

Controlling Heart Failure State-By-State in U.S.

I. New Noninvasive Monitor Could Control Heart Failure (HF) In U.S.

CVP Diagnostics' VeriCor® Monitor Could Control HF in Every U.S. State. A recently completed study using the first and only noninvasive ICU-caliber monitor, the VeriCor monitor, was more effective in reducing HF deaths, hospitalizations and costs than clinical assessment, the current "standard of care" for HF in the U.S.

Randomized Study Compares Clinical Assessment to VeriCor® Monitor for HF Outcomes & Costs. The study design called for the sequential randomization of 50 "stable" HF patients either to treatment guided by clinical assessment or treatment guided by the VeriCor® monitor. HF hospitalizations, deaths and care-costs were accounted for in each group.

More Hospitalizations Occurred In Patients Managed By Clinical Assessment Than In Patients Managed By VeriCor® At the end of the 12-month follow-up period in patients managed by clinical assessment, there were 22 hospitalizations while in patients managed by the VeriCor® monitor, there were 4 hospitalizations. Thus, there were 5.5 times as many hospitalizations in patients managed by clinical assessment than there were in patients managed by the VeriCor® monitor.

More Deaths Occurred In Patients Managed By Clinical Assessment Than In Patients Managed By VeriCor® In addition, there were three times as many deaths in patients managed by clinical assessment than in those managed by VeriCor®.

In Patients Managed By Clinical Assessment, Care-Costs Were Five Times Higher. Costs of care were more than 5 times higher in patients managed by clinical assessment than in those managed by VeriCor®.

Conclusions.

1. Treatment guided by the VeriCor monitor is far more effective in controlling HF hospitalizations, deaths and costs than is clinical assessment.
2. These data suggest that replacing clinical assessment with the VeriCor monitor could control HF deaths, hospitalizations and costs in all U.S. states.

Implications for HF Care In U.S. Potential human and financial benefits of replacing clinical assessment with the VeriCor® monitor for HF care in all U.S. states are considered below.

II. Projecting Reductions in Outcomes & Costs with VeriCor®

Potential Reductions in HF Outcomes & Costs in U.S. States To make the potential human and financial benefits of HF monitoring readily accessible to U.S. states, the Company projected likely reductions in HF outcomes and costs in each of the 50 states.

Table 1 projects current annual levels of HF hospitalizations, deaths and costs in 6 states that vary in population from among the smallest (Connecticut and Massachusetts) to among the largest (Texas and California).

Table 1. Annual HF Outcomes & Costs in 6 States by Population

Location	Population	Deaths	Hospitalizations	Costs
Connecticut	3.5M*	5,608	15,702	\$440.0M
Massachusetts	6.4M	10,300	28,838	\$808.0M
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	\$3.0B
California	36.0M	58,332	163,332	\$4.6B

*M, million

**B, billion

Comment. Connecticut and Massachusetts, the smallest of the 6 states, have populations of 3.5 million and 6.4 Million, respectively, annual HF deaths of more than 5.6 million and 10.3 million and annual HF care-costs of \$440 million and \$808 million.

Achievable Reductions In Outcomes & Care-Costs With VeriCor® Clinical studies have shown that replacing clinical assessment with the VeriCor® monitor reduced HF hospitalizations and costs by more than 80% and deaths by 67%. These data suggest reductions in HF deaths, hospitalizations and costs of at least 50% should be achievable by comprehensive VeriCor® monitoring at the state level.

Accordingly, for the purposes of projecting likely reductions in outcomes and care-costs with VeriCor® monitoring in U.S. states, reductions in HF deaths, hospitalizations and care-costs of 50% will be used.

Projecting VeriCor®-Mediated Annual Reductions Of 50% in Outcomes & Costs Table 2, below, indicates the number of deaths and hospitalizations and the care-cost savings after VeriCor®-mediated reductions of 50% in each of the 6 states identified Table 1.

Table 2. 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	\$220.0M
Massachusetts	6.4M	5,150	14,417	\$404.0M
Ohio	11.5M	9,182	27,711	\$720.0M
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

Comment on Table 2. In Connecticut, with a population of 3.5 Million, 2,802 HF deaths and 7,851 HF hospitalizations could be prevented and care-costs could be reduced by \$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 care-costs decrease relative to those shown in Table 1.

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

III. Number of States with Major Reductions in HF Outcomes & Costs

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		Care-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.*

IV. Potential Impact of VeriCor® Managed HF 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 are shown in 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 with VeriCor®
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 & While Reducing Deaths Dramatically. Based on reliable scientific evidence that treatment guided by the VeriCor® monitor could reduce HF hospitalizations and costs by 80% and deaths by 40 to 60%, 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 \$39 billion a year.

Replacing Clinical Assessment with the VeriCor® Monitor Will Decrease Heart Failure Outcomes & Costs In 50 States. Table 5-A and Table 5-B show that cost-savings and net-savings will be achieved by VeriCor® monitoring in all 50 states.

Cost-Effectiveness of VeriCor® in the 50 United States is shown In Tables 5-A and 5-B.

Table 5-A. Annual HF Deaths, Hospitalizations & Costs in Each of the 50 States

State	Population	Number of HF Patients	Patients with Elevated LVEDP	Annual Deaths	Annual Hospitalizations	Annual Care Costs For Hospitals
Alabama	4,447,100	74,120	47,437	8,153	31,130	\$435.8M
Alaska	626,932	10,449	6,687	483	1,843	\$39M
Arizona	5,130,632	85,512	54,928	6,020	23,070	\$322M
Arkansas	2,673,400	44,558	28,516	3,137	11,977	\$168M
California	33,871,648	564,539	361,238	39,743	151,745	\$2B
Colorado	4,301,261	71,689	45,880	5,047	19,270	\$270M
Connecticut	3,405,565	56,761	36,326	3,134	15,257	\$214M
Delaware	783,600	13,060	8,358	919	3,510	\$49M
Florida	15,982,378	266,378	170,479	18,753	111,877	\$1B
Georgia	8,186,453	136,444	87,322	9,605	36,675	\$514M
Hawaii	1,211,537	20,193	12,923	1,422	5,428	\$77M
Idaho	1,293,953	21,566	315	35	132	\$81M
Illinois	12,419,293	206,992	132,472	14,572	55,638	\$779M
Indiana	6,080,485	101,343	64,860	7,135	27,241	\$381M
Iowa	2,926,324	48,773	31,214	3,434	13,110	\$184M
Kansas	2,688,418	44,808	28,676	3,154	12,044	\$169M

State	Population	Number of HF Patients	Patients with Elevated LVEDP	Annual Deaths	Annual Hospitalizations	Annual Care Costs For Hospitals
Kentucky	4,041,769	67,364	43,112	4,742	18,107	\$254M
Louisiana	4,468,976	74,484	47,669	5,244	20,021	\$280M
Maine	1,274,923	21,249	13,599	1,996	5,712	\$80M
Maryland	5,296,486	88,277	56,496	6,215	23,728	\$332M
Massachusetts	6,349,097	105,820	67,724	7,450	28,444	\$398M
Michigan	9,938,444	165,644	106,010	11,661	49,424	\$623M
Minnesota	4,919,479	81,993	52,474	5,772	22,039	\$309M
Mississippi	2,844,658	47,412	30,343	3,338	12,744	\$178M
Missouri	5,595,211	93,255	59,682	6,565	25,066	\$351M
Montana	902,195	15,037	9,623	1,059	4,042	\$57M
Nebraska	1,711,263	28,522	18,253	2,008	7,666	\$107M
Nevada	1,998,257	33,305	21,315	2,347	8,952	\$125M
New Hampshire	1,235,786	20,597	13,182	1,450	5,536	\$78M
New Jersey	8,414,350	140,239	89,753	9,873	37,696	\$528M
New Mexico	1,819,046	30,318	19,404	2,134	8,150	\$114M
New York	18,976,457	316,274	202,415	22,266	85,014	\$1B
North Carolina	8,049,313	134,158	85,859	9,445	36,060	\$505M

State	Population	Number of HF Patients	Patients with Elevated LVEDP	Annual Deaths	Annual Hospitalizations	Annual Care Costs For Hospitals
North Dakota	642,200	10,704	6,850	754	2,877	\$40M
Ohio	11,353,140	189,223	121,100	13,321	50,820	\$712M
Oklahoma	3,450,654	57,512	36,807	4,049	15,459	\$216M
Oregon	3,421,399	57,024	36,495	4,414	15,328	\$215M
Pennsylvania	12,281,054	204,688	130,998	14,410	55,019	\$770M
Rhode Island	1,048,319	17,472	11,182	1,230	4,696	\$66M
South Carolina	4,012,012	66,868	42,795	4,707	17,974	\$252M
South Dakota	754,844	12,581	8,052	886	3,382	\$94M
Tennessee	5,689,283	94,823	60,687	6,676	23,321	\$652M
Texas	20,851,820	347,537	222,424	24,467	93,418	\$2.6B
Utah	2,233,169	37,220	23,821	2,620	10,005	\$280.2M
Vermont	608,827	10,147	6,494	714	2,727	\$76.4M
Virginia	7,078,515	117,978	75,506	8,306	31,713	\$888M
Washington	5,894,121	98,237	62,872	6,916	26,406	\$740M
West Virginia	1,808,344	30,140	19,290	2,122	8,102	\$226M
Wisconsin	5,363,675	89,396	57,213	6,293	24,029	\$672M
Wyoming	493,782	8,230	5,567	579	2,212	\$62M

State	Population	Number of HF Patients	Patients with Elevated LVEDP	Annual Deaths	Annual Hospitalizations	Annual Care Costs For Hospitals
Total	280,849,847	4,680,913	2,982,697	331,637	1,305,836	\$21B

Annual Care-Costs for Hospitalizations. Because hospitalization rates vary widely in U.S. states, a cost of \$14,000 per HF hospitalizations was used to project hospitalization costs in each of the 50 states.

Total Annual HF Care-Costs for Each State. There are two principle components of HF care-costs in the United States, hospitalization costs and all other costs. Since all other costs are approximately the same as hospitalization costs, total costs of HF care were projected by multiplying the costs of hospitalizations by two.

Table 5-B. HF Deaths, Hospitalizations & Costs After 50% VeriCor® Mediated Reductions

State	Number of HF Patients	Number of HF Patients with Elevated LVEDPs	Annual Deaths After 50% Reductions	Annual Hospitalizations After 50% Reductions	Annual Care Costs After 50% Reductions	Annual VeriCor® Monitoring Costs	Net Annual Care-Cost Savings
Alabama	74,120	47,437	3,558	9,962	\$279M	\$64M	\$215M
Alaska	10,449	6,687	502	1,405	\$39M	\$9M	\$30M
Arizona	85,512	54,728	4,105	11,493	\$322M	\$74M	\$248M
Arkansas	44,558	28,517	2,139	5,989	\$168M	\$38M	\$130M
California	564,539	361,305	27,098	75,874	\$2B	\$488M	\$1.5B
Colorado	71,689	45,881	3,441	9,635	\$270M	\$62M	\$208M
Connecticut	56,761	36,327	2,725	7,629	\$214M	\$49M	\$165M
Delaware	13,060	8,358	627	1,756	\$49M	\$11M	\$38M
Florida	266,378	170,482	12,786	35,801	\$1B	\$230M	\$770M
Georgia	136,444	87,324	6,550	18,338	\$514M	\$118M	\$396M
Hawaii	20,193	12,924	969	2,714	\$77M	\$17M	\$60M
Idaho	21,566	13,802	1,035	2,899	\$81M	\$19M	\$62M
Illinois	206,992	132,475	9,936	27,820	\$779M	\$179M	\$600M
Indiana	101,343	64,860	4,864	13,621	\$381M	\$88M	\$293M
Iowa	48,773	31,215	2,341	6,555	\$184M	\$42M	\$142M
Kansas	44,808	28,677	2,151	6,022	\$169M	\$39M	\$130M
Kentucky	67,364	43,113	3,233	9,054	\$254M	\$58M	\$196M

State	Number of HF Patients	Number of HF Patients with Elevated LVEDPs	Annual Deaths After 50% Reductions	Annual Hospitalizations After 50% Reductions	Annual Care Costs After 50% Reductions	Annual VeriCor® Monitoring Costs	Net Annual Care-Cost Savings
Louisiana	74,484	47,670	3,575	10,011	\$280M	\$64M	\$216M
Maine	21,249	13,599	1,020	2,856	\$80M	\$18M	\$62M
Maryland	88,277	56,497	4,237	11,864	\$332M	\$76M	\$256M
Massachusetts	105,820	67,725	5,079	14,222	\$398M	\$91M	\$307M
Michigan	165,644	106,012	7,951	22,263	\$623M	\$143M	\$480M
Minnesota	81,993	52,476	3,936	11,020	\$309M	\$71M	\$238M
Mississippi	47,412	30,344	2,276	6,372	\$178M	\$41M	\$137M
Missouri	93,255	59,683	4,476	12,534	\$351M	\$81M	\$270M
Montana	15,037	9,624	722	2,021	\$57M	\$13M	\$44M
Nebraska	28,522	18,254	1,369	3,833	\$107M	\$25M	\$82M
Nevada	33,305	21,315	1,599	4,476	\$125M	\$29M	\$96M
New Hampshire	20,597	13,182	989	2,768	\$78M	\$18M	\$60M
New Jersey	140,239	89,755	6,732	18,849	\$528M	\$121M	\$407M
New Mexico	30,318	19,404	1,455	4,075	\$114M	\$26M	\$88M
New York	316,274	202,420	15,181	42,508	\$1B	\$273M	\$727M
North Carolina	134,158	85,861	6,440	18,031	\$505M	\$116M	\$389M
North Dakota	10,704	6,851	514	1,439	\$40M	\$9M	\$31M
Ohio	189,223	121,103	9,083	25,432	\$712M	\$163M	\$549M
Oklahoma	57,512	36,808	2,761	7,730	\$216M	\$50M	\$166M

State	Number of HF Patients	Number of HF Patients with Elevated LVEDPs	Annual Deaths After 50% Reductions	Annual Hospitalizations After 50% Reductions	Annual Care Costs After 50% Reductions	Annual VeriCor® Monitoring Costs	Net Annual Care-Cost Savings
Oregon	57,024	36,495	2,737	7,664	\$215M	\$49M	\$166M
Pennsylvania	204,688	131,000	9,825	27,510	\$770M	\$177M	\$593M
Rhode Island	17,472	11,182	839	2,348	\$66M	\$15M	\$51M
South Carolina	66,868	42,796	3,210	8,987	\$252M	\$58M	\$194M
South Dakota	12,581	8,052	604	1,691	\$47M	\$11M	\$36M
Tennessee	94,823	60,687	4,552	12,744	\$357M	\$82M	\$275M
Texas	347,537	222,424	16,682	46,709	\$1B	\$300M	\$700M
Utah	37,220	23,821	1,787	5,002	\$140M	\$32M	\$108M
Vermont	10,147	6,494	487	1,364	\$38M	\$9M	\$29M
Virginia	117,978	75,506	5,663	15,856	\$444M	\$102M	\$342M
Washington	98,237	62,872	4,715	13,203	\$370M	\$85M	\$285M
West Virginia	30,140	19,290	1,447	4,051	\$113M	\$26M	\$87M
Wisconsin	89,396	57,213	4,291	12,015	\$336M	\$77M	\$259M
Wyoming	8,230	5,267	395	1,106	\$31M	\$7M	\$24M
Total	4,680,913	2,995,794	224,689	629,121	\$17B	\$5B	\$13B