Top Vent Study: Optimizing Urine Collection System Flow to Improve Patient Outcomes

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**Clinical problem:**
Current urine collection systems frequently cause sustained positive and negative pressure events on patient’s bladders under normal operating conditions. These pressure events create two main consequences in the clinical setting: 1) patient discomfort and 2) lack of urine flow which would require caregiver intervention.

Recent bladder cystoscope photographs show edema and vascular trauma after only a 20 minute catheterization. This trauma is most likely due to suction events.

### Test Results: Back Pressure:
System pressure was measured at a position to simulate bladder pressure with clinically relevant flow rates. The drain tubes were placed in a typical uphill-flow condition. Airlock, resulting from uphill urine flow, causes back pressure on the patient’s bladder, restricting urine flow.

- **Current non-top vented systems created sustained back pressure events between 26-34 cm of water pressure.**
- **The new DOVER top vented urine meters and drain bags measured no sustained positive back pressure events.**

### Test Results: Pressure Differential
At the conclusion of the back pressure test, the drain tubes were manually emptied to achieve system flow. The system pressure was recorded in order to compare the pressure drop for top vented vs. non-top vented systems. In a traditional non-top vented system, this pressure change creates a sustained pressure event within the bladder.

- **Non-top vented systems measured average pressure drops of 68 cm of water.**
- **The new DOVER top vented systems measured a pressure drop of 23 cm of water or a 66% reduction.**

### Test Results: Suction:
For this bench test, a balloon was placed over a Foley catheter tip to simulate a bladder, and the time to empty 60 cc of water from the drain tube was measured with a stopwatch.

- **Non-top vented systems took an average of 17.1 seconds to empty all of the fluid.**
- **The new DOVER top vented systems took an average of only 4.2 seconds (a 75% reduction in caregiver intervention time).**

While the drain tubes were emptying, a suction event was observed pulling the balloon into the eyehole (left photo). This event releases as soon as the tubing is fully cleared (right photo).

**Top vents were also shown to prevent suction events in the bladder which are caused by flow restrictions.**

### Conclusions:
In-vitro bench testing in this paper shows that the new DOVER Urine Collection systems with top vents prevent any sustained back pressure or suction events in order to maximize urine flow and improve patient comfort. Clinical trials are warranted to confirm these in-vitro results. It also shows a significant decrease in nursing intervention to correct these pressures.
INTRODUCTION:
All urine collection systems are designed to be gravity dependent. There are many challenges in the clinical environment that can compromise the system flow. These include bed limitations, drain bag and tube positioning, flow obstructions etc.

Until now, very little has been published regarding the pressures involved during typical urine collection system use. The Kendall R&D Urology group interviewed caregivers and observed collection systems in use at various hospitals. Here is a summary of the findings.

Positive Pressure Events “Back Pressure”:
The team observed that the most common way of hanging collection systems was to let the drain tube hang down on the side of the bed below the drain bag or urine meter so that urine has to flow uphill. Nurses regularly need to lift up the drain tube in order to empty the pooled urine into the bag or meter in this configuration. This is sometimes done in order to relieve patient discomfort and bladder fullness complaints which are most likely created by these sustained back pressure events.

Explanation: With current non-top vented systems, urine flows from the catheter down through the drain tube and pools at the lowest point in the drain tube. Once urine fills the tube at the low point, the air between the catheter and urine pool is trapped. The bag vents are not effective because the pooled urine is in the way. This “airlock” situation creates a sustained positive pressure on the patient’s bladder while the bladder empties until the pooled urine is manually emptied into the drain bag.

Negative Pressure Events “Suction”:
Urine collection systems are often susceptible to urine back-up near the entry point into the bag or meter. This situation was observed first-hand in hospitals. When this occurs, nurses typically have to either shake the drain tube or drop the bag or meter to the floor in order to get urine flow into the bag or meter.

Explanation: With current non-top vented systems, this urine back-up is caused by flow restrictions which can prevent urine from freely entering the bag or meter. This includes any restriction in diameter along the urine flow path. When this occurs, a meniscus or air bubble forms, which is difficult to break. Bench testing has shown that this situation causes a suction event until it is broken up. Suction events have also been shown to occur at the transition point between high to low urine flow i.e. at initial void or when drain tubes are manually emptied.

Why This Bench Test Was Developed:
This bench test was developed in order to understand the effects of positive and negative pressure events near the patient’s bladder in limiting urine flow through collection systems during realistic-use conditions.

With this bench test, both urine flow rates and drain tube configurations can be varied in order to measure the corresponding pressures in the system.

Through bench testing and observing collection systems in-use, the Kendall Urology R&D group has been able to understand and consistently simulate which conditions cause these pressure events and develop a new top vented urine collection system.

How Top Vents Work:
Top vents (see Photo #1 below) are designed to equalize collection system pressures in order to prevent pressure events from affecting the patient’s bladder. They do this by allowing air into the system to prevent siphon events and allowing air to escape the system to prevent back pressure events. These top vent filters have a plastic inner membrane that will not wet-out during use. This membrane also acts as a bacterial and viral barrier with greater than 99.99% efficiency.

This white paper describes the In-vitro bench test and provides test results in order to show the benefits of new DOVER top vented urine collection systems.
MATERIALS AND METHODS

Test System Description:

This In-vitro bench test was designed for the Kendall Urology R&D group by a fluid dynamics consulting company in order to evaluate different urine collection system designs. It accurately measures both positive and negative system pressures near the catheter, using highly sensitive pressure transducers, during realistic flow conditions. Below is a picture of the test setup (see photo #2).

Back Pressure Test:

System pressure was measured on a pressure transducer at a position to simulate bladder pressure with the following flow rate program, designed to simulate a clinically relevant initial void from a full bladder with the drain tubes placed in a U-shaped uphill-flow condition (see photo #3, top right):

<table>
<thead>
<tr>
<th>TIME (sec)</th>
<th>FLOW RATE (ml/min)</th>
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</thead>
<tbody>
<tr>
<td>15</td>
<td>250</td>
</tr>
<tr>
<td>30</td>
<td>100</td>
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HEAD HEIGHT: 12” from catheter level to hanger level

Three different premium drain bag and urine meter types were tested (n=5 each):

- Tyco Healthcare / Kendall codes 6308 bag & 7000 meter (without top vents).
- C.R. Bard codes 154102 bag & 153304 meter (without top vents).
- New DOVER codes PP bag & P4P meter (with top vents).

Suction Test #1A Pressure Differential:

At the end of the above back pressure test, in the final 30 seconds without flow, system pressures were measured in order to simulate the caregiver manually emptying the drain tube fluid into the collection bag or meter.

This was done in order to measure the pressure difference between the back pressure event caused by forcing urine flow uphill and the suction event that is created when caregivers empty the fluid contents into the bag or meter.

Suction Test #1B Drain Tube Clearing:

This In-vitro test relates to the suction test #1A above, but instead of measuring pressure differential, this test measures the time it takes to empty 60cc of fluid from the drain tube in typical closed systems. Ten new DOVER drain bag codes with and without top vents were tested to the procedure below.

Test Procedure: The drain tube was filled with 60cc of distilled water. A balloon was securely fastened to an 18F catheter to simulate the bladder (see photo #4 on page 5). The tube was lifted, and the time to fully empty all of the fluid into the drain bag was recorded with a stopwatch. The balloon was also observed for suction events while the tubes were clearing.

Suction Test #2 Flow Restriction:

For this test, a technique was developed to cause suction events every time on all non-top vented collection systems. That way, the top vent effectiveness could be evaluated when suction events occur.

These suction events were artificially created by placing a restriction into the drain tube near the bag inlet chamber. This restriction causes a meniscus or air bubble to form which restricts flow and causes suction events.
RESULTS

BACK PRESSURE TEST RESULTS:

Below are the graphical results from this test. Five samples were tested for each urine collection system type and averaged for this graph (see graph #1 below).

![Graph #1]

Using this bench test, it was discovered that uphill flow to the bag or meter caused back pressure events on the patient’s bladder every time without top vents.

The two non-top vented urine meters with longer drain tubes had the higher sustained back pressure events (32-34 centimeters of water pressure) compared to the two non-top vented drain bags (26-28 centimeters of water pressure). This makes sense because urine had to flow farther uphill with the longer drain tubes.

Both new drain bag and urine meter versions with top vents produced no positive back pressure events — stayed near the zero pressure line on the x-axis.

SUCTION TEST RESULTS:

TEST 1A Pressure Differential Test

As the tubes were lifted, the results show a drop from positive back pressure to negative suction events.

For both the current Kendall and Bard systems without top vents, the average pressure drop measured 68cm of water pressure when emptying the drain tube fluid.

For the new DOVER systems with top vents, the average pressure drop measured only 23cm of water pressure. This represents a 66% reduction in pressure differential in this clinically relevant situation (see graph #2 below).

### SUCTION TEST PROGRAM

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<th>TIME (sec)</th>
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**PROFILE— 0 to 90 Degrees**

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*HEAD HEIGHT: 12’ from catheter level to hanger level*

![Table #2]
TEST 1B Drain Tube Clearing Test

Along with the above pressure differential improvement, the time that it takes for the caregiver to clear the drain tube, and the suction event duration is also reduced for top vented systems.

With top vents, it only takes an average of 4.2 seconds to empty 60cc of urine from closed collection system drain tubes. This represents a 75% reduction in the time it takes for caregivers to clear drain tubes with non-top vented systems.

When these drain tubes are manually emptied by caregivers, a suction event can be seen sucking the balloon (simulated bladder) into the catheter eyehole for the entire duration until the tubing is cleared (see photos #5 & #6 for the suction and no suction event comparison).

Without top vents, these suction events reach up to negative 18 cm of water and last until the restriction is broken by either water head height pressure above it or by manually shaking the system near the restriction to break it up.

With top vents, the same systems do not allow any sustained suction events (stay near the zero line). They do this by allowing air into the system to eliminate the negative pressure (see graph #3 below).

TEST #2 Top Vent vs. No Top Vent Test (Flow Restricted)

This worst case urine flow bench testing showed that suction events could be intentionally created with an artificial flow restriction in all non-top vented systems, even those that wouldn’t otherwise be readily susceptible to siphons.
DISCUSSION:
This In-vitro bench test was able to accurately simulate the clinical environment and measure pressures near the patient.

Any pressure on the bladder due to the collection system will prevent optimal urine flow and can potentially cause patient discomfort events in the form of bladder fullness, urge to void, bladder distension, bladder spasm etc.

In-vitro test results demonstrate that top vents prevent any sustained back pressures from reaching the bladder, thus optimizing system urine flow and patient comfort and minimizing caregiver intervention.

A previous In-vivo top vent bladder study found that suction lesions formed due to sustained suction events on all 53 patient bladders with non-top vented systems while none formed on all 52 bladders with top vented systems. These lesions were shown to occur in less than 20 minutes and became progressively worse over time.

To confirm these McDonald study results, the following bladder cystoscope photographs of non-top vented systems were recently taken at Massachusetts General Hospital (see photos 7 & 8 below).

These photos show bladder vascular changes after less than a half hour of catheterization during a surgical urethral sling procedure. These changes most likely occur due to suction events which form at the transition point from high to low urine flow through the collection system.

CONCLUSIONS:
The Kendall Urology R&D group has developed a solution to improve flow in a urine collection system. In-vitro bench testing showed that the new DOVER Urine Collection systems with top vents significantly reduce any sustained back pressure or suction events.

The DOVER top vent is a unique state-of-the-art device designed for the patient and caregiver alike to:

- Cancel out both positive and negative pressures exerted on the bladder.
- Maximize urine flow.
- Improve patient comfort.
- Significantly decrease the need for nursing intervention.

REFERENCE: