Intermacs

#HHSN268201100025C

INTERMACS

Interagency Registry for Mechanically Assisted Circulatory Support

Data Quality Report

2015-05-01

[redacted]

Implant and event dates: June 23, 2006 to May 1, 2015

05/01/2015

Prepared by:

The Data and Clinical Coordinating Center
University of Alabama at Birmingham

James K. Kirklin, MD
Ryan S. Cantor, MSPH
Susan L. Myers
Mary Lynne Clark
Craig Collum, MPH
Kathryn Hollifield, RN

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[redacted]

Confidential

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This report contains information from [redacted] patients.

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I. Introduction and Methods

I.A. Purposes of this Report

Data quality is always a concern in a clinical registry. The purpose of this report is to provide each hospital an up to date snapshot of key data they have entered into INTERMACS and to provide lists of inconsistencies and improbable values that occur in the data. By addressing and correcting these data quality issues, the quality of the INTERMACS Registry and the resultant analyses will be improved.

I.B. Source of Data and Limitations

The data in this report are based on implants entered into the INTERMACS web-based data application through May 1, 2015. Patient enrollment in INTERMACS began on June 23, 2006. Your institution may have joined INTERMACS at a later date and therefore your patient enrollment may have begun at a later date.

INTERMACS is a registry that strives to meet the data quality standards of a prospective clinical trial. Many of the steps employed to increase the quality of the data (e.g. auditing, inconsistency resolution, etc.) are described in the INTERMACS protocol which can be found at www.intermacs.org. INTERMACS is an on-going registry and therefore data quality efforts will always have an associated lag time.

As you review the data from your hospital that are contained in this report, you may find some information that appears incorrect or inconsistent. Please remember that this report is a direct function of the data that has been entered at your hospital. Therefore, please check any data issues with your online submitted data. The only caveat to this is that any corrections that you have made to your data since May 1, 2015 will not appear in this report. They will appear in the next quarterly report.

I.C. Patient Coverage

This Data Quality Report contains information from ALL INTERMACS patients at your institution. This includes patients receiving primary, subsequent, retrospective devices, and pediatric patients that were entered prior to the launch of pediMACS.

A notable exception is information from transfer patients. For patients who have transferred away from your institution, only information prior to the transfer is listed. Information from patients that have transferred to your institution are included in this report. Please refer to table headings and descriptions for information on how transfer patients are handled in each exhibit.

Some of the patients and events listed in this report are not included in the accompanying Quality Assurance Report. The exclusion of these patients from the QA report is designed to facilitate the statistical comparison between your patient population and INTERMACS.

Exclusion reasons from the QA report include:
a) Retrospective patients (implanted prior to site activation)
b) Patients whose first implant in INTERMACS is not their primary implant
c) Patients only receiving an RVAD
d) Pediatric patients entered into INTERMACS prior to the launch of pediMACS

II. Data Quality Tables

Exhibit 1a. Implants by Year and Device Type

The following table summarizes the number of all device types implanted at your site by year. This includes all primary, subsequent, retrospective devices, and pediatric patients that were entered prior to the launch of pediMACS. **This table does not count devices in transfer patients that were implanted at other sites.**

Implant Year	Device Type			All
	LVAD	RVAD	BiVAD	All
	N	N	N	N
2006			3	3
2007			1	1
2008	4	2		6
2009	7		3	10
2010	17	2	2	21
2011	20	1		21
2012	17	1		18
2013	17	1	2	20
2014	18			18
All	100	7	11	118

Exhibit 1b. Total Patients Receiving Implants and Implant Operations

The following table lists the total number of patients enrolled at your site and the total number of implant operations. **Information from patients that have transferred to your institution is not listed in this table.**

Patients Implanted	Implant Operations
100	118

Exhibit 2a. Patient and Device Listing

The following table contains data from ALL INTERMACS patients at your institution. See section I.C. for a complete description of the patient coverage of this report. Please review this list for completeness and accuracy.

Pt #	Dev #	Pt ID	Dev ID	Age	Race	Sex	Pre-Implant Device Strategy	Implant Date	Device Type	Device Brand	Explant Date	Tx Date	Death Date	Explant Reason
1	1	[redacted]	[redacted]	64	W	M	BTT Likely	[redacted]	BiVAD	Thoratec IVAD/Thoratec IVAD	B[redacted]		[redacted]	B:Device Malfunction - Elective
2	1	[redacted]	[redacted]	34	W	F	BTT Listed	[redacted]	BiVAD	Thoratec PVAD/Thoratec PVAD	B[redacted]	[redacted]		B:Transplant
3	1	[redacted]	[redacted]	20	O	F	BTT Listed	[redacted]	BiVAD	HeartMate VE/Thoratec IVAD	B[redacted]		[redacted]	B:~Death~
4	1	[redacted]	[redacted]	21	O	M	BTT Likely	[redacted]	BiVAD	Thoratec IVAD/Thoratec IVAD	B[redacted]	[redacted]		B:Transplant
5	1	[redacted]	[redacted]	57	W	F	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device removed (or turned off) for reasons other than recovery, transplant, or death: Other, specify
	2	[redacted]	[redacted]	57	W	F	BTT Listed	[redacted]	RVAD	Thoratec Centrimag (Levitronix)	R[redacted]			R:Ventricular Recovery - Device Removed
	3	[redacted]	[redacted]	58	W	F	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]		[redacted]	L:~Death~
6	1	[redacted]	[redacted]	52	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
7	1	[redacted]	[redacted]	58	W	F	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
	2	[redacted]	[redacted]	58	W	F	BTT Listed	[redacted]	RVAD	Thoratec IVAD	R[redacted]	[redacted]		R:Transplant
8	1	[redacted]	[redacted]	20	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
9	1	[redacted]	[redacted]	39	W	M	BTT Listed	[redacted]	BiVAD	Thoratec PVAD/Thoratec PVAD	B[redacted]	[redacted]		B:Transplant
10	1	[redacted]	[redacted]	34	AA	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant

Exhibit 2a. Patient and Device Listing

Pt #	Dev #	Pt ID	Dev ID	Age	Race	Sex	Pre-Implant Device Strategy	Implant Date	Device Type	Device Brand	Explant Date	Tx Date	Death Date	Explant Reason
11	1	[redacted]	[redacted]	27	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
12	1	[redacted]	[redacted]	58	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
13	1	[redacted]	[redacted]	40	W	F	BTT Listed	[redacted]	BiVAD	Thoratec IVAD/Thoratec IVAD	B[redacted]	[redacted]		B:Transplant
14	1	[redacted]	[redacted]	59	W	M	BTT Likely	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
15	1	[redacted]	[redacted]	29	O	M	BTT Likely	[redacted]	LVAD	HeartMate II				
16	1	[redacted]	[redacted]	60	W	F	BTT Listed	[redacted]	BiVAD	Thoratec PVAD/Thoratec PVAD	B[redacted]	[redacted]		B:Transplant
17	1	[redacted]	[redacted]	24	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
18	1	[redacted]	[redacted]	45	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
19	1	[redacted]	[redacted]	51	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L:1[redacted]	[redacted]		L:Transplant
20	1	[redacted]	[redacted]	73	O	M	DT	[redacted]	LVAD	HeartMate II			[redacted]	
21	1	[redacted]	[redacted]	67	W	M	DT	[redacted]	LVAD	HeartMate II	L[redacted]		[redacted]	L:~Death~
22	1	[redacted]	[redacted]	31	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
23	1	[redacted]	[redacted]	20	W	M	BTT Likely	[redacted]	BiVAD	Thoratec PVAD/Thoratec PVAD	B[redacted]	[redacted]		B:Transplant
24	1	[redacted]	[redacted]	49	W	F	BTT Likely	[redacted]	BiVAD	Thoratec PVAD/Thoratec PVAD			[redacted]	
25	1	[redacted]	[redacted]	68	W	M	DT	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device Malfunction - Emergent
	2	[redacted]	[redacted]	68	W	M	DT	[redacted]	LVAD	HeartMate II			[redacted]	
26	1	[redacted]	[redacted]	57	W	F	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
27	1	[redacted]	[redacted]	69	W	M	DT	[redacted]	LVAD	HeartMate II				
	2	[redacted]	[redacted]	69	W	M	DT	[redacted]	RVAD	Thoratec Centrimag (Levitronix)			[redacted]	

Exhibit 2a. Patient and Device Listing

Pt #	Dev #	Pt ID	Dev ID	Age	Race	Sex	Pre-Implant Device Strategy	Implant Date	Device Type	Device Brand	Explant Date	Tx Date	Death Date	Explant Reason
28	1	[redacted]	[redacted]	31	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
29	1	[redacted]	[redacted]	55	O	M	DT	[redacted]	LVAD	HeartMate II				
30	1	[redacted]	[redacted]	52	W	M	DT	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device Malfunction - Emergent
	2	[redacted]	[redacted]	52	W	M	DT	[redacted]	LVAD	HeartMate II			[redacted]	
31	1	[redacted]	[redacted]	68	W	M	DT	[redacted]	LVAD	HeartMate II				
32	1	[redacted]	[redacted]	48	O	M	BTT Likely	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
33	1	[redacted]	[redacted]	52	O	F	BTT Moderate	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device Thrombosis - Emergent
	2	[redacted]	[redacted]	52	O	F	BTT Moderate	[redacted]	RVAD	Thoratec Centrimag (Levitronix)	R[redacted]			R:Ventricular Recovery - Device Removed
	3	[redacted]	[redacted]	55	O	F	DT	[redacted]	LVAD	HeartMate II			[redacted]	
34	1	[redacted]	[redacted]	60	W	M	DT	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
35	1	[redacted]	[redacted]	44	O	M	BTT Likely	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
36	1	[redacted]	[redacted]	50	W	M	BTT Likely	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
37	1	[redacted]	[redacted]	37	O	M	DT	[redacted]	LVAD	HeartMate II			[redacted]	
38	1	[redacted]	[redacted]	51	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
39	1	[redacted]	[redacted]	61	O	M	BTT Unlikely	[redacted]	LVAD	HeartMate II				
40	1	[redacted]	[redacted]	28	W	M	BTT Moderate	[redacted]	LVAD	HeartMate II				
41	1	[redacted]	[redacted]	59	W	M	BTT Moderate	[redacted]	LVAD	HeartMate II	L[redacted]		[redacted]	L:~Death~
42	1	[redacted]	[redacted]	51	W	M	BTT Listed	[redacted]	LVAD	HeartMate II				
43	1	[redacted]	[redacted]	63	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
44	1	[redacted]	[redacted]	60	O	F	BTT Moderate	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant

Exhibit 2a. Patient and Device Listing

Pt #	Dev #	Pt ID	Dev ID	Age	Race	Sex	Pre-Implant Device Strategy	Implant Date	Device Type	Device Brand	Explant Date	Tx Date	Death Date	Explant Reason
45	1	[redacted]	[redacted]	60	W	M	BTT Moderate	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device Malfunction - Emergent
	2	[redacted]	[redacted]	60	W	M	BTT Moderate	[redacted]	RVAD	Thoratec Centrimag (Levitronix)	R[redacted]			R:Ventricular Recovery - Device Removed
46	1	[redacted]	[redacted]	59	W	M	BTT Unlikely	[redacted]	LVAD	HeartMate II				
47	1	[redacted]	[redacted]	80	W	M	DT	[redacted]	LVAD	HeartMate II				
48	1	[redacted]	[redacted]	45	AA	F	BTT Likely	[redacted]	LVAD	HeartMate II			[redacted]	
49	1	[redacted]	[redacted]	66	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]		[redacted]	L:~Death~
50	1	[redacted]	[redacted]	31	W	M	BTT Moderate	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
51	1	[redacted]	[redacted]	49	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
52	1	[redacted]	[redacted]	62	W	M	DT	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device Malfunction - Elective
	2	[redacted]	[redacted]	63	W	M	DT	[redacted]	LVAD	HeartMate II				
53	1	[redacted]	[redacted]	56	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
54	1	[redacted]	[redacted]	33	AA	F	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
55	1	[redacted]	[redacted]	64	W	M	BTT Moderate	[redacted]	LVAD	HeartMate II			[redacted]	
56	1	[redacted]	[redacted]	48	W	M	BTT Likely	[redacted]	LVAD	HeartMate II				
57	1	[redacted]	[redacted]	62	W	F	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
58	1	[redacted]	[redacted]	67	W	M	DT	[redacted]	LVAD	HeartMate II				
59	1	[redacted]	[redacted]	82	W	M	DT	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device Thrombosis - Emergent
	2	[redacted]	[redacted]	82	W	M	DT	[redacted]	LVAD	HeartMate II				
60	1	[redacted]	[redacted]	49	W	M	BTT Likely	[redacted]	LVAD	HeartMate II				
61	1	[redacted]	[redacted]	28	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant

Exhibit 2a. Patient and Device Listing

Pt #	Dev #	Pt ID	Dev ID	Age	Race	Sex	Pre-Implant Device Strategy	Implant Date	Device Type	Device Brand	Explant Date	Tx Date	Death Date	Explant Reason
62	1	[redacted]	[redacted]	52	W	F	BTT Likely	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
63	1	[redacted]	[redacted]	52	W	F	BTT Likely	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device Thrombosis - Emergent
	2	[redacted]	[redacted]	52	W	F	BTT Moderate	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
64	1	[redacted]	[redacted]	30	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device Malfunction - Emergent
	2	[redacted]	[redacted]	30	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
	3	[redacted]	[redacted]	30	W	M	BTR	[redacted]	RVAD	Thoratec Centrimag (Levitronix)	R[redacted]			R:Ventricular Recovery - Device Removed
65	1	[redacted]	[redacted]	59	O	M	DT	[redacted]	LVAD	HeartMate II			[redacted]	
66	1	[redacted]	[redacted]	21	AA	F	BTT Likely	[redacted]	LVAD	HeartMate II	L[redacted]			L:Ventricular Recovery - Device Removed
67	1	[redacted]	[redacted]	56	AA	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
68	1	[redacted]	[redacted]	53	W	F	BTT Likely	[redacted]	LVAD	HeartMate II				
69	1	[redacted]	[redacted]	61	W	M	BTT Listed	[redacted]	LVAD	HeartWare HVAD				
70	1	[redacted]	[redacted]	65	W	M	DT	[redacted]	LVAD	HeartMate II				
71	1	[redacted]	[redacted]	64	W	M	DT	[redacted]	LVAD	HeartMate II				
	2	[redacted]	[redacted]	64	W	M	BTR	[redacted]	RVAD	Thoratec Centrimag (Levitronix)	R[redacted]			R:Ventricular Recovery - Device Removed
72	1	[redacted]	[redacted]	57	W	M	BTT Listed	[redacted]	LVAD	HeartWare HVAD	L[redacted]	[redacted]		L:Transplant
73	1	[redacted]	[redacted]	55	W	F	BTT Likely	[redacted]	BiVAD	HeartWare HVAD/Thoratec Centrimag (Levitronix)			[redacted]	
74	1	[redacted]	[redacted]	62	W	M	BTT Listed	[redacted]	LVAD	HeartMate II				
75	1	[redacted]	[redacted]	62	W	M	BTT Listed	[redacted]	LVAD	HeartWare HVAD	L[redacted]	[redacted]		L:Transplant

Exhibit 2a. Patient and Device Listing

Pt #	Dev #	Pt ID	Dev ID	Age	Race	Sex	Pre-Implant Device Strategy	Implant Date	Device Type	Device Brand	Explant Date	Tx Date	Death Date	Explant Reason
76	1	[redacted]	[redacted]	64	O	M	DT	[redacted]	LVAD	HeartMate II				
77	1	[redacted]	[redacted]	31	AA	M	DT	[redacted]	LVAD	HeartMate II				
78	1	[redacted]	[redacted]	67	O	M	DT	[redacted]	LVAD	HeartMate II				
79	1	[redacted]	[redacted]	72	W	F	DT	[redacted]	LVAD	HeartMate II				
80	1	[redacted]	[redacted]	29	W	F	DT	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device Malfunction - Elective
81	1	[redacted]	[redacted]	65	W	F	DT	[redacted]	LVAD	HeartMate II				
82	1	[redacted]	[redacted]	54	W	F	BTT Likely	[redacted]	BiVAD	HeartMate II/Thoratec Centrimag (Levitronix)	L[redacted] R[redacted]	[redacted]		L:Transplant R:Ventricular Recovery - Device Removed
83	1	[redacted]	[redacted]	54	AA	M	BTT Likely	[redacted]	LVAD	HeartMate II	L[redacted]	[redacted]		L:Transplant
84	1	[redacted]	[redacted]	48	W	M	BTT Listed	[redacted]	LVAD	HeartMate II				
85	1	[redacted]	[redacted]	54	W	M	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device Thrombosis - Emergent
	2	[redacted]	[redacted]	54	W	M	BTT Listed	[redacted]	LVAD	HeartMate II				
86	1	[redacted]	[redacted]	52	W	M	DT	[redacted]	LVAD	HeartMate II				
87	1	[redacted]	[redacted]	40	AA	M	BTT Listed	[redacted]	LVAD	HeartWare HVAD				
88	1	[redacted]	[redacted]	64	W	M	DT	[redacted]	LVAD	HeartMate II				
89	1	[redacted]	[redacted]	63	W	M	BTT Listed	[redacted]	LVAD	HeartMate II				
90	1	[redacted]	[redacted]	66	O	M	DT	[redacted]	LVAD	HeartMate II				
91	1	[redacted]	[redacted]	44	AA	M	BTT Listed	[redacted]	LVAD	HeartWare HVAD				
92	1	[redacted]	[redacted]	53	W	M	DT	[redacted]	LVAD	HeartMate II				
93	1	[redacted]	[redacted]	52	W	M	BTT Listed	[redacted]	LVAD	HeartMate II				
94	1	[redacted]	[redacted]	70	O	M	DT	[redacted]	LVAD	HeartMate II				
95	1	[redacted]	[redacted]	57	W	F	BTT Listed	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device Thrombosis - Emergent

Exhibit 2a. Patient and Device Listing

Pt #	Dev #	Pt ID	Dev ID	Age	Race	Sex	Pre-Implant Device Strategy	Implant Date	Device Type	Device Brand	Explant Date	Tx Date	Death Date	Explant Reason
	2	[redacted]	[redacted]	57	W	F	BTT Listed	[redacted]	LVAD	HeartMate II				
97	1	[redacted]	[redacted]	59	AA	F	BTT Listed	[redacted]	LVAD	HeartWare HVAD				
98	1	[redacted]	[redacted]	33	AA	M	BTT Listed	[redacted]	LVAD	HeartWare HVAD				
100	1	[redacted]	[redacted]	73	W	M	DT	[redacted]	LVAD	HeartMate II				
101	1	[redacted]	[redacted]	48	O	M	DT	[redacted]	LVAD	HeartMate II	L[redacted]			L:Device Thrombosis - Emergent
	2	[redacted]	[redacted]	48	O	M	DT	[redacted]	LVAD	HeartMate II				
102	1	[redacted]	[redacted]	46	O	F	BTT Listed	[redacted]	LVAD	HeartWare HVAD				
103	1	[redacted]	[redacted]	67	O	M	DT	[redacted]	LVAD	HeartMate II				

Exhibit 2b. Patients Missing or Incomplete Implant Form

The following table contains a list of patients who have been entered into the Registry, but the implant form has not been completed. Please complete the implant form and any adverse events and follow-up forms as indicated.

Patient ID	FORM	Implant Date	Form Status
[redacted]	Implant		Incomplete
[redacted]	Implant		Incomplete
[redacted]	Implant		Incomplete
[redacted]	Implant		Incomplete
[redacted]	Implant		Incomplete

Exhibit 3a. Patient Deaths - Primary Cause of Death

The following table lists deaths among your patients and the primary cause of death. See section I.C. for a complete description of the patient coverage of this report. This list is sorted by Patient ID. Please review this list for completeness and accuracy.

Causes of death listed as 'unknown' or 'other' or 'missing' are found on Exhibit 3b.

Non-Transfer Patients: Patients that were implanted at your site.

Obs	Patient ID	Death Date	Primary Cause of Death	Cause of Death Specific Details
1	[redacted]	[redacted]	Circulatory: Right Heart Failure	right heart failure
2	[redacted]	[redacted]	Nervous System: Neurological Dysfunction	
3	[redacted]	[redacted]	Nervous System: Neurological Dysfunction	
4	[redacted]	[redacted]	Circulatory: Major Bleeding	
5	[redacted]	[redacted]	Digestive: Hepatic Dysfunction	
6	[redacted]	[redacted]	Major Infection	
7	[redacted]	[redacted]	Digestive: Renal Dysfunction	
8	[redacted]	[redacted]	Major Infection	
9	[redacted]	[redacted]	Nervous System: Neurological Dysfunction	
10	[redacted]	[redacted]	Nervous System: Neurological Dysfunction	
11	[redacted]	[redacted]	Multisystem Organ Failure (MSOF)	
12	[redacted]	[redacted]	Withdrawal of Support, specify	
13	[redacted]	[redacted]	Respiratory: Respiratory Failure	
14	[redacted]	[redacted]	Circulatory: Heart Disease	

Transfer Patients: Patients that were implanted elsewhere and are now followed at your site.
(The following table is left blank if no transfer patient deaths identified)

Exhibit 3b. Patient Deaths - Primary Cause of Death - Other/Unknown/Missing

The following causes of death are missing or have been listed as 'Other' or 'Unknown', please review these causes of death and determine if they fall into one of the causes listed in the INTERMACS web-based data entry (WBDE). If so, make the change in the WBDE. If the cause of death is missing or 'Unknown' please check to see if any further information may have become available (additional notes in charts, autopsy report, phone call or correspondence from doctor, family or hospital).

Non-Transfer Patients: Patients that were implanted at your site.

Obs	Pt ID	Death Date	Primary Cause of Death	Primary Cause of Death Other Specify
1	[redacted]	[redacted]	Other, specify	Mapped from Unknown:
2	[redacted]	[redacted]	Other, specify	Mapped from Unknown:
3	[redacted]	[redacted]	Other, specify	Mapped from Unknown:

Transfer Patients: Patients that were implanted elsewhere and are now followed at your site.
(The following table is left blank if no transfer patient deaths identified)

Exhibit 3c. Patient Deaths - Primary Cause of Death - Distribution

The following table summarizes the distribution of causes of death at your site.

Non-Transfer Patients: Patients that were implanted at your site.

Primary Cause of Death	N
Circulatory: Heart Disease	1
Circulatory: Major Bleeding	1
Circulatory: Right Heart Failure	1
Digestive: Hepatic Dysfunction	1
Digestive: Renal Dysfunction	1
Major Infection	2
Multisystem Organ Failure (MSOF)	1
Nervous System: Neurological Dysfunction	4
Other, specify	3
Respiratory: Respiratory Failure	1
Withdrawal of Support, specify	1

Transfer Patients: Patients that were implanted elsewhere and are now followed at your site.
(The following table is left blank if no transfer patient deaths identified)

Exhibit 4. Follow-up Forms Past Due

The following table lists the follow-up forms that were past due at the end of this reporting period. Additional follow-up forms may have come due since this list was compiled. Please enter the follow-up on these patients as indicated making sure that all AE's that occurred during the follow-up window have also been entered. A form may be on this list because information has been entered, but the form was not submitted. Please submit these forms.

Patient ID	Device ID	Form Type	Expected Date	Form Status
[redacted]	[redacted]	2.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	4 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	4.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	4 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	4 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Year Follow-Up	[redacted]	PAST DUE

Exhibit 4. Follow-up Forms Past Due

Patient ID	Device ID	Form Type	Expected Date	Form Status
[redacted]	[redacted]	2.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	2 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1.5 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE

Exhibit 4. Follow-up Forms Past Due

Patient ID	Device ID	Form Type	Expected Date	Form Status
[redacted]	[redacted]	3 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	3 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	6 Month Follow-Up	[redacted]	PAST DUE
[redacted]	[redacted]	1 Year Follow-Up	[redacted]	PAST DUE

Exhibit 5. Adverse Event Check

The following table lists patients at your hospital that have been entered into INTERMACS and followed for more than a year with NO reported adverse events as of the end of this reporting period. Please review for accuracy.

Patient ID	Implant Date	Years Alive
[redacted]	[redacted]	3.8
[redacted]	[redacted]	1.9
[redacted]	[redacted]	1.5
[redacted]	[redacted]	1.4
[redacted]	[redacted]	1.4
[redacted]	[redacted]	1.1
[redacted]	[redacted]	1.2
[redacted]	[redacted]	1.1

Exhibit 6. Patients on a device greater than 4 years

The following table lists patients that have been followed at your hospital for more than 4 years with no terminal or censoring events (death, transplant, or device removal for recovery) or device exchanges and have not transferred from your site or withdrawn from INTERMACS. Please review these patients carefully and update their information in the INTERMACS Registry. This follow-up is based on the first implant recorded in the registry. Note: Some of our current investigations have revealed a number of these types of data issues were due to terminal events that were not reported.

Patient ID	Implant Date	Years Alive
[redacted]	[redacted]	5.7
[redacted]	[redacted]	4.7
[redacted]	[redacted]	4.6

Exhibit 7. Explants / Subsequent Implant Check

The following table lists patients with an explant for device exchange with NO subsequent device entered into INTERMACS. Please review for accuracy.

Patient ID	Device ID	Explant Date	Explant Device Type	Explant Reason	Explant Reason Other Specify
[redacted]	[redacted]	[redacted]	BiVAD	Device Malfunction - Elective	
[redacted]	[redacted]	[redacted]	LVAD	Device Malfunction - Emergent	
[redacted]	[redacted]	[redacted]	LVAD	Device Malfunction - Elective	

Exhibit 8. NYHA < 3

The following table lists patients with a pre-implant NYHA class of less than 3. Please review for accuracy.

Patient ID	Implant Date	Device Number	Form	NYHA Class
[redacted]	[redacted]	1	Pre-Implant	Class I

Exhibit 9a. Screened, Eligible, and Enrolled

The following table shows the number of screened, eligible, and enrolled patients. Please note that the INTERMACS electronic screening log was introduced on 03/05/2009. The numbers of screened patients prior to that date were not recorded in the Registry.

Screened	Eligible	Enrolled	Percent Enrolled
115	99	94	94.9%

Exhibit 9b. Reasons for Ineligibility

REASON FOR INELIGIBILITY	Patients	Percent
Non-FDA approved device	16	100.0%
Patient is incarcerated (prisoner)	0	0.0%

Exhibit 10. Implant Hospitalization Stay > 300 days

The following table lists patients that were still in the hospital more than 300 days following their implant. It is possible that the Implant Discharge form was not completed or that incorrect dates have been entered. Please review the patient's medical records for verification of implant hospitalization dates and/or complete the Implant Discharge form if indicated.

NOTE: This table lists patients implanted after the Protocol 3.0 re-launch (May 2, 2013).

No patients identified by this check.

Exhibit 11. LVAD Implanted with Concomitant RVAD

The following table lists patients with device type listed as 'LVAD' but, 'RVAD' has been checked as a concomitant surgery. The device type that most likely should have been entered is 'Both in the same OR'. Please review the patient's medical record to confirm that both devices were implanted in the same OR visit. If both LVAD and RVAD were implanted in the same OR visit, the device type will need to be changed. Please contact your nurse monitor to receive further instructions on how to make these changes.

Patient ID	Device ID	Implant Date
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Exhibit 12. 6 Minute Walk Distance Greater than 2400 ft

The following table lists patients with a 6 minute walk distance greater than 2400 ft. Please confirm that this is the correct value make any necessary changes in the web based data entry.

No patients identified by this check.

Exhibit 13. Gait Speed (1st 15 foot walk) < 1.5 sec

The following table lists patients with a Gait Speed first (1st 15 foot walk) < 1.5 sec. Please confirm that this is the correct value make any necessary changes in the web based data entry.

No patients identified by this check.

Exhibit 14. Transfer Patients

The following table lists patients that have transfered from your site. The table below lists the start and stop date of when these patients were followed at your site.

No patients identified by this check.

Glossary

BiVAD: BiVentricular Assist Device
BMI: Body Mass Index
BP: Blood Pressure
BSA: Body Surface Area
BTC: Bridge to Candidacy
BUN: Blood Urea Nitrogen
CMS: Centers for Medicare and Medicaid
COPD: Chronic Obstructive Pulmonary Disease
CNS: Central Nervous System
CRP: C - Reactive Protein
CVA: Cerebrovascular Accident
DCC: Data Coordinating Center
DT: Destination Therapy
ECMO: Extracorporeal-membrane Oxygenation
EQ-5D: Euro Quality of Life
FDA: Federal Drug Administration
HF: Heart Failure
IABP: Intra-Aortic Balloon Pump
IgG: Immunoglobulin G
INR: International Normalized Ratio
INTERMACS: Interagency Registry for Mechanically Assisted Circulatory Support
LVAD: Left Ventricular Assist Device
LVEF: Left Ventricular Ejection Fraction
LVEDD: Left Ventricular End Diastolic Dysfunction
LVSF: Left Ventricular Shortening Fraction
MCSD: Mechanically Circulatory Support Device
NHLBI: National Heart Lung and Blood Institute
NIH: National Institute of Health
NT pro brain natriuretic peptide: N-Terminal pro brain Natriuretic peptide
NYHA: New York Heart Association
OR: Operating Room
Regurg: Regurgitation
RVAD: Right Ventricular Assist Device
RVEF: Right Ventricular Ejection Fraction
SAE: Serious Adverse Event
SGOT-AST: Serum Glutamic Oxaloacetic Transaminase
SGPT-ALT: Serum Glutamic Pyruvic Transaminase
TAH: Total Artificial Heart
TIA: Transient Ischemic Attack
VAD: Ventricular Assist Device
VAS: Visual Analog Scale