Figure 2). This test method simulates a bolus fluid challenge and measures 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 were made at a set pressure of -75 mmHg (data not shown).

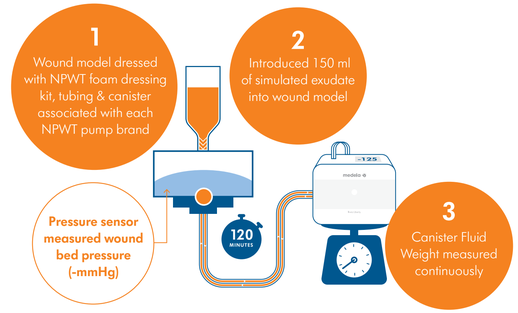


Figure 2. Test method at the same level.

RESULTS

System A‡ removed simulated wound fluid more efficiently than System B^ by evacuating 89% of the fluid from the simulated wound into the canister in under 20 minutes after introduction of the fluid. System B^ did not attain 89% fluid removal throughout the duration of the experiment (125 minutes long) (Figure 3).

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

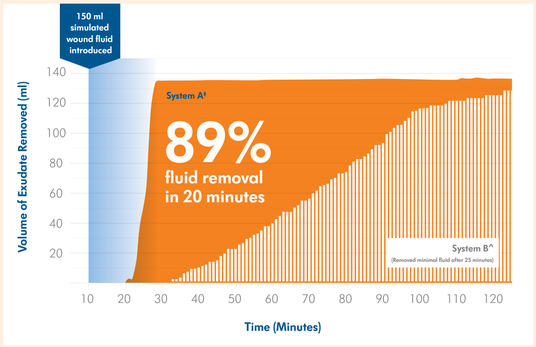


Figure 3. Comparison of exudate removal rates between both System A‡ and System B^.

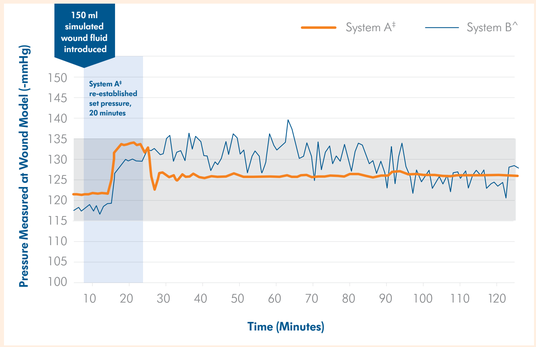


Figure 4. Comparison of pressure delivery at the wound for both System A‡ and System B^.

CONCLUSION: This study showed the Intelligent Pressure Control and Dynamic Exudate Removal technologies provided by System A‡ 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. Furthermore, 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^. Thus, System A‡ innovates the standard of care.