
VENTILATOR DISPLAYED TIDAL VOLUMES: A BENCH COMPARISON OF TWO NIV VENTILATORS IN SIMULATED TEST CONDITIONS

Valley Inspired Products
Bob McCoy & Ryan Diesem

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Introduction and Purpose

Small, portable ventilators capable of providing noninvasive ventilation (NIV) are utilized in both the hospital and home care settings. NIV ventilators have their roots in both larger hospital-based ventilators as well as smaller, home-care based bilevel machines. As with larger hospital-based ventilation systems, portable NIV ventilators have a wide array of settings to provide the patient with the necessary treatment, as well as display vital patient information during therapy. Portable NIV ventilators also come in a much smaller footprint, comparable to typical home care bilevel devices, and utilize noninvasive interfaces for treatment, similar to most bilevel devices.

Each NIV ventilator is marketed toward a similar audience, yet like most applied medical products on the market, each NIV ventilator has its own set of capabilities, features, and limitations. Patents, design, material, and specifications can all impact the performance abilities of a given ventilator, and these variables and capabilities often are not understood by the persons using or monitoring these unique devices. Additionally, patients are widely variable in their needs for treatment, and NIV-specific interfaces also have variable performance capabilities—leak rates, dead space volume, fit, etc. This combination of equipment variability and dynamic patient scenarios routinely creates unique scenarios for the clinician to adapt NIV therapy to, often with little support material to reference.

Hospital-based ventilation equipment faces similar issues—hospital ventilators also have performance variability with design and capabilities. One recent study by Marchese, et al, compared six hospital-based ventilators in varying patient and performance settings and concluded that there were, “important performance differences between the ventilators,” and that clinician chosen “optimal” settings resulted in better performance than default settings recommended by the manufacturer. They also reported that the majority of ventilators performed at an “acceptable” level during most of the tests, but that there were also performance inadequacies in some others. In the end, it was suggested that, “bedside clinical evaluation is needed.”

Unfortunately, there is very little support material like the Marchese article to help clinicians and users understand the product variability of portable NIV ventilators. Part of the reason for a lack of studies in the literature is the relatively recent introduction to the market of many of these devices—many people are still just learning of these devices’ availability and capabilities, and there just has not been enough time for significant and thorough product comparisons to be performed and reported on.



The aim of this paper and study was to document results from bench testing performed on two unique NIV ventilators with regards to one specific issue relating to volume monitoring in different ventilator/patient scenarios. Portable NIV ventilators report patient tidal volume (Vt) via the display screen to inform the operator of the current volumes being delivered. The purpose of this comparison was to determine the accuracy of the displayed tidal volumes in select conditions on two newer models of ventilators indicated for NIV use. It is hoped that this testing and the results will yield further clinical evaluation of NIV ventilator performance in the field.

Methods

The objective of this evaluation was to determine and compare reported tidal volume accuracy characteristics of ResMed’s Stellar™ 100 ventilator system (ResMed Corp., San Diego, CA) with ResPironics’ V60 ventilator system (ResPironics Inc., Murrysville, PA) in test scenarios mimicking passive adult ventilation treatment. Displayed and calculated volume accuracy, with and without unintentional leak present, were recorded and analyzed for several simulated passive adult patient and ventilation scenarios.

Equipment

The following ventilators and circuits were used for testing:

Stellar 100 Ventilation System – ResMed Corp
Equipped with standard ResMed SlimLine™ tubing.

V60 Ventilation System – Philips ResPironics Inc.
Equipped with Fisher & Paykel RT139 ventilator circuit.

Circuit is manufactured for use with ResPironics V60/Vision® ventilators

Ventilator circuits are equipped with the following mask:

Equipped with Fisher & Paykel RT040M Vented NIV mask

Mask is vented, so no exhalation valve used with vent circuits. F&P RT040M mask is a “neutral” mask (not made by ResMed or ResPironics) designed for NIV use, so the comparison has no bias relating to the interface. F&P has marketed the mask and circuit in the hospital for use with the V60 and Vision vents. It has been used actively in clinical settings.

The following additional equipment was used for conducting testing:

Series 1101 Breathing Simulator – Hans Rudolph, Inc.

3mm thick clear plastic plate

Great Stuff™ Foam Sealant – Dow Chemical

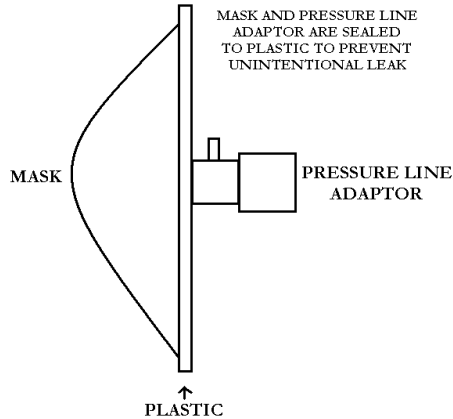
22mm ID/22mmOD Adapter (3) – Qosina

One adapter drilled to allow 36 LPM leak at 15cm H₂O pressure



Test Setup

Prior to testing, the RT040 mask was sealed to a plastic plate fitted with a 22mm ID/OD adaptor with foam sealant. This allowed the mask/circuit to be connected to the Breathing Simulator connection port for all adult simulated tests. Seals were checked prior to testing to ensure minimal to no unintentional leak.



Drawing of mask assembly

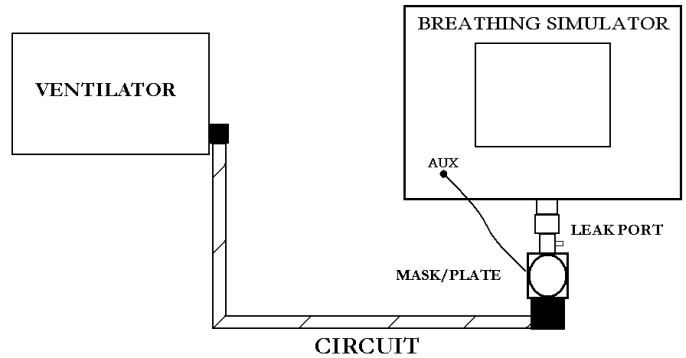
Simulated Passive Adult Test Setup Configurations:

The Stellar 100 ventilator was equipped with ResMed SlimLine tubing. There is no pressure line. The V60 ventilator was equipped with an RT139 circuit, with the proximal pressure line connected to the pressure port on the RT040 full face mask.

Prior to each series of ventilation tests, the circuit and/or mask was run through the selected ventilator's mask/circuit configuration test to account for resistance and/or leak through the circuit. The Stellar 100 unit's circuit configuration test required the mask/circuit to be open to atmosphere during the test. For each of the tests, the mask setting was set to "Full Face." The V60 unit's circuit configuration test was set to "Other/Other" and required the mask/circuit to be occluded at the patient connection to complete the test.

Each ventilator under test was set to operate in the ST mode (or equivalent), and set to breathe at a rate of 12 BPM with an I-time of 1.5 seconds.

The Breathing Simulator was set to operate in a passive state (i.e. no active breathing) by setting the Amplitude value of the breathing parameters to a value of 0. Data collection settings were configured such that patient flow, tidal volume, and airway pressure were recorded for at least four full, consecutive breaths.



Drawing of test setup

Test Procedures

Each ventilator was tested in a variety of passive adult ventilation scenarios, which are shown in the table below. Variable settings on the ventilator included IPAP/EPAP and Rise Time settings; variable patient parameters on the Breathing Simulator included Lung Resistance and Lung Compliance. There were a total of 162 ventilation configurations tested on each ventilator.

Testing Scenario Combinations			
Ventilator Settings		Simulator Settings	Leak Settings
IPAP/EPAP	Rise Time	Resistance / Compliance	Unintentional Leak
10/5			
20/5			
30/5			
40/5	"MIN" Stellar, "1" V60	5 ml/cmH ₂ O / 70 cmH ₂ O/l/s	No Leak
20/10	500ms Stellar, "3" V60	10 ml/cmH ₂ O / 50 cmH ₂ O/l/s	36 LPM @ 15 cmH ₂ O
30/10	900ms Stellar, "5" V60	20 ml/cmH ₂ O / 20 cmH ₂ O/l/s	
40/10			
30/20			
40/20			

For each ventilation configuration, the Breathing Simulator recorded data for no less than four full, consecutive breaths. Concurrently, the ventilator displayed tidal volume (a measure of averaged exhaled volume over a series of breaths) was recorded from the ventilator display.

For tests with unintentional leak added, the 22mm ID/OD adapter modified with leak ports that allow leak flow measuring 36 lpm @ 15cm H₂O was inserted between the mask and simulator airway port immediately after tests with no leak were completed.

Once all test data was collected, displayed volume was correlated and compared to recorded exhaled volume from the simulator in each test scenario. In the events where there was auto-triggering, mask anti-asphyxia valve activation, and/or Breathing Simulator high volume limit being reached during a given test, volume accuracy was not noted for that test due to the unpredictability of performance.

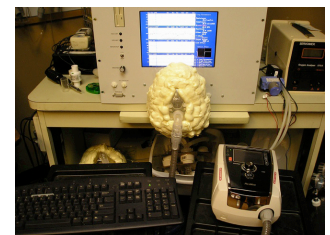


Image of test setup with Stellar

Findings

Volume Accuracy: Percent Difference Between Vent Displayed and Actual Exhaled Tidal Volume	
Stellar (No Leak)	0% (Std Dev 5.4%)
Stellar (w/Leak)	1% (Std Dev 5.2%)
V60 (No Leak)	19% (Std Dev 7.4%)
V60 (w/Leak)	12% (Std Dev 11.2%)

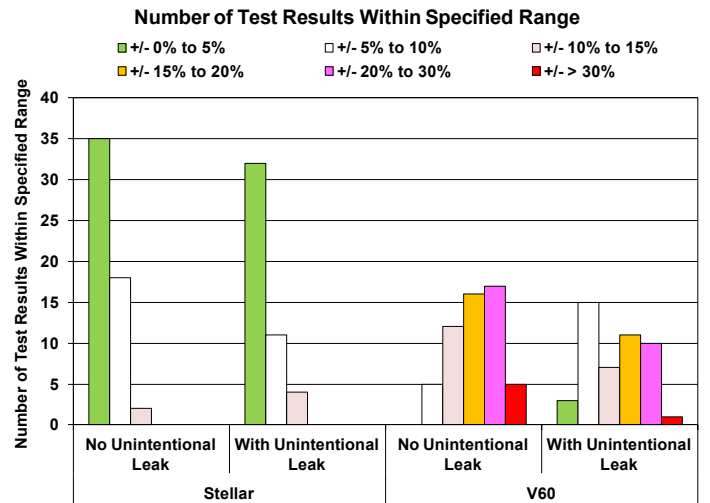
See appendix for more detailed results

Ventilator displayed volumes tended to be higher than actual tidal volumes, though there were several instances of lower volumes reported, many occurring in the low 10/5 pressure settings and/or scenarios where maximum Rise Time was selected. Issues seen during testing included the ventilator auto-triggering or skipping breaths, the Breathing Simulator having its high volume limit reached, and/or the mask's anti-asphyxia valve activating. These issues were more frequent in healthier lung scenarios with more extreme ventilator settings (e.g. 40/5 IPAP/EPAP), as well as when unintentional leak was present. In instances where only one ventilator was able to provide consistent data for a given scenario, that data was not included in the comparison results. All compared data is from tests where both ventilators tested were able to perform in a consistent manner.

The Stellar ventilator was more accurate in estimating tidal volume than the V60. With or without leak present, data from the various tests on the Stellar unit showed the overall average difference in displayed vs. actual volumes was only +0—1%, with the standard deviation value around 5%. Volume differentials from the V60 with leak were +18% (Std Dev 7.6%) and without leak were +13% (Std Dev 11.2%).

Both ventilator models estimate volume based on the flow. The mask and circuit used for this testing may have had an effect on a ventilator's ability to estimate tidal volume, though performing the ventilator's circuit test prior to each series of tests is meant to allow the ventilator to compensate for any mask and/or circuit configurations that affect performance.

Additionally, the RT040 mask used during testing features a vented shell as opposed to separate exhalation port, requiring a built-in anti-asphyxia valve in the mask swivel. This anti-asphyxia valve tended to open and close during large pressure swings, affecting each ventilator system's performance and results to varying degrees. Using a typical NIV mask with a standard exhalation port may have eliminated some auto-triggering seen in certain tests and yielded more significant results. If tests are repeated in the future, an NIV mask without an anti-asphyxia valve is recommended.



This graph shows the number of recorded test results where the volume displayed by the NIV ventilator was within the specified range of the actual tidal volume recorded from the Breathing Simulator.

Discussion and Conclusions

Noninvasive ventilation (NIV) has become a standard of care for initial intervention for mechanical ventilation to prevent the complications associated with invasive ventilation. Quick access to needed ventilation and improved patient tolerance has driven the adoption of this method of ventilation. Initial obstacles to acceptance of NIV have been overcome with clinician and patient education, new ventilation systems, and improved patient interfaces. NIV does have limitations that are not seen with invasive ventilation including control of the patient as patient interaction is required, control of the ventilator parameter as leak is necessary for a passive exhalation valve, and inadvertent leak which is common with mask seal issues. Blower-based ventilators also have limitations regarding delivery pressure and volume with varying patient resistance and compliance concerns.

Historically, ventilators had simple controls that were understandable by most clinicians which allowed anyone attending the patient to make ventilator changes. Initial use of NIV was applied either with a critical care ventilator set for noninvasive use or bilevel devices that were developed for sleep therapy. Monitoring the patient and ventilator with the early devices was a challenge as neither was developed for a routine use of NIV. The clinician would set the device and use clinical judgment to determine the effectiveness of the setting. Objective recording of settings was difficult so documentation of the settings was also difficult. As NIV devices evolved, more sophisticated monitoring was possible with ventilator parameters set for optimal patient outcomes, but it also became more difficult for any clinician other than trained users to make informed changes. There is still a need for effective communication between respiratory therapists monitoring and maintaining the ventilator to document any changes to ensure the continuity of care. If a therapist makes changes based on clinical judgment the monitoring of parameters provided by the ventilator may not be consistent with a prescription due to the variability of equipment.

Equipment variability is inherent with all respiratory products and no device should be considered a commodity when selecting a specific respiratory product. Any clinician managing equipment used to treat a patient should be familiar with equipment performance variables to make informed decisions relating to patients' settings and necessary changes. Monitoring of device performance requires knowledge of the product, critical decision making ability, and the ability to learn from experience.

With this thought in mind, and as an additional part of this evaluation, an informal, non-scientific survey was sent out to clinicians to gauge their opinions relating to the importance of ventilator volume estimation. When asked how important volume reporting accuracy was, all respondents scored their response between 7 and 9 on a 1-10 scale, with a majority also feeling that a +/- 10% difference in reported vs. actual volumes was acceptable range of error. All but one respondent said they do not assume that the ventilator's displayed tidal volume is accurate at all times.

Each survey respondent noted scenarios where they have had to adjust ventilation parameters due to an actual and/or perceived discrepancy between the ventilator displayed volume and actual delivered volumes. All respondents noted that due to factors like compression and leak, tidal volume related parameters on the ventilator have had to be set higher than what is expected to

be delivered, though some noted this occurred only occasionally while others have seen this often. All but one respondent felt that product education and familiarity/experience in understanding how well a ventilator delivers its volume was very important (with the other respondent noting it was somewhat important).

This evaluation on the monitoring of NIV ventilator reported volumes and the differences in product performance suggest that there is a need for better product knowledge to assist the clinical side of care in recognizing the accuracy of the recorded volume. More research on the variability of NIV devices and their performance is recommended as little to no information is available in the literature on this topic.

This testing and paper has shown only one area of information related to the differences in performance of NIV ventilators as they monitored volume variability. Hopefully more fully realized bench and clinical studies relating to NIV ventilator performance will be available sooner rather than later. Until then, clinicians should be provided information and education on the devices used for noninvasive ventilation along with other available resources until more peer reviewed evidence is available.

References

Marchese, Andrew D., et al. Performance of Current Intensive Care Unit Ventilators During Pressure and Volume Ventilation. *Respir Care* 2011; 56(7):928-940.

Appendix

Detailed Results

Overall Performance Results

Volume Accuracy: Percent Difference Between Vent Displayed and Actual Exhaled Tidal Volume	
Stellar (No Leak)	0% (Std Dev 5.4%)
Stellar (w/Leak)	1% (Std Dev 5.2%)
V60 (No Leak)	19% (Std Dev 7.4%)
V60 (w/Leak)	12% (Std Dev 11.2%)

Note that in the following tables, the grayed out cells with "N/A" indicate there was an issue that prevented the collection of consistent and reliable data on at least one ventilator. Issues seen during testing included the ventilator auto-triggering or skipping breaths, the Breathing Simulator having it's high volume limit reached, and/or the mask's anti-asphyxia valve activating. In instances where only one ventilator was able to provide consistent data for a given scenario, that data was not included in the comparison. All compared data is from tests where both ventilators tested were able to perform in a consistent manner.

Both the total volume difference and the percent difference between volumes are reported for each test scenario. Each colored cell represents the range of volume differences between ventilator reported and actual recorded exhaled volumes that the cell value falls within.

These ranges are shown below:

GREEN	+/- 0% to 5%
WHITE	+/- 5% to 10%
PINK	+/- 10% to 15%
GOLD	+/- 15% to 20%
MAGENTA	+/- 20% to 30%
RED	+/- > 30%

Passive Lung, r5C70, Min/Med/Max Rise Time

No Leak

		10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20	
5R/70C Rise: Min	Stellar	difference	16	9	N/A	N/A	43	N/A	N/A	87	N/A
		%diff	4.6%	0.8%	N/A	N/A	6.1%	N/A	N/A	12.5%	N/A
	V60	difference	23	155	N/A	N/A	124	N/A	N/A	130	N/A
		%diff	6.5%	15.0%	N/A	N/A	18.1%	N/A	N/A	19.3%	N/A

		10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20	
5R/70C Rise: Med	Stellar	difference	22	N/A	N/A	N/A	44	N/A	N/A	92	N/A
		%diff	6.4%	N/A	N/A	N/A	6.4%	N/A	N/A	13.3%	N/A
	V60	difference	43	N/A	N/A	N/A	134	N/A	N/A	148	N/A
		%diff	12.6%	N/A	N/A	N/A	20.0%	N/A	N/A	22.4%	N/A

		10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20	
5R/70C Rise: Max	Stellar	difference	-1	-56	N/A	N/A	19	N/A	N/A	63	N/A
		%diff	-0.3%	-5.5%	N/A	N/A	2.8%	N/A	N/A	9.5%	N/A
	V60	difference	31	138	N/A	N/A	106	N/A	N/A	115	N/A
		%diff	9.4%	14.2%	N/A	N/A	16.6%	N/A	N/A	18.3%	N/A

With Leak

		10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20	
5R/70C Rise: Min	Stellar	difference	45	N/A	N/A	N/A	79	N/A	N/A	N/A	N/A
		%diff	11.9%	N/A	N/A	N/A	10.0%	N/A	N/A	N/A	N/A
	V60	difference	8	N/A	N/A	N/A	68	N/A	N/A	N/A	N/A
		%diff	2.4%	N/A	N/A	N/A	9.8%	N/A	N/A	N/A	N/A

		10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20	
5R/70C Rise: Med	Stellar	difference	30	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		%diff	7.9%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	V60	difference	24	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		%diff	7.3%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

		10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20	
5R/70C Rise: Max	Stellar	difference	-7	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		%diff	-2.0%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	V60	difference	12	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		%diff	3.7%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Note: Refer to the appendix on page five for explanation of N/A

Passive Lung, r10C50, Min/Med/Max Rise Time

No Leak

			10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20
10R/50C Rise: Min	Stellar	difference	-15	-33	-90	N/A	-1	-26	N/A	15	N/A
		%diff	-6.3%	-4.6%	-7.6%	N/A	-0.2%	-2.7%	N/A	3.1%	N/A
	V60	difference	18	110	203	N/A	55	192	N/A	60	N/A
		%diff	7.5%	15.6%	17.2%	N/A	11.8%	20.6%	N/A	13.1%	N/A

			10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20
10R/50C Rise: Med	Stellar	difference	-14	-43	-94	N/A	12	-13	N/A	25	51
		%diff	-6.2%	-6.1%	-8.0%	N/A	2.5%	-1.4%	N/A	5.4%	5.5%
	V60	difference	27	122	208	N/A	59	207	N/A	62	227
		%diff	12.0%	17.7%	18.1%	N/A	13.1%	22.6%	N/A	14.0%	25.1%

			10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20
10R/50C Rise: Max	Stellar	difference	-8	-26	-90	N/A	2	-21	N/A	11	26
		%diff	-3.7%	-4.0%	-8.3%	N/A	0.4%	-2.5%	N/A	2.6%	3.1%
	V60	difference	12	76	149	N/A	30	149	N/A	57	172
		%diff	5.5%	11.6%	13.6%	N/A	7.0%	17.3%	N/A	13.5%	20.2%

With Leak

			10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20
10R/50C Rise: Min	Stellar	difference	-19	4	N/A	N/A	-5	19	N/A	8	32
		%diff	-7.6%	0.5%	N/A	N/A	-0.9%	1.9%	N/A	1.6%	3.2%
	V60	difference	-2	62	N/A	N/A	29	145	N/A	58	188
		%diff	-1.2%	8.7%	N/A	N/A	6.3%	15.5%	N/A	12.6%	20.2%

			10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20
10R/50C Rise: Med	Stellar	difference	-15	-15	N/A	N/A	-5	17	N/A	11	N/A
		%diff	-6.1%	-2.0%	N/A	N/A	-1.0%	1.7%	N/A	2.2%	N/A
	V60	difference	-2	65	N/A	N/A	36	148	N/A	49	N/A
		%diff	-1.3%	9.5%	N/A	N/A	7.8%	16.2%	N/A	10.9%	N/A

			10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20
10R/50C Rise: Max	Stellar	difference	-8	-17	-100	N/A	-14	3	N/A	6	32
		%diff	-3.5%	-2.5%	-8.6%	N/A	-3.0%	0.3%	N/A	1.3%	3.4%
	V60	difference	-12	36	158	N/A	26	109	N/A	34	170
		%diff	-6.5%	5.7%	14.5%	N/A	6.2%	12.6%	N/A	8.0%	20.0%

Passive Lung, r20C20, Min/Med/Max Rise Time

No Leak

		10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20	
20R/20C Rise: Min	Stellar	difference	-8	8	24	11	-9	19	39	2	33
		%diff	-7.4%	2.7%	5.0%	1.6%	-4.4%	4.9%	6.8%	1.0%	8.8%
	V60	difference	12	53	129	217	25	93	190	35	82
		%diff	12.2%	18.4%	27.0%	32.5%	12.9%	24.6%	33.4%	18.8%	22.1%

		10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20	
20R/20C Rise: Med	Stellar	difference	-7	10	15	3	0	23	28	8	32
		%diff	-6.8%	3.6%	3.2%	0.5%	0.3%	6.0%	4.8%	4.1%	8.6%
	V60	difference	12	63	143	222	26	107	201	30	107
		%diff	12.3%	22.3%	30.3%	33.4%	13.8%	28.7%	35.8%	16.7%	29.2%

		10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20	
20R/20C Rise: Max	Stellar	difference	-6	-5	-17	-51	-7	-7	-20	-4	-1
		%diff	-6.1%	-1.9%	-3.6%	-8.0%	-4.1%	-2.0%	-3.6%	-2.4%	-0.3%
	V60	difference	9	47	112	188	27	83	158	27	85
		%diff	9.3%	17.1%	24.8%	29.8%	15.4%	23.4%	29.5%	15.3%	24.3%

With Leak

		10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20	
20R/20C Rise: Min	Stellar	difference	-4	31	69	N/A	-1	29	50	3	30
		%diff	-3.8%	10.1%	13.7%	N/A	-0.3%	7.2%	8.3%	1.3%	7.4%
	V60	difference	-22	25	93	N/A	16	73	145	39	104
		%diff	-22.4%	8.7%	19.3%	N/A	8.2%	19.2%	25.1%	20.6%	27.5%

		10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20	
20R/20C Rise: Med	Stellar	difference	-1	12	27	N/A	1	16	36	5	18
		%diff	-0.8%	4.0%	5.5%	N/A	0.4%	4.1%	6.0%	2.7%	4.6%
	V60	difference	-12	34	88	N/A	24	72	152	28	112
		%diff	-12.4%	12.1%	18.7%	N/A	12.8%	19.4%	26.9%	15.5%	30.3%

		10/5	20/5	30/5	40/5	20/10	30/10	40/10	30/20	40/20	
20R/20C Rise: Max	Stellar	difference	-7	-11	-15	-32	-10	-11	-6	1	2
		%diff	-6.6%	-4.0%	-3.1%	-4.7%	-5.1%	-2.9%	-1.1%	0.5%	0.5%
	V60	difference	-16	33	88	137	18	66	142	28	96
		%diff	-17.3%	12.2%	19.7%	21.8%	9.9%	18.7%	26.6%	16.0%	27.4%

Note: Refer to the appendix on page five for explanation of N/A