AirWave™ Health Economics

in the adult ICU

A White Paper

Executive Summary

The SonarMed® AirWave™ airway monitoring system is a new offering in respiratory and anesthesia care that is expected to improve patient safety as well as hospital economics. By providing the clinician with actionable critical endotracheal tube status information – including placement, obstruction, and relative tube tip movement data – the AirWave supports the clinician in shifting the paradigm of artificial airway care from reactive to preventive. The resulting potential for reduction in adverse events provides a win-win for the hospital and patient: better outcomes, patient safety, and performance on QA targets, as well as improved margins for hospital operations. This White Paper outlines the clinical issues addressed by the AirWave, and provides analysis based on a large number of peer-reviewed publications that enables a projection of the impact adoption of the AirWave will have on a typical hospital. Data-based models project break-even on AirWave system purchase in less than three months.

March 24, 2011

1. Introduction

The SonarMed® AirWave™ acoustic airway monitoring system is an intubation aide and a continuous, real-time endotracheal tube (ETT) monitoring system for use in the hospital setting. This White Paper outlines some of the expected clinical and economic benefits of using the AirWave system in the adult ICU setting. These benefits are estimated using data from a large number of peer-reviewed publications as well as data from SonarMed's own studies.

The primary sources of economic benefit from using the AirWave in the adult ICU are expected to be driven by:

- A reduction in adverse events, leading to a shorter average per admission ICU stay for mechanically ventilated patients (while the lump-sum MS-DRG reimbursement payment remains unchanged).
- A reduction in procedural and material costs required for patient care.

2. Clinical Overview

2.1. Intubation and Post-intubation Clinical Issues

Intubation with an endotracheal tube is a common procedure in the adult intensive care unit; however, potential life-threatening complications can occur during intubation or mechanical ventilation. While there are many complications that may result from ETT use, the following list summarizes some of the most significant:
Esophageal intubation is the most common insertion error, and results in patient hypoxia, with a high potential for aspiration pneumonia or other long-term pulmonary issues.
Right mainstem bronchial intubation results in patient hypoxia and a risk of pneumothorax.
Unplanned extubation (UE), whether accidental or patient-induced, can happen quickly or over time, and results in many complications, including hypoxia and a need for emergency reintubation.
Maintenance of the ETT tip in a specific location is crucial in cases of vocal cord damage, airway edema, or thoracic surgery. ETT tip movement is also associated with increased VAP rates due to aspiration of the accumulated fluids that may leak from above the ETT cuff.
Obstructions from secretions or blood develop in spite of routine suctioning and increase the work of breathing, which can prolong ventilation and make weaning more challenging.
Tracheal stenosis at extubation may render the patient unable to maintain a patent airway, and make re-intubation challenging or impossible. Currently, tracheal stenosis is very difficult to detect.

The above-listed scenarios may also require bronchodilators, chest x-rays, or specialized procedures, such as a fiberoptic bronchoscopy, to regain patient stability.

2.2. Impact on Intubation and Endotracheal Tube Issues

The SonarMed AirWave acoustic airway monitoring system offers a solution that may assist clinicians in preventing complications associated with intubation and ETT use, improving patient safety and reducing hospital costs. The AirWave consists of a monitor and disposable adapter that provides direct, precise, real-time monitoring of the ETT:

- Provides information about the passageway (airway) diameter at the ETT tip to assist in differentiating among trachea, esophagus, and bronchus both during intubation and ventilation
- Provides information and clinician-set alarms for ETT tip movement to support prevention of ETT migration into the bronchus or unplanned extubation

- Provides information locating the position and identifying the percentage of ETT obstruction

The ability of the SonarMed AirWave to assist in preventing a long list of complications will have a positive patient and economic impact.

3. Hospital Economics for the Intubated Patient in the ICU

Patient complications that extend hospital length of stay beyond the expected length indicated by ICD-9 diagnostic admission codes are not reimbursable under the MS-DRG system and the hospital bears the extra costs directly. Any device that can reduce ICU complications and reduce length of ICU stay will provide incremental cash margin to the hospital.

A margin analysis for one large hospital in the Los Angeles area is shown in **Table 1**.

Table 1: Hospital Margin Impact of Intubated Patients

MS-DRG Code	Description	Average LOS (hours)	Avg. margin after patient deductible	# patients in 2007	Annual margin impact ($)
870	Septicemia or severe sepsis with mechanical ventilation 96+ hours (vent time estimated at admission)	310	($23,832)	80	**($1,907,000)**
207	Respiratory system diagnosis with vent. support 96+ hours (vent time estimated at admission)	307	($13,492)	84	**($1,130,000)**
208	Respiratory system diagnosis with vent. Support < 96 hours (vent time estimated at admission)	125	($1,076)	87	**($93,000)**
189	Pulmonary edema & respiratory failure	115	($798)	46	**($37,000)**
	TOTAL ANNUAL IMPACT (loss)				**($3,167,000)**

Codes 870 and 207 call for more than 96 hours on the ventilator, and the average loss for the hospital for those codes was over $18,500 per patient. Extended ICU stays with lengthy intubation caused annual losses of over $3 million at this hospital. Complications in general reduce hospital margins. Dimick[1] found that hospital margins declined from 23% for patients without complications to just 3.4% for patients with complications, a loss of $1633 per patient.

4. Hospital Costs for Intubated Adult ICU Patients – No Complications

4.1. Intubated ICU Patient Length of Stay

SonarMed extracted key data from four studies shown below in **Table 2**. These studies examined the average ventilator, ICU, and hospital days for an ICU patient without significant complications.

Table 2: Length of stay data – No Complications

Control Groups, no UE (days)			Source Study
Vent	ICU	Hospital	
5	6		Bouza, 2007[2]
7.3	10.7	17.9	Krivopal, 2003[3]
6	9	18.4	DeLassence, 2002[4]
11	14	21	Epstein, 2000[5]
7.3	**9.9**	**19.1**	average number

4.2. Daily Cost of Hospitalization

Dasta[6] and Candrilli[7] determined the average daily cost of hospitalization as:

- $4000 per day, ventilated in the ICU
- $3200 per day, extubated in the ICU
- $1600 per day on the general floor

These costs represent daily costs on or after day 3 in the ICU; the first two days of an ICU stay (ventilated) are more costly, as shown in **Table 3**.

Table 3: ICU with ventilation daily cost profile

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
$10794	$4796	$3968	$3968	$3968	$3968

Each additional day that a patient remains on mechanical ventilation costs the hospital approximately $4000. Other sources suggest that the cost may be as high as $5000 per day.[6]

4.3. Total Cost of Hospitalization

Combining the data from Table 2 and Table 3, the total average cost of stay for an intubated patient without complications is shown in **Table 4**.

Table 4: Average Cost per Stay without Complications

Setting	Cost per day	Days	Total cost
ICU, intubated	$4000	7.3	$29,200
ICU, extubated	$3200	2.6	$8,320
General ward	$1600	9.2	$14,720
TOTAL			**$52,240**

5. Incremental Hospital Costs due to Unplanned Extubation

5.1. Frequency of Unplanned Extubation

There are approximately two million ICU intubations per year in the U.S. Studies over the past 26 years show that unplanned extubation rates have remained essentially unchanged at approximately 10%,[2,4,5,9,11,12,13,14,15,16,17] which equates to 200,000 ICU UEs per year. For some patients, reintubation is not necessary and they are able to breathe spontaneously. Other patients require emergent reintubation to prevent brain damage, organ damage, or death.

5.2. Clinical Impact of UE

In addition to life-threatening events associated with UE, it also leads to multiple complications to the patient with attendant costs. Mort (1998) determined that patients with UE followed by reintubation experienced one or more of the following complications: hypotension (35%), tachycardia (30%), hypertension (14%), difficult reintubation (14%), esophageal reintubation (14%), and 1 mortality due to failure to reintubate.[9] These complications are what Epstein (2000) determined lead to a near tripling rate of post-ICU chronic care after UE compared to patients with planned extubations, translating to 80,000 patients requiring post-ICU chronic care due to UE.[5]

5.3. Impact of UE on Length of Stay Costs

Studies have shown that UE causes an approximate doubling of time on the vent and in the ICU as well as a 60% increase in hospital general ward time.[2,4,5] These effects of UE are shown translated into days and associated costs in **Table 5**.

Table 5: Incremental Cost of Unplanned Extubation

Setting	Cost per day	Incremental Days due to UE	Total cost
ICU, intubated	$4000	6.8	$27,200
ICU, extubated	$3200	0.9	$2,880
General ward	$1600	3.4	$5,440
TOTAL		**11.1**	**$35,520**

Based on 200,000 UE events per year at $35K per UE, the annual incremental cost due to length of stay extension from UE is approximately $7B.

6. The SonarMed AirWave and Unplanned Extubation

6.1. SonarMed AirWave Impact on UE is Expected to Depend on UE Type

Continuous ETT monitoring with the SonarMed AirWave may decrease the incidence of UE that is attributable to isolated patient location, patient transport, ETT movement (e.g. during routine oral care), patient movement (e.g. side-to-side turning or repositioning for portable chest x-ray), and slow self-extubation. Audible alarms will bring personnel to the bedside to take appropriate clinical action when significant ETT movement has placed it in a position that may lead to UE. If the patient is lightly sedated or agitated, the AirWave will monitor ETT movement, and may assist the clinician in preventing some, but not all, patient self-extubations. Self-extubations that occur quickly are less likely to be prevented; however, detection of the impending extubation may happen sooner by using the AirWave. Accidental UE nearly always requires emergency reintubation, whereas self-extubation requires reintubation less often. In three studies, self-extubation required reintubation 37%-56% of the time.[2,4,5] Should the self-extubation be triggered by ETT contact with the carina, the AirWave's ability to alarm for ETT tip movement downward may have a preventive impact. **Table 6** summarizes the potential impact use of the SonarMed AirWave may have on accidental and patient-induced UE.

Table 6: Types of UE and potential AirWave Impact

Basic type of UE	Sub-types		Potential SonarMed AirWave impact on reducing incidence rate
Accidental (25%)	Tube caught/pulled on external object		Moderate
	Patient movement		Significant
Self-Induced (75%)	Fast	Reaction to carina contact	Significant
		Spontaneous, no carina contact	Minimal to none
		High ETT position	Significant
	Slow (e.g. tonguing the tube out)		Significant

6.2. SonarMed AirWave Financial Impact Due to UE Reduction

Based on the data from Section 4 and interviews with clinicians, SonarMed models that use of the AirWave will enable clinicians to reduce UE by an average of 30% across all categories. SonarMed plans to verify AirWave impact on UE rates in a post-market prospective study. A 30% reduction (approximately 60,000 less UE events per year), would reduce the present $7.1B annual UE costs by approximately $2.1B.

Reducing unplanned extubations by 30% would result in a direct cost savings on average of $1,050 per intubated adult patient in the ICU, based on the following model**:**

- 2,000,000 ICU intubations per year in the U.S.
- 10% UE rate = 200,000 UE/year
- 30% UE decrease with AirWave use = 60,000 fewer UE each year
- $35,000 per UE = $2.1B savings/year
- $2.1B savings across 2,000,000 ICU intubated patients/year = $1050 average savings/intubated patient due solely to 30% UE reduction

This per intubated patient savings of $1050 is scalable. According to this UE reduction savings model, any ICU adopting the AirWave should over time realize this average per patient savings.

6.3. SonarMed AirWave Payback Analysis

While there may be multiple sources of costs savings due to use of the SonarMed AirWave, it is simplest to examine only the results projected by the UE reduction savings model in Section 6.2.

Assuming the following “high cost” scenario for a hospital that is adopting the AirWave;

- Monitor $2,500
- Acoustic Adapter $75
- Acoustic Adapter use 3 per patient for the average 7.3 day stay (see **Table 2**)

and assuming the following characteristics of a “typical” ICU in the U.S.:

- Number of beds 18 (U.S. average for an ICU)
- Bed occupancy 80% (U.S. average)
- Intubated census 40% (U.S. average)

This results in approximately 6 intubated patients per week for the ICU. Then assuming a “most costly” scenario of one AirWave Monitor per ICU bed, the cost of equipping the ICU with Monitors

would be $45,000, and the weekly cost of disposables would be $1,350 (6 patients x 3 acoustic Adapters x $75) in disposable costs.

Assuming that use of the AirWave reduces UE rates from the average 10% to 7% leads to the previously discussed (Section 6.2) $1050 per intubated patient average savings. With an average of 6 intubated patients per week, this would produce a long-term average of $6300 per week in savings. This weekly savings begins to offset the cost of Monitors and acoustic Adapters in short order, producing break-even for the hospital in approximately 9 - 10 weeks as shown below in **Figure 1**.

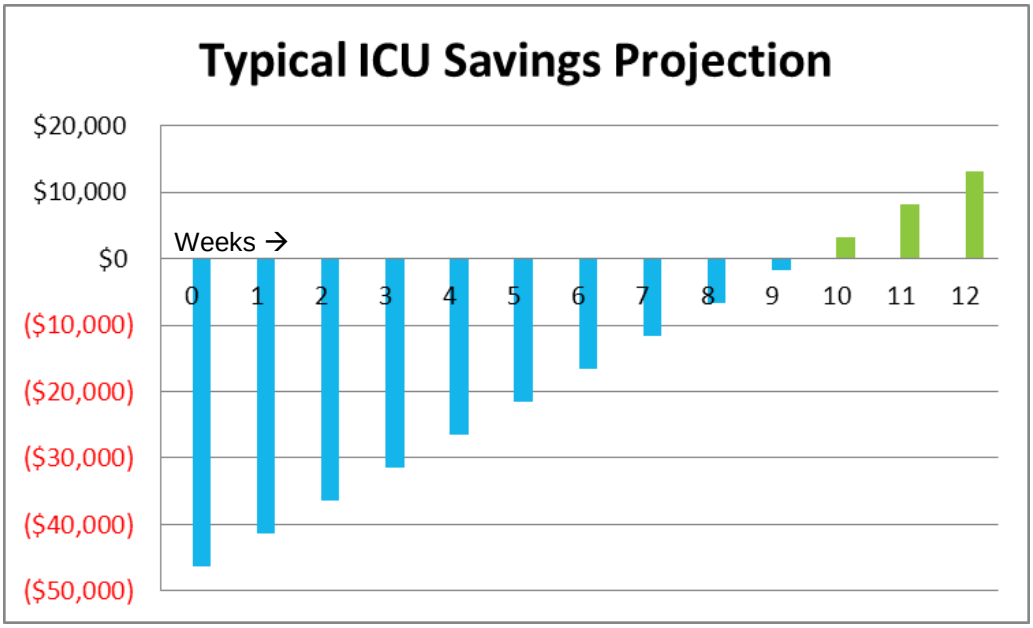

Figure 1: Projected long-term LOS savings due to UE reduction, typical ICU

Figure 1 includes only length of stay cost savings. Reducing UE by 30% would also result in a 30% reduction in associated post-ICU chronic care. These cost savings have not been modeled, but reducing the number of patients needing post-ICU chronic care by 24,000 patients per year is expected to result in significant additional cost savings. Likewise, the financial impact of reducing UE-associated complications and their attendant therapy costs has not been modeled at this time.

7. The SonarMed AirWave and VAP

7.1. Relationship Between UE and VAP

Ventilator-associated pneumonia (VAP) is considered a preventable nosocomial infection, and is being evaluated for inclusion on the list of hospital acquired conditions (HACs) that are not reimbursable under Medicare.
De Lassence (2002) studied the risk of VAP after UE with reintubation, and found that patients with UE were 1.8 times more likely to contract VAP as patients without UE.[4] Patients with accidental UE had a 5.3 greater risk of contracting VAP.[4]

Warren (2003) established the rate of VAP at 15.5%.[8] Assuming a 25% rate of accidental UE and 75% self-extubation, the risk of UE with subsequent VAP is:

- approximately 14% without UE
- approximately 26% with UE
- approximately 76% with accidental UE

With 2,000,000 ICU intubations per year, this translates into:

- 258,000 patients acquiring VAP without UE (83% of VAP cases)
- 52,000 patients acquiring VAP with UE (17% of VAP cases)

7.2. SonarMed AirWave Impact on VAP Rates and Costs

The AirWave may have a positive effect on three factors related to VAP rates:

- Reduction of VAP associated with UE
- Reduction of VAP associated with pathogen introduction due to ETT tip movement allowing accumulated fluids to seep past the cuff and into the lungs
- Reduction of VAP associated with suctioning which can introduce pathogens to the lungs

Regarding UE-associated VAP, studies by Warren and Rello indicate that VAP costs approximately $12.8B/year, exclusive of the costs already assigned to UE.[8,10] If the SonarMed AirWave leads to a 30% reduction in UE resulting in a 30% reduction in UE-associated VAP, the total VAP rate would reduce by approximately 5%, or 15,500 cases/year. Potential VAP-related savings would amount to $680M per year.

Regarding VAP associated with ETT tip movement and suctioning, potential impact on rates and savings by using the AirWave have not been modeled to date.

8. The SonarMed AirWave – Other Potential Length of Stay Benefits

8.1. Ventilator Weaning

Undetected obstruction in the ETT can increase the patient's work of breathing and extend or prevent ventilator weaning, thereby extending the patient's stay in the ICU. Today, verification of a clear ETT occurs via bronchoscopy or replacement of the ETT, each of which have their own inherent risks and costs. The SonarMed AirWave may assist the clinician in detecting obstructions and verifying their removal, thereby minimizing ETT resistance and allowing the clinician to more confidently assess the patient's ability to breathe on their own, leading to a reduction in unnecessary delays in weaning from the ventilator.

8.2. Endobronchial Intubation

Endobronchial intubation (EBI) is difficult to detect, and the consequences are not necessarily immediate, although they can include pneumothorax and hypoxia. Use of the SonarMed AirWave may have a positive impact on occurrence rates of EBI and associated consequences and that reduction would be expected to have a positive impact on the overall length of stay on the ventilator and in the ICU.

9. The SonarMed AirWave – Potential Procedural & Material Benefits

9.1. Chest X-Rays

Daily chest x-rays (CXR) performed in the ICU are routine, and are problematic for three reasons:

- Patient exposure to radiation
- Hospital cost are not separately reimbursed with MS-DRG
- CXR can lead to ETT displacement or UE due to patient movement

Studies conducted on reducing the CXRs taken to confirm ETT position suggest that if a method to provide a clinical indication of need for a CXR were available, patient risk would be decreased and the ICU would net a cost savings.[18] A Harvard study found that a change from a daily routine CXR to

a clinically-indicated CXR reduced the average number of CXRs from 6.8 per patient to 4.4 per patient without effect on patient stay, morbidity, or mortality. SonarMed's own week-long informal medical ICU survey indicated that CXRs focused primarily on ETT position constituted approximately 30% of all ICU CXRs. If the SonarMed AirWave can assist clinicians in performing CXRs when clinically indicated rather than daily, then the system may have the potential to reduce CXRs on intubated patients by approximately 30%.

While the safety benefits of such a CXR reduction are clear (reduced radiation exposure, reduced risk of ETT tip movement during patient positioning), the cost benefits are less obvious. CXR costs vary widely from hospital to hospital, and some major hospitals admit they have no idea what a CXR actually costs them. Based on its own survey, SonarMed estimates that a CXR costs a hospital approximately $80 to shoot and read, resulting in a hospital spending approximately $700-$1000 on CXRs during a typical intubated patient's ICU stay. These CXRs are not specifically reimbursable, so reducing CXRs by 30% would yield approximately $250 in direct per admission cost savings to the hospital. This savings by itself would more than offset the cost of the AirWave Adapters.

9.2. ETT Suctioning

Routine suctioning is performed to ensure ETT patency, but suctioning may not be completely effective, and clinicians don't always know if secretion removal has been totally successful. Because suctioning creates some risk and discomfort to the patient and creates costs for the hospital, initiatives are underway to reduce suctioning. One clinical study on routine ETT suctioning found that a 5x reduction in suctioning frequency is achievable without adverse impact to the patient, thereby reducing patient risk, discomfort, and ICU cost.[19]

Use of the SonarMed AirWave will support hospital initiatives to reduce suctioning by giving the clinician a valuable tool to both assist in determining when suctioning is necessary, and enhance the clinician's effectiveness in removing secretions. While the direct costs of staff time and equipment are difficult to quantify, any reduction in suctioning should create cost savings or free up staff to perform additional tasks, as well as improve patient comfort and satisfaction.

9.3. Obstruction Response

When a clinician responds to increased ventilator pressures, there can be multiple potential causes to assess. Initial clinician responses typically include bronchodilator use and fiberoptic bronchoscopy. In some cases, the obstruction is in the ETT, so bronchodilators will be ineffective. Use of bronchoscopy to verify ETT obstruction is expensive and time-consuming. Use of the SonarMed AirWave may assist the clinician in more efficiently identifying ETT involvement in a ventilator pressure increase. Because it provides the location of the obstruction in the ETT, the AirWave may further support the clinician in differentiating whether the obstruction is due to secretions, a kink, or from the patient biting the ETT.

10. Conclusion

The SonarMed AirWave airway monitoring system may assist the clinician in changing their paradigm of airway management from reactive to preventive. The system provides the clinician with information to support detection of conditions that may require prompt clinical attention and intervention, potentially preventing harmful and expensive health complications, furthering the shared objective of improved patient safety and quality of care as well as decreased hospital costs. Using "typical" ICU data for modeling, the SonarMed AirWave could be expected to pay for itself in as little as three months.

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Appendix A: UE Data Summary

The following table summarizes salient UE data from the referenced publications. One can see that the rate has remained essentially unchanged for many years.

Study	Year	UE rate	t/o accidental	t/o self
Bouza	2007	10%	3%	7%
DeLassence	2002	10%	3%	7%
Epstein	2000	11%	1%	10%
Sub-total average, recent studies		**10.3%**	**2.3%**	**8.0%**
Mort	1998	3%	0.4%	2.6%
Listello	1994	9%		
Seudeal	1992	9%		
Brown	1992	11%		
Coppollo	1990	7%		
Jayamanna	1988	11%		
Stauffer	1981	16%	3%	13%
Zwillich	1974	13%		
Sub-total average, older studies		**9.9%**	**3%**	**13%**
TOTAL AVG.		**10.0%**	**2.1%**	**7.9%**
Ratios:		100%	21%	79%

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