**STS Intermacs® USERS’ GUIDE**

This Site User’s Guide contains the instructions for navigating the web-based data entry system which describes the collected data elements.

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**1.0 Navigating the STS Intermacs® Application**

**1.1 Introduction**

All data will be entered electronically through the STS Intermacs**®** web-based data entry system (STS Intermacs**®** application). The forms should be filled out as the implant, follow-up dates, and events occur. Forms should generally be completed within seven days of an event, but always within 30 days. To begin the process, go to **www. Intermacs.org** to get to the secure login page below.

**Note: If the patient is > 19 years of age at the time of implant then enter the patient into STS Intermacs®. If the patient is < 19 years of age at the time of implant, please enter the patient into the Pedimacs portion of the registry.**

**1.2 How do I get started?**

***Entering a new patient***

Once you login to the STS Intermacs**®** application for patient data entry, select the STS Intermacs**®** portion of the registry. To enter a new patient you will select ‘Screen a New Patient’.

**Screening Log**

Once the patient has met the inclusion criteria listed on the screening log (see below) then you will automatically be directed to the STS Intermacs**®** patient data entry system

***Inclusion: Patient must meet all criteria: If patient meets any of the criteria then check the appropriate reasons below:***

***□ Patient receives a durable mechanical circulatory support device (MCSD) which is FDA approved***

***□ Implanted on or after March 1, 2006 (The device does not need to be the first implant for the patient)***

**Forms**

The STS Intermacs**®** patient data entry system is comprised of a series of forms. The data to be collected are divided into forms that correspond to the clinical time course of the patient.

**Inclusion/Exclusion Form**

Screening Log

**Clinical Data Forms**

Demographics Rehospitalization

Pre-Implant Reporting Adverse Events

Implant Death

1 Week Post ImplantExplant

1 Month Post Implant Patient Transfer/Consent

3 Month Follow up Withdrawal Forms

6 Month Follow up

Implant Discharge

List Date for Transplant

1 Year Post Cessation of Mechanical Support

**Quality of Life Forms** **Neurocognitive Form**

EuroQoL questionnaire Trailmaking Part B neurocognitive test

Modulated QoL

KCCQ

Each form must be addressed in its entirety. Each data element in a form must be addressed. There is a status bar (ST=) on most questions where “Unknown”, “Not Done”, or “Not Applicable” may be entered when information is just not available. Limited usage of this bar is expected. At the bottom of each form there is a ‘Save and Validate’ and a ‘Submit’ button. The ‘Save and Validate’ button allows you to leave the form before it is completed while saving the information you have entered. Once you have completed data entry for the entire form, the ‘Submit’ button should be selected. Once you select ‘Submit’, the application will validate the form through a process of range checks and internal consistency checks. Messages will appear for invalid or incomplete data entered. Even though a form has been submitted, you may edit information that has already been entered into the system. When you subsequently select ‘Submit’, the form will go through the validation process on the edited information.

Once you select “Screen A Patient,” then you begin entering the STS Intermacs**®** forms. The first form is the Demographic form. The specific data elements of this form are described in Section 2.0.

**Patient Summary Screen**

Once the Demographic form is completed then, an initial **Patient Summary** screen is generated. The Patient Summary screen is an automatic chronological history for a patient. You will begin the patient’s history by filling out the Pre-implant form and similarly fill out the Implant form (note: the corresponding buttons for these forms are located at the top of the screen). The patient summary screen will be a very important tool in managing your patient’s medical history. Please see the next section *(1.3 How do I manage an existing patient?*) for more information regarding the patient summary screen.

Once you complete the initial three STS Intermacs**®** forms (Demographic, Pre-implant and Implant) then the Patient Summary screen will allow you to enter and manage the subsequent forms. This summary screen gives you an immediate overview of your data entry status. You may continue to complete forms from this summary screen for a patient.

**1.3 How do I manage an existing patient’s record?**

To add information to an existing patient, click on **Edit a patient**. The User may search by first name, last name, medical record number, last 5 digits of Social Security number, date of birth, device type, device brand, implant date, or patient ID number.

When the appropriate patient is selected, the User will be directed to the **Patient Summary** screen. This is the primary tool for managing the data for a particular patient. This screen contains a chronological list of all existing forms for a patient. Each of these forms is accessible for viewing and editing by double-clicking on the form name. The **Patient Summary** screen gives a quick overview of the time course for a patient. The User will be able to view the status of each form, and it can serve as a reminder as to which events (forms) have been submitted. It may also serve as a condensed “medical record” that highlights the major events in an implanted patient. You may enter any information here for a given patient. The following sections will give a general overview for follow-up, adding an adverse event and adding a device to an existing patients’ record.

**Follow up**

Post-implant follow up forms will be completed at 1 week, 1 month, 3 months, 6 months, and every 6 months thereafter. The follow-up forms capture a patient’s hemodynamics, medications and laboratory values. The follow-up forms at 3 months and beyond also collect the patient’s current device strategy, pump parameters, functional capacity measures, quality of life (EuroQoL, a modulated QoL survey, and KCCQ) and neurocognitive test (Trailmaking Test Part B) and Stroke Scales (Modified Rankin, NIH Stroke Scale) when applicable. The follow-up forms also contain a table as a reminder to complete any adverse events that may have occurred during the associated follow-up time period.

Collection of follow-up data is an essential part of STS Intermacs**®**. For each of the follow-up forms, the following check list will appear:

***Check one of the following:***

* + ***Inpatient*** *(complete follow-up form)*
  + ***Outpatient*** *(complete follow-up form)*
  + ***Other Facility****: Yes No*
    - * *If other facility: Name of Facility: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*(complete follow-up form)*

* + ***Unable to obtain follow-up information*** *- this will result in an incomplete follow-up (cannot complete follow-up form)*
    - * *State reason why you are unable to obtain follow-up information (check one):* 
        + *patient didn’t come to clinic*
        + *Not able to contact patient*
        + *Not addressed by site*

In order to capture as much follow-up information as possible, the time windows for the follow-up visits are quite generous. For example, the 6 month follow-up form is to be completed if the patient was seen at any time from 4 months to 8 months post implant (+/- 2 months or +/- 60 days). For all the follow-up time windows, please see the table below:

**Clinic (or hospital) visit time table for follow-up**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Example: Apr 1st implant** | |
| **Expected  Clinic Visit** | **Acceptable Time Window for Clinic Visit** | **Expected Clinic Visit** | **Acceptable Time Window for Clinic Visit** |
| 1 week | (+/- 3 days) | Apr 8 | Apr 5 - Apr 11 |
| 1 month | (+/- 7 days) | May 1 | Apr 24 - May 8 |
| 3 month | (+/- 1 month) | Jul 1 | Jun 1 - Aug 1 |
| 6 months | (+/- 2 months) | Oct 1 | Aug 1 - Dec 1 |
| 12 months | (+/- 2 months) | Apr 1 | Feb 1 – Jun 1 |
| 18 months | (+/- 2 months) | Oct 1 | Aug 1 - Dec 1 |
| 24 months | (+/- 2 months) | Apr 1 | Feb 1 - Jun 1 |

**Adding an Adverse Event**

The STS Intermacs**®** application has been modified to help in streamlining the entry of adverse events for a patient. Most adverse events will occur in a hospital setting (i.e. rehospitalization or initial hospitalization). There are ‘reminder’ tables that will facilitate the entry of adverse events which will be explained in the users’ guide section of this document.

We understand that there are many scenarios for an adverse event to occur so the registry will allow you to enter these events in one area of the registry. Please see the examples below.

**Note: An Index hospital is referring to the site where the patient was initially enrolled into STS Intermacs®.**

**Adverse event occurs during index hospitalization:**

For example, if an adverse event occurs during the index hospitalization for a patient you can enter this adverse event once the implant form is successfully submitted. The following button will appear at the top of the patient summary screen. Click this button and you will be taken to the adverse event report screen:



**Adverse event occurs during rehospitalization:**

Another example might be that an adverse event occurred during a rehospitalization. Again, you would click on the button listed above and enter the appropriate adverse event.

**Adverse event occurs outside a hospitalization:**

Once you have confirmed that this is an adverse event, you may enter this adverse event in the same way that you entered the above adverse event examples. Remember that the implant form must be successfully submitted before this button appears.

**Adding a Device**

STS Intermacs**®** allows for entry of multiple implants for an individual patient. The LVAD implantation date will be the “driving force” of the follow up clock. If an LVAD is removed and then replaced with a new LVAD then the follow up clock restarts with the new LVAD. If the initial device implanted is a durable RVAD alone then the RVAD will ‘drive’ the follow-up clock and if an LVAD is implanted then the LVAD will ‘restart’ the follow-up ‘clock’.

There are two possible scenarios.

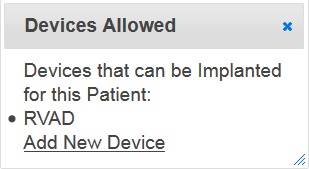
**Replacement of an existing device**

If a patient has a device replaced (e.g., a patient with an LVAD receives a replacement LVAD) then the previous implant for the patient must be explanted and all forms related to this implant must be completed and validated. Once the forms for the previous implant have been submitted then the “Add New Device” icon is available for the entry of a new implant for the patient.

**Additional device**

If an additional device is implanted (e.g., a patient with an LVAD subsequently receives an RVAD) then select the “Add New Device” icon for the entry of a new implant for the patient.





If “Add New Device” is selected, the framework for the new device data entry will begin with a new Pre-Implant form. The same patient demographic data will be shared between the original implant and any subsequent implants associated with the selected patient.

**1.4 Ending Patient Participation**

A patient’s participation in STS Intermacs**®** may end for clinical or administrative reasons:

**Clinical**

(1) Death: Complete **Death** form and relevant **AE forms**.

(2) Transplant: Complete **Transplant** form. Patient will be followed through the OPTN database.

(3) 1 year after removal of all devices with no new implant: Regular follow-up form completion ceases, but the coordinator reports to the registry whether the patient died or was transplanted for a period of 1 year post-explant.

**Administrative**

(1) Patient transfers medical care to another hospital: Complete all forms up to the date of transfer. Note: This will end the patient participation at your hospital. The receiving hospital will then continue following this patient. Please see section 2.13 Users’ guide: Patient Registry Status Form

**2.0 Users’ guide for the STS Intermacs® Application**

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# 2.1 Screening Log

Each patient who receives a durable, **FDA approved** mechanical circulatory support device (MCSD) at your institution must be screened for eligibility into STS Intermacs**®**. The screening log records the results of the inclusion/exclusion criteria.

**Please refer to Appendix K for the current list of devices.**

**Implant date:** Enter VAD implant date in MMDDYYYY format.

**Inclusion: Patient must meet *all* inclusion criteria:** If patient meets any of the inclusion criteria then check the appropriate inclusion reasons below:

Patient receives a durable mechanical circulatory support device (MCSD) which isFDA approved

Yes or No

Implanted on or after March 1, 2006 (The device does not need to be the first implant for the patient)

Yes or No

Once you have selected all patient inclusion criteria then you will be prompted to enter the initial implant information below.

**Device Type:** Select from the drop down list given:

LVAD (Left Ventricular Assist Device)

RVAD (Right Ventricular Assist Device)

Both (LVAD+RVAD in same OR visit)

TAH (Total Artificial Heart)

**Device Brand:**  Select from the lists provided dependent upon the selection made under Device Type above. If a single device (LVAD or RVAD) is selected from the Device Type then select from the provided drop down box. If ‘Both (LVAD+RVAD in the same OR visit)’ is selected then enter the appropriate device for the LVAD and the RVAD from the provided drop down boxes. Please refer to **Appendix K** (Device Brand Table available at [http://www.uab.edu/medicine/STS Intermacs/appendices/app-k-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-k-5-0) for reference purposes).

|  |  |  |  |
| --- | --- | --- | --- |
| **Durable Devices** |  | **Temporary Devices (include only in conjunction** |  |
| **LVAD, BiVAD, TAH** |  | **with a durable device listed above)** |  |
| HeartMate II LVAS |  | Abiomed AB5000 |  |
| HeartMate 3 |  | Abiomed BVS 5000 |  |
| HeartMate IP |  | Biomedicus |  |
| HeartMate VE |  | Thoratec Centrimag (Levitronix) |  |
| HeartMate XVE |  | Sorin Revolution |  |
| HeartWare HVAD |  | TandemHeart |  |
| Micromed DeBakey VAD – Child |  | Abiomed Impella 2.5 |  |
| Novacor PC |  | Abiomed Impella 5.0 |  |
| Novacor PCq |  | Abiomed Impella CP |  |
| Thoratec IVAD |  | Abiomed Impella RP |  |
| Thoratec PVAD |  | **Other, Specify** |  |
| Abiocor TAH |  |  |  |
| Syncardia Cardiowest TAH – 70cc |  |  |  |
| Berlin Heart EXCOR (paracorporeal) |  |  |  |
| **Other, Specify** |  |  |  |

**Exclusion: *Any* exclusion will disqualify the patient for entry into STS Intermacs®**:

If patient meets **ANY** exclusion criteria then check any of the appropriate exclusion reasons below: Select all that apply:

Patient receives a durable (MCSD) which is ***not*** FDA approved

Yes or No

Patient is incarcerated (prisoner)

Yes or No

**If the patient meets all of the STS Intermacs criteria and none of the exclusion criteria then this patient is enrolled in STS Intermacs® and you will be directed to the Patient Demographics Form.**

**If Patient is EXCLUDED, please complete STS Intermacs® required screening information below:**

**Implant date:** Enter the patient’s implant date in MMDDYYYY format.

**Device Type:** Enter the appropriate device side for this implant

LVAD (Left Ventricular Assist Device)

RVAD (Right Ventricular Assist Device)

Both (in same OR visit)

TAH (Total Artificial Heart)

**Device Brand:** Select the implanted device from the drop down provided. If **Other, specify** is selected, then type in the implanted device in the block provided. (**see list provided under inclusion section**)

**Age range (years):** Select the appropriate age range below for the patient’s age at time of implant:

19 to 39

40 to 59

60 to 79

80+

**Race:** Enter all race choices that apply from the list below:

American Indian or Alaska Native

Asian

African-American

Hawaiian or other Pacific Islander

White

Unknown/Undisclosed

Other/none of the above

**Ethnicity: Hispanic or Latino.**

Yes, No, or Unknown

**Gender:** Click the appropriate box to indicate the implant patient's gender.

Male

Female

Unknown

**Did death occur within 2 days post implant?** Select the appropriate answer Yes or No

**Is this VAD an investigational device?**  Select the appropriate answer

Yes or No

**Is patient involved in a VAD related study?** Select the appropriate answer

Yes, No, or Unknown

If **Yes** selected, specify:

**What is the name of the study?**

If **Yes**, is this an **industry sponsored post approval study?**

Yes, No, or Unknown

**\*\*\**If the patient meets ANY of the exclusion criteria – Please complete the questions listed above and you will have fulfilled the requirement for STS Intermacs*® *data entry for this excluded patient.***

# 2.2 Demographics Form

The patient **Demographics Form** is to be completed prior to implant and as close to implant as possible.

**Institution:** Auto-fills based on user information.

**First name**: Enter the implant patient's first name.

**Middle Initial:** Enter the implant patient's middle initial.

**Last name**: Enter the implant patient's last name.

**Medical record number**: Enter the patient's hospital chart number.  (The medical record number entry is optional)

**SSN (last 5 digits)**: Enter the implant patient's last 5-digits of their social security if patient has been issued an SSN. If the social security number is not available, enter the last 5-digits of their UNOS waitlist ID if on the UNOS transplant wait list. If the social security number or a UNOS waitlist ID are not available, enter 12345. **ST=** Undisclosed or Not Assigned.

**Health Insurance Claim Number (HICN):** Enter the HICN issued by CMS.  **ST=** Unknown

**Date of birth**: Enter the implant patient's date of birth in MMDDYYYY format.

**Note: This Users’ Guide is for patients who are 19 years or older at time of implant.**

**Gender**: Click in the appropriate circle to indicate the implant patient's gender.

Male

Female

Unknown

**Ethnicity:** Hispanic or Latino**:** Select

Yes, No, or Unknown

**Race**: Enter all race choices that apply from the list below:

American Indian or Alaska Native

Asian

African-American

Hawaiian or other Pacific Islander

White

Unknown/Undisclosed

Other/none of the above

**Marital status:** Enter patient’s current marital status from the list below:

Single

Married

Domestic Partners

Divorced/Separated

Widowed

Unknown

**Highest education level**: Enter patient’s current highest education level from the list below:

None

Grade School (0-8)

High School (9-12)

Attended College/Technical School

Associate/Bachelor Degree

Post-College Graduate Degree

Not Applicable

Unknown

**Working for income: Select Yes if the patient was currently working for income or attending school within 3 months pre implant. If not, select No. If Unknown, select Unknown.**

Yes, No, or Unknown

**If Yes, select one of the following:**

**Working Full Time**

**Working Part Time due to Demands of Treatment**

**Working Part Time due to Disability**

**Working Part Time due to Insurance Conflict**

**Working Part Time due to Inability to Find Full Time Work**

**Working Part Time due to Patient Choice**

**Working Part Time Reason Unknown**

**Working, Part Time vs. Full Time Unknown**

**If No, select reason patient was not working from one of the following:**

**Disability**

**Demands of Treatment**

**Insurance Conflict**

**Inability to Find Work**

**Patient Choice – Homemaker**

**Patient Choice - Student Full Time/Part Time**

**Patient Choice – Retired**

**Patient Choice – Other**

**Not Applicable – Hospitalized**

**Unknown**

**Is patient involved in a VAD related study?** Select the appropriate answer

Yes, No, or Unknown

If **Yes** selected, specify:

**What is the name of the study?**

If **Yes**, is this an **Industry sponsored post approval study?**

Yes, No, or Unknown

# 2.3 Pre-Implant Form

**The Pre-implant Form should be collected at time of implant or closest to implant date within 60 days pre-implant but not in the OR. The Quality of Life surveys need to be collected within 30 days pre-implant.**

## Pre-Implant Status

**DEMOGRAPHICS**

**Height:** Enter the height of the patient at the time of implantation in inches or centimeters.  The height must fall between 10 and 96 inches or 25 and 244 centimeters. **ST=** Unknown or Not Done

**Weight**: Enter the weight of the patient at the time of implantation in the appropriate space, in pounds or kilograms.  The weight must fall between 5 and 600 pounds or 2 and 273 kilograms. **ST=** Unknown or Not Done

**Blood Type:** Select the patient's blood type.

O

A

B

AB

Unknown

**MEDICAL SUPPORT STATUS**

**Current Device Strategy at time of implant**: This should be determined in conjunction with the heart failure cardiologist and surgeon at the time of the implant. This determination will be re-visited and recorded at 3 months, 6 months, and every 6 months thereafter. The strategy should be selected as:

**Bridge to recovery -** Use of a durable device to allow recovery from

chronic cardiac failure (at least 3 months in duration).

**Rescue therapy** - Use of a durable device to support resolution from an

acute event without major previous cardiac dysfunction.

**Bridge to transplant**– This is for a patient ALREADY listed for transplant

or listed within 24 hours before device implantation.

**List Date for Transplant**:

Enter list date for transplant in the format MMDDYYYY. **ST**= Unknown.

**Possible bridge to transplant -** *Likely to be eligible*: defines a patient in

whom the transplant evaluation has not been completed, but no contra-indications

are anticipated, or in whom a current contra-indication is anticipated to resolve

rapidly, such as recent infection.

**Possible bridge to transplant -** *Moderate likelihood of becoming eligible*:

similar to above, but with some potential concerns that might prevent eligibility.

**Possible bridge to transplant -** *Unlikely to become eligible:* should be used for a

patient in whom major concerns have already been identified. These may not have

been quantified yet, such as in a patient with known chronic lung disease without

recent pulmonary function test measurement, or might be reversible, such as severe

renal insufficiency or pulmonary hypertension that might improve after chronic

mechanical support. It may be the expectation at the time of implant that the patient

will most likely have the assist device as “permanent” or “destination” therapy.

**Destination therapy -** (patient definitely not eligible for transplant). All factors that

weigh in to the decision of non–transplant candidacy should be indicated below.

If **Other, specify –** is selected, type in the specification in the block provided.

**Current ICD device in place:** If the patient currently has an implantable defibrillator, then **Yes** should be checked. If the patient has already had it explanted at the time of the MCSD implant, then “**No**” should be checked. Note that patients with bi-ventricular pacing and ICD should have **Yes** checked for ICD also. Or check **Unknown.**

**Time since first cardiac diagnosis**: The length of time that the patient had any known cardiac diagnosis. For example, the time since the patient had a myocardial infarction, congenital heart disease was noted or the patient was noted to have heart failure. Select one of the drop down choices

< 1 month

1 month – 1 year

1-2 years

> 2 years

Unknown

**Number of cardiac hospitalizations in the last 12 months**:(choose one of the following)

0-1

2-3

4 or more

Unknown

**Cardiac diagnosis/primary: Check one** primary reason for cardiac dysfunction (See drop down list). If **Other, specify** is selected, type in the specification in the block provided.

Cancer

Congenital Heart Disease: Biventricular: CAVC/VSD/ASD

Congenital Heart Disease: Biventricular: Congenitally Corrected Transposition (I-TGA) (CC-TGA)

Congenital Heart Disease: Biventricular: Ebstein's Anomaly

Congenital Heart Disease: Biventricular: Kawasaki Disease

Congenital Heart Disease: Biventricular: Left Heart Valve/Structural Hypoplasia

Congenital Heart Disease: Biventricular: TOF/TOF Variant

Congenital Heart Disease: Biventricular: Transposition of the Great Arteries (d-TGA)

Congenital Heart Disease: Biventricular: Truncus Arteriosus

Congenital Heart Disease: Single Ventricle: Heterotaxy / Complex CAVC

Congenital Heart Disease: Single Ventricle: Hypoplastic Left Heart

Congenital Heart Disease: Single Ventricle: Other - **If other, please complete textbox**

Congenital Heart Disease: Single Ventricle: Pulmonary Atresia with IVS

Congenital Heart Disease: Single Ventricle: Pulmonary Atresia with IVS (RVDC)

Congenital Heart Disease: Single Ventricle: Unspecified

Coronary Artery Disease

Dilated Myopathy: Adriamycin

Dilated Myopathy: Alcoholic

Dilated Myopathy: Familial

Dilated Myopathy: Idiopathic

Dilated Myopathy: Ischemic

Dilated Myopathy: Myocarditis

Dilated Myopathy: Other, Specify – **If other specify please complete textbox**

Dilated Myopathy: Post Partum

Dilated Myopathy: Viral

Hypertrophic Cardiomyopathy

Restrictive Myopathy: Amyloidosis

Restrictive Myopathy: Endocardial Fibrosis

Restrictive Myopathy: Idiopathic

Restrictive Myopathy: Other, specify – **If other specify please complete textbox**

Restrictive Myopathy: Sarcoidosis

Restrictive Myopathy: Sec to Radiation/Chemotherapy

Valvular Heart Disease

Unknown

None

**Cardiac diagnosis/secondary: Select all that apply:** Secondary reasons for cardiac dysfunction. If **Other, specify** is selected, type in the specification in the block provided.

Cancer

Congenital Heart Disease: Biventricular: CAVC/VSD/ASD

Congenital Heart Disease: Biventricular: Congenitally Corrected Transposition (I-TGA) (CC-TGA)

Congenital Heart Disease: Biventricular: Ebstein's Anomaly

Congenital Heart Disease: Biventricular: Kawasaki Disease

Congenital Heart Disease: Biventricular: Left Heart Valve/Structural Hypoplasia

Congenital Heart Disease: Biventricular: TOF/TOF Variant

Congenital Heart Disease: Biventricular: Transposition of the Great Arteries (d-TGA)

Congenital Heart Disease: Biventricular: Truncus Arteriosus

Congenital Heart Disease: Single Ventricle: Heterotaxy / Complex CAVC

Congenital Heart Disease: Single Ventricle: Hypoplastic Left Heart

Congenital Heart Disease: Single Ventricle: Other - **If other, please complete textbox**

Congenital Heart Disease: Single Ventricle: Pulmonary Atresia with IVS

Congenital Heart Disease: Single Ventricle: Pulmonary Atresia with IVS (RVDC)

Congenital Heart Disease: Single Ventricle: Unspecified

Coronary Artery Disease

Dilated Myopathy: Adriamycin

Dilated Myopathy: Alcoholic

Dilated Myopathy: Familial

Dilated Myopathy: Idiopathic

Dilated Myopathy: Ischemic

Dilated Myopathy: Myocarditis

Dilated Myopathy: Other, Specify - **If other, please complete textbox**

Dilated Myopathy: Post Partum

Dilated Myopathy: Viral

Hypertrophic Cardiomyopathy

Restrictive Myopathy: Amyloidosis

Restrictive Myopathy: Endocardial Fibrosis

Restrictive Myopathy: Idiopathic

Restrictive Myopathy: Other, specify **If other, please complete textbox**

Restrictive Myopathy: Sarcoidosis

Restrictive Myopathy: Sec to Radiation/Chemotherapy

Valvular Heart Disease

Unknown

None

**Known Cardiac biopsy:** If the patient has had an endomyocardial or direct myocardial biopsy, select from the diagnoses listed in the drop down. If the patient has had more than one biopsy (within their lifetime), the one closest to implantation date should be listed it is okay to use cardiac biopsy removed during the implant operation. If no biopsy is known, select “no biopsy known”. If **Other, specify** is selected, type in the specification in the block provided.

No biopsy known

Sarcoidosis

Giant cell myocarditis

Eosiniphilic myocarditis

Other myocarditis

Hemochromatosis

Mitochondiral myopathy

Other, specify **if other, specify, please complete text box**

**Previous cardiac operation:** Select all cardiac operations that the patient has had prior to MCSD implantation. If **Other, specify** is selected, type in the specification in the block provided.

None

CABG

Aneursyomectomy (DOR)

Aortic Valve replacement / repair

Mitral Valve replacement / repair

Triscuspid replacement /repair

Congenital card surgery

LVAD

RVAD

TAH

Previous heart transplant

Previous ECMO

Other, specify: (Include ONLY operations actually performed on heart or great vessels)

**If Other, specify: please complete text box.**

**If Congenital cardiac surgery, then Check all that apply:**

Congenitally Corrected Transposition Repair (double switch)

Congenitally Corrected Transposition Repair (classic)

PA Banding

TOV/DORV/RVOTO Repair

Ebstein's Anomaly Repair

VSD Repair

Norwood Stage I

Glenn, Bi-directional

Glenn, Classical

Fontan Procedure

d- Transposition of the Great Vessels Repair – arterial switch operation

d- Transposition of the Great Vessels Repair – atrial switch (Senning/Mustard)

Truncus Arteriosus Repair

Complete AV Septal Defect Repair

AP Shunt

ASD Repair

Damus Kaye Stansel (DKS)

Other, specify

**If Other, specify: please complete text box.**

**Admitting Diagnosis or Planned Implant:** Select one primary reason the patient was admitted.

Heart failure

Cardiac surgery

Non-cardiac medical problem

VAD placement

TAH placement

Other cardiology

Acute MI

Non-cardiac surgery

Unknown

**Clinical Events and Interventions this hospitalization (Pre-implant):** Pertaining to this implant hospitalization, select all events and interventions that occurred more than 48 hours before the implant.

Cardiac arrest

Dialysis

Intubation

Major MI

Cardiac surgery, other

Positive blood cultures

Other surgical procedures

Major Infections

Unknown

None

IABP

Ultrafiltration

Ventilator

Feeding tube

ECMO

CABG

Aortic Valve replacement / repair

Mitral valve replacement / repair

Congenital cardiac surgery

LVAD

RVAD

TAH

Aneursyomectomy (DOR)

**If event this hospitalization is Major Infection (new or ongoing), Select type of infection:** Select the type of infection that occurred during the implant hospitalization.  
 Bacterial   
 Fungal   
 Viral   
 Protozoan   
 Unknown

**If event this hospitalization is Major Infection (new or ongoing), Select location of infection:** Select the location of the infection that occurred during the implant hospitalization. If **Other, specify** is selected, type in the specification in the block provided (see lists above).  
 Blood   
 Endocarditis, native   
 Line Sepsis   
 Mediastinum   
 Pneumonia   
 Urine   
 Unknown   
 Other - **If other, please complete the text box.**

**If event this hospitalization is Congenital Cardiac Surgery**, Select all that apply:

Congenitally Corrected Transposition Repair (double switch)

Congenitally Corrected Transposition Repair (classic)

PA Banding

TOV/DORV/RVOTO Repair

Ebstein's Anomaly Repair

VSD Repair

Norwood Stage I Glenn, Bi-directional

Glenn, Classical

Fontan Procedure

d- Transposition of the Great Vessels Repair – arterial switch operation

d- Transposition of the Great Vessels Repair – atrial switch (Senning/Mustard)

Truncus Arteriosus Repair

Complete AV Septal Defect Repair

AP Shunt

ASD Repair

Damus Kaye Stansel (DKS)

Other, specify – **If selected please complete text box.**

**IV inotrope therapy within 48 hours of implant:** If the patient has gone to the operating room for the purpose of the implant and is on intravenous inotropes of any sort, the answer should be **Yes**. If an agent is known to have been used but discontinued within **48** hours prior to arriving in the operating room, **Yes** should also be checked.

Yes, No, or Unknown

**If Yes, IV inotrope therapy agents:** Select all intravenous inotropes used at the time of the MCSD implant that apply. If **Other, specify** is selected, type in the specification in the block provided.

Dobutamine

Dopamine

Milrinone

Levosimendan

Epinephrine

Norepinephrine

Isoproterenol

Other, specify- **If other specify, then complete text box.**

Unknown

**Interventions within 48 hours of implant:** Select all interventions within the **48** hour time period prior to the implant.

IABP

Dialysis

Ultrafiltration

Ventilator

Feeding tube

ECMO

None

CABG

Aortic Valve replacement / repair

Mitral Valve replacement / repair

Congenital cardiac surgery

LVAD

RVAD

TAH

Aneursyomectomy (DOR)

**If Congenital Cardiac Surgery:** Select all that apply:

Congenitally Corrected Transposition Repair (double switch)

Congenitally Corrected Transposition Repair (classic)

PA Banding

TOV/DORV/RVOTO Repair

Ebstein's Anomaly Repair

VSD Repair

Norwood Stage I

Glenn, Bi-directional

Glenn, Classical

Fontan Procedure

d- Transposition of the Great Vessels Repair – arterial switch operation

d- Transposition of the Great Vessels Repair – atrial switch (Senning/Mustard)

Truncus Arteriosus Repair

Complete AV Septal Defect Repair

AP Shunt

ASD Repair

Damus Kaye Stansel (DKS)

Other, specify – **If selected please complete text box.**

**Is this implant the primary MCSD (LVAD or TAH) for this patient? Answer Yes or No.**

Yes or No

Please click on the link below to be taken to the Patient Profiles in **Appendix O**.

[http://www.uab.edu/medicine/ Intermacs/appendices/app-o-5-0](http://www.uab.edu/medicine/%20Intermacs/appendices/app-o-5-0)

**Intermacs® Patient Profile at time of implant:** Select one. These profiles will provide a *general* clinical description of the patients receiving LVAD or TAH implants. If there is significant clinical change between the initial decision to implant and the actual implant procedure, then the profile closest to the time of implant should be recorded. Patients admitted electively for implant should be described by the profile just prior to admission.

**Note: The Intermacs® Patient Profiles are required at pre-implant and at all times when an implant occurs even if this is NOT the primary LVAD or TAH implant.**

**Intermacs® 1:** Critical cardiogenic shock describes a patient who is “crashing

and burning”, in which a patient has life-threatening hypotension and rapidly

escalating inotropic pressor support, with critical organ hypoperfusion often

confirmed by worsening acidosis and lactate levels. This patient can have modifier

A or TCS (see ‘Modifiers’ below)

**Intermacs® 2:** Progressive decline describes a patient who has been

demonstrated “dependent” on inotropic support but nonetheless shows signs

of continuing deterioration in nutrition, renal function, fluid retention, or other

major status indicator. Patient profile 2 can also describe a patient with refractory

volume overload, perhaps with evidence of impaired perfusion, in whom inotropic

infusions *cannot be maintained* due to tachyarrhythmias, clinical ischemia, or other intolerance. This patient can have modifiers A or TCS.

**Intermacs® 3:** Stable but inotrope dependent describes a patient who is

clinically stable on mild-moderate doses of intravenous inotropes (or has a

temporary circulatory support device) after repeated documentation of failure

to wean without symptomatic hypotension, worsening symptoms, or progressive

organ dysfunction (usually renal). It is critical to monitor nutrition, renal function,

fluid balance, and overall status carefully in order to distinguish between a

patient who is truly stable at Patient Profile 3 and a patient who has unappreciated

decline rendering them Patient Profile 2. This patient may be either at home or in

the hospital. Patient Profile 3 can have modifier A, and if in the hospital with

circulatory support can have modifier TCS. If patient is at home most of the time

on outpatient inotropic infusion, this patient can have a modifier FF if he or she

frequently returns to the hospital.

**Intermacs® 4:** Resting symptoms describes a patient who is at home on oral

therapy but frequently has symptoms of congestion at rest or with activities of

daily living (ADL). He or she may have orthopnea, shortness of breath during

ADL such as dressing or bathing, gastrointestinal symptoms (abdominal

discomfort, nausea, poor appetite), disabling ascites or severe lower extremity

edema. This patient should be carefully considered for more intensive

management and surveillance programs, which may in some cases, reveal

poor compliance that would compromise outcomes with any therapy. This patient

can have modifiers A and/or FF.

**Intermacs® 5:** Exertion Intolerant describes a patient who is comfortable at

rest but unable to engage in any activity, living predominantly within the house

or housebound. This patient has no congestive symptoms, but may have

chronically elevated volume status, frequently with renal dysfunction, and may be characterized as exercise intolerant. This patient can have modifiers A and/or FF.

**Intermacs® 6:** Exertion Limited also describes a patient who is comfortable

at rest without evidence of fluid overload, but who is able to do some mild

activity. Activities of daily living are comfortable and minor activities outside the

home such as visiting friends or going to a restaurant can be performed, but

fatigue results within a few minutes of any meaningful physical exertion. This

patient has occasional episodes of worsening symptoms and is likely to have

had a hospitalization for heart failure within the past year. This patient can have

modifiers A and/or FF.

**Intermacs® 7:** Advanced NYHA Class 3 describes a patient who is clinically

stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent. This patient is usually able to walk more than

a block. Any decompensation requiring intravenous diuretics or hospitalization

within the previous month should make this person a Patient Profile 6 or lower.

This patient may have a modifier A only.

**MODIFIERS of the Intermacs® Patient Profiles:**

**A - Arrhythmia.** This modifier can modify any profile. Recurrent ventricular tachyarrhythmias that have recently contributed substantially to the overall clinical course. This includes frequent shocks from ICD or requirement for external defibrillator, usually more than twice weekly.

Yes, No, or Unknown

**TCS –Temporary Circulatory Support.** This modifier can modify only patients who are confined to the hospital, Patient Profiles 1, 2, and 3 (a patient who is listed as Patient Profile 3 stable on inotropes who has been at home until elective admission for implantable VAD cannot have a TCS modifier); support includes, but is not limited to, IABP, ECMO, TandemHeart, Levitronix, BVS 5000 or AB5000, Impella.

Yes, No, or Unknown

**FF – Frequent Flyer.** This modifier is designed for Patient Profiles 4, 5, and 6. This modifier can modify Patient Profile 3 if usually at home (frequent admission would require escalation from Patient Profile 7 to Patient Profile 6 or worse). Frequent Flyer is designated for a patient requiring frequent emergency visits or hospitalizations for intravenous diuretics, ultrafiltration, or brief inotropic therapy. Frequent would generally be at least two emergency visits/admissions in the past 3 months or 3 times in the past 6 months. Note: if admissions are triggered by tachyarrhythmias or ICD shocks then the modifier to be applied to would be A, not FF.

Yes, No, or Unknown

Hemodynamics **(Prior to implant – closest to implant but not in OR)**

**General Hemodynamics – closest to implant but not in OR**

**Heart rate:** Beats per minute. **ST=** Unknown or Not Done

**Systolic bp:** mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. **ST=** Unknown or Not Done

**Diastolic bp:** mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. **ST=** Unknown or Not Done

**Doppler Opening Pressure:** Record the pressure on the BP cuff at the time of sound on the Doppler as the cuff is released and this is the Doppler opening pressure which may correspond to the MAP. **ST=** Unknown, Not Done, or Not Applicable

**Peripheral edema:** Does patient have moderate or worse peripheral edema? **Yes, No,** or **Unknown**

Yes, No, or Unknown

**Ascites: Yes, No,** or **Unknown.** This is in the clinicians’ best judgment, as it is sometimes difficult to tell whether abdominal protuberance is fluid or adipose tissue.

Yes, No, or Unknown

**ECG rhythm (cardiac rhythm):** Select one of the following. If **Other, specify** is selected, type in the specification in the block provided.

Sinus

Atrial fibrillation

Atrial flutter

Paced: Atrial pacing

Paced: Ventricular pacing

Paced: Atrial and ventricular pacing

Unknown

Not done

Other, specify **– please complete text box**

**Echo Findings - closest to implant but not in OR**

**Mitral regurgitation:** Mitral regurgitation should be recorded on a qualitative scale (if ‘trivial’ then assign as mild). Moderate-severe would be recorded as “severe”.

0 (none)

1 (mild)

2 (moderate)

3 (severe)

Not Recorded or Not Documented

**Tricuspid regurgitation:** Tricuspid regurgitation should be recorded on a qualitative scale (if ‘trivial’ then assign as mild). Moderate-severe would be recorded as “severe”.

0 (none)

1 (mild)

2 (moderate)

3 (severe)

Not Recorded or Not Documented

**Aortic regurgitation:** Aortic regurgitation should be recorded on a qualitative scale (if ‘trivial’ then assign as mild). Moderate-severe would be recorded as “severe”.

0 (none)

1 (mild)

2 (moderate)

3 (severe)

Not Recorded or Not Documented

Not Applicable

Unknown

**LVEF%** **Left ventricular ejection fraction.** If a number or range is available, check the number range that best applies. E.g. 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as “left ventricular function” or “systolic function” in words. “Mild impairment, mildly reduced, or mild decrease” would all be characterized as “mild”.

> 50 (normal)

40-49 (mild)

30-39 (moderate)

20-29 (moderate/severe)

< 20 (severe)

Not Recorded or Not Documented

**LVEDD:** **Left ventricular end-diastolic dimension** in centimeters (cm).

**ST=** Not Recorded or Not Documented

**RVEF:** RV Function is generally NOT measured in numbers, as it is difficult to quantify. It may be described as “right ventricular function” or “right ventricular contractility”. “Mild impairment, mildly reduced, or mild decrease” would all be characterized as “mild”. Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as “severe”.

Normal

Mild

Moderate

Severe

Not Done

Not Applicable

Unknown

**Swan Hemodynamics - closest to implant but not in OR**

**NOTE: You may be able to get the following information from a right heart catheterization test if it was performed.**

**Pulmonary artery systolic pressure:** This may be abbreviated PAS or pulmonary pressures. mmHg (millimeters of mercury). **ST=** Unknown or Not Done

**Pulmonary artery diastolic pressure:** This may be abbreviated PAD or pulmonary pressures. mmHg (millimeters of mercury). **ST=** Unknown or Not Done

**Mean Pulmonary artery wedge pressure:** May be listed also as PCW or pulmonary capillary wedge pressure. It is not always provided in the hemodynamic data. mmHg (millimeters of mercury). **ST=** Unknown or Not Done

**Mean RA Pressure:** May be listed also as RAP or CVP. mmHg (millimeters of mercury). **ST=** Unknown or Not Done

**Central Venous Pressure (CVP):** \_\_\_\_\_ mmHg (millimeters of mercury).

**ST=** Unknown or Not Done

**Cardiac Index**: Will be expressed as L/min/M2. Enter this number.

**ST=** Unknown or Not Done

**Cardiac Index Measured by Fick or Thermodilution**:

Yes, No, or Unknown.

If **Yes** (select all that apply):

Fick

Thermodilution

**Cardiac Output:** Will be expressed as Liters/min or L/min. Enter this number. The cardiac index is NOT what we want; it is a smaller number expressed as Liters/min/m2 or L/min/m2. **ST=** Unknown or Not Done

**Cardiac Output Measured by Fick or Thermodilution**:

Yes, No, or Unknown.

If **Yes** (select all that apply):

Fick

Thermodilution

Laboratory Valuescollected **nearest to time of implant but not in OR**

The laboratory values are the LAST values available prior to implant. It is anticipated that the blood urea nitrogen, creatinine, total bilirubin, sodium, INR, white blood cell count, platelet count, and SGOT and SGPT will usually be measured within 48 hours of the implant surgery. Other lab values may be less recent. Values obtained more than 60 days prior to the implant date should NOT be included. For all of the tests listed below, give the appropriate measurement. **ST=** Unknown or Not Done .Please contact your local lab to verify the upper limit of the normal range for Plasma-Free Hemoglobin and LDH.

Laboratory Value: Unit(s) of Measure (US/SI):

Sodium mEq/L

mmol/L

Potassium mEq/L

mmol/L

Blood urea nitrogen mg/dL

mmol/L

Creatinine mg/dL

umol/L

SGPT/ALT (alanine aminotransferase/ALT) u/L

SGOT/AST (aspartate aminotransferase/AST) u/L

LDH units/L

U/L

ukat/L

Total Bilirubin mg/dL

umol/L

Albumin g/dL

g/L

Pre- Albumin mg/dL

mg/L

TotalCholesterol mg/dL

mmol/L

*If value is outside given range please see 'Status (****ST=****)' drop down field*

*If < 50 mg/dL select from the ‘status’ drop down field*

Institutions generally perform only one of the two following assays. The other one should be indicated as “Not Done”.

Brain natriuretic peptide BNP pg/mL

ng/L

*If value is outside given range please see 'status (****ST=****)' drop down field*

*If* > 7500 pg/mL *select from the ‘status’ drop down field*

NT pro brain natriuretic peptide Pro-BNP pg/mL

ng/L

White blood cell count x103/uL

x109/uL

Hemoglobin g/dL

g/L

mmol/L

Hemoglobin A1c/Estimated Average Glucose (eAG) %

mmol/mol

mg/dL

mmol/L

Platelets x103/uL

x109/uL

INR international units

CRP or hs-CRP (C Reactive Protein) mg/L

Lupus anticoagulant Positive, Negative, Unknown

Uric Acid mg/dL

umol/L

*If value is outside given range please see 'Status (****ST=****)' drop down field*

*If < 1 mg/dL select from the ‘status’ drop down field*

Lymphocyte Count %

x103 cells/uL

x109 cells/L

*If value is outside given range please see 'status (****ST=****)' drop down field*

*If* <2% *select from the ‘status’ drop down field*

Concerns and Contraindications

**Current Device Strategy:**

**Please check any condition below that is a co-morbidity and/or concern for patient treatment or contraindication for transplant.**

Checking any of these contraindications/co-morbidities/concerns does not necessarily mean that a condition is a contraindication or concern for the patient. No specific thresholds are provided for these concerns or contraindications. They should represent the results of formal discussion with the medical and surgical transplant team prior to the decision for device implantation. If there are no contraindications or concerns specified then select **No**.

If so, limitation for

Concerns/Contraindications: Is condition present? transplant listing?

***Overall status:***

Advanced age Yes/No Yes/No

Frailty Yes/No Yes/No

Patient does not want transplant Yes/No Yes/No

Musculoskeletal limitation to ambulation Yes/No Yes/No

Contraindication to immunosuppression Yes/No Yes/No

Allosensitization Yes/No Yes/No

***Chronic renal disease*** Yes/No Yes/No

***Cardiothoracic issues:***

Frequent ICD shocks Yes/No Yes/No

Pulmonary Disease Yes/No Yes/No

Pulmonary Hypertension Yes/No Yes/No

Recent Pulmonary Embolus Yes/No Yes/No

History of Atrial Arrhythmia Yes/No Yes/No

Unfavorable Mediastinal Anatomy Yes/No Yes/No

(includes sternotomies, sternal resection, radiation, flail chest, etc)

Thoracic Aortic disease Yes/No Yes/No

***Nutritional/GI:***

Large BMI Yes/No Yes/No

Severe diabetes Yes/No Yes/No

Malnutrition/Cachexia Yes/No Yes/No

History of GI Ulcers Yes/No Yes/No

History of Hepatitis Yes/No Yes/No

Liver Dysfunction Yes/No Yes/No

***Vascular issues:***

Heparin-Induced Thrombocytopenia Yes/No Yes/No

Chronic coagulopathy Yes/No Yes/No

Major Stroke Yes/No Yes/No

Other Cerebrovascular Disease Yes/No Yes/No

Peripheral Vascular Disease Yes/No Yes/No

***Oncology/infection issues:***

History of Solid Organ Cancer Yes/No Yes/No

History of Lymphoma, Leukemia Yes/No Yes/No

History of Bone Marrow Transplant (BMT) Yes/No Yes/No

History of HIV Yes/No/Unknown Yes/No

(If Yes, answer HIV questions below)

Chronic Infectious Concerns Yes/No Yes/No

***Psychosocial issues:***

Limited Cognition/Understanding Yes/No Yes/No

Limited Social Support Yes/No Yes/No

Repeated Noncompliance Yes/No Yes/No

History of Illicit Drug Use Yes/No Yes/No

History of Alcohol Abuse Yes/No Yes/No

Narcotic Dependence Yes/No Yes/No

History of Smoking Yes/No Yes/No

Currently Smoking Yes/No Yes/No

Severe Depression Yes/No Yes/No

Other Major Psychiatric Diagnosis Yes/No Yes/No

***Other Comorbidity*** Yes/No Yes/No

**HIV Sub-questions:**

**HIV diagnosis date:** Enter HIV diagnosis date in MMDDYYYY format.

**ST=** Unknown or Not Done.

**Plasma HIV-1 RNA (Viral load) – Closest to Implant:** \_\_\_\_\_\_\_ copies/ml.

**ST=** Not Done.

**CD4 T-Cell Count – Closest to Implant:** \_\_\_\_\_\_\_\_ cells/mm3. **ST**= Not Done.

**Erythrocyte Sedimentation Rate (ESR):** \_\_\_\_\_\_\_\_\_ mm/hr. **ST**= Not Done.

**C-Reactive Protein (CRP) or hs-CRP:** \_\_\_\_\_\_\_\_\_ mg/L. **ST**= Not Done.

**Antiretroviral Therapy:** Select all that apply:

Abacavir (ABC) / Ziagen

Atripla (FTC/EDV/TDF)

Atazanavir (ATV) / Reyataz

Combivir (3TC/ZDV)

Complera (FTC/RPV/TDF)

Darunavir (DRV) / Prezista

Delavirdine (DLV) / Rescriptor

Didanosine (ddI) / Videx EC

Dolutegravir / Tivicay

Efavirenz (EFV) / Sustiva

Emtricitabine (FTC) / Emtriva

Enfuvirtide (T20) / Fuzeon

Epzicom (3TC/ABC)

Etravirine (ETR) / Intelence

Fosamprenavir (FPV) / Lexiva

Indinavir (IDV) / Crixivan

Kaletra (LPV/r)

Lamivudine (3TC) / Epivir

Maraviroc (MVC) / Selzentry

Nelfinavir (NFV) / Viracept

Nevirapine (NVP) / Viramune / Viramune XR

Raltegravir (RAL) / Isentress

Rilpivirine (RPV) / Edurant

Ritonavir (RTV) / Norvir

Saquinavir (SQV) / Invirase

Stavudine (d4T) / Zerit

Stribild (FTC/EVG/COBI/TDF)

Tenofovir Disoproxil Fumarate (TDF) / Viread

Tipranivir (TPV) / Aptivus

Trizivir (3TC/ZDV/ABC)

Truvada (FTC/TDF)

Zidovudine (ZDV) / Retrovir

None

Unknown

**Infection Prophylaxis:** Select all that apply:

Atovaquone

Azithromycin

Dapsone

Fluconazole

Pentamidine, aerosolized

Trimethroprim-sulfamethoxazole (TMP-SMX)

None

Unknown

**History of Opportunistic Infection:** Select all that apply:

Cryptococcosis

Cytomegalovirus (CMV)

Epstein Barr virus (EBV)

Esophageal candidiasis

Histoplasmosis

Kaposi’s sarcoma

Mycobacterium avium complex (MAC), disseminated

Pneumocystis jiroveci (carinii) pneumonia (PCP)

Toxoplasmosis

Tuberculosis

None

**History of Hepatitis B:** Positive or Negative.  **ST=** Unknown or Not Done.

**History of Hepatitis C:** Positive or Negative. **ST=** Unknown or Not Done.

Medicationscollected at time **nearest to** implant **but not in OR**. Mark whether the medications listed fall into one of the following categories:

**Currently using -** At the time of VAD placement.

**Known previous use within the past year-** Is intended to capture the adequacy of medical therapy prior to determining heart failure to be refractory. For instance, ACEI, beta blockers, and diuretics are considered standard necessary therapy for heart failure but may be stopped due to hypotension or renal failure during a hospitalization for severely decompensated heart failure. If patients are known to have received these agents within the past year, please check **known previous use.**

**No (not being used)** - If there is no reason to believe that they have taken those agents, and reasonable certainty that information is accurate, check **No.**

**Unknown** - If it is not known whether the patient has taken those agents within the previous year, check **Unknown.**

**List of medications**

Allopurinol

Currently Using

Known previous use (within past year)

No

Unknown

Angiotensin receptor blocker drug

Currently Using

Known previous use (within past year)

No

Unknown

Amiodarone

Currently Using

Known previous use (within past year)

No

Unknown

ACE inhibitors

Currently Using

Known previous use (within past year)

No

Unknown

Beta-blockers

Currently Using

Known previous use (within past year)

No

Unknown

Aldosterone antagonist

Currently Using

Known previous use (within past year)

No

Unknown

Warfarin (coumadin)

Currently Using

Known previous use (within past year)

No

Unknown

Antiplatelet therapy drug

Currently Using

Known previous use (within past year)

No

Unknown

**Nesiritide** – Check **Yes** for **Nesiritide** only if currently being administered. Note that there is no option for previously taken. Or check **No** or **Unknown.**

**Nitric oxide** (document Flolan here) – Check **Yes** for **Nitric oxide** only if currently being administered. Note that there is no option for previously taken. Or check **No** or **Unknown.**

**Loop diuretics** – Check **Yes**, **No**, or **Unknown**.

Enter the total daily dose the patient received at home before hospitalization.

If **Yes**, Enter **Dosage** \_\_\_\_\_ mg/day – 24 hrs mg total **ST=** Unknown

If dose is entered, then check **type of loop diuretic** (select all that apply):

Furosemide

Torsemide

Bumetanide

Other

**Outpatient (prior to admission) inotrope infusion:** Check **Yes** or **No** or **Unknown.**

**Cardiac ResynchronizationTherapy (CRT)?** Check **Yes** or **No** or **Unknown.**

**Is patient on Metalozone/Thiazide?** Check **Yes** or **No** or **Unknown.**

**If Yes, then select (check one):** Regular (ex. Daily)

Intermittent (ex. 3 times per week or PRN)

**Is patient on Phosphodiesterase inhibitors?** Check **Yes** or **No** or **Unknown.**

(Please enter only for the indication of Pulmonary Hypertension or Right Heart Failure).

Quality of Life **(EURoQoL and KCCQ)**

Please See the EURoQoL, Intermacs QoLand KCCQ section of the Users’ guide for further instructions on administration and web-based data entry for the EURoQoL, Intermacs QoLand KCCQ [(Section 2.14)](#Qol_KCCQ).

Exercise/Trailmaking

**EXERCISE FUNCTION**

**All patients should attempt to complete these functional capacity measurements especially for those patients classified as Intermacs® patient profile level 4-7.**

**6 minute walk:** This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk *behind* the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here. **NOTE: You may use the time from the first 15 feet of the 6minute walk for the Gait speed test listed below (please see instructions for the gait speed test below.) ST=** **Not Done: Too sick**, **Not Done: Other**, and **Unknown**.

**All efforts should be made to perform the 6 minute walk test for any patient able to walk more than a few steps. A distance as short as 3 feet may be recorded. If the test is not done, the reason must be indicated as “not done: too sick” or “not done: other”, for which an example might be a patient needing to remain supine**

**after a groin puncture for routine catheterization. Any musculoskeletal limitation to walking should be recorded as “not done: too sick”.**

**Gait speed (1st 15 foot walk): \_\_\_\_ seconds**

Instructions: Record the time (seconds) required for the patient to walk the first 15 feet of the 6 minute walk. The “starting” line and the 15 foot line should be clearly marked. Record the time to the first footfall at 0 feet and ends with the first footfall at 15 feet in the nearest. 0.1 sec with a stopwatch. **NOTE: You may use the time from the first 15 feet of the 6 minute walk for the Gait speed test. ST=** **Not Done: Too sick**, **Not Done: Other**, and **Unknown**.

**Peak VO2 Max: Maximum volume of oxygen the body can consume during exercise (mL/kg/min)** is the ml/kg/min of oxygen consumed during symptom-limited exercise testing either on a bicycle or treadmill. The values recorded during the bicycle are usually 1-2 ml/min lower than for the treadmill, but it is assumed that most institutions will use only one instrument. If both are available, the bicycle is preferable as the mode easiest to standardize. **ST=** **Not Done: Too sick**, **Not Done: Other**, and **Unknown**.

**R Value at peak:** Is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort. **ST=** Unknown or Not Done.

**Neurocognitive Trail Making Test – Part B**

Please See the Trail Making Test Part B Instructions section of the Users’ guide for further instructions on administration and web-based data entry for the Trail Making Test [(Section 2.15)](#Trailmaking).

**MEDICAL CONDITION**

**NYHA Class:** New York Heart Association Class for heart failure:

**Class I:**       No limitation of physical activity; physical activity does not cause fatigue,

palpitation or shortness of breath.

**Class II:**      Slight limitation of physical activity; comfortable at rest, but ordinary physical

activity results in fatigue, palpitations or shortness of breath.

**Class III:**    Marked limitation of physical activity; comfortable at rest, but less than ordinary

activity causes fatigue, palpitation or shortness of breath.

**Class IV:** Unable to carry on minimal physical activity without discomfort; symptoms may

be present at rest.

**Unknown**

# 2.4 Implant Form

The **Implant Form** is to be completed within 1 week post implant.

**Implant date:** Enter VAD implant date in MMDDYYYY format.

**PAYOR INFORMATION**

**Check one of the following:**

Government Health Insurance

Commercial Health Insurance

Health Maintenance Organization

Non-U.S. Insurance

None / Self

Unknown

If **Government Health Insurance**, please **select** one of the following:

Medicare

Medicaid

State-Specific Plan

Correctional Facility

If **Medicare**, please **select** one of the following:

Health Insurance Claim Number (HIC) **ST=** Unknown

Medicare Fee for Service

Military Health Care

Indian Health Service

Not Applicable

Other, Specify **- If selected please complete text box.**

**NATIONAL PROVIDER IDENTIFIER (NPI) INFORMATION**

**Operator First Name**: Enter the implanting physician’s first name. **ST=** Unknown

**Operator Middle Name:** Enter the implanting physician's middle name. **ST=** Unknown

**Operator Last Name**: Enter the implanting physician’s last name. **ST=** Unknown

**Operator NPI:** Enter the implanting physician’s National Provider Identification Number. **ST=** Unknown

**Additional Indication for VAD:** Select one of the following as indication for VAD: **Failure to wean from CPB, Post cardiac surgery,** **Failure to wean from ECMO,** or **None.**

Failure to wean from CPB

Post Cardiac Surgery

None

Failure to wean from ECMO

If post cardiac surgery, **Enter Cardiac operation**: Type the cardiac operation performed in the block provided.

**Device Type: This element’s value will automatically appear which was taken from the Screening Log (See Section 2.1). If this element’s value is not correct, please enter the correct device type. If greyed out, then contact your Nurse Monitor.**

LVAD   
RVAD  
Both (LVAD+RVAD in the same OR visit)   
Total Artificial Heart (TAH)

**Device Brand:**  **This element’s value will automatically appear which was taken from the Screening Log (See Section 2.1). If this element’s value is not correct, please enter correct device brand. If greyed out, then contact your Nurse Monitor.**

Please refer to **Appendix K** (Brand Device Table) if you have questions or are unsure as to which devices should and should not be included into STS Intermacs**®**. **Appendix K** is available on [http://www.uab.edu/medicine/STS Intermacs/appendices/app-k-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-k-5-0)

**Surgical approach:** Please specify the surgical approach.

Sternotomy

Thoracotomy

Subcostal

Unknown

Other, Specify

**If Other Specify: Textbox**

**LVAD: Serial Number:** Enter unique Serial Number for each device. **ST=** Unknown .

**LVAD:**

**Inflow Cannula Location:** Select one of the following for LVAD cannula inflow location.

LA appendage   
LA interatrial groove   
LV apex

LV diaphragmatic surface   
Unknown

**Outflow Cannula Location:** Select one of the following for LVAD cannula outflow location. Ascending aorta   
Descending thoracic aorta   
Abdominal aorta

Unknown

Subclavian

Other, Specify - **If Other Specify: Textbox**

**RVAD: Serial Number:** Enter unique Serial Number for each device. **ST=** Unknown .

**RVAD:**

**Inflow Cannula Location:** Select one of the following for RVAD cannula inflow location.

RA   
RV   
Unknown

**Outflow Cannula Location:** Select one of the following for RVAD cannula outflow location.

MPA (main pulmonary artery)   
LPA (left pulmonary artery)

RPA (Right Pulmonary Artery)   
Conduit   
Other, specify - **If Other Specify: Textbox**

**TAH: Serial Number:** Enter unique Serial Number for each device. **ST=** Unknown

**Associated Findings (Surgical observations or Intraoperative TEE):**

Select all that apply:

PFO/ASD

Aortic Insufficiency

Select: Mild, Moderate, Severe

Tricuspid Insufficiency

Select: Mild, Moderate, Severe

None

**Concomitant surgery**: Select all concomitant surgeries that apply. If **Other, specify** is selected, type in the specification in the block provided.

None

ASD closure

PFO closure

RVAD Implant

RVAD Explant

ECMO Decannulation

CABG

VSD closure

IABP Removal

Congenital cardiac surgery, other

Aortic Valve Surgery - Repair (no valve closure)

Aortic Valve Surgery - Repair with valve closure

Aortic Valve Surgery - Replacement - Biological

Aortic Valve Surgery - Replacement - Mechanical

Mitral Valve Surgery – Repair

Mitral Valve Surgery – Replacement - Biological

Mitral Valve Surgery – Replacement - Mechanical

Tricuspid Valve Surgery - Repair - DeVega

Tricuspid Valve Surgery - Repair - Ring

Tricuspid Valve Surgery - Repair - Other

Tricuspid Valve Surgery - Replacement - Biological

Tricuspid Valve Surgery - Replacement - Mechanical

Pulmonary Valve Surgery - Repair

Pulmonary Valve Surgery - Replacement - Biological

Pulmonary Valve Surgery - Replacement - Mechanical

Other, specify -

**If Other, Specify: Textbox**

Was patient put on **Cardio Bypass Pump?** Yes, No, or Unknown

If **yes** enter **CPB time: (Total cardiopulmonary bypass time):** time in minutes.

**ST** = Unknown or Not done.

**Surgery Time:** Enter total surgery time from primary incision to closure: \_\_\_\_\_\_ (min). **ST=** Unknown

**Cross Clamp** used: Yes, No, or Unknown

If **yes** enter total cross CCT **clamp time** in minutes: \_\_\_\_\_\_(min).

**ST** = Unknown or Not done.

# 2.5 1 Week and 1 Month Follow-up

The data on this form are collected at the following time periods:

1 week (+/- 3days) post-implant

1 month (+/- 7 days) post implant

When doing medical chart abstraction, please use clinic visit closest to follow-up period.

Followup Status

**Check one of the following:**

**Inpatient** (complete follow-up form)

**Outpatient** (complete follow-up form)

**Other Facility** (complete follow-up form)

Nursing Home/Assisted Care

Hospice

Another hospital

Rehabilitation Facility

Unknown

**Unable to obtain follow-up information** - this will result in an incomplete follow-up

(cannot complete follow-up form)

State reason why you are unable to obtain follow-up information (check one):

Patient didn’t come to clinic

Not able to contact patient

Not addressed by site

**If Inpatient, outpatient or other facility is checked then --**

Enter **follow-up date: MM/DD/YYYY please enter the actual follow-up date post implant.**

**Was patient intubated since implant?** This includes all time since last follow-up.

Yes, No, or Unknown

**Was patient on dialysis since implant?** This includes all time since last follow-up.

Yes, No, or Unknown

**PUMP CHANGE - Please answer all questions regarding pump status considering all time since previous visit and current follow-up date.**

**Was there a pump exchange of a para- or extra- corporeal pump?**

Yes, No, or Unknown

If **yes**, Please select the  **Pump Exchange Reason:**

Thrombus NOT associated with hemolysis

Change in hemodynamics

Clinical status

Device parameters (please enter Device Malfunction Form)

Upsizing device because of patient growth status

All other reasons would categorize the pump change as a Device Malfunction. If selected, please fill out the Device Malfunction Form.

**Was there a console change?**

Yes, No, or Unknown

**If Yes please complete the following:**

**Date of console change: Enter date in MMDDYYYY format. ST=** Unknown

**Original console name: Text.**

**New console name: Text.**

**MEDICAL CONDITION**

**NYHA Class::** New York Heart Association Class for heart failure:

**Class I:**       No limitation of physical activity; physical activity does not cause fatigue,

palpitation or shortness of breath.

**Class II:**      Slight limitation of physical activity; comfortable at rest, but ordinary physical

activity results in fatigue, palpitations or shortness of breath.

**Class III:**    Marked limitation of physical activity; comfortable at rest, but less than ordinary

activity causes fatigue, palpitation or shortness of breath.

**Class IV:** Unable to carry on minimal physical activity without discomfort; symptoms may

be present at rest.

**Unknown**

**ZONES**

**Hemolysis Zone – Information that you provide in this section will be used to assess the existence of hemolysis and its degree.**

**Note: You may use either PFh or LDH.**

**Please enter the peak Plasma-free hemoglobin (PFh) since the last Follow-Up visit:** \_\_\_\_\_\_\_ mg/dL. **ST=** Unknown or Not Done

**What is your hospital’s upper limit of the normal range of peak PFh:** \_\_\_\_\_\_\_mg/dl. **ST=** Unknown or Not Done

**Please enter the peak serum lactate dehydrogenase (LDH) since the last Follow-Up visit:** \_\_\_\_\_\_\_ U/L. **ST=** Unknown or Not Done

**What is your hospital’s upper limit of the normal range of LDH:** \_\_\_\_\_\_\_\_ U/L.

**ST=** Unknown or Not Done

**Enter the Maximum and Minimum HCT or HGB since the last Follow-Up visit:**

**Min. HCT:** \_\_\_\_\_\_\_\_\_ **ST=** Unknown or Not Done

**Max. HCT:** \_\_\_\_\_\_\_\_\_ **ST=** Unknown or Not Done

**Min. HGB:** \_\_\_\_\_\_\_\_\_ **ST=** Unknown or Not Done

**Max. HGB:** \_\_\_\_\_\_\_\_\_ **ST=** Unknown or Not Done

**Highest Total Bilirubin since the last Follow-Up visit:** \_\_\_\_\_\_\_ mg/dl.

**ST=** Unknown or Not Done

**Has the following been present at any time since the last Follow-Up visit?**

**Physical Findings:** Select all that apply:

Hemoglobinuria (Tea-Colored Urine)?

Yes, No, Unknown

Pump malfunction and/or abnormal pump parameters?

Yes, No, Unknown

(If **yes,** please fill out the Device Malfunction Adverse Event Form)

**Right Heart Failure Zone – Information that you provide in this section will be used to assess the existence of right heart failure and its degree.**

**Clinical Findings – Since the last Follow-Up visit.**

**CVP or RAP > 16 mmHg?**

Yes, No, Unknown, or Not Done

**Dilated Vena Cava with absence of Inspiratory Variation by Echo (If absence of Inspiratory Variation is not documented, Check No)?**

Yes, No, Unknown, or Not Done

**Clinical findings of elevated jugular venous distension at least half way up the**

**neck in an upright patient (If ≥ 6 cm, Check Yes)?**

Yes, No, Unknown

**Peripheral Edema (If ≥ 2, Check Yes)?**

Yes, No, Unknown

**Ascites?**

Yes, No, Unknown

**Has the patient been on Inotropes since the last Follow-Up visit?**

Yes, No, Unknown

If **yes,** select all that apply:

Dopamine

Dobutamine

Milrinone

Isoproterenol

Epinephrine

Norepinephrine

Levosimendan

Unknown

**Nesiritide?**

Yes, No, Unknown

**Has the patient had a RVAD implant since the last Follow-up visit?**

Yes, No, Unknown

Please click on the link below for further instruction on administering Stroke Scales in **Appendix I**.

[http://www.uab.edu/medicine/STS Intermacs/appendices/app-i-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-i-5-0)

**Has the patient experienced a Neurological Event since time of implant?**

Yes, No, Unknown

**Note: This only applies to patients who have a CVA, TIA, or Anoxic Brain Injury. Once “Yes” is selected you must complete this section for the patient’s complete STS Intermacs® lifespan.**

If **yes, provide Modified Rankin Scale:**

**0 – No symptoms at all**

**1 – No Significant disability:** despite symptoms: able to carry out all usual duties and activities

**2 –** **Slight disability:** unable to carry out all previous activities but able to look after own affairs without assistance

**3 –** **Moderate disability:** requiring some help, but able to walk without assistance.

**4 –** **Moderately severe disability:** unable to walk without assistance, and unable to attend to own bodily needs without assistance.

**5 –** **Severe disability:** bedridden, incontinent and requiring constant nursing care and attention.

**6 –** **Dead**

**ST=** Not Done or Not Documented

**OR**

If **yes, provide NIH Stroke Scale:**

**0 – No Stroke**

**1-4 – Minor Stroke**

**5-15 –** **Moderate Stroke**

**16-20 –** **Moderate to Severe Stroke**

**21-42 –** **Severe Stroke**

**ST=** Not Done or Not Documented

Hemodynamics **(Prior to implant – closest to implant but not in OR)**

**General Hemodynamics – during report interval**

**Heart rate:** Beats per minute. **ST=** Unknown or Not Done

**Systolic bp:** mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. **ST=** Unknown or Not Done

**Diastolic bp:** mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. **ST=** Unknown or Not Done

**Doppler Opening Pressure:** \_\_\_\_\_\_ mmHg **ST=** Unknown or Not Done

Record the pressure on the BP cuff at the time of sound on the doppler as the cuff is released and this is the Doppler opening pressure which may correspond to the MAP.

**ECG rhythm (cardiac rhythm):** Select one of the following. If **Other, specify** is selected, type in the specification in the block provided.

Sinus

Atrial fibrillation

Atrial flutter

Paced: Atrial pacing

Paced: Ventricular pacing

Paced: Atrial and ventricular pacing

Unknown

Not done

Other, specify **– please complete text box**

**Weight**: Enter the weight of the patient at the time of follow-up in the appropriate space, in pounds or kilograms.  The weight must fall between 5 and 600 pounds or 2 and 273 kilograms. **ST=** Unknown or Not Done

**Echo Findings – during report interval**

**Mitral regurgitation:** Mitral regurgitation should be recorded on a qualitative scale (if ‘trivial’ then assign as mild). Moderate-severe would be recorded as “severe”.

0 (none)

1 (mild)

2 (moderate)

3 (severe)

Not Recorded or Not Documented

**Tricuspid regurgitation:** Tricuspid regurgitation should be recorded on a qualitative scale (if ‘trivial’ then assign as mild). Moderate-severe would be recorded as “severe”.

0 (none)

1 (mild)

2 (moderate)

3 (severe)

Not Recorded or Not Documented

**Aortic regurgitation:** Aortic regurgitation should be recorded on a qualitative scale (if ‘trivial’ then assign as mild). Moderate-severe would be recorded as “severe”.

0 (none)

1 (mild)

2 (moderate)

3 (severe)

Not Recorded or Not Documented

Not Applicable

Unknown

**LVEF%** **Left ventricular ejection fraction.** If a number or range is available, check the number range that best applies. For example, a reported ejection fraction of 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as “left ventricular function” or “systolic function” in words. “Mild impairment, mildly reduced, or mild decrease” would all be characterized as “mild”.

> 50 (normal)

40-49 (mild)

30-39 (moderate)

20-29 (moderate/severe)

< 20 (severe)

Not Recorded or Not Documented

**LVEDD:** **Left ventricular end-diastolic dimension** in centimeters.

**ST =** Not Record or Not Documented

**RVEF:** RV Function is generally NOT measured in numbers, as it is difficult to quantify. It may be described as “right ventricular function” or “right ventricular contractility”. “Mild impairment, mildly reduced, or mild decrease” would all be characterized as “mild”. Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as “severe”.

Normal

Mild

Moderate

Severe

Not Done

Unknown

**Swan Hemodynamics – during report interval**

**NOTE: You may be able to get the following information from a right heart catheterization test if it was performed.**

**Pulmonary artery systolic pressure:** This may be abbreviated PAS or pulmonary pressures. mmHg (millimeters of mercury). **ST=** Unknown or Not Done

**Pulmonary artery diastolic pressure:** This may be abbreviated PAD or pulmonary pressures. mmHg (millimeters of mercury). **ST=** Unknown or Not Done

**Mean RA Pressure:** \_\_\_\_\_\_\_ mmHg. **ST=** Unknown or Not Done

**Central Venous Pressure:** \_\_\_\_\_\_\_\_\_ mmHg. **ST=** Unknown or Not Done

**Mean Pulmonary artery wedge pressure:** May be listed also as PCW or pulmonary capillary wedge pressure. It is not always provided in the hemodynamic data. mmHg (millimeters of mercury). **ST=** Unknown or Not Done

**Cardiac Index**: Will be expressed as L/min/M2. Enter this number.

**ST=** Unknown or Not Done

**Cardiac Index Measured by Fick or Thermodilution**:

Yes, No, or Unknown.

If **Yes** (select all that apply):

Fick

Thermodilution

**Cardiac Output:** Will be expressed as Liters/min or L/min. Enter this number. The cardiac index is NOT what we want; it is a smaller number expressed as Liters/min/m2 or L/min/m2. **ST=** Unknown or Not Done

**Cardiac Output Measured by Fick or Thermodilution**:

Yes, No, or Unknown.

If **Yes** (select all that apply):

Fick

Thermodilution

Medications

Mark whether the medications listed are used during the follow-up time period: **Yes, No,** or **Unknown.**

**List of medications**

Hydralazine (at 1 month only)

Calcium channel blockers (at 1 month only)

Angiotensin receptor blocker drug

Amiodarone

ACE inhibitors

Thrombolytic (Streptokinase, Alteplase [tPA], Reteplase [rPA], Tenecteplase [TNK-tPA], Lanoteplase[nPA], Anistreplase [APSAC], Urokinase)

Beta-blockers

Aldosterone antagonist

Low molecular weight heparin (Lovenox, Fragmin, Innohep)

UFH: Unfractionated Heparin

Warfarin (coumadin)

Arixtra (fondaparinux)

Antiplatelet therapy drug –additionally, (select all that apply).

Aspirin

Dextran

Dipyridamole

Clopidogrel

Ticlopidine

Unknown

**Other, specify**– if selected, type in the block provided.

Nitric oxide (document Flolan here)

Phosphodiesterase Inhibitor (Please enter only for the indication of Pulmonary Hypertension or Right Heart Failure).

Digoxin

Loop diuretics

If **yes** and follow-up is 1 month or later post implant then Enter

Dosage \_\_\_\_\_ mg/day – 24 hrs mg total **ST=** Unknown

If dose is entered, then check type of loop diuretic (select all that apply):

Furosemide

Torsemide

Bumetanide

Other

Laboratory Values

Values closest to 1 week and 1 month anniversaries. For all of the tests listed below, give the appropriate measurement. **ST**= Unknown or Not Done

Laboratory Value: Unit(s) of Measure (US/SI):

Sodium mEq/L

mmol/L

Potassium mEq/L

mmol/L

Blood urea nitrogen mg/dL

mmol/L

Creatinine mg/dL

umol/L

SGPT/ALT (alanine aminotransferase/ALT) u/L

SGOT/AST (aspartate aminotransferase/AST) u/L

LDH units/L

U/L

ukat/L

Total Bilirubin mg/dL

umol/L

Bilirubin direct mg/dL

umol/L

Bilirubin indirect mg/dL

umol/L

Albumin g/dL

g/L

Pre- Albumin mg/dL

mg/L

TotalCholesterol mg/dL

mmol/L

*If value is outside given range please see 'Status (****ST=****)' drop down field*

*If < 50 mg/dl select from the ‘status’ drop down field*

Institutions generally perform only one of the two following assays. The other one should be indicated as “Not Done”.

Brain natriuretic peptide BNP pg/mL

ng/L

*If value is outside given range please see 'status (****ST=****)' drop down field*

*If* > 7500 pg/mL *select from the ‘status’ drop down field*

NT pro brain natriuretic peptide Pro-BNP pg/mL

ng/L

White blood cell count x103/uL

x109/uL

Reticulocyte count %

Hemoglobin g/dL

g/L

mmol/L

Hemoglobin A1c/Estimated Average Glucose (eAG) %

mmol/mol

mg/dL

mmol/L

Platelets x103/uL

x109/uL

INR international units

Plasma-free hemoglobin mg/dL

g/L

Positive antiheparin/platelet antibody(HIT)

Yes, No, Unknown

If **Yes**, are they on **direct thrombin inhibitors**

Yes, No, Unknown

If **Yes**, **Enter Drugs:** (select all that apply)

Aspirin

Dipyridamole

Plavix

Heparin

Coumadin

Direct thrombin inhibitors (ex: arg, lip, val…)

Was a **TEG** done? Yes, No, Unknown

If **Yes**

ThrombElastoGraph Hemostasis System (TEG) profile, MA k

ThrombElastoGraph Hemostasis System (TEG) profile, R k

ThrombElastoGraph Hemostasis System (TEG) profile, R h

CRP or hs-CRP (C Reactive Protein) mg/L

Lupus anticoagulant Positive, Negative, Unknown

Uric Acid mg/dL

umol/L

*If value is outside given range please see 'Status (****ST=****)' drop down field*

*If < 1 mg/dL select from the ‘status’ drop down field*

**Major Outcomes and Adverse Events**

**Note: Please check that you have entered all Major Outcomes and Adverse Events since the last follow-up. The adverse events are usually entered during a rehospitalization (or during the index hospitalization). To enter an adverse event click on the button located at the top of the patient overview screen.**



* **Rehospitalization**
* **Major Infection**
* **Neurological Dysfunction**
* **Device Malfunction** (if suspected device thrombosis, then enter as Device Malfunction)
* **Major Bleeding**
* **Cardiac Arrhythmia**
* **Pericardial Fluid Collection**
* **Myocardial Infarction**
* **Psychiatric Episode**
* **Respiratory Failure**
* **Arterial Non-CNS Thromboembolism**
* **Venous Thromboembolic Event**
* **Wound Dehiscence**
* **Hepatic Dysfunction**
* **Renal Dysfunction**
* **Other SAE**
* **Death**
* **Explant due to Exchange**
* **Explant due to Recovery**
* **Explant due to Transplant**

Note: Please click on the link below to be taken to the AE definitions in **Appendix A**.

[http://www.uab.edu/medicine/STS Intermacs/appendices/app-a-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-a-5-0)

# 2.6 3 Month and 6 Month Follow-up

The data on this form are collected at the following time periods:

3 months post-implant (+/- **30** **days**)

6 months post-implant (perpetual, - +/- **60 days**)

When doing medical chart abstraction, please use clinic visit closest to follow-up period.

## Follow-up Status

**Check one of the following:**

**Inpatient** (complete follow-up form)

**Outpatient** (complete follow-up form)

**Other Facility** (complete follow-up form)

Nursing Home/Assisted Care

Hospice

Another hospital

Rehabilitation Facility

Unknown

**Unable to obtain follow-up information** - this will result in an incomplete follow-up

(cannot complete follow-up form)

State reason why you are unable to obtain follow-up information (check one):

Patient didn’t come to clinic

Not able to contact patient

Not addressed by site

**If Inpatient, outpatient or other facility is checked then --**

Enter **follow-up date: MM/DD/YYYY please enter the actual follow-up date post implant.**

**Was patient intubated since last follow-up?** This includes all time since last follow-up.

Yes, No, or Unknown

**Was patient on dialysis since last follow-up?** This includes all time since last follow-up.

Yes, No, or Unknown

**PATIENT STATUS**

**Current Device Strategy**: This should be determined in conjunction with the heart failure cardiologist and surgeon. This determination should be re-visited and recorded at 3 months, 6 months, and every 6 months thereafter. The strategy should be selected as:

**Bridge to recovery -** Use of a durable device to allow recovery from

chronic cardiac failure (at least 3 months in duration).

**Rescue therapy** - Use of a durable device to support resolution from an

acute event without major previous cardiac dysfunction.

**Bridge to transplant**– This is for a patient who has been listed for transplant since

initial implantation.

**List Date for Transplant**:

Enter list date for transplant in the format MMDDYYYY. ST=Unknown

**Possible bridge to transplant -** *Likely to be eligible*: defines a patient in

whom the transplant evaluation has not been completed, but no contra-indications

are anticipated, or in whom a current contra-indication is anticipated to resolve

rapidly, such as recent infection.

**Possible bridge to transplant -** *Moderate likelihood of becoming eligible*:

similar to above, but with some potential concerns that might prevent eligibility.

**Possible bridge to transplant -** *Unlikely to become eligible:* should be used for a

patient in whom major concerns have already been identified. These may not have

been quantified yet, such as in a patient with known chronic lung disease without

recent pulmonary function test measurement, or might be reversible, such as severe

renal insufficiency or pulmonary hypertension that might improve after chronic

mechanical support. It may be the expectation at the time of implant that the patient

will most likely have the assist device as “permanent” or “destination” therapy.

**Destination therapy -** (patient definitely not eligible for transplant). All factors that

weigh in to the decision of non–transplant candidacy should be indicated below.

If **Other, specify –** is selected, type in the specification in the block provided.

**PUMP CHANGE - Please answer all questions regarding pump status considering all time since previous visit and current follow-up date.**

**Was there a pump exchange of a para- or extra- corporeal pump?**

Yes, No, or Unknown

If **yes**, Please select the **Pump Exchange Reason:**

Thrombus NOT associated with hemolysis

Change in hemodynamics

Clinical status

Device parameters (please enter Device Malfunction Form)

Upsizing device because of patient growth status

All other reasons would categorize the pump change as a Device Malfunction. If selected, please fill out the Device Malfunction Form.

**Was there a console change?**

Yes, No, or Unknown

**If Yes please complete the following:**

**Date of console change: Enter date in MMDDYYYY format. ST=** Unknown

**Original console name: Text.**

**New console name: Text.**

**ZONES**

**Hemolysis Zone – Information that you provide in this section will be used to assess the existence of hemolysis and its degree.**

**Note: You may use either PFh or LDH.**

**Please enter the peak Plasma-free hemoglobin (PFh) since the last Follow-Up visit:** \_\_\_\_\_\_\_ mg/dL. **ST=** Unknown or Not Done

**What is your hospital’s upper limit of the normal range of peak PFh:** \_\_\_\_\_\_\_mg/dl. **ST=** Unknown or Not Done

**Please enter the peak serum lactate dehydrogenase (LDH) since the last Follow-Up visit:** \_\_\_\_\_\_\_ U/L. **ST=** Unknown or Not Done

**What is your hospital’s upper limit of the normal range of LDH:** \_\_\_\_\_\_\_\_ U/L.

**ST=** Unknown or Not Done

**Enter the Maximum and Minimum HCT or HGB since the last Follow-Up visit:**

**Min. HCT:** \_\_\_\_\_\_\_\_\_ **ST=** Unknown or Not Done

**Max. HCT:** \_\_\_\_\_\_\_\_\_ **ST=** Unknown or Not Done

**Min. HGB:** \_\_\_\_\_\_\_\_\_ **ST=** Unknown or Not Done

**Max. HGB:** \_\_\_\_\_\_\_\_\_ **ST=** Unknown or Not Done

**Highest Total Bilirubin since the last Follow-Up visit:** \_\_\_\_\_\_\_ mg/dl.

**ST=** Unknown or Not Done

**Has the following been present at any time since the last Follow-Up visit?**

**Physical Findings:** Select all that apply:

Hemoglobinuria (Tea-Colored Urine)?

Yes, No, Unknown

Pump malfunction and/or abnormal pump parameters?

Yes, No, Unknown

(If **yes,** please fill out the Device Malfunction Adverse Event Form)

**Right Heart Failure Zone – Information that you provide in this section will be used to assess the existence of right heart failure and its degree.**

**Clinical Findings – Since the last Follow-Up visit.**

**CVP or RAP > 16 mmHg?**

Yes, No, Unknown or Not Done

**Dilated Vena Cava with absence of Inspiratory Variation by Echo (If absence of Inspiratory Variation is not documented, Check No)?**

Yes, No, Unknown or Not Done

**Clinical findings of elevated jugular venous distension at least half way up the**

**neck in an upright patient (If ≥ 6 cm, Check Yes)?**

Yes, No, Unknown

**Peripheral Edema (If ≥ 2, Check Yes)?**

Yes, No, Unknown

**Ascites?**

Yes, No, Unknown

**Has the patient been on Inotropes since the last Follow-Up visit?**

Yes, No, Unknown

If **yes,** select all that apply:

Dopamine

Dobutamine

Milrinone

Isoproterenol

Epinephrine

Norepinephrine

Levosimendan

Unknown

**Nesiritide?**

Yes, No, Unknown

**Has the patient had a RVAD implant since the last Follow-Up visit?**

Yes, No, Unknown

Please click on the link below for further instruction on administering Stroke Scales in **Appendix I**.

[http://www.uab.edu/medicine/STS Intermacs/appendices/app-i-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-i-5-0)

**Has the patient experienced a Neurological Event since time of implant?**

Yes, No, Unknown

**Note: This only applies to patients who have a CVA, TIA, or Anoxic Brain Injury. Once “Yes” is selected you must complete this section for the patient’s complete STS Intermacs® lifespan.**

If **yes, provide Modified Rankin Scale:**

**0 – No symptoms at all**

**1 – No Significant disability:** despite symptoms: able to carry out all usual duties and activities

**2 –** **Slight disability:** unable to carry out all previous activities but able to look after own affairs without assistance

**3 –** **Moderate disability:** requiring some help, but able to walk without assistance.

**4 –** **Moderately severe disability:** unable to walk without assistance, and unable to attend to own bodily needs without assistance.

**5 –** **Severe disability:** bedridden, incontinent and requiring constant nursing care and attention.

**6 –** **Dead**

**ST=** Not Done or Not Documented

**OR**

If **yes, provide NIH Stroke Scale:**

**0 – No Stroke**

**1-4 – Minor Stroke**

**5-15 –** **Moderate Stroke**

**16-20 –** **Moderate to Severe Stroke**

**21-42 –** **Severe Stroke**

**ST=** Not Done or Not Documented

Hemodynamics

**General Hemodynamics - during report interval**

**Heart rate:** Beats per minute. **ST=** Unknown or Not Done

**Systolic bp:** mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. **ST=** Unknown or Not Done

**Diastolic bp:** mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. **ST=** Unknown or Not Done

**Doppler Opening Pressure:** \_\_\_\_\_\_ mmHg **ST=** Unknown or Not Done

Record the pressure on the BP cuff at the time of sound on the doppler as the cuff is released and this is the Doppler opening pressure which may correspond to the MAP.

**ECG rhythm (cardiac rhythm):** Select one of the following. If **Other, specify** is selected, type in the specification in the block provided.

Sinus

Atrial fibrillation

Atrial flutter

Paced: Atrial pacing

Paced: Ventricular pacing

Paced: Atrial and ventricular pacing

Unknown

Not done

Other, specify **– please complete text box**

**Weight**: Enter the weight of the patient at the time of follow-up in the appropriate space, in pounds or kilograms.  The weight must fall between 5 and 600 pounds or 2 and 273 kilograms. **ST=** Unknown or Not Done

**Echo Findings - during report interval**

**Mitral regurgitation:** Mitral regurgitation should be recorded on a qualitative scale (if ‘trivial’ then assign as mild). Moderate-severe would be recorded as “severe”.

0 (none)

1 (mild)

2 (moderate)

3 (severe)

Not Recorded or Not Documented

**Tricuspid regurgitation:** Tricuspid regurgitation should be recorded on a qualitative scale (if ‘trivial’ then assign as mild). Moderate-severe would be recorded as “severe”.

0 (none)

1 (mild)

2 (moderate)

3 (severe)

Not Recorded or Not Documented

**Aortic regurgitation:** Aortic regurgitation should be recorded on a qualitative scale (if ‘trivial’ then assign as mild). Moderate-severe would be recorded as “severe”.

0 (none)

1 (mild)

2 (moderate)

3 (severe)

Not Recorded or Not Documented

Not Applicable

Unknown

**LVEF%** **Left ventricular ejection fraction.** If a number or range is available, check the number range that best applies. For example, a reported ejection fraction of 30-35 would be entered as 30-40. Occasionally the LVEF may be described only as “left ventricular function” or “systolic function” in words. “Mild impairment, mildly reduced, or mild decrease” would all be characterized as “mild”.

> 50 (normal)

40-49 (mild)

30-39 (moderate)

20-29 (moderate/severe)

< 20 (severe)

Not Recorded or Not Documented

**LVEDD:** **Left ventricular end-diastolic dimension** in centimeters.

**ST =** Not Record or Not Documented

**RVEF:** RV Function is generally NOT measured in numbers, as it is difficult to quantify. It may be described as “right ventricular function” or “right ventricular contractility”. “Mild impairment, mildly reduced, or mild decrease” would all be characterized as “mild”. Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as “severe”.

Normal

Mild

Moderate

Severe

Not Done

Unknown

**Swan Hemodynamics - during report interval**

**NOTE: You may be able to get the following information from a right heart catheterization test if it was performed.**

**Pulmonary artery systolic pressure:** This may be abbreviated PAS or pulmonary pressures. mmHg (millimeters of mercury). **ST=** Unknown or Not Done

**Pulmonary artery diastolic pressure:** This may be abbreviated PAD or pulmonary pressures. mmHg (millimeters of mercury). **ST=** Unknown or Not Done

**Mean RA Pressure:** \_\_\_\_\_\_\_ mmHg. **ST=** Unknown or Not Done

**Central Venous Pressure:** \_\_\_\_\_\_\_\_\_ mmHg. **ST=** Unknown or Not Done

**Mean Pulmonary artery wedge pressure:** May be listed also as PCW or pulmonary capillary wedge pressure. It is not always provided in the hemodynamic data. mmHg (millimeters of mercury). **ST=** Unknown or Not Done

**Cardiac Index**: Will be expressed as L/min/M2. Enter this number.

**ST=** Unknown or Not Done

**Cardiac Index Measured by Fick or Thermodilution**:

Yes, No, or Unknown.

If **Yes** (select all that apply):

Fick

Thermodilution

**Cardiac Output:** Will be expressed as Liters/min or L/min. Enter this number. The cardiac index is NOT what we want; it is a smaller number expressed as Liters/min/m2 or L/min/m2. **ST=** Unknown or Not Done

**Cardiac Output Measured by Fick or Thermodilution**:

Yes, No, or Unknown.

If **Yes** (select all that apply):

Fick

Thermodilution

Medications

Mark whether the medications listed are used during the follow-up time period: **Yes, No,** or **Unknown.**

**List of medications**

Hydralazine

Calcium channel blockers

Angiotensin receptor blocker drug

Amiodarone

ACE inhibitors

Thrombolytic (Streptokinase, Alteplase [tPA], Reteplase [rPA], Tenecteplase [TNK-tPA], Lanoteplase[nPA], Anistreplase [APSAC], Urokinase)

Beta-blockers

Aldosterone antagonist

Low molecular weight heparin (Lovenox, Fragmin, Innohep)

UFH: Unfractionated Heparin

Warfarin (coumadin)

Arixtra (fondaparinux)

Antiplatelet therapy drug –additionally, (select all that apply).

Aspirin

Dextran

Dipyridamole

Clopidogrel

Ticlopidine

Unknown

**Other, specify** – if selected, type in the block provided.

Nitric oxide (document Flolan here)

Phosphodiesterase Inhibitor (Please enter only for the indication of Pulmonary Hypertension or Right Heart Failure).

Digoxin

Loop diuretics

If **yes** and follow-up is 1 month or later post implant then Enter

Dosage \_\_\_\_\_ mg/day – 24 hrs mg total **ST=** Unknown

If dose is entered, then check type of loop diuretic (select all that apply):

Furosemide

Torsemide

Bumetanide

Other

Laboratory Values

Collect laboratory values closest to the follow-up time period (as specified at beginning of this form). For all of the tests listed below, give the appropriate measurement.

**ST=** Unknown or Not Done

Laboratory Value: Unit(s) of Measure (US/SI):

Sodium mEq/L

mmol/L

Potassium mEq/L

mmol/L

Blood urea nitrogen mg/dL

mmol/L

Creatinine mg/dL

umol/L

SGPT/ALT (alanine aminotransferase/ALT) u/L

SGOT/AST (aspartate aminotransferase/AST) u/L

LDH units/L

U/L

ukat/L

Total Bilirubin mg/dL

umol/L

Bilirubin direct mg/dL

umol/L

Bilirubin indirect mg/dL

umol/L

Albumin g/dL

g/L

Pre- Albumin mg/dL

mg/L

TotalCholesterol mg/dL

mmol/L

*If value is outside given range please see 'Status (****ST=****)' drop down field*

*If < 50 mg/dl select from the ‘status’ drop down field*

Institutions generally perform only one of the two following assays. The other one should be indicated as “Not Done”.

Brain natriuretic peptide BNP pg/mL

ng/L

*If value is outside given range please see 'status (****ST=****)' drop down field*

*If* > 7500 pg/mL *select from the ‘status’ drop down field*

NT pro brain natriuretic peptide Pro-BNP pg/mL

ng/L

White blood cell count x103/uL

x109/uL

Reticulocyte count %

Hemoglobin g/dL

g/L

mmol/L

Hemoglobin A1c/Estimated Average Glucose (eAG) %

mmol/mol

mg/dL

mmol/L

Platelets x103/uL

x109/uL

INR international units

Plasma-free hemoglobin mg/dL

g/L

Positive antiheparin/platelet antibody(HIT)

Yes, No, Unknown

If **Yes**, are they on **direct thrombin inhibitors**

Yes, No, Unknown

If **Yes**, **Enter Drugs:** (select all that apply)

Aspirin

Dipyridamole

Plavix

Heparin

Coumadin

Direct thrombin inhibitors (ex: arg, lip, val…)

Was a **TEG** done? Yes, No, Unknown

If **Yes**

ThrombElastoGraph Hemostasis System (TEG) profile, MA k

ThrombElastoGraph Hemostasis System (TEG) profile, R k

ThrombElastoGraph Hemostasis System (TEG) profile, R h

CRP or hs-CRP (C Reactive Protein) mg/L

Lupus anticoagulant Positive, Negative, Unknown

Uric Acid mg/dL

umol/L

*If value is outside given range please see 'Status (****ST=****)' drop down field*

*If < 1 mg/dL select from the ‘status’ drop down field*

Device Details

**Depending on the device brand of the implanted device(s) you will be guided through the questions listed.**

**DEVICE FUNCTION**

**Pump Flow:** Will be expressed as LPM. Enter this number. **ST=** Unknown

**Stroke Volume:** Will be expressed as ml. Enter this number.**ST=** Unknown

**DEVICE PARAMETERS**

**Control Mode:** Please specify the control mode.

Fixed

Auto

Async/Fixed

Synchronous

Asynchronous

Independent

Fill-Rate

Fixed-Rate

Normal

Weaning

External

Volume/Auto

Not Applicable

**Pump Rate:**  Will be expressed as BPM. Enter this number. **ST=** Unknown

**Ejection Duration:** Will be expressed as ms. Enter this number. **ST=** Unknown

**DEVICE INSPECTION**

**Auscultation:** Please choose an option for auscultation.

Abnormal

Normal

Not Applicable

**Driveline:** Please choose an option for the driveline appearance.

Abnormal

Normal

Not Applicable

Exercise/Trailmaking

**EXERCISE FUNCTION**

**All patients should answer these functional capacity and quality of life questions especially for those patients classified as STS Intermacs® patient profile level 4-7.**

**6 minute walk:** This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk *behind* the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here. **NOTE: You may use the time from the first 15 feet of the 6 minute walk for the Gait speed test listed below (please see instructions for the gait speed test below). ST=** **Not Done: Too sick**, **Not Done: Other**, and **Unknown**.

**All efforts should be made to perform the 6 minute walk test for any patient able to walk more than a few steps. A distance as short as 3 feet may be recorded. If the test is not done, the reason must be indicated as “not done: too sick” or “not done: other”, for which an example might be a patient needing to remain supine**

**after a groin puncture for routine catheterization. Any musculoskeletal limitation to walking should be recorded as “not done: too sick”.**

**Gait speed (1st 15 foot walk): \_\_\_\_ seconds**

Instructions: Record the time (seconds) required for the patient to walk the first 15 feet of the 6 minute walk. The “starting” line and the 15 foot line should be clearly marked. Record the time to the first footfall at 0 feet and ending with the first footfall at 15 feet rounded to the nearest 0.1 sec with a stopwatch. **NOTE: You may use the time from the first 15 feet of the 6 minute walk for the Gait speed test. ST=** **Not Done: Too sick**, **Not Done: Other**, and **Unknown**.

**Peak VO2 Max: Maximum volume of oxygen the body can consume during exercise (mL/kg/min)** is the ml/kg/min of oxygen consumed during symptom-limited exercise testing either on a bicycle or treadmill. The values recorded during the bicycle are usually 1-2 ml/min lower than for the treadmill, but it is assumed that most institutions will use only one instrument. If both are available, the bicycle is preferable as the mode easiest to standardize. **ST=** **Not Done: Too sick**, **Not Done: Other**, and **Unknown**.

**R Value at peak:** Is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort. **ST=** Unknown or Not Done

**Neurocognitive Trail Making Test – Part B**

Please See the Trail Making Test Part B Instructions section of the Users’ guide for further instructions on administration and web-based data entry for the Trail Making Test [(Section 2.15)](#Trailmaking).

**MEDICAL CONDITION**

**NYHA Class::** New York Heart Association Class for heart failure:

**Class I:**       No limitation of physical activity; physical activity does not cause fatigue,

palpitation or shortness of breath.

**Class II:**      Slight limitation of physical activity; comfortable at rest, but ordinary physical

activity results in fatigue, palpitations or shortness of breath.

**Class III:**    Marked limitation of physical activity; comfortable at rest, but less than ordinary

activity causes fatigue, palpitation or shortness of breath.

**Class IV:** Unable to carry on minimal physical activity without discomfort; symptoms may

be present at rest.

**Unknown**

Concerns and Contraindications

**Current Device Strategy:**

**Transplant Eligibility Issues or Contraindications to Transplant**:

**If you select Possible Bridge to Transplant or Destination Therapy, then indicate which of the following present major concerns for current care and/or for cardiac transplantation listing.**

Checking these does not necessarily mean that a condition is a contraindication and/or concern. There are often many reasons why a patient is not an ideal candidate for transplantation, although it may still represent the best option for the patient. No specific thresholds are provided for these concerns or contraindications. They should represent the results of formal discussion with the medical and surgical transplant team prior to the decision for device implantation.

If so, limitation for

Concerns/Contraindications: Is condition present? transplant listing?

***Overall status:***

Advanced age Yes/No Yes/No

Frailty Yes/No Yes/No

Patient does not want transplant Yes/No Yes/No

Musculoskeletal limitation to ambulation Yes/No Yes/No

Contraindication to immunosuppression Yes/No Yes/No

Allosensitization Yes/No Yes/No

***Chronic Renal Disease*** Yes/No Yes/No

***Cardiothoracic issues:***

Frequent ICD Shocks Yes/No Yes/No

Pulmonary Disease Yes/No Yes/No

Pulmonary Hypertension Yes/No Yes/No

Recent Pulmonary Embolus Yes/No Yes/No

History of Atrial Arrhythmia Yes/No Yes/No

Unfavorable Mediastinal Anatomy Yes/No Yes/No

(includes sternotomies, sternal resection, radiation, flail chest, etc)

Thoracic Aortic Disease Yes/No Yes/No

***Nutritional/GI:***

Large BMI Yes/No Yes/No

Severe Diabetes Yes/No Yes/No

Malnutrition/Cachexia Yes/No Yes/No

History of GI Ulcers Yes/No Yes/No

History of Hepatitis Yes/No Yes/No

Liver Dysfunction Yes/No Yes/No

***Vascular issues:***

Heparin Induced Thrombocytopenia Yes/No Yes/No

Chronic Coagulopathy Yes/No Yes/No

Major Stroke Yes/No Yes/No

Other Cerebrovascular Disease Yes/No Yes/No

Peripheral Vascular Disease Yes/No Yes/No

***Oncology/infection issues:***

History of Solid Organ Cancer Yes/No Yes/No

History of Lymphoma, Leukemia Yes/No Yes/No

History of Bone Marrow Transplant (BMT) Yes/No Yes/No

History of HIV Yes/No/Unknown Yes/No

(If Yes, answer HIV questions below)

Chronic Infectious Concerns Yes/No Yes/No

***Psychosocial issues:***

Limited Cognition/Understanding Yes/No Yes/No

Limited Social Support Yes/No Yes/No

Repeated Noncompliance Yes/No Yes/No

History of Illicit Drug Use Yes/No Yes/No

History of Alcohol Abuse Yes/No Yes/No

Narcotic Dependence Yes/No Yes/No

History of Smoking Yes/No Yes/No

Currently Smoking Yes/No Yes/No

Severe Depression Yes/No Yes/No

Other Major Psychiatric Diagnosis Yes/No Yes/No

***Other Comorbidity*** Yes/No Yes/No

**HIV Sub-questions:**

**HIV diagnosis date:** Enter in MMDDYYYY format. **ST=** Unknown or Not Done.

**Plasma HIV-1 RNA (Viral load) – Closest to Implant:** \_\_\_\_\_\_\_ copies/ml.

**ST=** Not Done.

**CD4 T-Cell Count – Closest to Follow-up:** \_\_\_\_\_\_\_\_ cells/mm3. **ST**= Not Done.

**Erythrocyte Sedimentation Rate (ESR):** \_\_\_\_\_\_\_\_\_ mm/hr. **ST**= Not Done.

**C Reactive Protein (CRP) or hs-CRP:** \_\_\_\_\_\_\_\_\_ mg/L. **ST**= Not Done.

**Antiretroviral Therapy:** Select all that apply:

Abacavir (ABC) / Ziagen

Atripla (FTC/EDV/TDF)

Atazanavir (ATV) / Reyataz

Combivir (3TC/ZDV)

Complera (FTC/RPV/TDF)

Darunavir (DRV) / Prezista

Delavirdine (DLV) / Rescriptor

Didanosine (ddI) / Videx EC

Dolutegravir / Tivicay

Efavirenz (EFV) / Sustiva

Emtricitabine (FTC) / Emtriva

Enfuvirtide (T20) / Fuzeon

Epzicom (3TC/ABC)

Etravirine (ETR) / Intelence

Fosamprenavir (FPV) / Lexiva

Indinavir (IDV) / Crixivan

Kaletra (LPV/r)

Lamivudine (3TC) / Epivir

Maraviroc (MVC) / Selzentry

Nelfinavir (NFV) / Viracept

Nevirapine (NVP) / Viramune / Viramune XR

Raltegravir (RAL) / Isentress

Rilpivirine (RPV) / Edurant

Ritonavir (RTV) / Norvir

Saquinavir (SQV) / Invirase

Stavudine (d4T) / Zerit

Stribild (FTC/EVG/COBI/TDF)

Tenofovir Disoproxil Fumarate (TDF) / Viread

Tipranivir (TPV) / Aptivus

Trizivir (3TC/ZDV/ABC)

Truvada (FTC/TDF)

Zidovudine (ZDV) / Retrovir

None

Unknown

**Infection Prophylaxis:** Select all that apply:

Atovaquone

Azithromycin

Dapsone

Fluconazole

Pentamidine, aerosolized

Trimethroprim-sulfamethoxazole (TMP-SMX)

None

Unknown

**Has patient had an opportunistic infection since last follow-up?**

Yes, No, Unknown

If **yes**, enter **Infection Date:** Enter as MMDDYYYY. **ST=** Unknown or Not Done.

If **yes**, **Type of Infection:** Select all that apply:

Cryptococcosis

Cytomegalovirus (CMV)

Epstein Barr virus (EBV)

Esophageal candidiasis

Histoplasmosis

Kaposi’s sarcoma

Mycobacterium avium complex (MAC), disseminated

Pneumocystis jiroveci (carinii) pneumonia (PCP)

Toxoplasmosis

Tuberculosis

**History of Hepatitis B:** Positive or Negative.  **ST=** Unknown or Not Done.

**History of Hepatitis C:** Positive or Negative. **ST=** Unknown or Not Done.

Quality of Life **(EuroQoL, Intermacs QoLand KCCQ)**

Please See the **EuroQoL, Intermacs QoLand KCCQ** section of the Users’ guide for further instructions on administration and web-based data entry for the **EuroQoL, Intermacs QoLand KCCQ** [(Section 2.14)](#Qol_KCCQ).

**Major Outcomes and Adverse Events**

**Note: Please check that you have entered all Major Outcomes and Adverse Events since the last follow-up. The adverse events are usually entered during a rehospitalization (or during the index hospitalization). To enter an adverse event click on the button located at the top of the patient overview screen.**



* **Rehospitalization**
* **Major Infection**
* **Neurological Dysfunction**
* **Device Malfunction** (if suspected device thrombosis, then enter as Device Malfunction)
* **Major Bleeding**
* **Cardiac Arrhythmia**
* **Pericardial Fluid Collection**
* **Myocardial Infarction**
* **Psychiatric Episode**
* **Respiratory Failure**
* **Arterial Non-CNS Thromboembolism**
* **Venous Thromboembolic Event**
* **Wound Dehiscence**
* **Hepatic Dysfunction**
* **Renal Dysfunction**
* **Other SAE**
* **Death**
* **Explant due to Exchange**
* **Explant due to Recovery**
* **Explant due to Transplant**

Note: Please click on the link below to be taken to the AE definitions in **Appendix A**.

[http://www.uab.edu/medicine/STS Intermacs/appendices/app-a-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-a-5-0)

# 2.7 Implant Discharge

The **Implant Discharge Form** is intended to collect information about a patient from the device implant to one of the following occurrences during the implant hospitalization:

* + **Patient is discharged from the hospital with a device in place.**
  + **Patient receives a transplant during the implant hospitalization. The date of transplant will be considered the date of discharge.**
  + **Patient dies during the implant hospitalization. The date of death is considered to be the date of discharge.**
  + **Patient has the device(s) explanted due to recovery. The date of device(s) explant is considered to be the date of discharge.**
  + **Patient has device exchange (excluding RVAD exchange).**

**Chronology of Hospital Time Course**

**During the implant hospitalization was the patient? (check one)**

Discharged alive with a device in place

Died during the implant hospitalization

Transplanted during the implant hospitalization

Explanted due to recovery during the implant hospitalization

Patient has device exchange (excluding RVAD exchange)

**If patient alive with device in place at time of implant discharge**, select facility from the list below

**Patient discharged to:** Select one of the following facility types.

Home - residential setting

Nursing Home/Assisted Care

Hospice

Another hospital

Rehabilitation Facility

Unknown

**NOTE: Enter the following information based on implant time to time of discharge from the hospital / Date of device exchange (excluding RVAD exchange). Remember that implant discharge is based on the time in the hospital referring to the implant hospitalization.**

Enter **implant discharge date:** In MMDDYYYY format.  ***This is the date from the selected event above*. ST=** Unknown

***Please select the appropriate discharge date from the list below:***

* + Patient is discharged from the hospital with a device in place. The date of discharge is considered to be the implant discharge date.
  + Patient receives a transplant during the implant hospitalization. The date of transplant will be considered the date of discharge.
  + Patient dies during the implant hospitalization. The date of death is considered to be the date of discharge.
  + Patient has the device(s) explanted due to recovery. The date of device(s) explant is considered to be the date of discharge.
  + Patient has a device exchange (excluding RVAD exchange).

**Acute care (ICU / CCU) - duration of stay:** Type the number of days patient in Acute care (i.e. ICU/CCU). Days should not exceed number of days from implant date to implant discharge date. **ST=** Unknown

**Intermediate/step-down care - duration of stay:** Type the number of days patient in Intermediate care (i.e. Step Down care). Days should not exceed number of days from implant date to implant discharge date. **ST=** Unknown

**Note: ICU/CCU duration + Intermediate/step-down duration cannot exceed the total days from implant date to implant discharge date (remember if the patient was transplanted, explanted or died during the implant hospitalization, then the discharge date is the transplant date, explant date or death date respectively).**

**Date of approximate discontinuation of inotropes:** Select the approximate time when patient stopped taking inotrope therapy from the list below:

< 1 week

1-2 weeks

2-4 weeks

> 4 weeks

Ongoing

Unknown

Not applicable

**Intervention since implant** **:**   Select all that apply:  Interventions since VAD implant date from the list below.

Transplant

Invasive Cardiac Procedures (Other than Heart Cath)

Unknown

None

**Surgical Procedures:**

Device related operation

Surgical Procedure - Non Cardiac Surgical Procedure

Surgical Procedure - Other Procedure                   Surgical Procedure - Unknown

**Cardiac Surgical Procedures:**

Reoperation for Bleeding within 48 hours of implant

Reoperation for Bleeding and/or tamponade > 48 hours

Surgical Drainage of pericardial effusion

Aortic Valve Surgery - Repair (no valve closure)

Aortic Valve Surgery - Repair with valve closure

Aortic Valve Surgery - Replacement – Biological

Aortic Valve Surgery - Replacement – Mechanical

Mitral Valve Surgery – Repair

Mitral Valve Surgery - Replacement – Biological

Mitral Valve Surgery - Replacement – Mechanical

Tricuspid Valve Surgery - Repair – DeVega

Tricuspid Valve Surgery - Repair – Ring

Tricuspid Valve Surgery - Repair – Other

Tricuspid Valve Surgery – Replacement - Biological

Tricuspid Valve Surgery – Replacement - Mechanical

Pulmonary Valve Surgery - Repair

Pulmonary Valve Surgery – Replacement - Biological

Pulmonary Valve Surgery – Replacement - Mechanical

Other Cardiac Surgical Procedure - **textbox**

Cardiac Surgical Procedure – Unknown

**Other Procedures:**

Reintubation due to Respiratory Failure

Dialysis   
Bronchoscopy

Other, specify - **textbox**

**PUMP CHANGE - Please answer all questions regarding pump status considering all time since previous visit and current follow-up date.**

**Was there a pump exchange of a para- or extra- corporeal pump? Example: PVAD, Berlin Heart.**

Yes, No, or Unknown

If **yes**, Please select the  **Pump Exchange Reason:**

Thrombus NOT associated with hemolysis

Change in hemodynamics

Clinical status

Device parameters (please enter Device Malfunction Form)

Upsizing device because of patient growth status

All other reasons would categorize the pump change as a Device Malfunction. If selected, please fill out the Device Malfunction Form.

**Was there a console change? For TAH or Berlin Heart Consoles.**

Yes, No, or Unknown

**If Yes please complete the following:**

**Date of console change: Enter date in MMDDYYYY format.** **ST=** Unknown

**Original console name: Text.**

**New console name: Text.**

**Major Outcomes and Adverse Events**

**Note: Please check that you have entered all Major Outcomes and Adverse Events since the last follow-up. The adverse events are usually entered during a rehospitalization (or during the index hospitalization). To enter an adverse event click on the button located at the top of the patient overview screen.**



* **Rehospitalization**
* **Major Infection**
* **Neurological Dysfunction**
* **Device Malfunction** (if suspected device thrombosis, then enter as Device Malfunction)
* **Major Bleeding**
* **Cardiac Arrhythmia**
* **Pericardial Fluid Collection**
* **Myocardial Infarction**
* **Psychiatric Episode**
* **Respiratory Failure**
* **Arterial Non-CNS Thromboembolism**
* **Venous Thromboembolic Event**
* **Wound Dehiscence**
* **Hepatic Dysfunction**
* **Renal Dysfunction**
* **Other SAE**
* **Death**
* **Explant due to Exchange**
* **Explant due to Recovery**
* **Explant due to Transplant**

Note: Please click on the link below to be taken to the AE definitions in **Appendix A**.

[http://www.uab.edu/medicine/STS Intermacs/appendices/app-a-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-a-5-0)

# 2.8 Listing Date for Transplant

If the patient was NOT listed for transplant at the time of implant, then please answer now regarding the list date for transplant if applicable to patient. Once you enter the list date for transplant for a patient, you will not have to enter this information again.

**Has the patient been listed (first time) for transplant since implant?**

Yes or No

If **Yes**, enter **the List Date**: MMDDYYYY. **ST=** Unknown.

# 2.9 Rehospitalization

The **Rehospitalization Form** is to be collected within 1 week from **rehospitalization** discharge. The **Rehospitalization Form** is intended to collect information about a patient from the date of rehospitalization to one of the following occurrences during the rehospitalization:

* + **Patient is discharged from the hospital with a device in place.**
  + **Patient receives a transplant during the rehospitalization. The date of transplant will be considered the date of discharge.**
  + **Patient dies during the rehospitalization. The date of death is considered to be the date of discharge.**
  + **Patient has the device(s) explanted due to recovery during the rehospitalization. The date of device(s) explant is considered to be the date of discharge.**

**Rehospitalization**

**Was there an occurrence of rehospitalization?**

Yes or No

**Is this rehospitalization at your hospital?** Please enter **Yes** or **No.**

Yes or No

Enter **date of admission:** In MMDDYYYY format. **ST**= Unknown.

Enter **discharge date:** In MMDDYYYY format. **ST**= Unknown.

***Please select the appropriate discharge date from the list below:***

* + Patient is discharged from the hospital with a device in place. The date of discharge is considered to be the discharge date.
  + Patient receives a transplant during this rehospitalization. The date of transplant will be considered the date of discharge.
  + Patient dies during this rehospitalization. The date of death is considered to be the date of discharge.
  + Patient has the device(s) explanted due to recovery during this rehospitalization. The date of device(s) explant is considered to be the date of discharge.

**Primary reason for rehospitalization:** please check the primary reason for this rehospitalization. The primary reason is not necessarily the presenting complaint at rehospitalization.

Major Bleeding

Cardiac Arrhythmia

Major Infection

Pericardial Fluid Collection

Neurological Dysfunction

Myocardial Infarction

Hypertension

Device Malfunction

Cardiac Tamponade

Psychiatric Episode

Hematoma

GI Disorder

Transplant

Hemolysis

Arterial Non-CNS Thrombo-embolism

Hepatic Dysfunction

Limb vascular complication

Explant

Pulmonary Embolism/Hemorrhage

Venous Thromboembolic Event

Respiratory Failure

Wound Dehiscence

Syncope without known cause

Planned Medical Management

Renal Dysfunction

Fever without known cause

Planned Procedure

Right Heart Failure

Diagnostic Procedure

Wound Complication

Unknown

Pneumonia

Catastrophe (i.e. weather)

Gastroenteritis

Anticoagulation adjustment

Metabolic/Electrolyte Disturbance

Pulmonary, Other

Hematological

Trauma/Accident

Fluid Overload

**Other, specify**

If Other Specify, then **Specify:** complete text box

**Rehospitalization Intervention:** Select the type of rehospitalization intervention from the list below

Transplantation

Surgical Procedure

Heart Cath

Invasive Cardiac Procedures (Other than Heart Cath)

Specify type of invasive cardiac procedure other than heart cath in the text box

Unknown

Other

None

If ***Surgical Procedure***, please enter **Type of Surgical Procedure:**

Device related operation

*(if this is selected as the surgical procedure, please remember to go to the Device Malfunction Adverse Event form and complete.)*

Other Cardiac Surgical Procedure

Non Cardiac Surgical Procedure

Other Procedure

Unknown

If ***Other Cardiac Surgical Procedure***, Enter the **Type of Other Cardiac Procedure:**

Reoperation for Bleeding within 48 hours of implant

Reoperation for Bleeding and/or tamponade > 48 hours

Surgical Drainage of pericardial effusion

Aortic Valve Surgery - Repair (no valve closure)

Aortic Valve Surgery - Repair with valve closure

Aortic Valve Surgery - Replacement - Biological

Aortic Valve Surgery - Replacement - Mechanical

Mitral Valve Surgery - Repair

Mitral Valve Surgery - Replacement - Biological

Mitral Valve Surgery - Replacement - Mechanical

Tricuspid Valve Surgery - Repair - DeVega

Tricuspid Valve Surgery - Repair - Ring

Tricuspid Valve Surgery - Repair - Other

Tricuspid Valve Surgery – Replacement - Biological

Tricuspid Valve Surgery – Replacement - Mechanical

Pulmonary Valve Surgery - Repair

Pulmonary Valve Surgery – Replacement - Biological

Pulmonary Valve Surgery – Replacement - Mechanical

Other, specify - please **Enter Type of Procedure:** Textbox

Unknown

If ***Non Cardiac Surgical Procedure***, Enter the **Type of procedure: (non cardiac surgical procedure)**

If ***Heart Cath***, please complete the following questions:

**Enter PA systolic pressure:** In mm/Hg. **ST=** Unknown or Not Done.

**Enter PA diastolic pressure:** In mm/Hg. **ST=** Unknown or Not Done.

**Enter PCW pressure:** In mm/Hg. **ST=** Unknown or Not Done.

**Enter Cardiac Output:** In L/min. **ST=** Unknown or Not Done.

If ***Invasive Cardiac Procedures (Other than Heart Cath)***, Enter the **Type of Cardiac procedure:**

If ***Other***, Enter the **Other procedure:**

Intubation and Vent Support

Dialysis

Bronchoscopy

Other, Specify **– if other specify complete textbox**

**CLINICAL OBSERVATIONS**

**Systolic bp:** mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. **ST=** Unknown or Not Done

**Diastolic bp:** mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. **ST=** Unknown or Not Done

**Doppler Opening Pressure:** Record the pressure on the BP cuff at the time of sound on the Doppler as the cuff is released and this is the Doppler opening pressure which may correspond to the MAP. **ST=**Unknown, Not Done, or Not Applicable.

Please click on the link below for further instruction on administering Stroke Scales in **Appendix I**.

[http://www.uab.edu/medicine/STS Intermacs/appendices/app-i-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-i-5-0)

**Has the patient experienced a Neurological Event since time of implant?**

Yes, No, Unknown

**Note: This only applies to patients who have a CVA, TIA, or Anoxic Brain Injury. Once “Yes” is selected you must complete this section for the patient’s complete STS Intermacs® lifespan.**

If **yes, provide Modified Rankin Scale:**

**0 – No symptoms at all**

**1 – No Significant disability:** despite symptoms: able to carry out all usual duties and activities

**2 –** **Slight disability:** unable to carry out all previous activities but able to look after own affairs without assistance

**3 –** **Moderate disability:** requiring some help, but able to walk without assistance.

**4 –** **Moderately severe disability:** unable to walk without assistance, and unable to attend to own bodily needs without assistance.

**5 –** **Severe disability:** bedridden, incontinent and requiring constant nursing care and attention.

**6 –** **Dead ST=** Not Done or Not Documented

**OR**

If **yes, provide NIH Stroke Scale:**

**0 – No Stroke**

**1-4 – Minor Stroke**

**5-15 –** **Moderate Stroke**

**16-20 –** **Moderate to Severe Stroke**

**21-42 –** **Severe Stroke**

**ST=** Not Done or Not Documented

**Major Outcomes and Adverse Events**

**Note: Please check that you have entered all Major Outcomes and Adverse Events since the last follow-up. The adverse events are usually entered during a rehospitalization (or during the index hospitalization). To enter an adverse event click on the button located at the top of the patient overview screen.**



* **Rehospitalization**
* **Major Infection**
* **Neurological Dysfunction**
* **Device Malfunction** (if suspected device thrombosis, then enter as Device Malfunction)
* **Major Bleeding**
* **Cardiac Arrhythmia**
* **Pericardial Fluid Collection**
* **Myocardial Infarction**
* **Psychiatric Episode**
* **Respiratory Failure**
* **Arterial Non-CNS Thromboembolism**
* **Venous Thromboembolic Event**
* **Wound Dehiscence**
* **Hepatic Dysfunction**
* **Renal Dysfunction**
* **Other SAE**
* **Death**
* **Explant due to Exchange**
* **Explant due to Recovery**
* **Explant due to Transplant**

Note: Please click on the link below to be taken to the AE definitions in **Appendix A**.

[http://www.uab.edu/medicine/STS Intermacs/appendices/app-a-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-a-5-0)

# 2.10 Reporting of Adverse Events

**Enter Information You Are Reporting**

Rehospitalization, Adverse Events, Death or Explant. All events below have default answers as ‘No’. Please answer ‘Yes’ to any of these events that apply and fill out all of that event’s information.

**Please enter the date of the event you are reporting:** In MMDDYYYY format

**Please enter a label describing this event:** Text

Please click on the link below to be taken to the AE definitions in **Appendix A**. [http://www.uab.edu/medicine/STS Intermacs/appendices/app-a-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-a-5-0)

## AE Infection

**Was there a major infection?**

Yes, No, or Unknown

The **Adverse Event: Major Infection Form** is to be collected at time of event.

**Major Infection**

A clinical infection accompanied by pain, fever, drainage and/or leukocytosis that is treated by anti-microbial agents (non-prophylactic). A positive culture from the infected site or organ should be present unless strong clinical evidence indicates the need for treatment despite negative cultures. The general categories of infection are listed below:

**Localized Non-Device Infection**

Infection localized to any organ system or region (e.g. mediastinitis) without evidence of systemic involvement (See sepsis definition), ascertained by standard clinical methods and either associated with evidence of bacterial, viral, fungal or protozoal infection, and/or requiring empirical treatment.

**Percutaneous Site and/or Pocket Infection**

A positive culture from the skin and/or tissue surrounding the drive line or from the tissue surrounding the external housing of a pump implanted within the body, coupled with the need to treat with antimicrobial therapy when there is clinical evidence of infection such as pain, fever, drainage, or leukocytosis.

**Internal Pump Component, Inflow or Outflow Tract Infection**

Infection of blood-contacting surfaces of the LVAD documented by positive site culture. (There should be a separate data field for paracorporeal pump that describes infection at the percutaneous cannula site, e.g. Thoratec PVAD).

**Sepsis**

Evidence of systemic involvement by infection, manifested by positive blood cultures and/or hypotension.

Enter **Date of onset** of adverse event: In MMDDYYYY format. **ST=** Unknown

**Did this infection contribute to death?:** Enter **Yes** if this infection contributed to the death of this patient. Enter **No** if this infection did not contribute to the death of this patient. If not known, select **Unknown.**

Yes, No, or Unknown

**Location of patient:** Select whether patient was **In Hospital**, or **Out of Hospital** at time of adverse event. If location was not known, select **Unknown**.

In hospital

Out of hospital

Unknown

**Location of infection:** Select all locations of infection that apply to this adverse event. If Other, specify is selected, type in the specification in the block provided.

Pump / related - Drive Line

Pump / related – Exit Cannula   
Pump / related - Pump Pocket   
Pump / related - Pump Interior   
Positive Blood cultures   
Line Sepsis

Pulmonary

Urinary Tract

Mediastinum

Peripheral Wound

GI

Unknown

Other, specify

If **Other, specify**, then **Specify:** please complete textbox

**Type of infection:** Select one of the following types of infection.

Bacterial   
 Fungal   
 Viral   
 Protozoan   
 Unknown

**Was drug therapy an intervention for this AE?:**

Yes, No, or Unknown

**If yes, what was the route?:**

IV

Oral

Topical   
 Unknown

**Was surgery an intervention for this AE?:**

Yes, No, or Unknown

**Is this a Device Related Event?:** If this event was caused by the device then please check yes. Only complete a device malfunction form if it meets the device malfunction definition.

Yes, No, or Unknown

## AE Major Bleeding

**Was there a Major Bleeding Event?**

Yes, No, or Unknown

The **Adverse Event: Major Bleeding Form** is to be collected at time of event

**Major Bleeding**

An episode of SUSPECTED INTERNAL OR EXTERNAL BLEEDING that results in one or more of the following:

a. Death,

b. Re-operation,

c. Hospitalization,

d. Transfusion of red blood cells as follows:

If transfusion is selected, then apply the following rules:

During first 7 days post implant

**•** ≥ 50 kg: ≥ 4U packed red blood cells (PRBC) within any 24 hour period during first 7 days post implant.

• < 50 kg: ≥ 20 cc/kg packed red blood cells (PRBC) within any 24 hour period during first 7 days post implant.

After 7 days post implant: **Please See Reminder Below**

**•** A transfusion of packed red blood cells (PRBC) after 7 days following implant with the investigator recording the number of units given (Record total number of units transfused for the bleeding episode).

Note: Hemorrhagic stroke is considered a neurological event and not as a separate bleeding event.

**REMINDERS and “check list” for a Bleeding Episode:**

**“It is not the transfusion that determines bleeding, but the recognized bleeding event.” --Dr. Kormos**

**Transfusions for anemia and hemolysis are not considered bleeding events.**

Did the bleeding episode occur during the 1st 7 days post implant?

* If yes, Did the patient receive more than 4 units during any 24 hour period of the bleeding episode? (Fill out the bleeding form as appropriate).

Did the bleeding episode occur 8 or more days post implant?

* If yes, Was the patient re-hospitalized? Had an intervention/re-operation for the bleeding event? Did the patient die? Did the patient receive 1 or more units during any 24 hour period of the bleeding episode AND it meets the definition of an STS Intermacs Major Bleeding Event? (Fill out the bleeding form as appropriate).

**Date of bleeding episode onset:** Enter date of bleeding episode as MMDDYYYY, if date of bleeding onset is unknown select **Unknown** from the status element. **ST=** Unknown

**Location of patient:** Select whether patient was **In Hospital**, or **Out of Hospital** at time of adverse event. If location was not known, select **Unknown**.

In hospital

Out of hospital

Unknown

**Did the major bleeding episode result in one or more of the following:** Select from the following list (select all that apply):

Episode resulted in death (fill out death form)

Episode resulted in re-operation

Episode resulted in rehospitalization

Episode resulted in transfusion(s) for bleeding episode

if **transfusion** is checked, then answer the following questions:

**Total units PRBC**:

Enter total number of units received for this bleeding episode\_\_\_\_\_ **ST=** Unknown

**Enter the Date of first transfusion for this episode**:

Enter date of transfusion as MMDDYYYY. **ST= Unknown.**

**Source/cause/location of Bleeding:** (select all that apply).If **Other, specify** is selected, type in the specification in the block provided.

Mediastinal: chest wall

Mediastinal: outflow-aorta anastomosis

Mediastinal: outflow conduit

Mediastinal: inflow conduit

Mediastinal: aortic-venous cannulation site

Mediastinal: coagulopathy with no surgical site

Mediastinal: other surgical site

Pump Pocket

Mediastinal: Unspecified

Pleural space

Intra-abdominal

Retroperitoneal

Pulmonary

Device anastamosis

Urinary tract

GI: Upper gastrointestinal (esophagus, stomach, duodenum, small bowel)

GI: Lower gastrointestinal (colon, rectum, and anus)

GI: unknown, but guaiac positive stools

ENT / Dental

Other, specify

**If Other, specify, then complete text box.**

**INR:** Enter value of INR. **ST=** Unknown or Not Done

**Anticoagulant therapy at time of event** (select all that apply). If **Other, specify** is selected, type in the specification in the block provided.

Warfarin

Heparin

Lovenox

Aspirin

Dipyridamole

Clopidogrel (plavix)

Argatroban

Bivalirudin

Fondaparinux

Dextran

Ticlopidine

Hirudin

Lepirudin

Ximelagatran

None

Other, specify

**If Other, specify, then complete text box.**

**Is this a Device Related Event?:** If this event was caused by the device then please check yes. Only complete a device malfunction form if it meets the device malfunction definition.

Yes, No, or Unknown

## AE Neurological Dysfunction

**Was there a neurological dysfunction?**

Yes, No, or Unknown

The **Adverse Event: Neurological Dysfunction Form** is to be collected at time of event.

**Neurological Dysfunction**

Any new, temporary or permanent, focal or global neurologic dysfunction ascertained by a standard neurological history and examination administered by a neurologist or other qualified physician and documented with appropriate diagnostic tests and consultation note; or an abnormality identified by surveillance neuroimaging. The examining physician will classify the event as a cerebrovascular event as defined below or as a non-vascular acute neurologic event.  A neurologic event may be recognized by a clinically evident sign or symptom, or by clinically-silent electrographic seizure activity, or as a clinically silent lesion detected by surveillance neuroimaging. Each neurologic event should be classified by the clinical provider following complete neurologic assessment as one of the following event types:

* 1. Transient ischemic attack, defined as an acute transient neurologic deficit conforming anatomically to arterial distribution cerebral ischemia, which resolves in < 24 hours and is associated with no infarction on brain imaging (head CT performed >24 hours after symptom onset; or MRI\*).
  2. Ischemic stroke, defined as a new acute neurologic deficit (or acute encephalopathy or seizures in children <6 months\*\*) of any duration associated with acute infarction on imaging corresponding anatomically to the clinical deficit. Ischemic stroke should be sub classified as due to arterial-distribution ischemia or due to venous thrombosis.
  3. Acute symptomatic intracranial hemorrhage, defined as new acute neurologic deficit (or acute encephalopathy or seizures in children < 6 months\*\*) attributable to Intracranial hemorrhage (ICH). ICH subtype should be specified as one or a combination of the following types: subarachnoid, intraventricular, parenchymal, subdural.
  4. Clinically covert ischemic stroke or ICH: infarction or ICH seen by surveillance imaging, without clinical findings of stroke or ICH at the time of event recognition.
  5. Hypoxic-Ischemic Encephalopathy: Acute new encephalopathy\*\*\* due to hypoxic-ischemic injury (HIE), manifest as clinically- evident signs or symptoms, or subclinical electrographic seizures found by complete neurological diagnostic evaluation to be attributable to acute global or focal hypoxic or ischemic brain injury not meeting one of ischemic stroke or ICH events as defined above.
  6. Acute new encephalopathy\*\*\*  due to other causes, manifest as clinically-evident signs or symptoms or subclinical electrographic seizures found by complete neurological diagnostic evaluation to be attributable causes other than stroke, ICH or HIE, as defined above. This category of "other" acute encephalopathy includes neurologic signs or symptoms or subclinical seizures found to be attributable to other conditions such as meningitis, toxic-metabolic or drug-related processes.

\*\*\* Acute encephalopathy is a sign or symptom of some underlying cerebral disorder, and is manifest as depressed consciousness with or without any associated new global or multifocal neurologic deficits in cranial nerve, motor, sensory, reflexes and cerebellar function.

**NOTE: Confusion and Encephalopathy adverse events will be captured after being weaned from sedatives for 72 hours.**

Enter **Date of onset** of adverse event: in MMDDYYYY format. **ST=** Unknown

**Location of patient:** Select whether patient was **In Hospital**, or **Out of Hospital** at time of adverse event. If location was not known, select **Unknown**.

In hospital

Out of hospital

Unknown

**Neurological Dysfunction Categories:** Select one of the neurological dysfunction categories. If **Neurological Dysfunction – Other, specify** is selected, type in the specification in the block provided.

TIA

Confusion

CVA

If CVA, **Type of CVA:**

Ischemic / Embolism

Hemorrhagic

Other

**Stroke Severity:**

Left sided weakness   
Right sided weakness   
Left sided paralysis   
Right sided paralysis   
Speech deficit   
Altered mental status   
Coma   
Other, specify

If Other Specify, then **Specify:** complete text box

**Is this a Device Related Event?:** If this event was caused by the device then please check yes. Only complete a device malfunction form if it meets the device malfunction definition.

Yes, No, or Unknown

Seizure

If Seizure, then enter **Seizure Type:**

Generalized

Focal

Encephalopathy

If Encephalopathy, the enter **Encephalopathy Type:**

Metabolic

Anoxic

Traumatic

Other

**Did this Neurological Dysfunction Adverse Event contribute to the patient's death?** If this adverse event caused or contributed to this patient’s death, answer **Yes.** If this adverse event did not cause or contribute to this patient’s death, answer **No.** If not known, select **Unknown.**

Yes, No, or Unknown

**Location of CNS event:** Select all that apply: Select any of the neurological dysfunction event locations from the list provided. If **Other, specify** is selected, type in the specification in the block provided.

Right hemisphere: frontal

Right hemisphere: temporal

Right hemisphere: occipital

Right hemisphere: parietal

Right hemisphere: unspecified

Left hemisphere: frontal

Left hemisphere: temporal

Left hemisphere: occipital

Left hemisphere: parietal

Left hemisphere: unspecified

Bilateral: frontal

Bilateral: temporal

Bilateral: occipital

Bilateral: parietal

Occipital

Brain stem

Cerebellar

Thalamic

Unknown

Other, specify

If Other Specify, then **Specify:** complete text box

**Method of Diagnosis of CNS event:** Select oneof the methods of diagnosis of the neurological dysfunction event from the list provided. If **Other, specify** is selected, type in the specification in the block provided

CT   
MRI   
Angiogram   
Clinical   
Unknown

Other, specify

If Other, specify, **then complete the text box.**

**Anticoagulant therapy at time of event:** If anticoagulant therapy was used at the time of this event, select all therapies that apply. If **Other, specify** is selected, type in the specification in the block provided.

Warfarin

Heparin

Lovenox

Aspirin

Dipyridamole

Clopidogrel (plavix)

Argatroban

Bivalirudin

Fondaparinux

Dextran

Ticlopidine

Hirudin

Lepirudin

Ximelagatran

None

Other, specify

If Other, specify, **then complete the text box.**

Please click on the link below for further instruction on administering Stroke Scales in **Appendix I**.

[http://www.uab.edu/medicine/ Intermacs/appendices/app-i-5-0](http://www.uab.edu/medicine/%20Intermacs/appendices/app-i-5-0)

**Has the patient experienced a Neurological Event since time of implant?**

Yes, No, Unknown

**Note: This only applies to patients who have a CVA, TIA, or Anoxic Brain Injury. Once “Yes” is selected you must complete this section for the patient’s complete STS Intermacs® lifespan.**

If **yes, provide Modified Rankin Scale:**

**0 – No symptoms at all**

**1 – No Significant disability:** despite symptoms: able to carry out all usual duties and activities

**2 –** **Slight disability:** unable to carry out all previous activities but able to look after own affairs without assistance

**3 –** **Moderate disability:** requiring some help, but able to walk without assistance.

**4 –** **Moderately severe disability:** unable to walk without assistance, and unable to attend to own bodily needs without assistance.

**5 –** **Severe disability:** bedridden, incontinent and requiring constant nursing care and attention.

**6 –** **Dead**

**ST=** Not Done or Not Documented

**OR**

If **yes, provide NIH Stroke Scale:**

**0 – No Stroke**

**1-4 – Minor Stroke**

**5-15 –** **Moderate Stroke**

**16-20 –** **Moderate to Severe Stroke**

**21-42 –** **Severe Stroke**

**ST=** Not Done or Not Documented

## Device Adverse Event: Malfunction / Failure and/or Pump Thrombus

*This form should be completed if a device malfunction has occurred or a thrombus (suspected or confirmed) has been detected or both have occurred.*

**Was there a device malfunction / failure and / or a pump thrombus?**

Yes, No, or Unknown

**Device Malfunction**

A **Device Malfunction** occurs when any component of the MCSD system ceases to operate to its designed performance specifications or otherwise fails to perform as intended. Performance specifications include all claims made in the Instructions for Use.

Device malfunctions can be further defined as **major** or **minor**:

1. **Major device malfunction,** otherwise known as failure, occurs when of one or more of the components of the MCSD system either directly causes or could potentially induce a state of inadequate circulatory support (low cardiac output state) or death. A failure that was iatrogenic or recipient-induced will be classified as an Iatrogenic/Recipient-Induced Failure. A device malfunction or failure is considered major when one of the following conditions occurs:
   1. Suspected or confirmed pump thrombus (see below)
   2. Urgent transplantation (immediate 1A listing for transplant)
   3. Pump replacement
   4. Pump explant
   5. Breach of integrity of drive line that required repair
   6. Death
2. **Minor device malfunction** includes inadequately functioning external components which require repair or replacement but do not result in 1a-f. Device malfunction does not apply to “routine” maintenance which includes repair/replacement of: external controller, pneumatic drive unit, electric power supplies, batteries and interconnecting cables.

**Device Malfunction**

**Pump Thrombus** represents a special case of major device malfunction and can be delineated as **suspected pump thrombus** or **confirmed pump thrombus**. Pump thrombus will be classified as “SUSPECTED” (see definition below) based upon clinical, biochemical, or hemodynamic findings or “CONFIRMED” (see definition below) based upon device inspection or incontrovertible radiologic studies or absence of appropriate Doppler flow signals that confirms thrombus within the device or its conduits that results in or could potentially induce circulatory failure.

1. **Suspected pump thrombus** is a pump-related malfunction in which clinical or MCSD parameters suggest thrombus on the blood contacting components of the pump, cannulae, or grafts. Signs and symptoms should include at least 2 of the 3 following criteria:
   1. **Presence of hemolysis**
   2. **Presence of heart failure not explained by structural heart disease**
   3. **Abnormal pump parameters**

Suspected pump thrombus should be accompanied by 1 or more of the following events or interventions:

1. treatment with intravenous anticoagulation (e.g., heparin), intravenous thrombolytics (e.g., tPA), or intravenous antiplatelet therapy (e.g., eptifibatide, tirofiban)
2. pump replacement
3. pump explantation
4. urgent transplantation (UNOS status 1A)
5. stroke
6. arterial non-CNS thromboembolism
7. death
8. **Confirmed pump thrombus** is a major pump-related malfunction in which thrombus is confirmed within the blood contacting surfaces of device inflow cannula or outflow conduit or grafts. This can be reported via direct visual inspection or by incontrovertible contrast radiographic evidence or by the absence of an appropriate Doppler flow signal that results in or could potentially induce circulatory failure or result in thromboembolism.

If a Suspected Pump Thrombus event is ultimately confirmed through visual inspection following pump replacement, urgent transplantation or upon autopsy following death, the event will be adjudicated by the CEC for reclassification to Confirmed Pump Thrombus.

**General Information**

Enter **Date of onset** of adverse event: in MMDDYYYY format.

**Malfunctioning Device Type**: For BiVAD patients select from the drop down list given:

LVAD

RVAD

Both (in the same OR visit)

**Location of patient:** Select whether patient was **In hospital** or **Out of hospital** at time of adverse event. If location was not known, select **Unknown.**

In Hospital

Out of Hospital

Unknown

**Please briefly describe this device adverse event (malfunction and/or thrombus) including what happened, which component was involved, method of diagnosis, intervention(s) if any, and the result in the text box provided:**

### Thrombus Event

*If a device malfunction is associated with this thrombus event (suspected or confirmed) please remember to fill out the device malfunction section of this form.*

**Did the patient experience a thrombus event (suspected or confirmed)?**

Yes, No, or Unknown

If **yes**, then complete the following questions:

**Was the suspected or confirmed thrombus associated with one or more**  **of the following signs or symptoms?** Select all that apply:

Hemolysis

(complete the Hemolysis form)

Heart Failure

Abnormal Pump Parameters

Stroke

(complete the Neurological Dysfunction Form)

TIA

(complete the Neurological Dysfunction Form)

Arterial Non-CNS Thromboembolism

(complete the Arterial Non-CNS

Thromboembolism Form)

None

Other, Specify

If Other, specify, **then complete the text box.**

**Did the patient have one or more of the following?** Select all that apply:

Treatment with intravenous anticoagulation (e.g. heparin)

Intravenous thrombolytic (e.g. TPA)

Intravenous antiplatelet therapy (e.g. eptifibatide)

Other, Specify

If Other, specify, **then complete the text box.**

**Was the thrombus event confirmed (see definition below)?**

Yes, No, or Unknown

**Confirmed pump thrombus** is a major pump-related malfunction in which thrombus is confirmed within the blood contacting surfaces of device inflow cannula, or outflow conduit, or grafts. This can be reported via direct visual inspection, or by incontrovertible contrast radiographic evidence, or by the absence of an appropriate Doppler flow signal that results in or could potentially induce circulatory failure or result in thromboembolism.

If **yes**, then complete the following question:

**Please select method of confirmation:** Select all that apply:

Imaging Study

Visual Inspection

Manufacturer’s Report

### Device Malfunction Event

*If a thrombus (suspected or confirmed) is associated with this device malfunction event please remember to fill out the thrombus specific section of this form.*

**Did the patient experience a device malfunction (failure of one or more of the**  **components of the MCSD system which either directly causes or could potentially**  **induce a state of inadequate circulatory support or death)?**

Yes, No, or Unknown

If **yes,** please select all of the components that apply:

**Pump**

Pump Body (including bearings and rotor)

Driveline

Inflow Cannula

Outflow Graft (including bend relief)

**Controller / Driver**

Primary System Failure (running in backup mode)

Complete System Failure (primary and backup failure)

Power Cable (attached to controller)

Power Connectors (attached to controller)

Power Connectors (attached to controller)

Other, Specify

If Other, specify, **then complete the text box.**

**Peripherals**

External Battery

Cell Battery (in controller)

Power Module

Patient Cable

System Monitor / Display

Battery Charger

Battery Clip

**Outcomes of Device Adverse Event: Malfunction / Failure and/or Pump Thrombus**

**Patient Outcome:** Select all that apply:

Death (complete the death form)

Serious Injury (see FDA/CDRH definition below)

Urgent Transplantation (complete the transplant/explant form)

Explant Without Replacement (complete the explant form)

Exchange (complete the explant form & enter subsequent device)

Breach of Integrity of Drive Line that Required Repair

Other Surgical Procedure

None of the Above

**Causative or Contributing Factors to the Device Adverse Event:** Select all that apply:

Patient Accident

Patient Non-Compliance

Sub Therapeutic Anticoagulation

Prothrombotic States

End of Component Expected Life

Technical and/or Procedural Issues (e.g. cannula or graft malposition or kinking)

No Cause Identified

**5.15 Serious Injury [§803.3(aa)]**

“Serious injury” means an injury or illness that is:

• life threatening;

• results in permanent impairment of a body function or permanent damage to a body structure; or

• necessitates medical or surgical intervention to preclude permanent damage or impairment.

Medical Device Reporting for User Facilities

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Services, Food and Drug Administration

Center for Devices and Radiological Health (CDRH)

Rockville, Maryland 20857

April 1996

## Additional Adverse Events

### Cardiac Arrhythmias

**Cardiac arrhythmias**

Any documented arrhythmia that results in clinical compromise (e.g., abnormal VAD function [e.g., diminished VAD flow or suction events], oliguria, pre-syncope or syncope, angina, dyspnea), or requires hospitalization or treatment (drug therapy, defibrillation, cardioversion, ICD therapy (e.g., shock or anti-tachycardia pacing) or arrhythmia ablation procedure). Cardiac arrhythmias are classified as 1 of 2 types:

* 1. Sustained ventricular arrhythmia resulting in clinical compromise, or requiring hospitalization or drug treatment, defibrillation, cardioversion, ICD therapy, or arrhythmia ablation procedure.
  2. Sustained supraventricular arrhythmia resulting in clinical compromise, or requiring hospitalization or drug treatment, cardioversion, ICD therapy, or arrhythmia ablation procedure.

**Did a documented arrhythmia result in clinical compromise since last STS Intermacs® report / last followup?**

Yes, No, or Unknown

If **yes,** Enter **Event date** in MMDDYYYY format. **ST=** Unknown

Enter **Type of arrhythmia** from selection below:

Sustained ventricular arrhythmia requiring defibrillation or cardioversion

Sustained supraventricular arrhythmia requiring drug treatment or cardioversion

Unknown

### Pericardial Fluid Collection

**pericardial fluid collection**

Accumulation of fluid or clot in the pericardial space that requires surgical intervention or percutaneous catheter drainage. This event will be subdivided into those with clinical signs of tamponade (e.g. increased central venous pressure and decreased cardiac/VAD output) and those without signs of tamponade.

**Did a pericardial effusion that required drainage occur since last STS Intermacs®**

**report / last followup?**

Yes, No, or Unknown

If **yes,** Enter **Event date** in MMDDYYYY format. **ST=** Unknown

Were there **Signs of tamponade?**

Yes, No, or Unknown

**Method of Drainage**

Surgical Intervention

Cath

Unknown

### Hepatic Dysfunction

**hepatic dysfunction**

An increase in any two of the following hepatic laboratory values (total bilirubin, aspartate aminotransferase/**AST and** alanine aminotranferease/**ALT**) to a level greater than three times the upper limit of normal for the hospital, beyond 14 days post-implant (or if hepatic dysfunction is the primary cause of death) .

**Did Clinical evidence of liver dysfunction since last STS Intermacs**® **report / last**  **followup occur beyond 14 days post implant?:** **Yes, No,** or **Unknown.**

Yes, No, or Unknown

If **yes,**

**Total bilirubin measurement:** in mg/dL. **ST=** Unknown or Not Done

**SGOT / AST measurement:** in u/L. **ST=** Unknown or Not Done

**SGPT / ALT measurement:** in u/L. **ST=** Unknown or Not Done

Enter **Event date** in MMDDYYYY format. **ST=** Unknown

### Myocardial Infarction

**Myocardial infarction**

Two categories of myocardial infarction will be identified:

**Peri-Operative Myocardial Infarction**

The clinical suspicion of myocardial infarction together with CK-MB or Troponin > 10 times the local hospital upper limits of normal, found within 7 days following VAD implant together with ECG findings consistent with acute myocardial infarction. (This definition uses the higher suggested limit for serum markers due to apical coring at the time of VAD placement, and does not use wall motion changes because the apical sewing ring inherently creates new wall motion abnormalities.)

**Non-Perioperative Myocardial Infarction**

The presence at > 7 days post-implant of two of the following three criteria:

a) chest pain which is characteristic of myocardial ischemia,

b) ECG with a pattern or changes consistent with a myocardial infarction, and

c) Troponin or CK (measured by standard clinical pathology/laboratory medicine methods) greater than the normal range for the local hospital with positive MB fraction (≥ 3% total CK). This should be accompanied by a new regional LV or RV wall motion abnormality on a myocardial imaging study.

**Did a myocardial infarction occur since last STS Intermacs® report / last followup / admission?:**

Yes, No, or Unknown

If **yes,** Enter **Event date** in MMDDYYYY format. **ST=** Unknown

### Psychiatric Episode

**psychiatric episode**

Disturbance in thinking, emotion or behavior that causes substantial impairment in functioning or marked subjective distress requiring intervention. Intervention is the addition of new psychiatric medication, hospitalization, or referral to a mental health professional for treatment.

Suicide is included in this definition.

**Did a disturbance in thinking, emotion, or behavior that required intervention occur in patient since last STS Intermacs® report / last followup?:**

Yes, No, or Unknown

If **yes,** Enter **Event date** in MMDDYYYY format. **ST=** Unknown

### Renal Dysfunction

**renal dysfunction**

Two categories of renal dysfunction will be identified:

**Acute Renal Dysfunction**

Abnormal kidney function requiring dialysis (including hemofiltration) in patients who did not require this procedure prior to implant, or a rise in serum creatinine of greater than 3 times baseline or greater than 5 mg/dL **(in children,** creatinine greater than 3 times upper limit of normal for age) sustained for over 48 hours.

**Chronic Renal Dysfunction**

An increase in serum creatinine of 2 mg/dl or greater above baseline, or requirement for hemodialysis sustained for at least 90 days.

**Did renal dysfunction (by definition) occur since last STS Intermacs**® **report / last followup?:**

Yes, No, or Unknown

If **yes,**

Enter **Event date** in MMDDYYYY format. **ST=** Unknown

**Dialysis duration:** in days. **ST=** Unknown, Not Done, or Ongoing

**Peak Creatinine measurement:** mg/dL. **ST=** Unknown or Not Done

### Respiratory Failure

**respiratory failure**

Impairment of respiratory function requiring reintubation, tracheostomy or the inability to discontinue ventilatory support within six days (144 hours) post-VAD implant. This excludes intubation for re-operation or temporary intubation for diagnostic or therapeutic procedures.

**Did an impairment of respiratory function requiring intubation or mechanical ventilation occur since last STS Intermacs® report / last followup?:**

Yes, No, or Unknown

If **yes,** Enter **Event date** in MMDDYYYY format. **ST=** Unknown or Ongoing

**Enter Intubation duration in days. ST=** Unknown or Ongoing

**Was a tracheotomy performed?** **Yes, No,** or **Unknown.**

Yes, No, or Unknown

### Arterial Non-CNS Thromboembolism

**arterial non-cns thromboembolism**

An acute systemic arterial perfusion deficit in any non-cerebrovascular organ system due to thromboembolism confirmed by one or more of the following:

Standard clinical and laboratory testing.

Operative findings.

Autopsy findings.

This definition excludes neurological events.

**Did an acute perfusion deficit in any non-cerebrovascular organ system occur**  **since last STS Intermacs® report / last followup?:**

Yes, No, or Unknown

If **yes,** Enter **Event date** in MMDDYYYY format. **ST=** Unknown

**Location:**

Pulmonary

Renal

Hepatic

Splenic

Limb

**Other** – If selected, enter in block provided

Unknown

**Enter Confirmation source:**

Standard clinical and laboratory testing

Operative findings

Autopsy finding

**Other** – if selected, enter in block provided

Unknown

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

Warfarin

Heparin

Lovenox

Aspirin

Dipyridamole

Clopidogrel (plavix)

Argatroban

Bivalirudin

Fondaparinux

Dextran

Ticlopidine

Hirudin

Lepirudin

Ximelagatran

None

**Other**– if selected, enter in block provided

### Venous Thromboembolism

**Venous thromboembolism**

Evidence of venous thromboembolic event (e.g. deep vein thrombosis, pulmonary embolism) by standard clinical & laboratory testing.

**Evidence of venous thromboembolic event since last STS Intermacs® report / last followup** (e.g. deep vein thrombosis, pulmonary embolism) by standard clinical and laboratory testing: (select all that apply).

Deep Vein thrombosis – **Enter Date** in MMDDYYYY format. **ST=** Unknown

Pulmonary Embolus – **Enter Date** in MMDDYYYY format. **ST=** Unknown

**Other, Specify** – if selected, enter in block provided.

**Enter Date** in MMDDYYYY format. **ST=** Unknown

Unknown

None

If **Deep Vein thrombosis**, **Pulmonary Embolus**, or **Other, Specify**:

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

Warfarin

Heparin

Lovenox

Aspirin

Dipyridamole

Clopidogrel (plavix)

Argatroban

Bivalirudin

Fondaparinux

Dextran

Ticlopidine

Hirudin

Lepirudin

Ximelagatran

None

**Other**– if selected, enter in block provided

### Wound Dehiscence

**Wound dehiscence**

Disruption of the apposed surfaces of a surgical incision, excluding infectious etiology, and requiring surgical repair.

**Did a disruption of the apposed surfaces of surgical incision require surgical repair since last STS Intermacs**® **report / last followup?**

Yes, No, or Unknown

If **yes,**

Enter **Event date** in MMDDYYYY format. **ST=** Unknown

**Enter Location:** Select one:

Sternum

Driveline sites

Site of thoracotomy

Other, specify

**If Other Specify, then complete text box.**

### Other SAE

**other sae**

An event that causes clinically relevant changes in the patient’s health (e.g. cancer).

**Did an Other Major Serious Adverse Event occur since last STS Intermacs**® **report**  **/ last followup?**

Yes, No, or Unknown

If **yes,**

**OtherMajor Serious Adverse Event since last STS Intermacs**® **report/last followup** - enter in block provided

Enter **Event date** in MMDDYYYY format. **ST=** Unknown

# 2.11 Explant: For Device Exchange, Recovery or Transplant

**Note: Complete this section for devices that are removed or devices that are “turned off” AND left in place.**

The **Explant Form** is to be collected at time of explant or transplant or both.

**Was the device explanted for any reason (includes exchanges or “turned off”)?**

Yes or No

**Explant date:**  Enter explant date in MMDDYYYY format. **ST=** Unknown

Enter **Device explanted:** Select appropriate device type for this explant event:

LVAD   
RVAD   
Both (LVAD+RVAD)

TAH

**Explant reason:** Select one of the following as the reason for explant. If **Device is removed (turned off) for reasons other than recovery, transplant, or death**, type in the specification in the block provided.

Explant - Death – *Fill out death form*

If **Yes**, Evidence of **Pump Thrombosis**? Yes, No, or Unknown

Explant - Transplanted - *Enter Transplant Date and Waitlist ID below*

If **Yes**, Evidence of **Pump Thrombosis**? Yes, No, or Unknown

**Transplant date:** Enter the transplant date in MMDDYYYY format.

**ST=** Unknown

**Waitlist ID:**  UNOS waitlist identifier. **(May enter “99999” when ID is unknown)**

Explant - Exchange

Explant Reasons (Check all that apply):

Device Malfunction: Elective

Device Malfunction: Emergent

Device Thrombosis: Elective

Device Thrombosis: Emergent

Infection: Elective

Infection: Emergent

Other, Specify

**If Other, Specify: please complete text box**

**New device part of an FDA IDE trial?** Yes, No, or Unknown

If **Yes,** enter name of **FDA IDE Trial** in the text box provided.

Explant - No New Device

Explant Reasons (Check all that apply):

Recovery

Withdrawal of Support

Device Malfunction: Elective

Device Malfunction: Emergent

Device Thrombosis: Elective

Device Thrombosis: Emergent

Infection: Elective

Infection: Emergent

Other, Specify

**If Other, Specify: please complete text box**

Turned Off (Decommissioned)

Reasons (Check all that apply):

Recovery

Withdrawal of Support

Device Malfunction: Elective

Device Malfunction: Emergent

Device Thrombosis: Elective

Device Thrombosis: Emergent

Infection: Elective

Infection: Emergent

Other, Specify

**If Other, Specify: please complete text box**

**Note: If patient is transplanted, that patient will no longer be followed in the STS Intermacs® Registry, but will be followed in the UNOS web-based data entry for transplant system.**

**Note: If the explanted device was not functioning normally (malfunction or thrombosis) then complete the Device Malfunction Form.**

**Note: If the patient is explanted due to ventricular recovery or all devices are removed (or turned off), STS Intermacs® will continue a 1 year follow-up for this patient for death and/or transplant**.

# 2.11b 1 Year Post Cessation of Mechanical Support

This form collects outcome data for one year after the removal of support when subsequent devices are not implanted or utilized. The start of this year is determined by the date of one of the following events:

Ventricular Recovery - Device Removed

Ventricular Recovery - Device not removed but turned off

Device removed (or turned off) for reasons other than recovery, transplant, or death

When you perform medical chart abstraction, please use the day closest to the time point specified above.

**Please enter the date of the event you are reporting:** In MMDDYYYY format

**Is the patient deceased?:**

Yes or No

If **Yes**, **Death Date:** In MMDDYYYY format

**Primary Cause of Death:**

Respiratory: Venous Thromboembolism Event

Respiratory: Respiratory Failure

Respiratory: Pulmonary: Other, specify

**If Respiratory: Pulmonary: Other, specify*: type in the text box provided***

Circulatory: Arterial Non-CNS Thromboembolism

Circulatory: Myocardial Infarction

Circulatory: Myocardial Rupture

Circulatory: Ruptured Aortic aneurysm

Circulatory: Right Heart Failure

Circulatory: Major Bleeding

Circulatory: Cardiac Arrhythmia

Circulatory: Hemolysis

Circulatory: Hypertension

Circulatory: Other, Specify

**If Circulatory: Other, Specify: *type in the text box provided***

Circulatory: Sudden unexplained death

Circulatory: CHF

Circulatory: Heart Disease

Circulatory: End Stage Cardiomyopathy

Circulatory: End Stage Ischemic Cardiomyopathy

Circulatory: Pericardial Fluid Collection (effusion)

Digestive (Intestinal or GI/GU): Hepatic Dysfunction

Digestive (Intestinal or GI/GU): Renal Dysfunction

Digestive (Intestinal or GI/GU): GI Disorder

Digestive (Intestinal or GI/GU): Fluid/Electrolyte Disorder

Digestive (Intestinal or GI/GU): Pancreatitis

Nervous System: Neurological Dysfunction

Psychiatric Episode/Suicide

Major Infection

Device Malfunction

Multiple System Organ Failure (MSOF)

Withdrawal of Support, specify

**If Withdrawal of Support, specify: *type in the text box provided***

Cancer

**If Cancer, *select the type of cancer from the list:***

CNS

GI

Lymph

ENT

Pulmonary

Renal

Breast

Reproductive

Skin

Other

**If Other, specify: *type in the text box provided***

Unknown

Wound Dehiscence

Trauma/accident, specify

**If Trauma/accident, specify: *type in the text box provided***

Endocrine

Hematological

Other, specify

**If Other, specify: *type in the text box provided***

**Was the patient transplanted?:**

Yes or No

If **Yes**, **Transplant Date:** In MMDDYYYY format

# 2.12 Death

The **Death Form** is to be collected at time of death.

**Is the patient deceased?:**

Yes or No

Enter **Death date:** In MMDDYYYY format. **ST**= Unknown

**Device functioning normally:** If the device was functioning normally at time of death, select **Yes.** If the device was not functioning normally at time of death, select **No** and fill out the **Device Malfunction Adverse Event Form**. If it is not known whether the device was functioning normally at time of death, select **Unknown**.

Yes, No, Unknown

**If No, Was There an operation associated with the device malfunction?:**

Yes, No, Unknown

**Post mortem device explant:** Was the device explanted post mortem?

Yes, No, Unknown

**If Yes, did device go to manufacturer:**

Yes, No, Unknown

**Location of death:** Select whether patient was **In Hospital** or **Out of Hospital** at time of death. If location was not known, select **Unknown.**

In Hospital

Out of Hospital

Unknown

**Timing of death:** Select one of the timings of death: **Expected**, **Unexpected** or the timing of death was **Unknown**.

Expected

Unexpected

Unknown

**Primary cause of Death:** Many of the causes of death also represent an adverse event. Please complete the associated adverse event form in collaboration with the primary cardiologist and the CT surgeon. Select one primary cause of death from the list below:

Respiratory: Venous Thromboembolism Event

Respiratory: Respiratory Failure

Respiratory: Pulmonary: Other, specify

**If Respiratory: Pulmonary: Other, specify*: type in the text box provided***

Circulatory: Arterial Non-CNS Thromboembolism

Circulatory: Myocardial Infarction

Circulatory: Myocardial Rupture

Circulatory: Ruptured Aortic aneurysm

Circulatory: Right Heart Failure

Circulatory: Major Bleeding

Circulatory: Cardiac Arrhythmia

Circulatory: Hemolysis

Circulatory: Hypertension

Circulatory: Other, Specify

**If Circulatory: Other, Specify: *type in the text box provided***

Circulatory: Sudden unexplained death

Circulatory: CHF

Circulatory: Heart Disease

Circulatory: End Stage Cardiomyopathy

Circulatory: End Stage Ischemic Cardiomyopathy

Circulatory: Pericardial Fluid Collection (effusion)

Digestive (Intestinal or GI/GU): Hepatic Dysfunction

Digestive (Intestinal or GI/GU): Renal Dysfunction

Digestive (Intestinal or GI/GU): GI Disorder

Digestive (Intestinal or GI/GU): Fluid/Electrolyte Disorder

Digestive (Intestinal or GI/GU): Pancreatitis

Nervous System: Neurological Dysfunction

Psychiatric Episode/Suicide

Major Infection

Device Malfunction

Multiple System Organ Failure (MSOF)

Withdrawal of Support, specify

**If Withdrawal of Support, specify: *type in the text box provided***

Cancer

**If Cancer, *select the type of cancer from the list:***

CNS

GI

Lymph

ENT

Pulmonary

Renal

Breast

Reproductive

Skin

Other

**If Other, specify: *type in the text box provided***

Unknown

Wound Dehiscence

Trauma/accident, specify

**If Trauma/accident, specify: *type in the text box provided***

Endocrine

Hematological

Other, specify

**If Other, specify: *type in the text box provided***

# 2.13 Patient Transfer / Consent Withdrawal Forms

2.13 Transfer Form

Notes to Originating Hospital and Receiving Hospital – Please read the following:

* All forms prior and up to the transfer date must be completed by the originating hospital (the transfer form cannot be validated until all prior forms are completed).
* The originating hospital can no longer make any changes to patient records after the transfer form has been completed. The originating hospital will be able view the patient as ‘read only’. The originating hospital will NOT be able to view the patient’s record beyond the transfer date.
* The receiving hospital will have ‘read only’ access to all forms prior and up to the transfer date.
* Any Follow-up entries automatically generated past the transfer date will be the responsibility of the receiving hospital to complete.
* If the receiving hospital is not an STS INTERMACS® hospital then patient records are ‘stopped’ at time of transfer.

PLEASE READ:

Before a date of transfer can be entered, all prior forms must be completed. If the patient is transferred to another STS Intermacs® hospital, then that hospital will have “read only” access to the pre-transfer records.

Please use this form to record the date of transfer if a patient transfers their care to another hospital.

**Transferred care to another hospital (patient followed exclusively at another hospital)?**

Yes or No

If **Yes,** Enter **Date transferred care**: Enter as MMDDYYYY. **ST=** Unknown

**Please Specify the transferring hospital in the text box provided.**

.

# 

# 2.14 Quality of Life

The combined **EuroQoL (EQ-5D)** and **Modulated QoL Questionnaire** andthe separate **Kansas City Cardiomyopathy Questionnaire (KCCQ)** areprovided in **Appendices F** and **H** respectively**.** The **EQ-5D/Modulated QoL** and **KCCQ** questionnaires can be printed from the STS Intermacs® website [http://www.uab.edu/medicine/STS Intermacs/appendices/app-f-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-f-5-0) and [http://www.uab.edu/medicine/STS Intermacs/appendices/app-h-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-h-5-0) respectively.

Quality of life is to be measured by the EQ-5D/Modulated QoL and the KCCQ instruments. EQ-5D/Modulated QoL and KCCQ are to be administered pre-implant and post-implant (3 months, 6 months, and every 6 months thereafter).

**All adult patients should complete the EQ-5D/Modulated QoL and KCCQ.**

**Data collection**

The EQ-5D/Modulated QoL and KCCQ are administered by research or clinical coordinators as designated by each participating medical center. The EQ-5D/Modulated QoL and KCCQ instruments can be printed from the STS Intermacs® website [www.STS Intermacs.org](http://www.intermacs.org) .

**Pre-implant data collection**

* The patient is to complete the EQ-5D/Pre-Implant Modulated QoL and KCCQ before MCSD implant. Pre-implant assessment of quality of life is essential in evaluating MCSD therapy. Please make every effort to obtain this information. All eligible patients should complete these questionnaires.

**Post-implant data collection (3, 6, and every 6 months post implant)**

* The patient is to complete these instruments at the return clinic visits closest to the appropriate data collection time points (given the patient has been discharged prior to the data collection time points). All eligible patients should complete these questionnaires.
* Patients who remain hospitalized at the 3, 6 or 12 month time point should complete the EQ-5D/Post-Implant Modulated QoL and KCCQ, if able.

**Instrument Administration**

* The patient is to complete the EQ-5D/Modulated QoL and KCCQ instruments via self-report independently.

If the patient is unable to complete the EQ-5D/STS Modulated QoL and KCCQ instruments, the coordinator or a family member is to read the questions to the patient and complete the instruments documenting the patient’s responses. Indicate on the instruments that the EQ- 5D and KCCQ were self-administered or administered verbally by another.

* There should be no coaching regarding responses.
* Enter the patient’s answers from the paper form into the database through [www.STS Intermacs.org](http://www.intermacs.org).

**Data Screening**

* The EQ-5D/STS Modulated QoL and KCCQ are to be reviewed for missing or unclear data at the time of instrument completion. Corrections must be made with the patient at that time.

**Non Submission of EQ-5D and KCCQ**

* For patients who do not complete the EQ-5D/STS Modulated QoL or KCCQ, please enter reason as to why the EQ-5D/STS Modulated QoL or KCCQ were not completed as stated above.

## EuroQol (EQ-5D)

**Did the patient complete a EuroQol (EQ-5D) form:** Enter **Yes or No**

Yes or No

**If No, Please select a reason why the EuroQol (EQ-5D) was not completed:** Select the reason for non-completion of the EuroQol (EQ-5D) from the drop down list provided.

Too sick (ex., intubated/sedated, critically ill, on short-term VAD)

Too tired

Too stressed, anxious, and/or depressed

Can't concentrate

No time / too busy

Too much trouble/don't want to be bothered/not interested

Unwilling to complete instruments, no reason given

Unable to read English and/or illiterate

Administrative (check specific reason below)

**If Administrative: Select a specific reason:**

Urgent/emergent implant, no time to administer QOL instruments

Coordinator too busy or forgot to administer QOL instruments

Unable to contact patient (ie., not hospitalized or no clinic visit)

within the window for QOL instrument completion

Other reason (describe)

**If Other reason (describe):** Please specify in text box.

**If Yes,** enterthe patients answers from the EuroQol (EQ-5D) printed form into the STS Intermacs**®** application.

**How was the test administered:**

Self-administered

Coordinator administered

Family member administered

**Mobility:**

I have no problems in walking about

I have some problems in walking about

I am confined to bed

Unknown

**Self-care:**

I have no problems with self-care

I have some problems washing or dressing myself

I am unable to wash or dress myself

Unknown

**Usual activities:** (e.g. work, study, housework, family or leisure activities)

I have no problem with performing my usual activities

I have some problems with performing my usual activities

I am unable to perform my usual activities

Unknown

**Pain/Discomfort:**

I have no pain or discomfort

I have moderate pain or discomfort

I have extreme pain or discomfort

Unknown

**Anxiety/Depression:**

I am not anxious or depressed

I am moderately anxious or depressed

I am extremely anxious or depressed

Unknown

**Patient Visual Analog Status (VAS):** Enter \_\_\_\_\_.(0 = Worst,100 = Best)

If Unknown, please select the corresponding box.

## Pre/Post-Implant QoL

**1. Which of the following best describes your main activity?:**

Actively working

Retired

Keeping house

Student

Seeking work

Too sick to work (disabled)

Unknown

Other

**If Other**,Please specify in text box.

**Is this “one” main activity considered:**

Full time

Part time

Unknown

**2. How many of your close friends or relatives do you see in person, speak to on the telephone, or contact via the Internet at least once a month? (Please count each person one time) If Unknown, please select the corresponding box.**

**3. Have you unintentionally lost more than 10 pounds in the last year?**

Yes, No, or Unknown

**4. Do you currently smoke cigarettes?**

Yes, No, or Unknown

**If Yes, How many cigarettes are you currently smoking, on average?**

Half a pack or less per day

More than half to 1 pack per day

1 to 2 packs per day

2 or more packs per day

**5. Do you currently smoke e-cigarettes?**

Yes, No, or Unknown

**6. How much stress do you feel you've been under during the past one month, related to your health issues?** (1 = No stress, 10 = Very much stress) If Unknown, please select the corresponding box.

**7. How well do you feel you've been coping with or handling your stress during the past one month, related to your health issues?** (1 = Coping poorly, 10 = Coping very well) If Unknown, please select the corresponding box.

**8. How confident are you that you can do the tasks and activities needed to manage your heart failure so as to reduce how much having heart failure affects your everyday life?** (1 = Not at all confident, 10 = Totally confident) If Unknown, please select the corresponding box.

**9. How satisfied are you with the results of your therapy for heart failure during the past six months?** (1 = Not satisfied at all, 10 = Very satisfied) If Unknown, please select the corresponding box.

**If this is a post implant follow up, then answer the following additional question:**

**10. If you had to do it all over again, would you decide to have a ventricular assist device knowing what you know now?**

Definitely No

Probably No

Not Sure

Probably Yes

Definitely Yes

Unknown

## Kansas City Cardiomyopathy Questionnaire (KCCQ) - 12

**Did the patient complete a KCCQ form:** Enter **Yes or No.**

Yes or No

**If No, Please select a reason why the KCCQ was not completed:** Select the reason for non-completion of the KCCQ from the drop down list provided.

Too sick (ex., intubated/sedated, critically ill, on short-term VAD)

Too tired

Too stressed, anxious, and/or depressed

Can't concentrate

No time / too busy

Too much trouble/don't want to be bothered/not interested

Unwilling to complete instruments, no reason given

Unable to read English and/or illiterate

Administrative (check specific reason below)

**If Administrative: Select a specific reason:**

Urgent/emergent implant, no time to administer QOL instruments

Coordinator too busy or forgot to administer QOL instruments

Unable to contact patient (ie., not hospitalized or no clinic visit)

within the window for QOL instrument completion

Other reason (describe)

**If Other reason (describe):** Please specify in text box.

If **Yes,** enter the patients answers from the KCCQ printed form into the MedaMACS application.

**How was the test administered:**

Self-administered

Coordinator administered

Family member administered

**THE KANSAS CITY CARDIOMYOPATHY QUESTIONNAIRE:**

*The following questions refer to your heart failure and how it may affect your life. Please read and complete the following questions. There is no right or wrong answer. Please mark the answer that best applies to you.*

1. **Heart Failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** (*shortness of breath or fatigue*) in your ability to do the following activities over the past 2 weeks.

**a. Showering/Bathing**

Extremely limited

Quite a bit limited

Moderately Limited

Slightly Limited

Not at all limited

Limited for other reasons or did not do the activity

Unknown

**b. Walking 1 block on level ground**

Extremely limited

Quite a bit limited

Moderately Limited

Slightly Limited

Not at all limited

Limited for other reasons or did not do the activity

Unknown

**c. Hurrying or jogging (as if to catch a bus)**

Extremely limited

Quite a bit limited

Moderately Limited

Slightly Limited

Not at all limited

Limited for other reasons or did not do the activity

Unknown

2. Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in in the morning?

Every morning

3 or more times a week, but not every day

1-2 times a week

Less than once a week

Never over the past 2 weeks

Unknown ⁯

3. Over the past 2 weeks, on average, how many times has **fatigue** limited your ability to do what you want?

All the time

Several times per day

At least once a day

3 or more times per week, but not every day

1-2 times per week

Less than once a week

Never over the past 2 weeks

Unknown

4. Over the past 2 weeks, on average, how many times has **shortness of breath** limited your ability to do what you wanted?All the time

Several times per day

At least once a day

3 or more times per week, but not every day

1-2 times per week

Less than once a week

Never over the past 2 weeks

Unknown

5. Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night

3 or more times a week, but not every day

1-2 times a week

Less than once a week

Never over the past 2 weeks

Unknown

6. Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has extremely limited my enjoyment of life

It has limited my enjoyment of life quite a bit

It has moderately limited my enjoyment of life

It has slightly limited my enjoyment of life

It has not limited my enjoyment of life at all

Unknown

7. If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied

Mostly dissatisfied

Somewhat satisfied

Mostly satisfied

Completely satisfied

Unknown

8. How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

**a. Hobbies, recreational activities**

Severely limited

Limited quite a bit

Moderately limited

Slightly limited

Did not limit at all

Does not apply or did not do for other reasons

Unknown

**b. Working or doing household chores**

Severely limited

Limited quite a bit

Moderately limited

Slightly limited

Did not limit at all

Does not apply or did not do for other reasons

Unknown

**c. Visiting family or friends out of your home⁯**

Severely limited

Limited quite a bit

Moderately limited

Slightly limited

Did not limit at all

Does not apply or did not do for other reasons

Unknown

Developed by John Spertus et al., Mid America Heart Institute, Saint Luke’s Hospital, Kansas City, MO.

# 2.15 Neurocognitive Function Test

The **Trail-Making Sample B** and **Part B** areprovided in **Appendix G.** The **Trail-Making Sample B** and **Part B** instruments can be printed from [http://www.uab.edu/medicine/STS Intermacs/appendices/app-g-5-0](http://www.uab.edu/medicine/intermacs/appendices/app-g-5-0)

**SAMPLE**

Neurocognitive function is to be measured by the Trail-Making Part B test. Trail-Making Part B is to be administered **pre-implant** and **post-implant** (3 months, 6 months, and every 6 months thereafter).

After the subject completes Part B, take the test sheet and record the time in seconds.

Errors contribute to the evaluation of the performance principally by increasing the total

performance time. If the patient completes the test, but the test is considered invalid,

select “completed but invalid (score not entered)”. ***Do not allow patient to retake the test.***

**Administering the test**

**1. Let patient practice with Sample B**

***Script:***

*"On this page are some numbers and letters. Begin at 1* (point) *and draw a line from 1 to A"*(point to A*) "A to 2,"*(point to 2), *“2 to B”* (point to B), *“B to 3”* (point to 3), *“3 to C”*(point to C),*“and so on, in order, until you reach the end”* (point to the circle marked "end").

***Then say:***

*“Remember, first you have a number”* (point to 1), *“then a letter”* (point to A), *“then a number”* (point to 2),*“then a letter”* (point to B), “*and so on. Draw the lines as fast as you can. Ready--- Begin!”*

If the subject completes the sample B correctly say: *"Good! Let’s try the next one."*Proceed immediately to Part B. **If the subject makes a mistake on sample B, point out the error and explain why it is incorrect.** The following explanations of mistakes serve as illustrations:

*“You started with the wrong circle. This is where you start* (point to 2).“*You skipped this circle”* (point to the circle the subject omitted). “*You should go from 1”* (point to 1) *“to A”* (point to A), *“A to 2”* (point to 2), *“2 to B”* (point to B), *“B to 3”* (point to 3), *“and so on until you reach the circle marked ‘end’*.*”* (point)

**If the subject cannot complete Sample B**, take his/her hand and guide the pencil, using the eraser end, through the circles. Then say:

*”Now you try it. Remember, you begin at number 1”* (point), *“and draw a line from 1 to A”* (point to A), *“A to 2”* (point to 2), *“2 to B”* (point to B), *“B to 3”* (point to 3), *“and so on until you reach the circle marked ‘end’.”* (point), *“Ready --- Begin!”*

**2. Ask patient to complete Part B**

If the subject succeeds this time, go on to Part B. If not, repeat the procedure until the task is performed successfully or it becomes evident that the subject cannot do the task.

After the subject has completed the sample, turn the paper over to Part B and say:

*“On this page, there are both numbers and letters. Do this the same way. Begin at number 1”* (point to 1), *“and draw a line from 1 to A”* (point to A), *“A to 2”* (point to 2), *“2 to B”* (point to B), *”B to 3”* (point to 3), *“3 to C”* (point to C), *“and so on, in order, until you reach the end”* (point to the circle marked "end"*). “Remember, first you have a number”* (point to 1), *“then a letter”* (point to A), “*then a number”* (point to 2), *“then a letter”* (point to B), *“and so on. Do not skip around, but go from one circle to the next in the proper order. Draw the lines as fast as you can. Ready ---Begin!”*

Using the stopwatch, start timing as soon as the subject is told to begin. Remember to be alert for mistakes. If the subject makes an error, DO NOT STOP TIMING.  Point it out immediately, return the subject to the last correct circle and say, *“Now, are you looking for a number or a letter?”* Continue the test from that point. DO NOT STOP TIMING.

After the subject completes Part B, take the test sheet, and record the time in seconds. Errors contribute to the evaluation of the performance principally by increasing the total performance time. If the patient completes the test, but the test is considered invalid, select “**Other, specify**” and, specify the reason you are not entering a score. ***Do not allow patient to retake the test.***

**To enter the Trailmaking Data results**

**Status:** Select the appropriate choice from the drop down box provided:

Completed

Completed but invalid (scores not entered)

Attempted but not completed

Not attempted

If you select: **Completed**, then the following element will appear:

**Time:**  Enter the time in seconds