

OSCILLATION AND LUNG EXPANSION (OLE) THERAPY:

Measured Effects of Adding Continuous High Frequency Oscillation (CHFO) to Mechanical Ventilation in a Laboratory Test Setting

Hillrom contracted Valley Inspired Products as an independent lab to test the effect of adding OLE therapy to a mechanical ventilator. The data in this report are representative of the interaction of OLE therapy with mechanical ventilation utilizing Pressure Control and Volume Control ventilation modes in two common mechanical ventilators, Puritan Bennett 840 and Maquet Servo-i. All testing in this report was done using a Series 1101 Breathing Simulator-Hans Rudolph, Inc. Normal adult lung volume and compliance settings were used.

This data is provided to serve as a guide to clinicians regarding the effects of using OLE therapy inline in two common ventilator modes.

When using OLE therapy with mechanically ventilated patients, the individual patient diagnosis and clinical condition must be considered.

PURITAN BENNETT 840	Tidal Volume	Peak Pressure	PEEP	Itime	Alarm	Alarm	Alarm	Alarm
Ventilator/Mode					Pk Press	F	Min Ve	Mand Vol
Pressure AC	NA	11 (6>PEEP)	5	1.33	25	30	5/15	300/900
Volume AC	670	NA	5		25	30	5/15	300/900

MAQUET SERVO-I	Tidal Volume	Peak Pressure	PEEP	Itime	Alarm	Alarm	Alarm	Alarm
Ventilator/Mode					Pk Press	F	Min Ve	EEP
Pressure AC	NA	11 (6>PEEP)	5	1:2	25	5/30	5/15	2/10
Volume AC	600	NA	5	1:2	25	5/30	5/15	2/10

Findings of this laboratory study suggest the following:

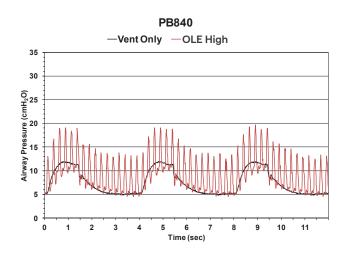
- a. Tidal volume and minute volume measurements as shown on the ventilator may be skewed. Breathing simulator measures, which are indicative of actual tidal volume and minute volume, were considerably less than that shown on the ventilator.
- Peak pressure measurements are somewhat elevated with OLE therapy inline. Mean pressures are also elevated, but the change in mean pressure is relatively
- small. This suggests that elevations seen with peak pressures are not sustained within the lung. Pressure increases are greater in Volume Control modes than in the Pressure Control modes.
- c. In this laboratory test, minor adjustments were made to alarms and sensitivity settings. The breathing simulator in this test did not generate spontaneous breaths. Adjustments made may underestimate the adjustments that are needed when using OLE therapy on a spontaneously breathing patient.

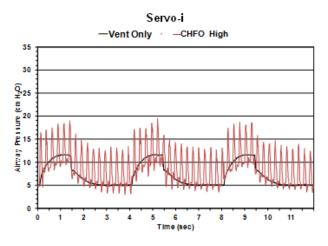
PRESSURE CONTROL VENTILATION

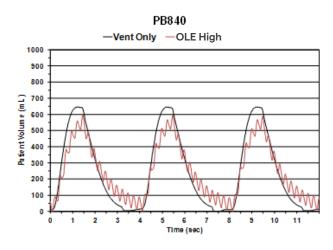
PRESSURE AND VOLUME WAVEFORMS

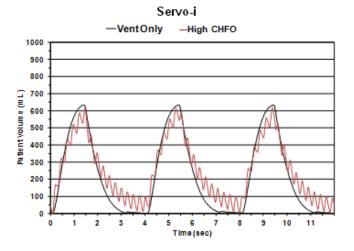
Graphs below show waveforms generated from breathing simulator data. Breathing simulator data taken using the Puritan Bennett 840 ventilator is in the left column and data from the test using the Maquet Servo-i is in the right column. These graphics represent waveforms generated from the ventilator breaths alone and concurrently with OLE therapy (superimposed colored waveforms).

PRESSURE VENTILATION MODE: CHFO HIGH







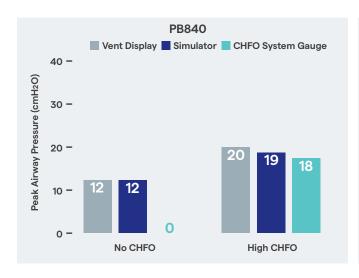


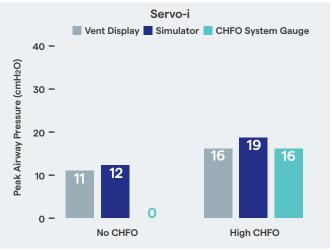
PRESSURE CONTROL VENTILATION AIRWAY PRESSURE MEASUREMENT

PEAK AIRWAY AND MEAN AIRWAY PRESSURE

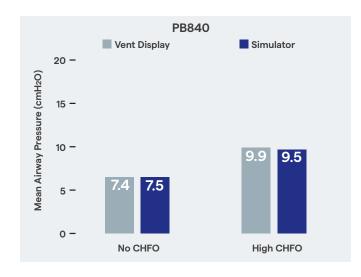
Peak airway pressures measured in the breathing simulator increased somewhat with both High and Low CHFO. Mean pressures show a relatively small increase with the introduction of OLE therapy, suggesting that higher pressures are not sustained. Simulator pressure measurements represented by the blue colored bars are suggestive of actual pressure in the lung.

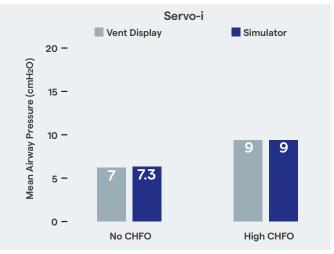
CHFO HIGH: PEAK AIRWAY PRESSURE MEASUREMENTS





CHFO HIGH: MEAN AIRWAY PRESSURE MEASUREMENTS



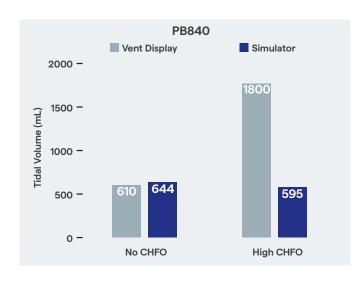


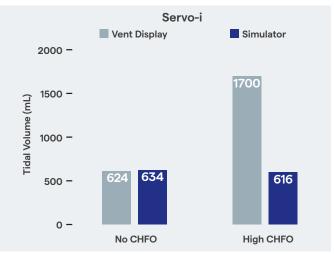
PRESSURE CONTROL VENTILATION TIDAL VOLUME AND MINUTE VOLUME MEASUREMENTS

TIDAL VOLUME AND MINUTE VOLUME

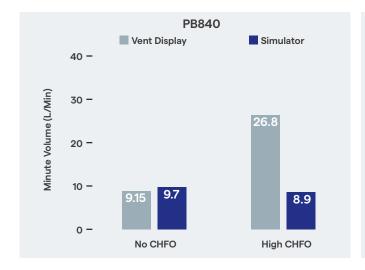
Tidal volume and minute volume measured in the breathing simulator shows little change with the addition of OLE therapy. Readings on both ventilators showed considerably higher volumes. Simulator volume measurements are represented by the blue colored bars.

CHFO HIGH: TIDAL VOLUME MEASUREMENTS





CHFO HIGH: MINUTE VOLUME MEASUREMENTS



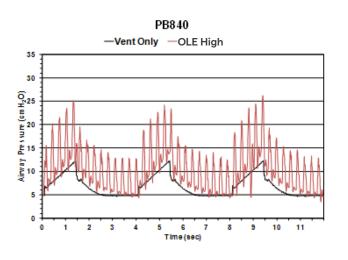


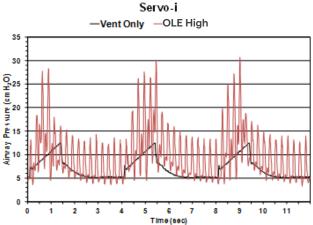
VOLUME CONTROL VENTILATION

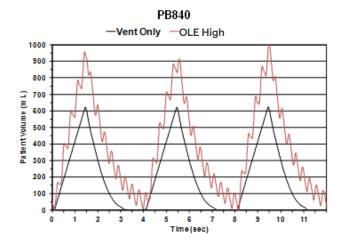
PRESSURE AND VOLUME WAVEFORMS

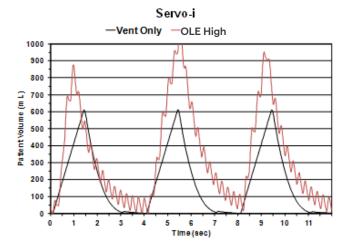
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VOLUME VENTILATION MODE: CHFO HIGH









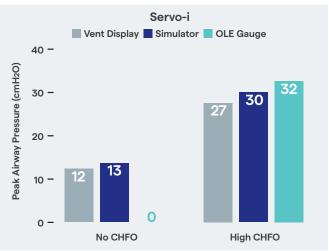
VOLUME CONTROL VENTILATION AIRWAY PRESSURE MEASUREMENT

PEAK AIRWAY AND MEAN AIRWAY PRESSURE

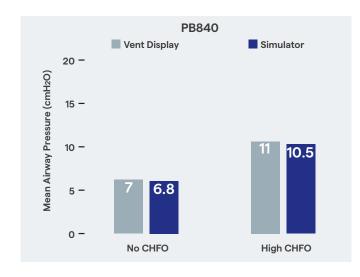
Peak airway pressures measured in the breathing simulator increased somewhat with both High and Low CHFO. Pressure increases are somewhat higher than those seen in pressure control modes. Similar to what is seen in the pressure control modes, mean pressures show a relatively small increase with the introduction of OLE therapy, suggesting that higher pressures are not sustained. Simulator pressure measurements represented by the blue colored bars are suggestive of actual pressure in the lung.

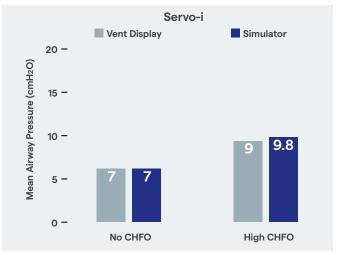
CHFO HIGH: PEAK AIRWAY PRESSURE MEASUREMENTS





CHFO HIGH: MEAN AIRWAY PRESSURE MEASUREMENTS



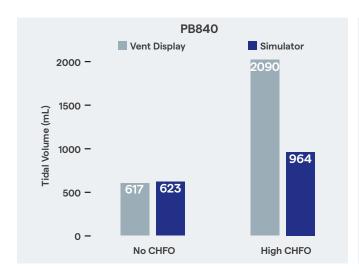


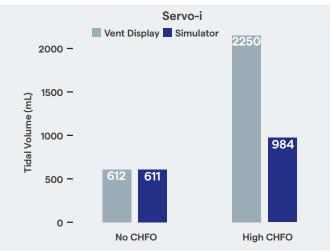
VOLUME CONTROL VENTILATION TIDAL VOLUME AND MINUTE VOLUME MEASUREMENTS

TIDAL VOLUME AND MINUTE VOLUME

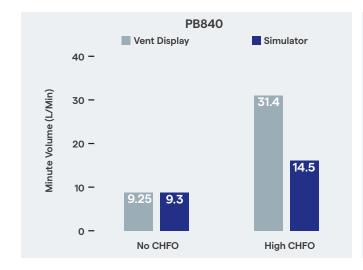
Tidal volume and minute volume measured in the breathing simulator shows approximately a 30% increase with the addition of OLE therapy. Readings on both ventilators showed considerably higher volume than that measured in the breathing simulator. Breathing simulator volume measurements are represented by the blue colored bars.

CHFO HIGH: TIDAL VOLUME MEASUREMENTS





CHFO HIGH: MINUTE VOLUME MEASUREMENTS





ALARMS AND BREATH TRIGGER SENSITIVITY

In this laboratory test, minor adjustments to alarms and sensitivity settings were made. The breathing simulator in this test did not generate spontaneous breaths. Therefore, adjustments made in this test may underestimate the changes that will be needed for spontaneous breathing patients. Procedure for adjusting alarms and sensitivity is described below.

With the ventilator display screen continually monitored, individual adjustments to both the flow trigger setting and pressure trigger setting were made so that all breaths in either trigger mode were ventilator initiated.

All changes if any, were manually recorded. The ventilator was then set to remain in pressure trigger mode.

With the ventilator display continually monitored for real-time parameters, adjustments to the alarm limits were made by changing any limit that is shown to have been exceeded during CHFO mode (e.g., peak pressure). When all alarm limits were adjusted as needed, the ventilator ceased alarming. Any changes to alarm limits to silence the ventilator were manually recorded.

PRESSURE CONTROL VENTILATION MODE

Required setting changes marked in Turquoise.

Measure: Alarm Settings

PB840	Pk Press	F	Min Ve	Mand Vol
No CHFO	25	30	5/15	300/900
High CHFO	25	30	5/28	300/1900

SERVO-I	Pk Press	F	Min Ve	Mand Vol
No CHFO	25	5/30	5/15	2/10
High CHFO	25	5/30	5/27	2/10

VOLUME CONTROL VENTILATION MODE

Required setting changes marked in Turquoise.

Measure: Alarm Settings

PB840	Pk Press	F	Min Ve	Mand Vol
No CHFO	25	30	5/15	300/900
High CHFO	28	30	5/32	300/2200

SERVO-I	Pk Press	F	Min Ve	Mand Vol
No CHFO	25	5/30	5/15	2/10
High CHFO	28	5/30	5/34	2/10

Measure: Trigger Settings

PB840	Flow	Pressure
No CHFO	2.5	0.5
High CHFO	2.5	1.5

SERVO-I	Pressure	Pressure
No CHFO	1	-1
High CHFO	1	-1

Measure: Trigger Settings

PB840	Flow	Pressure
No CHFO	1.0	1.0
High CHFO	1.0	1.5

SERVO-I	Pressure	Pressure
No CHFO	1	-1
High CHFO	1	-1

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