Rehospitalization

Was there an occurrence of rehospitalization?* ○ YES ⊙ NO

Date of admission:* _____ mm/dd/yyyy ST= _____

Discharge associated with this hospitalization/explant/transplant* _____ mm/dd/yyyy ST= _____

Reason for admission (check all that apply):*

- ☐ Cardiac Arrhythmia
- ☐ Bleeding
- ☐ Cardiac Tamponade
- ☐ Hematoma
- ☐ Hemolysis
- ☐ Hepatic Dysfunction
- ☐ Hypertension
- ☐ Infection
- ☐ GI Disorder
- ☐ Pulmonary Disorder
- ☐ Limb vascular complication
- ☐ Pulmonary Embolism/Hemorrhage
- ☐ Planned Procedure, specify
- ☐ Device Malfunction
- ☐ Myocardial Infarction
- ☐ Neurological Dysfunction
- ☐ Psychiatric Episode
- ☐ Renal Dysfunction
- ☐ Right Heart Failure
- ☐ Non-CNS Thromboembolic (TE) Event
- ☐ Wound Complication
- ☐ Unknown
- ☐ Other, specify

Procedure:* _____

Specify:* _____

Rehospitalization intervention:* _____

Type of surgical procedure:* _____

Type of cardiac procedure:* _____

Other procedure:* _____

Specify:* _____

Enter CVP:* _____ mm/Hg ST= _____

Enter PA systolic pressure:* _____ mm/Hg ST= _____

Enter PA diastolic pressure:* _____ mm/Hg ST= _____

Enter PCW pressure:* _____ mm/Hg ST= _____

Enter cardiac output:* _____ L/min ST= _____

Adverse Events Appendix A: Adverse Event Definitions

Was there a major infection?* ○ YES ⊙ NO ○ UNK

Date of onset:* _____ ST= _____

Is this infection:* ○Newly Diagnosed ○Ongoing

Location of patient:* ○In hospital ○Out of hospital ○Unknown

Location of infection: (check all that apply)*

- ☐ Pump / related - Drive Line
- ☐ Pump / related - Pump Pocket
- ☐ Pump / related - Pump Interior
- ☐ Positive Blood cultures
- ☐ Line Sepsis
- ☐ Pulmonary
- ☐ Urinary Tract
- ☐ Mediastinum
- ☐ Peripheral Wound
- ☐ GI
- ☐ Unknown
- ☐ Other, specify

Specify:*

Type of infection:*

Causative or contributing factors to the infection AE: (check all that apply)*

- ☐ Patient condition
- ☐ Patient non-compliance with Medications
- ☐ Patient non-compliance with Device Maintenance
- ☐ Patient non-compliance with Followup Visits
- ☐ Device related
- ☐ Complexities of Medical Management
- ☐ Unknown

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Intervention:*

Infection contribute to Death:* ○YES ○NO ○UNK

Was there a neurological dysfunction?* ○ YES ◉ NO ○ UNK

Was there a device malfunction?* ○ YES ◉ NO ○ UNK

Device type:*

Date of onset:* mm/dd/yyyy ST=

Location of patient:* ○In hospital ○Out of hospital ○Unknown

Major pump unit involved (check all that apply):*

- ☐ Blood Pump
- ☐ Drive Unit Failure
- ☐ External Control System Failure
- ☐ Device Thrombosis

Blood Pump Specify:*

Drive Unit Failure Specify:*

External Control System Failure Specify:*

Device Thrombosis Specify:*

Specific component affected (check all that apply):*

- ☐ External Battery Malfunction
- ☐ Internal Battery Malfunction
- ☐ External Controller Malfunction
- ☐ Internal Controller Malfunction
- ☐ Driveline Malfunction
- ☐ Inflow Graft Malfunction/Malposition
- ☐ Outflow Graft Malfunction/Malposition
- ☐ Pump Drive Unit Malfunction
- ☐ TET System Malfunction
- ☐ Inflow Valve
- ☐ Outflow Valve
- ☐ Volume Compensator Malfunction
- ☐ Other Component Malfunction, specify

External Battery Specify:*

Internal Battery Specify:*

External Controller Specify:*

Internal Controller Specify:*

Driveline Specify:*

Inflow Graft Specify:*

Outflow Graft Specify:*

Pump Drive Unit Specify:*

TET System Specify:*

Inflow Valve Specify:*

Outflow Valve Specify:*

Volume Compensator Specify:*

Other, specify:*

Causative or contributing factors to the Device Malfunction (check all that apply):*

- ☐ Patient noncompliance in device maintenance and protection
- ☐ Patient error in caring for system
- ☐ Inadequate instructions from caregivers
- ☐ No specific contributing cause identified

Device malfunction intervention (check all that apply):*

- ☐ Replacement of Internal Battery
- ☐ Replacement of External Battery
- ☐ Replacement of External Controller
- ☐ Replacement of Internal Controller
- ☐ Replacement of Driveline
- ☐ Replacement of Inflow Graft
- ☐ Replacement of Outflow Graft
- ☐ Replacement of Pump
- ☐ Replacement of TET System
- ☐ Replacement of Pump Valve
- ☐ Replacement of Volume Compensator
- ☐ Replacement of Other Component, specify
- ☐ Switch from Vented Electric to Pneumatic-mode
- ☐ Other Interventions, specify
- ☐ None
- ☐ Unknown

Specify component:*

Other, specify:*

Surgical procedure required:* ○YES ○NO ○UNK

Device explanted:* ○YES ○NO ○UNK

Device malfunction adverse event cause patient's death:* ○YES ○NO ○UNK

Was there a Major Bleeding Event?:* ○ YES ◉ NO ○ UNK

Date of bleeding episode onset:* mm/dd/yyyy ST=

Check all conditions resulting from this bleeding episode:*

- ☐ Episode resulted in Death
- ☐ Episode resulted in re-operation
- ☐ Episode resulted in rehospitalization
- ☐ Episode resulted in transfusion

Date of transfusion:* mm/dd/yyyy ST=

Approximate # of units p.c. received:*

Location of patient:* ○In hospital ○Out of hospital ○Unknown

Drug intervention:* ○YES ○NO ○UNK

Source/cause/location of bleeding ☐Mediastinal

(check all that apply):*

- ☐ Pump pocket
- ☐ Thoracic plural space
- ☐ Intra abdominal
- ☐ Respiratory
- ☐ Retroperitoneal
- ☐ Device anastamosis
- ☐ Outflow or inflow conduit
- ☐ Aortic or venous cannulation sites
- ☐ Chest wall
- ☐ Urinary tract
- ☐ Upper gastrointestinal
- ☐ Lower gastrointestinal

Causative or contributing factors to this Bleeding episode (check all that apply):*

- ☐ Poor compliance with monitoring anticoagulation therapy
- ☐ Documented history of lesion or condition in the organ site of bleeding that could potentiate a bleeding episode
- ☐ Elevated preoperative INR or platelet count less than 60,000
- ☐ Management: Over anticoagulation
- ☐ Complexities of Medical Management
- ☐ Procedural related to implant procedure
- ☐ Procedural related to any re-operative procedure
- ☐ Procedural related to any diagnostic procedure (e.g. bronchoscopy, endoscoopy, or transesophageal echo)
- ☐ Unknown

Name of condition:* _____

Enter the following lab values which fall closest to the bleeding episode:

INR:* _____ ST= _____ Test date:* _____ mm/dd/yyyy ST= _____

PTT:* _____ seconds ST= _____ Test date:* _____ mm/dd/yyyy ST= _____

pH:* _____ ST= _____ Test date:* _____ mm/dd/yyyy ST= _____

Anticoagulant therapy at time of event (check all that apply):*

- ☐ Warfarin
- ☐ Heparin
- ☐ Lovenox
- ☐ Aspirin
- ☐ Dipyridamole
- ☐ Clopidogrel (plavix)
- ☐ Argatroban
- ☐ Bilvalirudin
- ☐ Fondaparinux
- ☐ Hirudin
- ☐ Lepirudin
- ☐ Ximelagatran
- ☐ None
- ☐ Other

Specify:* _____

Were there any other adverse events?* ○ YES ◉ NO

ex: cardiac arrythmia, pericardial fluid, hemolysis, hepatic dysfunction, hypertension, MI, psychiatric episode, renal dysfunction, respiratory failure, RHF, thromboembolism, wound dehiscence, other serious adverse event

Adverse Event Reminders **Appendix A: Adverse Event Definitions**

Cardiac Arrhythmia

Did a documented arrhythmia result in clinical compromise since last INTERMACS report/last followup?* ○ YES ◉ NO ○ UNK

Event Date:* mm/dd/yyyy ST=

Type of cardiac arrhythmia:*

Pericardial Fluid Collection

Did a pericardial effusion that required drainage occur since last INTERMACS report/last followup?:* ○ YES ◉ NO ○ UNK

Event date.:* mm/dd/yyyy ST=

Signs of tamponade:* ○YES ○NO ○UNK

Method of drainage:* ○Surgical Intervention ○Cath ○Unknown

Hemolysis

Did clinical signs associated with hemolysis (plasma-free hemoglobin PFHgb > 40 mg/dl) occur after the first 72 hours post-implant and since last INTERMACS report/last followup? :* ○ YES ◉ NO ○ UNK

Plasma-free hemoglobin measurement:* mg/dL ST=

Hematocrit measurement:* % ST=

Cause of Hemolysis:*

Other, specify:*

Hepatic Dysfunction

Did Clinical evidence of liver dysfunction since last INTERMACS report/last followup occur beyond 14 days post implant?:*

YES	NO	UNK
○	◉	○

Total bilirubin measurement:* mg/dL ST=

SGOT/AST measurement:* u/L ST=

SGPT/ALT measurement:* u/L ST=

Hypertension

Did onset bp >= 140mm Hg

YES	NO	UNK
○	◉	○

systolic or 90mm Hg diastolic (Pediatric patient: > 95th percentile, see definition) occur since last INTERMACS report/last followup?:*

Systolic bp:* mm Hg ST=

Diastolic bp:* mm Hg ST=

Myocardial Infarction

Did a myocardial infarction occur since last INTERMACS report/last followup/admission?:* ○ YES ⊙ NO ○ UNK

Date of event:* mm/dd/yyyy ST=

Psychiatric Episode

Did a disturbance in thinking, emotion or behavior that required intervention occur in patient since last INTERMACS report/last followup?:* ○ YES ⊙ NO ○ UNK

Renal Dysfunction

Did renal dysfunction (by definition) occur since last INTERMACS report/last followup?:* ○ YES ⊙ NO ○ UNK

Event date.:* mm/dd/yyyy ST=

Dialysis duration:* weeks ST=

Peak creatinine measurement:* mg/dL ST=

Respiratory Failure

Did an impairment of respiratory function requiring intubation or mechanical ventilation occur since last INTERMACS report/last followup?:* ○ YES ⊙ NO ○ UNK

Date of event:* mm/dd/yyyy ST=

Intubation duration:* days ST=

Was a trachoetomy performed?:* ○ YES ○ NO ○ UNK

Right Heart Failure

Did symptoms or signs of right heart failure occur requiring RVAD implantation or inotropic therapy at least 14 days post implant and since last update?:* ○ YES ⊙ NO ○ UNK

Event date.:* mm/dd/yyyy ST=

Check all signs/symptoms that apply:*
☐ CVP > 18 mmHg
☐ CI < 2.0 L/min/M2

- [ ] Ascites
- [ ] Peripheral Edema

Arterial Non-CNS Thromboembolism

Did an acute perfusion deficit in any non-cerebrovascular organ system occur since last INTERMACS report/last followup?* ○ YES ◉ NO ○ UNK

Date:* mm/dd/yyyy ST=

Location:*

Other acute perfusion deficit:*

Confirmation source:*

Anticoagulant therapy at time of event - check all that apply - :*

- [ ] Warfarin
- [ ] Heparin
- [ ] Lovenox
- [ ] Aspirin
- [ ] Dipyridamole
- [ ] Clopidogrel (plavix)
- [ ] Argatroban
- [ ] Bilvalirudin
- [ ] Fondaparinux
- [ ] Hirudin
- [ ] Lepirudin
- [ ] Ximelagatran
- [ ] None
- [ ] Other

Specify:*

Venous Thromboembolism Event

Evidence of Venous Thromboembolic event since last INTERMACS report/last followup - check all that apply - :*

- [ ] Deep Vein thrombosis
- [ ] Pulmonary Embolis
- [ ] Other, specify
- [ ] Unknown
- [x] None

Specify event:*

Enter deep vein thrombosis date:* mm/dd/yyyy ST=

Enter pulmonary embolis date:* mm/dd/yyyy ST=

Enter other date:* mm/dd/yyyy ST=

Anticoagulant therapy at time of event - check all that apply - :*

- [ ] Warfarin
- [ ] Heparin
- [ ] Lovenox
- [ ] Aspirin
- [ ] Dipyridamole
- [ ] Clopidogrel (plavix)
- [ ] Argatroban
- [ ] Bilvalirudin
- [ ] Fondaparinux
- [ ] Hirudin

- ☐ Lepirudin
- ☐ Ximelagatran
- ☐ None
- ☐ Other

Specify:* [ ]

Wound Dehiscence

Did a disruption of the apposed surfaces of surgical incision require surgical repair since last INTERMACS report/last followup?* ○ YES ◉ NO ○ UNK

Date:* [ ] mm/dd/yyyy ST= [ ]

Other

Did an Other Major Serious Adverse Event occur since last INTERMACS report/last followup? :* ○ YES ◉ NO ○ UNK

Other Major Serious Adverse Event since last INTERMACS report/last followup: [ ]

Death

Is the patient deceased?* ○ YES ◉ NO

Death date:* mm/dd/yyyy ST=

Was device functioning normally?:* ○ YES ○ NO ○ UNK

Was there an operation associated with device malfunction?:* ○ YES ○ NO ○ UNK

Post mortem device explant?* ○ YES ○ NO ○ UNK

Did device go to manufacturer?* ○YES ○NO ○UNK

Location of death:* ○In hospital ○Out of hospital ○Unknown

Timing of death:* ○Expected ○Unexpected ○Unknown

Autoposy: * ○YES ○NO ○UNK

Primary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Secondary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Secondary cause of death:*

Cancer:*

Other, specify:*

Other cancer:*

Explant

Was the device explanted/patient transplanted?* ○ YES ◉ NO

Device explanted:*

Explant date:* ST=

Explant reason:*

Other, specify:*

Transplant date:* ST=

Waitlist ID:*