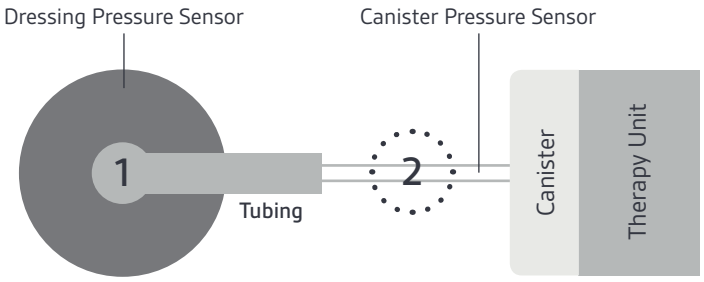
v.a.c.® therapy

NOT ALL NPWT IS THE SAME: BLOCKAGE ALARMS

Background: Blockage alarms on Negative Pressure Wound Therapy (NPWT) Systems serve to detect and notify caregivers of existing blockages that could prevent the programmed negative pressure from being delivered to the wound site. Of equal importance is how the NPWT system responds to a blockage being present. If the unit does not alarm to notify the caregiver to clear the blockage or does not clear the blockage by introducing air and/or increasing pressure, the wound may not receive the programmed therapy, which can result in poor outcomes. To better understand the capability of NPWT systems at detecting and responding to blockages, KCI initiated a bench study designed to evaluate the parameters.

Methods: Multiple NPWT units underwent evaluation: 1) The KCI V.A.C.ULTA™ Therapy System, INFOV.A.C.™ Therapy System and ACTIV.A.C.™ Therapy System 2) Cardinal Health™ NPWT PRO at HOME and PRO to GO Kit; and 3) Smith and Nephew RENASYS™ TOUCH. The various therapy units and their respective foam based dressing kits were set to default parameters of -120/-125mmHg and were evaluated for their ability to trigger blockage alerts or alarms. Blockages* were intentionally created (1) at the interface of the SENSAT.R.A.C.™ Pad or connector interface with the dressing or (2) in the tubing/connector between the simulated wound and the canister. The units of each type were tested in triplicate for a total of 9 evaluations.

Experimental Design Set Up



*The blockage at site 1 was created by placing a polymeric disc at the simulated wound site directly below the connector/SENSAT.R.A.C.™ Dressing site. The blockage at site 2 was created by controlling airflow into the test set-up using needle valves that were based upon the condition being evaluated, either partially or completely close

Results: KCI vs. Cardinal Health™

Location & Blockage Status			Cardinal Health™ Therapy Units (PRO & PRO-TO-GO)				KCI™ Therapy Units - (V.A.C.ULTA™ System, INFOV.A.C.™ System & ACTIV.A.C.™ System)			
	1	2	Blockage Alarm Incidence	Time (s) to Alarm	NP @ Dressing (mmHg)	NP @ Canister (mmHg)	Blockage Alarm Incidence	Time(s) to Alarm	NP @ Dressing (mmHg)	NP @ Canister (mmHg)
A	○	○	No Blockage Alarm	N/A	-123.8 to -124.4	-123.8 to -124.4	0/27	N/A	-120.1 to -128.9	-120.9 to -129.3
B	●	○	**No Blockage Alarm**	**N/A**	**-0.2 to 0.2**	-124.2 to -124.4	27/27	99 – 183	-0.2 to -0.6	-197.0 to -219.7
C	○	●	**No Blockage Alarm**	**N/A**	**-12.0 to -12.8**	-123.8 to -124.1	27/27	62 – 94	-5.9 to -11.4	-191.2 to -221.5
D	○	◐	**No Blockage Alarm**	N/A	-114.4 to -119.1	-132.4 to -138.7	0/27	N/A	-116.3 to -129.6	-129.2 to -160.2

A. Control: No Blockage
- 0% of any units alarmed and no increase in any canister pressures

B. Blockage at the interface of the SENSAT.R.A.C.™ Dressing or SpeedConnect™ connector interface with the dressing
- 100% of KCI NPWT units alarmed and demonstrated higher canister pressures indicating that the systems were actively trying to clear the blockage
- 0% of Cardinal Health™ PRO and PRO to GO units alarmed or demonstrated higher canister pressures

C. Blockage in the tubing/connector between the simulated wound and canister
- 100% of all KCI NPWT units alarmed and demonstrated higher canister pressures indicating that the systems were actively trying to clear the blockage
- 0% of the Cardinal Health™ PRO and PRO TO GO units alarmed or demonstrated evidence of higher canister pressure

D. Partial Blockage in the tubing/connector between the simulated wound and canister
- 0% of both KCI and Cardinal Health™ units alarmed and both demonstrated higher canister pressures

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Results: KCI vs. Smith & Nephew RENASYS™ TOUCH

Location & Blockage Status			Smith & Nephew Therapy Unit (RENASYS™ Touch)†				KCI™ Therapy Units - (V.A.C.ULTA™ System, INFOV.A.C.™ System & ACTIV.A.C.™ System)			
	1	2	Blockage Alarm Incidence	Time (s) to Alarm	NP @ Dressing (mmHg)	NP @ Canister (mmHg)	Blockage Alarm Incidence	Time(s) to Alarm	NP @ Dressing (mmHg)	NP @ Canister (mmHg)
A	○	○	0/9	N/A	-124	-125	0/27	N/A	-120 to -126	-120 to -127
B	●	○	**0/9**	**>600**	~0	-121	27/27	88 – 108	-1	-170 to -196
C	○	●	**9/9**	**141**	-5	-125	27/27	90 - 106	-6 to -7	-202 to -218
D	○	◐	0/9	N/A	**-87**	-125	0/27	N/A	-116 to -126	-134 to -149

†Smith & Nephew RENASYS™ TOUCH set at -120mmHg; KCI Therapy units set at -125mmHg

A. Control: No Blockage
- 0% of any units alarmed and no increase in any canister pressures

B. Blockage at the interface of the SENSAT.R.A.C.™ Pad or SoftPort™ connector interface with the dressing
- 100% of KCI NPWT units alarmed and demonstrated higher canister pressures indicating that the systems were actively trying to clear the blockage
- 0% of the RENASYS TOUCH™ units alarmed or demonstrated higher canister pressures

C. Blockage in the tubing/connector between the simulated wound and canister
- 100% of all KCI NPWT units alarmed and demonstrated higher canister pressures indicating that the systems were actively trying to clear the blockage
- 100% of the RENASYS TOUCH™ units alarmed
- 0% of the RENASYS TOUCH™ units demonstrated evidence of higher canister pressures

D. Partial Blockage in the tubing/connector between the simulated wound and canister
- 0% of both KCI and Smith & Nephew units alarmed
- 100% of all KCI NPWT units demonstrated higher canister pressures indicating that the systems were actively trying to clear the blockage
- 0% of all RENASYS TOUCH™ units demonstrated evidence of higher canister pressures

Discussion: Introduction of air into a closed NPWT system is important for a number of reasons. KCI V.A.C.® Therapy products accomplish this through patented SENSAT.R.A.C.™ Dressings with EASYCLEAR PURGE™ Technology. EASYCLEAR PURGE™ Technology triggers a positive blast of air approximately every 5 minutes through the 4 outer lumens to aid in the prevention and clearance of blockages. EASYCLEAR PURGE™ Technology also helps move exudate from the inner lumen into the canister and assists in the clearance of fluid from the outer lumens, helping to maintain their pressure sensing ability.

The Cardinal Health™ units do not have blockage alarms or a method to introduce air into the system.

The RENASYS TOUCH™ introduces air into the system via an aeration disc located at the end of the SoftPort™ tubing, close to the orange connectors. If a blockage occurs above this aeration disc on the pump side of the tubing, air flow to the unit sensors is interrupted and the blockage alarm is triggered (Scenario C). If the blockage is located closer to the wound, below the aeration disc, air flow is not interrupted to the sensors and the blockage alarm is not triggered (Scenario B).

Conclusions

KCI V.A.C.® Negative Pressure Wound Therapy integrated with SENSAT.R.A.C.™ Technology was shown in bench testing to:
- Perform significantly better in monitoring negative pressure delivery at a simulated wound site and notifying users if blockages exist that could the prevent the programmed negative pressure from being delivered to the simulated wound site.
- Attempt to overcome blockages by increasing negative pressure at the canister

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NOTE: Specific indications, contraindications, warnings, precautions and safety information exist for KCI Products and therapies. Please consult a clinician and product instructions for use. Rx only.

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