

CVP Diagnostics Revenues From Heart Failure Monitoring

I. Heart Failure Is A Major Medical & Financial Problem In U.S.

Heart Failure (HF) In U.S. There are 5 million patients with overt HF and 60 million at-risk to develop HF in the U.S. In spite of conscientious efforts to reduce HF outcomes and costs, there are 1 million HF hospitalizations and 300,000 deaths a year in the U.S. In addition, annual care-costs for HF are immense, i.e., \$39 billion in 2008, and even as new approaches to treatment emerge, HF outcomes and costs continue to rise.

II. New Noninvasive Monitor Could Reduce HF Outcomes & Costs

First Noninvasive Monitor Identifies Cause of Most HF Hospitalizations, Deaths & Costs. LVEDP (left ventricular end-diastolic pressure) is the pressure of blood entering the heart from the lungs. It is the most reliable indicator of the presence and severity of HF. However, until recently, LVEDP could only be measured by passing a catheter through the heart and into the lungs in a hospital ICU, a costly and potentially dangerous procedure.

First Noninvasive Hemodynamic Monitor Cleared by US FDA. CVP Diagnostics, a Massachusetts company, developed the first noninvasive monitor, the VeriCor® monitor, and showed that it is as accurate for LVEDP as catheters used to treat patients with life-threatening HF in hospital ICUs. The VeriCor® monitor has been cleared by the U.S. FDA.

VeriCor® Monitor Shows Clinical Assessment Cannot Control LVEDP Levels. Although clinical assessment (patient history and physical exam) guides the treatment of virtually all 5 million HF patients in the U.S., it has never been evaluated. To provide the first evaluation of clinical assessment, the noninvasive VeriCor® monitor measured LVEDP levels in a population of 115 ambulatory HF patients most of whom were free of the clinical signs of HF, i.e., rales, JVD (jugular venous distention) and edema.

Surprisingly, nearly 2 of every 3 (64%) of these patients thought to be “well-controlled” by clinical assessment had abnormally elevated LVEDPs (>20mmHg).

Patients With elevated LVEDPs Account For Most HF Outcomes & Costs. By the end of 1-year, there were 33 hospitalizations and 31 (94%) were in patients with elevated LVEDPs. There were 11 deaths and 8 of the 11 (73%) were in patients with elevated LVEDPs. The 1-year care-costs were \$957,000 of which \$870,000 (91%) were for patients with LVEDPs >20mmHg. The 1-year care-costs for patients with LVEDPs ≤ 20mmHg were \$87,000, or less than 10% of the total costs.

The care-costs for patients with abnormally elevated LVEDPs could be 10 times greater than those with LVEDPs in the normal/near-normal range (≤ 20mmHg).

Conclusion. The limitations of clinical assessment may be responsible for more than 90% of HF hospitalizations, 70% of HF deaths and more than 90% of HF care-costs in the U.S. each year. If the management of HF is to be optimized, clinical assessment will need to be supplemented by noninvasive monitoring.

Currently, the only available noninvasive monitor is the VeriCor® monitor. Treatment guided by the VeriCor® monitor could reduce elevated LVEDPs which, in turn, could achieve major reductions in HF deaths, hospitalizations and costs in the U.S.

Table 2. Impact of Reductions of 50% in Annual HF Outcomes & Costs in 6 States

Location	Population (N)	HF Patients (N)	Reductions Deaths	Reductions Hospitalizations	Costs Saved*
Connecticut	3.5M	57,000	2,804	7,851	\$220M
Massachusetts	6.4M	106,000	5,150	14,419	\$404M
Ohio	11.5M	189,000	9,182	25,711	\$720M
Florida	18M	266,000	14,472	40,522	\$1.1B
Texas	23.5M	348,000	18,806	52,658	\$1.5B
California	36M	565,000	29,166	81,666	\$2.3B

*Under “Reductions Deaths”, “Reductions Hospitalizations” & “Costs Saved”, numbers indicate the number of hospitalizations, deaths and costs that would be reduced by reductions of 50%. They also indicate deaths & hospitalizations prevented and costs saved.

Comment on Table 2.

Connecticut. In the population of 3.5 million in Connecticut, the 57,000 HF patients account for 5,608 deaths, 15,702 hospitalizations and \$440 million in care-costs each year. As shown in Table 2, line 1, 50% reduction in each of these would reduce deaths by 2,804, hospitalizations by 7,851 and costs by \$220 million a year.

Massachusetts. There are 106,000 HF patients, HF deaths of 10,300 a year and costs of \$808 million. As shown in Table 2, a 50% reduction in each of these would reduce deaths by 5,150, hospitalizations by 14,419 and care costs by \$404 million.

Ohio. There are 189,000 HF patients, 18,364 HF deaths, 51,422 hospitalizations and care costs of \$1.4 billion. A 50% reduction in each of these would reduce deaths by 9,182, hospitalizations by 25,711 and costs by \$720 million.

Florida. There are 266,000 HF patients in Florida. They account for 28,944 deaths, 81,044 deaths and \$2.2 billion in costs each year. A 50% reduction in each of these would prevent 14,472 deaths, 40,522 hospitalizations and \$1.1 billion in HF care costs.

Texas. The 348,000 HF patients in Texas account for 37,612 deaths, 105,316 hospitalizations and \$3 billion in HF care-costs each year. A 50% reduction would reduce deaths by 18,806, hospitalizations by 52,658 and care-costs by \$1.5 billion a year.

California. The 565,000 HF patients account for 58,332 deaths, 163,332 hospitalizations and \$4.6 billion a year in HF care-costs. A 50% reduction would reduce HF deaths by 29,166, hospitalizations by 81,666 and care-costs by \$2.3 billion a year.

Relevance of Table 2 to Benefits of Monitoring In 50 States. Analyses comparable to those in Table 2 have now been completed for all 50 U.S. states. Results show that monitor-mediated treatment would result in significant reductions in HF deaths and costs in all U.S. states and, as in Table 2, will be proportional to population size.

V. Revenues to CVP Diagnostics in Various Venues & Patient Groups

Revenue projections at 80% market penetration are presented in the Table 3, below. They are based on typical monitoring requirements for the clinical applications identified in numbers 1 through 8 in the Table 3, as follows:

- (1-4) deal with HF patients in-hospital and ambulatory patients with mild to moderately advanced HF;
- (5) deals with renal dialysis patients at risk for dangerous fluctuations in intravascular volume including life-threatening HF;
- (6) deals with patients at emergency units with unexplained shortness of breath;
- (7) & (8) deal with patients at increased risk for HF because of high blood pressure or age >65 years.

Table 3. Clinical Venues & Conditions, Monitoring Burden & Revenues to CVP

Clinical Application*	# VeriCor[®] Monitor Tests	Revenues
(1) Hospital ICU- PA Catheter Replacement	1.8M	\$180M
(2) Hospitalized HF Patients (800,000 patients)	4M	\$400M
(3) Ambulatory Patients with Mild-Moderate HF (2.4M)	4.8M	\$480M
(4) Ambulatory HF Patients with Advanced HF (1.2M)	4.8M	\$480M
(5) Renal Dialysis Units	40.1M	\$4.0B
(6) Emergency Units - Unexplained Shortness of Breath	3.2M	\$320M
(7) High Risk Patients with Hypertension	48M	\$4.8B
(8) Routine HF Screening Of Patients >65 Years Old	28M	\$2.8B
	Total	\$13.8B

Comment. Based on the monitoring applications shown for numbers 1-8 in Table 3, annual revenues to CVP Diagnostics are expected to be \$13.5 billion from these sources.

VI. Biomedical Engineering Professor Projects Revenues from VeriCor[®] Home Monitors at Full Market Penetration

In a confidential report, a cardiologist who is also a chaired professor in biomedical engineering projected that home monitoring of HF patients would achieve full market penetration in 5-years and annual revenues to CVP Diagnostics would have reached \$30B a year at that time. The professor also projected that the potential U.S. office market (fully penetrated) would be \$2.6B a year in 5-years.

The professor's report may be made available on request to qualified investors.

VII. Revenues from CVP Diagnostics' Hybrid VeriCor[®] Monitors

Emergence of VeriCor[®] Hybrid Diagnostics. One of the Company's strategies to accelerate the rate at which comprehensive HF monitoring could be achieved is to merge the current cardiopulmonary diagnostics, i.e., the EKG, pulmonary function testing (PFT), etc., with the VeriCor[®] monitor to provide VeriCor[®] Hybrid diagnostics. Table 4 shows that LVEDP "Tests/Year" and CVP revenues could increase significantly.

Acceptability of Hybrid Monitors by Care Providers. Cardiologists and other care providers use the EKG, PFT and other currently available cardiopulmonary diagnostics frequently, often in patients with HF or at risk to develop HF. A reliable indicator of the presence and severity of HF could help optimize their management.

Hybrid Diagnostics Could Dominate Cardiopulmonary Device Market. A technical advance could give a producer an important strategic advantage over competition. The company that produces a technology with superior diagnostic reach could increase its market share significantly. For example, the replacement market for EKGs in the U.S. is said to be 300,000 units a year. The introduction of the *EKG-VeriCor® Hybrid* could come to dominate this market while other VeriCor® Hybrids may well dominate other diagnostic markets.

Patents for Hybrid Technologies. A patent was allowed by the U.S. patent office for CVP’s VeriCor® Hybrids in 2008. Additional patent applications covering the hybrid technologies have been submitted to the U.S. patent office and others are in preparation. Table 4 identifies 5 widely used cardiopulmonary diagnostics for which patents have either been allowed or patent proposals are in preparation.

Table 4. Annual Monitor Capacity & Revenue Potential of VeriCor® Hybrid Monitors

	Tests/Year	Per-Test Cost	Hybrid Cost	Revenue/Yr ¹
EKG²	300M	\$15	\$85	\$30B
PFT³	50M	\$75	\$225	\$11.2B
PAC⁴	1M	\$2000	\$150	\$150M
Echo⁵	2M	\$600	\$750	\$1.5B
Oximetry⁶	3M	\$80	\$230	\$690M
Total Tests	356M³		Total (\$)	\$43.5B³

¹At theoretical full market penetration. ²EKG: electrocardiogram. ³PFT: pulmonary function testing.

⁴PAC pulmonary artery catheterization. ⁵Echo: echocardiogram. ⁶Oximetry: blood oxygen level. M=million. B=billion.

Advantages of VeriCor® Hybrids for HF Control. The availability of 356M LVEDP measurements will help to provide LVEDPs conveniently for patients with HF and those at-risk for HF. As a result, the time to HF control could be reduced in the U.S.

Conclusion. Merger of the VeriCor® monitor with the standard cardiopulmonary diagnostics shown in Table 4 to produce new VeriCor® Hybrid monitors will permit early recognition of HF and also quantify the impact of HF treatment. By increasing the availability of LVEDP measurements by 356M (Table 4, line 6, under “Tests/Year”), easy access to LVEDP measurements will be readily available for the 5M HF patients and the 60M at-risk to develop HF in the U.S.

This number of LVEDP measurements is 5-times the estimated number of LVEDP measurements needed to control HF in the 5M U.S. patients with overt HF. As noted above, this level of availability could reduce the time to control of HF in the U.S. while also having a significant positive impact on the prognosis of HF patients.

VIII. Awareness of Monitoring Benefits Will Increase Monitoring Demand

Noninvasive Monitoring Can Overcome Limitations of Clinical Assessment. While managed by clinical assessment, HF causes 83,000 hospitalizations, 25,000 deaths and costs of \$2.3B in the U.S. every month. Based on currently available data, it is now reasonable to conclude that monitor-mediated treatment could reduce HF deaths, hospitalizations and costs by 50% or more.

These reductions could prevent 42,000 hospitalizations and 12,000 deaths a month while also saving \$1.2B in HF care-costs each month.

Argument For Comprehensive Monitoring Is Compelling. The argument for implementation of comprehensive monitoring is now compelling and, in view of the deaths and costs that could be saved every month, such a program should be implemented with all deliberate speed.

IX. Total Revenues from All-Source Monitoring At Full Market Penetration

While there undoubtedly will be some overlap in the revenue projections from the sources presented above, projections of annual revenues to CVP Diagnostics from these sources are summarized in Table 5. As shown in Table 5, below, total annual revenues from these 3 sources are projected to reach \$87 billion in as few as 5 to 8 years.

With Control of HF, Monitoring Costs Will Decline Significantly. Once control of HF is achieved, the need for monitoring will be reduced as will the per-test cost. The total cost of monitoring will also be significantly reduced, likely to below \$30 billion a year.

Table 5. Community Monitoring, Home Monitoring & Hybrid Monitoring

	Annual Revenues
(1) Hospital & Community-Based Markets*	\$13.5B
(2) Home Monitoring**	\$30.0B
(3) Hybrid Technologies***	<u>\$43.5B</u>
Total	\$87.0B

*Table 3, above. **Section VI, above. ***Section VII, "Revenues From CVP Diagnostics' Hybrid VeriCor® Monitors".

Conclusion Per Table 5. *As shown in Table 5, above, total annual revenues from these 3 sources could be as much as \$87.0 billion until comprehensive monitoring is achieved.*