

NEW MONITOR COULD CONTROL HEART FAILURE

1. Heart Failure, a Major Human & Financial Problem in U.S.

There are 5 million heart failure patients in the U.S. and 60 million at risk to develop heart failure. Other critical heart failure statistics are shown in the table below.

Heart Failure (HF): A Major Human & Financial Problem in U.S.

Annual HF Outcomes & Costs in U.S.

Patients (N)	Hospitalizations	Deaths	Costs
5 Million	1 Million	300,000	\$39 Billion

New Noninvasive Monitor Could Control HF. The objective of this presentation is to show that as many as 800,000 hospitalizations, 120,000 deaths and \$31.2 billion in HF care-costs could be prevented by the new, noninvasive, FDA cleared VeriCor® monitor.

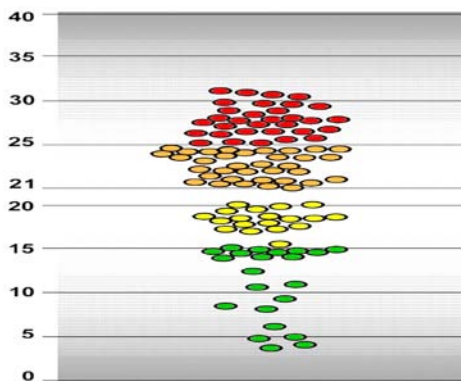
2. Elevated LVEDPs Drive Most HF Deaths, Hospitalizations & Costs

CVP Diagnostics (the Company) developed the first noninvasive ICU-caliber monitor, the VeriCor® monitor, and the U.S. FDA cleared the VeriCor® monitor in 2004 as an adjunct in the management of heart failure.

The results of the first-ever analysis of the relationship between LVEDP level and subsequent hospitalizations, deaths and costs in “stable” heart failure patients was provided by the VeriCor® monitor and the results are shown in Figure 1, below.

To the right of the figure, hospitalizations, deaths and cost in the subsequent 12 months are shown both for patients with abnormally elevated LVEDPs (>20mmHg, upper panel) and for those with LVEDPs (<20mmHg, lower panel).

Figure 1
Range of LVEDP Levels in Stable Clinical Assessment Patients



	Hospitalizations	Deaths	Costs
LVEDP > 20mmHg	31 (94%)	8 (73%)	\$434K
LVEDP < 20mmHg	2 (6%)	3 (27%)	\$28K

Comment on Figure 1. Of the 115 “stable” patients accessed to the study, 74 (64%) had abnormally elevated LVEDPs (20 mmHg, upper panel) that led to 31 (94%) of 33 hospitalizations and 8 of 11 deaths in 1-year.

In addition, care-costs for 1-year for patients in the lower panel were \$28,000 while care-costs for patients in the upper panel were \$434,000, 15.5 times higher.

Conclusion. With more than 90% of hospitalizations and costs and 60% of HF deaths occurring in patients with abnormally elevated LVEDPs, it is clear that clinical assessment is ineffective for the management of heart failure patients.

Since less than 10% of hospitalizations and costs and less than 30% of heart failure deaths occurred in patients with LVEDPs \leq 20mmHg, the key to the control of heart failure may be to maintain LVEDP levels in heart failure patients \leq 20 mmHg.

3. HF Outcomes & Costs Reduced By Reducing Elevated LVEDPs

Study Shows VeriCor® Monitor More Effective Than Clinical Assessment for Control of HF Hospitalizations & Costs. A group of 50 hospitalized HF patients were randomized in-hospital to treatment guided either by clinical assessment (n 25) or the VeriCor® monitor (n 25) to determine which was more effective in reducing HF hospitalizations.

Randomized patients were followed for 12 months after hospital discharge to document hospitalizations, deaths and costs in each group.

Monthly Hospitalizations in Patients Managed by Clinical Assessment.

Monthly hospitalizations in patients managed by clinical assessment are indicated by an “x” in Table 1-A, below.

**TABLE 1-A
HF HOSPITALIZATIONS IN 12 MONTHS: CLINICAL ASSESSMENT**

HEART FAILURE HOSPITALIZATIONS: CLINICAL ASSESSMENT													
Month	1	2	3	4	5	6	7	8	9	10	11	12	
		X		X									
	X	X					X						
	X		X										
			X	X	X								
				X			X		X				
			X				X				X		
										X			
	X										X		
	X												
										X			
	X												
Subtotals	5	2	3	3	1	0	3	0	1	2	2	0	22

Hospitalizations in Clinical Assessment Patients. As shown in Table 1-A, there were 5 hospitalizations in the 1st follow-up month, 2 in the 2nd month, 3 in the 3rd and 4th months, 1 in the 5th month and none in the 6th month.

Hospitalizations in 1st 6 Months: **14.**
 Hospitalizations in 2nd 6 Months: **8.**
 Hospitalizations in 12 Months: **22.**

Hospitalizations in VeriCor® Monitor Patients. Hospitalizations in patients managed by the VeriCor® monitor are shown by an “x” in Table 1-B.

**TABLE 1-B
HF HOSPITALIZATIONS IN 12 MONTHS: VERICOR MONITOR**

HEART FAILURE HOSPITALIZATIONS: VERICOR MONITORING													
Month	1	2	3	4	5	6	7	8	9	10	11	12	
					x								
								x					
									x				
												X	
Subtotals	0	0	0	0	1	0	0	1	1	0	0	1	4

Hospitalizations In VeriCor® Patients. There was 1 hospitalization in the 1st 6 months of follow-up in patients managed by the VeriCor® monitor and in the 2nd 6 months, there were 3 hospitalizations bringing the 12 month total to 4 hospitalizations in the VeriCor® monitor patients.

Hospitalizations in 1st 6 Months: **1.**
 Hospitalizations in 2nd 6 Months: **3.**
 Hospitalizations in 12 Months: **4.**

Comment.

- In patients in whom clinical assessment was replaced by the VeriCor® monitor, 1-year hospitalizations were reduced from 22 to 4, a reduction of 82%.
- Since clinical assessment manages virtually all HF patients in the U.S., and there are 1 million hospitalizations a year, replacement of clinical assessment with the VeriCor® monitor could prevent 800,000 hospitalizations and save \$11.2 billion a year in care-costs.
- In addition, the VeriCor monitor patients had more than 60% fewer deaths in the 12 month follow-up period than clinical assessment patients.
 A 60% reduction could reduce HF deaths from 300,000 to 120,000 a year, saving 160,000 lives a year.

Conclusion. If the care of HF patients is to be optimized in the U.S., clinical assessment must be supplemented by the VeriCor® monitor with all deliberate speed.

4. Reductions in Outcomes & Costs with Comprehensive VeriCor® Monitoring In Selected U.S. States

Potential Reductions in HF Outcomes & Costs In U.S. States. To make the potential benefits of HF monitoring available to states, the Company projected likely reductions in HF outcomes and costs in each of the 50 states. Tables 2-A & 2-B, below, show HF hospitalizations, deaths and costs by population in 6 states with population sizes that range from among the smallest (Connecticut and Massachusetts) to the largest (Texas and California).

Table 2-A. Table 2-A projects current levels of hospitalizations deaths and costs in these 6 states while managed by clinical assessment.

Table 2-A. Annual HF Outcomes & Costs in 6 States by Population

Location	Population	Deaths	Hospitalizations	Costs
Connecticut	3.5M	5,608	15,702	\$440M
Massachusetts	6.4M	10,300	28,838	\$808M
Ohio	11.5M	18,364	51,422	\$1.4B
Florida	18.0M	28,944	81,044	\$2.2B
Texas	23.5M	37,612	105,316	\$3B
California	36.0M	58,332	163,332	\$4.6B

Table 2-B. Table 2-B projects levels of deaths, hospitalizations and costs after 50% reductions mediated by the VeriCor® monitor.

Table 2-B. Levels of HF Outcomes & Costs After 50% Reductions With Treatment Guided by VeriCor® Monitoring

Location	Population	Deaths	Hospitalizations	Costs
Connecticut	3.5M	2,802	7,851	\$220M
Massachusetts	6.4M	5,150	14,417	\$404M
Ohio	11.5M	9,182	27,711	\$720M
Florida	18.0M	14,472	40,522	\$1.1B
Texas	23.5M	18,806	52,658	\$1.5B
California	36.0M	29,166	81,666	\$2.3B

Reductions In HF Outcomes & Costs By 50% Equal Outcomes Prevented & Care-Costs Saved. Of note, levels of HF outcomes and costs after 50% reductions are also equal to the number of deaths and hospitalizations prevented and care-costs saved by VeriCor® monitoring.

Comment on Table 2-B. In Connecticut, with a population of 3.5 million, 2,802 deaths and 7,851 hospitalizations could be prevented and savings in care-costs could be \$220 million a year.

As shown under “Population”, as populations increase in each of the other 5 states from Massachusetts to California, reductions in HF deaths, hospitalizations and costs increase proportionately while cost of care decrease.

For example, in California, with a population of 36 million, annual HF deaths could be reduced by 29,166, hospitalizations by 81,666 and care-costs could be reduced by \$2.3 billion in California.

5. Number of States with Major Reductions in HF Outcomes & Cost

Many States Will Have Major Reductions In HF Outcomes & Costs With VeriCor® Monitoring. Table 3, below, shows the number of states in which deaths could be reduced by >4,800 to >15,000, hospitalizations could be reduced by >15,000 to > 40,000 and care-costs could be reduced by \$300 million to \$2 billion.

Table 3. Reductions in Deaths, Hospitalizations & Costs with Monitoring

Deaths		Hospitalizations		Costs	
>4,800	12	>15,000	10	>\$300M	19
>6,000	11	>20,000	8	>\$400M	10
>8,000	7	>25,000	7	>\$500M	10
>10,000	4	>30,000	4	>\$600M	8
>12,000	4	>35,000	4	>\$700M	7
>15,000	3	>40,000	3	>\$800M	3
				>\$1B	4
				>\$2B	1

Deaths. Monitoring is expected to reduce deaths by >4,800 a year in 12 states, by >6,000 in 11 states, by >8,000 in 7 states, by >10,000 in 4 states, by >12,000 in 4 states and by >15,000 in 3 states.

Hospitalizations. Monitoring is expected to reduce hospitalizations by >15,000 a year in 10 states, by >20,000 in 8 states, by >25,000 in 7 states, by >30,000 in 4 states, by >35,000 in 4 states and by >40,000 in 3 states.

Care-Costs. Care-costs could be reduced by >\$300 million a year in 19 states, by >\$400 million in 10 states, by >\$500 million in 10 states, by >\$600 million in 8 states, by >\$700 million in 7 states, by >\$800 million in 3 states, by >\$1 billion in 4 states and by >\$2 billion in 1 state.

Conclusion. Now that it is clear that the serious limitations of clinical assessment are responsible for most HF deaths, hospitalizations and costs in the U.S. and the ICU-caliber VeriCor® monitor can overcome these limitations, clinical assessment must be supplemented by the VeriCor® monitor in all states if HF is to be optimized in the U.S.

6. Potential Impact of VeriCor®-Managed Care in All States

Current HF Outcomes & Costs with Clinical Assessment. The current levels of HF hospitalizations, deaths and costs in patients managed by clinical assessment are shown in the column at the left of Table 4, below.

Projected Outcomes & Costs with VeriCor® Monitor. In the middle column of Table 4, levels of hospitalization, deaths and costs expected after clinical assessment is replaced by the VeriCor® monitor are shown.

Potential Reductions In Hospitalizations, Deaths & Costs In HF Patients With VeriCor® Monitor Across U.S. Expected reductions in hospitalizations and deaths along with expected annual cost-savings with treatment guided by the VeriCor® monitor across the U.S. are shown in the column to the right of Table 4.

Table 4. Annual Outcomes & Costs in Patients Managed By Clinical Assessment v. Patients Managed By VeriCor® Monitor

	Current Status with Clinical Assessment	Reductions with VeriCor Monitor	Reductions & Savings
Hospitalizations	1 Million	200,000	800,000
Deaths	300,000	180,000	120,000
Costs	\$39 Billion	\$7.8 Billion	\$31.2 Billion

Current Annual Levels of Hospitalizations, Deaths & Costs with Clinical Assessment. As shown under “**Current Status with Clinical Assessment**” in Table 4, there are 1 million hospitalizations, 300,000 deaths and care-costs of \$39 billion a year in the U.S.

Replacement of Clinical Assessment with VeriCor® Monitor Could Prevent Most HF Hospitalizations & Costs & Reduce Deaths. Based on the reliable scientific evidence that treatment guided by the VeriCor® monitor could reduce HF hospitalizations and costs by 80% and deaths by 40%, comprehensive HF management with the VeriCor® monitor could reduce hospitalizations to 200,000 a year from 1 million a year and care-costs to \$7.8 billion a year from \$31.2 billion a year.

In addition, deaths could be reduced by at least 40% from 300,000 to 180,000 a year and possibly by as much as 60% which would reduce HF deaths per year to 120,000.

7. In 12 Minutes, Patient Friendly VeriCor® Monitor Measures LVEDP

In the photograph shown below, LVEDP is being measured in a patient by a secretary trained to be a VeriCor® technician, a role in which she performs exceptionally well.



Comment on Photograph. As shown in the photograph, LVEDP is being measured by the VeriCor® monitor. The patient being tested has a sensor over his right radial artery to acquire a continuous record of his arterial pressure and waveform during the test.

Measuring LVEDP with VeriCor® Monitor. As shown in the photograph above, the patient being tested is holding a tube with a mouthpiece that is connected to the VeriCor® medical grade computer to record his expiratory pressure during the test.

When the prompt on the monitor screen shows a balloon-shaped circle, the patient is asked to blow into the mouthpiece until the circle turns green. This requires only a modest expiratory effort, i.e., about 20 mmHg, and the test is completed.

Analysis & Storage of Results. Once patient testing is completed, the VeriCor® monitor computer analyzes the acquired data and a proprietary software program calculates LVEDP. The LVEDP level is then displayed on the computer screen and stored under the patients name for future reference.

8. Cardiology Leaders in U.S. Favor Widespread VeriCor® Availability. A survey of more than 70 leaders in HF care in the U.S. showed that more than 90% want the VeriCor® monitor in their hospital ICUs, on the medical wards of their hospitals and in their offices.

9. Regulatory Status. The VeriCor® monitor was cleared to market by FDA in 2004.

10. Publications. A total of 13 abstracts and 4 papers have been published in peer-reviewed medical scientific journals and the most compelling data proving the positive impact of the VeriCor® monitor on HF hospitalizations, deaths and costs could be published in a highly respected scientific journal in the first quarter of 2010.

11. Patent Estate. 58 patents have been submitted and most were incorporated in part into a foundation patent. Patents have been allowed or are pending in the U.S., Canada, Europe, Japan and Australia.

12. Strategic Options & Exit Strategy. As many as 15,000 of the 25,000 HF deaths and 60,000 of the 82,000 HF hospitalizations a month could be prevented by the VeriCor® monitor. In addition, the VeriCor® monitor could save \$2.2 billion a month in scarce medical care resources.

Accordingly, CVP Diagnostics feels obliged to get the VeriCor® monitor to as many HF patients as possible as soon as possible.

This view includes but is not limited to selling, leasing or partnering with a major medical device provider.