Appendix N. STS Pedimacs Site Users' Guide

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

Guide to the STS Pedimacs web-based data entry system

1.0 Navigating the STS Pedimacs Application

1.1 Introduction

All data will be entered electronically through the STS Pedimacs web-based data entry system (STS Pedimacs 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 https://intermacs.kirso.net/, click on STS Pedimacs tab and select 'Patient Data Entry' to get to the secure login page below.

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

1.2 How do I get started?

Entering a new patient

Once you login to the STS Pedimacs application for patient data entry, 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 Pedimacs patient data entry system

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 FDA approved device***
- □ ***Implanted on or after September 19, 2012 (The device does not need to be the first implant for the patient)***

Forms

The STS Pedimacs 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. The Data Dictionary for these forms is found in Section 2.0 of this manual.

Inclusion/Exclusion Form
Screening Log

Clinical Data Forms
Demographics
Pre-Implant
Implant
1 Week Post Implant
1 Month Post Implant
3 Month Follow up
6 Month Follow up
Implant Discharge
1 Year Post Cessation of Mechanical Support
Rehospitalization
Reporting Adverse Events
Death
Explant
Patient Transfer Form

Quality of Life Forms
PedsQL
VADQoL

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 a 'Submit' button. The 'Save' 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 "Add A Patient," then you begin entering the STS Pedimacs forms. The first form is the Demographic form. The specific data elements of this form are described in Section 2.0 "Data Dictionary".

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 Pedimacs 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 overview 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, and quality of life (PedsQL and VADQoL) and Modified Rankin Scale when applicable. The follow-up forms also contain a table as a reminder to fill out any adverse events that have occurred during the relevant follow-up time period.

Collection of follow-up data is an essential part of STS Pedimacs. 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*
- ***Telehealth Consultation*** *(complete follow-up form)*

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 Pedimacs 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 data dictionary 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 Pedimacs.

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 Pedimacs allows for entry of multiple implants for an individual patient. The LVAD or 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 an 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'.

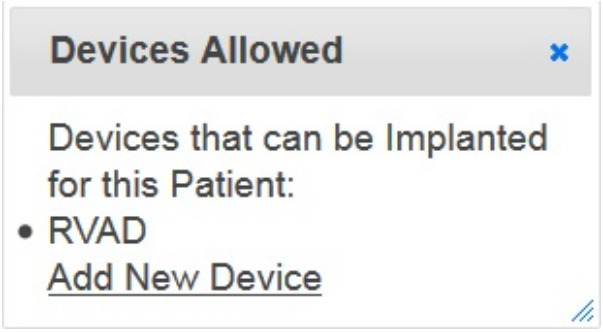
There are two possible scenarios.

Replacement of an existing device

If a patient has a device replaced (e.g., a patient with an LVAD or RVAD receives a replacement LVAD or RVAD) 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 Pedimacs 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 Data Dictionary: Patient Registry Status Form

2.0 Data Dictionary for the STS Pedimacs Application

Section Form Page

2.1 Screening Log

Each patient who receives a mechanical circulatory support device (MCSD) at your institution must be screened for eligibility into STS Pedimacs. 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 all inclusion criteria then check 'ALL' inclusion reasons below:

Patient less than 19 years of age at time of implant
Yes or No

Patient receives an (MCSD) which is FDA approved
Yes or No

Implanted on or after September 19, 2012 (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: Systemic Support)
RVAD (Right Ventricular Assist Device: Pulmonic Support)
Both (LVAD+RVAD in same OR visit)
TAH (Total Artificial Heart)
NOTE: If this is a single ventricle patient, please select LVAD as the device type

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 https://intermacs.kirso.net/pedimacs/pedimacs-documents/ for reference purposes).

Durable Devices LVAD, BiVAD, TAH	Temporary Devices
HeartMate II LVAS	Abiomed AB5000
HeartMate 3	Abiomed BVS 5000
HeartMate IP	Thoratec Centrimag (Levitronix)
HeartMate VE	Thoratec Pedimag
HeartMate XVE	TandemHeart
Micromed DeBakey VAD – Child	Biomedicus
Novacor PC	Maquet Rotaflow
Novacor PCq	Sorin Revolution
Thoratec IVAD	Abiomed Impella 2.5
Thoratec PVAD	Abiomed Impella 5.0
AbioCor TAH	Abiomed Impella CP
HeartWare HVAD	Abiomed Impella RP
SynCardia TAH – 70cc	Abiomed Impella 5.5
SynCardia TAH – 50cc	**Other, Specify**
Berlin Heart EXCOR (paracorporeal)	
Other, Specify	

Exclusion: *Any* exclusion will disqualify the patient for entry into STS Pedimacs:
If patient meets 'ANY' exclusion criteria then check any of the appropriate exclusion reasons below (select all that apply):

Patient 19 years or older at time of implant (patient should be enrolled in STS INTERMACS)
Yes or No

Patient receives an (MCSD) which is not FDA approved
Yes or No

Patient is incarcerated (prisoner)
Yes or No

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

If Patient is EXCLUDED, please complete STS Pedimacs 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: Systemic Support)
RVAD (Right Ventricular Assist Device: Pulmonic Support)
Both (LVAD+RVAD in same OR visit)
TAH (Total Artificial Heart)
NOTE: If this is a single ventricle patient, please select LVAD as the device type

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:

0 to 2
3 to 4
5 to 9
10 to 12
13 to 15
16 to 18

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 this 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 Pedimacs 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.

Enter patient's home **Street Address**. **ST**= Unknown

Enter patient's home **City**. **ST**= Unknown

Patient's home **State, Territory, Province**. Select from dropdown, if not known, select **Unknown**.

Enter patient's home **Zip Code**. **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 younger than 19 years 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:
- American Indian or Alaska Native
- Asian
- African-American
- Hawaiian or other Pacific Islander
- White
- Unknown/Undisclosed
- Other/none of the above

Is patient involved in a VAD related study? Select the appropriate answer
Yes, No, or Unknown
If **Yes** selected, **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

Admission Date for This Hospitalization - MMDDYYYY
ST= Not Applicable, or Unknown

DEMOGRAPHICS

Height: Enter the height of the patient at the time of implantation in inches or centimeters. The height must fall between 10 and 80 inches or 25 and 203 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 3 and 450 pounds or 2 and 205 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 device to allow recovery from chronic cardiac failure (at least 3 months in duration)
Rescue therapy - Use of a 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.
Bridge to Decision

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.

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.

Yes No or 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.

Was the patient treated for heart failure prior to admission?

Yes, No, or Unknown

If **yes**, **number of heart failure hospitalizations** in the last year

0-1
2-3
≥4
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 (l-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: Biventricular: Unspecified
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
Congenital Heart Disease: Other - **If other, please complete textbox**
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
Dilated Myopathy: LV non-compaction
Dilated Myopathy: Unspecified
Hypertrophic Cardiomyopathy
Non-Compaction Cardiomyopathy
Post Transplant / Graft Dysfunction
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
Restrictive Myopathy: Unspecified
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
Dilated Myopathy: LV non-compaction
Dilated Myopathy: Unspecified
Hypertrophic Cardiomyopathy
Post Transplant / Graft Dysfunction
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
Restrictive Myopathy: Unspecified
Non-Compaction Cardiomyopathy
Valvular Heart Disease
Congenital Heart Disease: Biventricular: Unspecified

Unknown
Congenital Heart Disease: Other - **If other, please complete textbox**
None

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,Procedure
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
Hybrid Repair
AP Shunt
ASD Repair
Damus Kaye Stansel (DKS)
Other, specify
If Other, specify: complete textbox.

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

Heart failure
Cardiac surgery
Non-cardiac medical problem
Non-cardiac surgery
VAD placement
TAH placement
Other cardiology
Acute MI
Unknown

If Non-Cardiac medical problem, then Check all that apply:

GI (nausea, vomiting, diarrhea)

Respiratory (SOB, wheezing, respiratory failure)
FTT
Lethargy
Other, specify
If Other, specify: complete textbox.

Did this patient test positive for COVID-19 prior to admission?
Yes, No, or Unknown

If yes, select all symptoms that apply:
Cough
Diarrhea
Fever
Anosmia (loss of sense of smell)
Sore Throat
Difficulty Breathing
None
Other, specify
If Other, specify: please complete text box.

If yes, select all Interventions that apply:
Intubation
New Inotropes
ECMO
Dialysis
RVAD
None
Other, specify
If Other, specify: please complete text box.

If yes, select all Therapies the Patient Received:
Hydroxychloroquine
Azithromycin
Immunoglobulin
Anti-viral Therapy, specify
If Anti-viral Therapy, specify: please complete text box.
None
Other, specify
If Other, specify: please complete text box.

Did this patient test positive for COVID-19 during this pre-implant admission?
Yes, No, or Unknown

If yes, select all symptoms that apply:
Cough
Diarrhea
Fever
Anosmia (loss of sense of smell)
Sore Throat
Difficulty Breathing
None
Other, specify
If Other, specify: please complete text box.

If yes, select all Interventions that apply:
Intubation

New Inotropes
ECMO
Dialysis
RVAD
None
Other, specify
If Other, specify: please complete text box.

If yes, select all Therapies the Patient Received:
Hydroxychloroquine
Azithromycin
Immunoglobulin
Anti-viral Therapy, specify
If Anti-viral Therapy, specify: please complete text box.
None
Other, specify
If Other, specify: please complete text box.

Clinical Events and Interventions this hospitalization (Pre-implant): Pertaining to this implant hospitalization select all events and interventions that occurred before the implant. For each event below, please check "Yes" if event/intervention occurred during this pre-implant hospitalization.

CABG
Aortic Valve replacement / repair
Mitral Valve replacement / repair
Congenital cardiac surgery
Other surgical procedures - **If other, please complete textbox**
IABP
ECMO
LVAD
RVAD
TAH
Dialysis
Ultrafiltration
Feeding Tube
Intubation
Major MI
Major infections / Positive blood cultures
Unknown
None
Escalation to CPAP
Arrhythmia
Previous ECMO
Previous heart transplant
Treatment of Rejection
Peritoneal Drain
Non-cardiac procedure
CardioMEMS
Mitraclip
TAVR

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,Procedure
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
Hybrid Repair
AP Shunt
ASD Repair
Damus Kaye Stansel (DKS)
Other, specify
If Other, specify: complete textbox.

Listing status at implant date: Select status. If Canadian center, select from Canadian options

1	1 (Canada)
2	2 (Canada)
3	3 (Canada)
4	3.5 (Canada)
5	4 (Canada)
6	4S (Canada)
7	
Not Listed	

Primary and secondary reasons for implant:

Primary Reason: Clinical manifestation of heart failure prompting VAD insertion according to the implanting physician (select primary reason):"

Decline in renal function
Decline in hepatic function
Decline in respiratory function
Refractory fluid retention/volume overload
Decline in cardiac output (by exam, mixed venous saturation, or cath)

prior to onset of worsening acidosis/lactate
Decline in nutrition/feeding intolerance, if so, (select all that apply):
- Emesis or inadequate calories (<70% prescribed) requiring enteral feeding tube placement
- Recurrent emesis with adequate caloric intake despite feeding tube placement
- Inadequate caloric intake (with or without emesis) despite feeding tube placement
- Requiring parenteral (IV) nutrition

Incessant severe sinus tachycardia
Worsening tachyarrhythmia
Other, please specify _____
Not reported

Secondary Reason(s): Clinical manifestations of heart failure prompting VAD insertion according to the implanting physician (select all other reasons that apply that are not the primary reason selected above):"

Decline in renal function
Decline in hepatic function
Decline in respiratory function
Refractory fluid retention/volume overload
Decline in cardiac output (by exam, mixed venous saturation, or cath) prior to onset of worsening acidosis/lactate
Decline in nutrition/feeding intolerance, if so, (select all that apply):
- Emesis or inadequate calories (<70% prescribed) requiring enteral feeding tube placement
- Recurrent emesis with adequate caloric intake despite feeding tube placement
- Inadequate caloric intake (with or without emesis) despite feeding tube placement
- Requiring parenteral (IV) nutrition

Incessant severe sinus tachycardia
Worsening tachyarrhythmia
Other, please specify _____
Not reported

Was IV inotrope or vasopressor therapy used 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 therapy agents: Select all that apply: 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
Vasopressin

Phenylephrine
Angiotensin II
Unknown
Other, specify - If selected please complete text box.

Nesiritide?
Yes, No, or Unknown

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

Please click on the link below to be taken to the Patient Profiles in **Appendix O**.
https://intermacs.kirso.net/pedimacs/pedimacs-documents/

Pedimacs Patient Profile at time of implant: Select one. These profiles will provide a *general* clinical description of the patients receiving 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 Pedimacs Patient Profiles are required at pre-implant and at all times when an implant occurs.

Pedimacs 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 hypo perfusion often confirmed by worsening acidosis and lactate levels. This patient can have modifier A or TCS (see 'Modifiers' below).

Pedimacs 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, hepatic function, respiratory function, fluid retention, tachyarrhythmia, 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 tachyarrhythmia, clinical ischemia, or other intolerance. This patient can have modifiers A or TCS.

Pedimacs 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.

Pedimacs 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 peripheral edema (extremity or facial). 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.

Pedimacs 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.

Pedimacs 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.

Pedimacs 7: "Advanced NYHA Class 3" or "Ross Class III" 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 Pedimacs 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 or 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, Rota flow**,** Tandem Heart, Levitronix, BVS 5000 or AB5000, Impella, Sorin Revolution, Biomedicus.

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 tachyarrhythmia or ICD shocks then the modifier to be applied to would be A, not FF.

Yes, No, or Unknown

Best Functional Capacity within 24 hours of implant:

Answer Yes/No for within 24 hours prior to MCSD implant

Paralyzed
- Yes, No, or Unknown

Intubated
- Yes, No, or Unknown

Ambulating
- Yes, No, Unknown, or Not Applicable

Primary Nutrition
- Orally
- Per feeding tube
- TPN
- Not Applicable

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

General Hemodynamics – closest to implant but not in OR

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

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

Ascites: 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 any of the following within 48 hrs prior to implant. 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

Systemic AV Valve Regurgitation: Systemic AV valve 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

Right AV Valve Regurgitation (Pulmonary): Right AV valve 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

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

Systemic Ventricle Systolic Function 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 EF 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 (mildly decreased)
30-39 (moderately decreased)
20-29 (moderately/severely decreased)
< 20 (severely decreased)
Not Obtained

If Systemic Ventricle EF not done then collect:
LVSF (Left ventricular shortening fraction): is a measure of contractility instead of ejection fraction, used largely in pediatrics. This does NOT need to be recorded if a left ventricular ejection fraction (LVEF) is available:

Normal
Mild
Moderate
Severe
Not Done or Not Available

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

Was there thrombus identified by ECHO? Enter Yes or No,
If **yes**- please (select all that apply):
RA – Right Atrium
RV – Right Ventricle
LA – Left Atrium
LV – Left Ventricle
SVC – Superior Vena Cava
IVC – Inferior Vena Cava
Unknown

Invasive Hemodynamics - closest to implant (within one month of implant)

Date of Measurement : _____ MMDDYYYY **ST=** Unknown or Not Done

Heart Rate: _____ beats per minute. **ST=** Unknown or Not Done

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

PVR: _____ **(wood units)** **ST=** Unknown or Not Done

Mean Pulmonary artery wedge pressure OR LVEDP: _____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/M^2. 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

Laboratory Values – closest to implant (or appropriate guidance)

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:	**Units(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
Total Cholesterol	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	$x10^3$/uL
	$x10^9$/uL
Reticulocyte count	%
Hemoglobin	g/dL
	g/L
	mmol/L
Platelets	$x10^3$/uL
	$x10^9$/uL
Hemoglobin A1c/Estimated Average Glucose (eAG)	%
	mmol/mol
	mg/dL
	mmol/L

INR	international units
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	%
	$x10^3$ cells/uL
	$x10^9$ cells/L
*If value is outside given range please see 'status (**ST=**)' drop down field If <2% select from the 'status' drop down field*	
Lupus anticoagulant	Positive, Negative, Unknown
Fibrinogen	Mg/dL
	g/L
*If value is outside given range please see 'status (**ST=**)' drop down field Select 'Higher than the Maximum' or 'Lower than the Minimum' as appropriate*	
Anti-Factor Xa	Units/mL
*If value is outside given range please see 'status (**ST=**)' drop down field Select 'Higher than the Maximum' or 'Lower than the Minimum' as appropriate*	
PTT	seconds
*If value is outside given range please see 'status (**ST=**)' drop down field Select 'Higher than the Maximum' or 'Lower than the Minimum' as appropriate*	

Concerns and Contraindications

Current Device Strategy:
Please check any condition below that are 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 **None**.

Concerns/Contraindications:	Is condition present?	If so, limitation for transplant listing?
Overall Status:		
Patient (family) does not want transplant	Yes/No	Yes/No
Musculoskeletal limitation to ambulation (includes skeletal myopathy)	Yes/No	Yes/No
Contraindication to immunosuppression	Yes/No	Yes/No
Allosensitization	Yes/No	Yes/No
Frailty	Yes/No	Yes/No
Chronic Renal Disease	Yes/No	Yes/No
History of dialysis dependent renal failure	Yes/No	Yes/No
History of neurological brain injury other than CVA	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.)		
Enter # of Sternotomies: _____		
Thoracic Aortic Disease	Yes/No	Yes/No
Tracheostomy	Yes/No	Yes/No
Plastic Bronchitis	Yes/No	Yes/No

Nutritional/GI/Genetics:

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
Anasarca	Yes/No	Yes/No
Protein Losing enteropathy	Yes/No	Yes/No
Genetic Syndrome	Yes/No	Yes/No

(Dropdown: Muscular Dystrophy
Down's syndrome
Noonan's
Other _____)

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: If patient is < 10 years old at time of implant, based on chart review of the patient, are these conditions present or absent.

Limited Cognition/Understanding	Yes/No/Unknown	Yes/No
Limited Social Support	Yes/No/Unknown	Yes/No
Repeated Noncompliance	Yes/No/Unknown	Yes/No
History of Illicit Drug Use	Yes/No/Unknown	Yes/No
History of Alcohol Abuse	Yes/No/Unknown	Yes/No
Narcotic Dependence	Yes/No/Unknown	Yes/No
History of Smoking	Yes/No/Unknown	Yes/No
Currently Smoking	Yes/No/Unknown	Yes/No
Severe Depression	Yes/No/Unknown	Yes/No
Other Major Psychiatric Diagnosis	Yes/No/Unknown	Yes/No
Neurological/developmental abnormalities	Yes/No/Unknown	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.

(CRP) or hs-CRP (C Reactive Protein): _____ 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.

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

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

Chronic Resynchronization Therapy (CRT)?

Yes No or Unknown

Antithrombotic

Unfractionated Heparin (aPTT/Anti-Xa) used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,

Enter **Unfractionated Heparin: Date Started** in MMDDYYYY format

ST= Unknown

Enter **aPTT or Anti-Xa**?

aPTT
Anti-Xa
Unknown

If **aPTT**,

Enter **aPTT: Lower Target** (in seconds)

ST = Unknown, or Lower than the Minimum

Enter **aPTT: Upper Target** (in seconds)
ST = Unknown, or Higher than the Maximum

If **Anti-Xa**,
Enter **Anti-Xa: Lower Target** (units/ml)
ST = Unknown, or Lower than the Minimum
Enter **Anti-Xa: Upper Target** (units/ml)
ST = Unknown, or Higher than the Maximum

Enter **Unfractionated Heparin: Date goal first achieved** in MMDDYYYY format
ST= Unknown

Low molecular weight Heparin (Lovenox, Fragmin, Innohep) - (Anti-factor Xa) used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Low molecular weight Heparin: Date Started** in MMDDYYYY format
ST= Unknown
Enter **Low molecular weight Heparin: Lower target** (IU/mL)
ST= Unknown, or Lower than the Minimum
Enter **Low molecular weight Heparin: Upper target** (IU/mL)
ST= Unknown, or Higher than the Maximum
Enter **Low molecular weight Heparin: Date goal first achieved** in MMDDYYYY format
ST= Unknown

Warfarin (INR) used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Warfarin: Date Started** in MMDDYYYY format
ST= Unknown
Enter **Warfarin: Lower target**
ST= Unknown, or Lower than the Minimum
Enter **Warfarin: Upper target**
ST= Unknown, or Higher than the Maximum
Enter **Warfarin: Date goal first achieved** in MMDDYYYY format
ST= Unknown

Argatroban (aPTT) used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Argatroban: Date Started** in MMDDYYYY format
ST= Unknown
Enter **Argatroban: Lower target** (in seconds)
ST= Unknown, or Lower than the Minimum
Enter **Argatroban: Upper target** (in seconds)
ST= Unknown, or Higher than the Maximum
Enter **Argatroban: Date goal first achieved** in MMDDYYYY format
ST= Unknown

Bivalirudin (aPTT) used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Bivalirudin: Date Started** in MMDDYYYY format
ST= Unknown

Enter **Bivalirudin: Lower target** (in seconds)
ST= Unknown, or Lower than the Minimum
Enter **Bivalirudin: Upper target** (in seconds)
ST= Unknown, or Higher than the Maximum
Enter **Bivalirudin: Date goal first achieved** in MMDDYYYY format
ST= Unknown

Aspirin used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Aspirin: Date Started** in MMDDYYYY format
ST= Unknown

Dipyridamole used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Dipyridamole: Date Started** in MMDDYYYY format
ST= Unknown

Clopidogrel used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Clopidogrel: Date Started** in MMDDYYYY format
ST= Unknown

Other antithrombotic medication used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Other antithrombotic medication: Name**
Enter **Other antithrombotic medication: Date Started** in MMDDYYYY format
ST= Unknown
Enter **Other antithrombotic medication: Lab Test Name**
Enter **Other antithrombotic medication: Lower target**
ST= Unknown, or Lower than the Minimum
Enter **Other antithrombotic medication: Upper target**
ST= Unknown, or Higher than the Maximum
Enter **Other antithrombotic medication: Date goal first achieved** in MMDDYYYY format
ST= Unknown

Quality of Life (PedsQL)

Please See the **PedsQL** and **VADQoL** section of the Data Dictionary for further instructions on administration and web-based data entry for the **PedsQL and VADQoL** (Section 2.14).

Exercise Function

EXERCISE FUNCTION

All patients ≥ 10 yrs. of age at time of implant 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.
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", "Not Done: Too Sick", "Not Done: Other", "Not Done: Age Inappropriate", or "Not Done: Patient Refused to Walk" 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, Not Done: Other, Not Done: Too sick**, **Not Done: Age Inappropriate, Not Done: Patient Refused to Walk**.

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, Not Done: Other, Not Done: Too sick**, **Not Done: Age Inappropriate**.

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= Not Done, Not Done: Other, Not Done: Too sick**, **Not Done: Age Inappropriate**.

MEDICAL CONDITION

NYHA Class: New York Heart Association Class for heart failure:
NOTE: If classification is defined as a range (i.e. 2 to 3) select the higher classification.

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

Ross Classification of Congestive Heart Failure (patient < 2 yrs of age):

If Ross Class I: No limitations or symptoms.

If Ross Class II: No growth failure. If selected, choose all indicated symptoms that apply.

- Mild tachypnea with feeds in infant
- Mild diaphoresis with feeds in infant
- Dyspnea on exercise in older children
- Unknown

If Ross Class III: Growth failure. If selected, choose all indicated symptoms that apply.

- Marked tachypnea with exertion or with feeding
- Marked diaphoresis with exertion or with feeding
- Unknown

If Ross Class IV: Symptomatic at rest. If selected, choose all indicated symptoms that apply.

- Tachypnea
- Retractions
- Grunting
- Diaphoresis
- Unknown

Not Applicable: >=2 years of age

Unknown

If the User is unfamiliar with using the ROSS Classification, apply the following steps: Click on the drop down list for Ross Classification choosing Ross Class IV (Symptomatic at rest). A check list of symptoms will appear below the drop down choice selected. Review this check list and if any of these symptoms apply, select all that apply to the patient. If these symptoms do not apply to the patient click again on the Ross Classification drop down and choose another classification (Ross Class III (growth failure). A different set of symptom check list will appear. If these symptoms still do not apply to the patient, then go back to the Ross Classification drop down and select Ross Class II (no growth failure) and review this set of symptom check lists. If these symptoms do not apply to the patient, these select Ross Class I (No limitations or symptoms. If the Ross Classification is unknown then select 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 with what was taken from the Screening Log (See Section 2.1). If this element's value is not correct, please contact your STS INTERMACS / STS Pedimacs Nurse Monitor.

LVAD (Left Ventricular Assist Device: Systemic Support)
RVAD (Right Ventricular Assist Device: Pulmonic Support)
Both (LVAD+RVAD in the same OR visit)
Total Artificial Heart
NOTE: If this is a single ventricle patient, please select LVAD as the device type

Device Brand : This element's value will automatically appear with what 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 (STS Pedimacs)** (Brand Device Table) if you have questions or are unsure as to which devices should and should not be included into STS Pedimacs. **Appendix K** is available on https://intermacs.kirso.net/pedimacs/pedimacs-documents/

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

Inflow Cannula Size: _____ mm **ST=** 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

Outflow Cannula Size: _____ mm. **ST=** Unknown

Pump Size: Select one of the following for Pump Size

10 cc
25 cc
30 cc
50 cc
60 cc

80cc
N/A

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

Inflow Cannula Size: _____ mm **ST=** Unknown

Outflow Cannula Location: Select one of the following for RVAD cannula outflow location.
MPA (main pulmonary artery)
LPA (left pulmonary artery)
Conduit
Other, Specify - If Other Specify: Textbox

Outflow Cannula Size: _____ mm **ST=** Unknown

Pump Size: Select one of the following for Pump Size
10 cc
25 cc
30 cc
50 cc
60 cc
80cc
N/A

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
Mechanical Valve
Mitral Valve
Aortic Valve
Tricuspid Valve
None

Was the patient on any other form of mechanical support when entering operating room? (select all that apply):
None
LVAD – Durable
LVAD – Temporary
RVAD – Durable

RVAD – Temporary
TAH
ECMO
IABP
Unknown
Other, Specify
If Other, Specify: Textbox

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
Thrombectomy
Other, specify
If Other, Specify: Textbox

Did patient have **Fever within 7 days prior to implant** Yes, No, or Unknown
If **yes** enter **number of days:** prior to implant.
ST = Unknown .

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.

Cross Clamp used: Yes, No, or Unknown
If **yes** enter total cross CCT **clamp time** in minutes: _____(min).
ST = Unknown or Not done.

Was circulatory arrest required? Yes/No
If **yes**, _____minutes. **ST=** Unknown

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

2.5 1 Week and 1 Month Follow-up

The data on this form are **collected** at the following time periods post implant:
1 week (+/- 3 days) post-implant
1 month (+/- 7 days) post implant
When doing medical chart abstraction, please use clinic visit closest to or on the visit date. If data from multiple dates are available before and after the visit, with the same number of days from visit, use data prior to the visit

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
Telehealth Consultation (complete follow-up form)

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.**

Enter patient's home **Street Address**. **ST**= Unknown

Enter patient's home **City**. **ST**= Unknown

Patient's home **State, Territory, Province**. Select from dropdown, if not known, select **Unknown**.

Enter patient's home **Zip Code**. **ST**= Unknown

Was the patient intubated since implant? This includes all time since last follow-up. This excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures.
Yes, No, or Unknown

Was the patient on dialysis since implant? This includes all time since last follow-up.
Yes, No, or Unknown

Since the last follow-up has the patient tested positive for COVID-19?
Yes, No, or Unknown

If yes, select all symptoms that apply:

Cough
Diarrhea
Fever
Anosmia (loss of sense of smell)
Sore Throat
Difficulty Breathing
None
Other, specify
If Other, specify: please complete text box.

If yes, select all Interventions that apply:

Intubation
New Inotropes
ECMO
Dialysis
RVAD
None
Other, specify
If Other, specify: please complete text box.

If yes, select all Therapies the Patient Received:

Hydroxychloroquine
Azithromycin
Immunoglobulin
Anti-viral Therapy, specify
If Anti-viral Therapy, specify: please complete text box.
None
Other, specify
If Other, specify: please complete text box.

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

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:
NOTE: If classification is defined as a range (i.e. 2 to 3) select the higher classification.

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

Ross Classification of Congestive Heart Failure (patient < 2 yrs of age):

If Ross Class I: No limitations or symptoms.

If Ross Class II: No growth failure. If selected, choose all indicated symptoms that apply.

- Mild tachypnea with feeds in infant
- Mild diaphoresis with feeds in infant
- Dyspnea on exercise in older children
- Unknown

If Ross Class III: Growth failure. If selected, choose all indicated symptoms that apply.

- Marked tachypnea with exertion or with feeding
- Marked diaphoresis with exertion or with feeding
- Unknown

If Ross Class IV: Symptomatic at rest. If selected, choose all indicated symptoms that apply.

- Tachypnea
- Retractions
- Grunting
- Diaphoresis
- Unknown

Not Applicable: >=2 years of age

Unknown

If the User is unfamiliar with using the ROSS Classification, apply the following steps:
Click on the drop down list for Ross Classification choosing Ross Class IV (Symptomatic at rest). A check list of symptoms will appear below the drop down choice selected. Review this check list and if any of these symptoms apply, select all that apply to the patient. If these symptoms do not apply to the patient click again on the Ross Classification drop down and choose another classification (Ross Class III (growth failure). A different set of symptom check list will appear. If these symptoms still do not apply to the patient, then go back to the Ross Classification drop down and select Ross Class II (no growth failure) and review this set of symptom check lists. If these symptoms do not apply to the patient, these select Ross Class I (No limitations or symptoms. If the Ross Classification is unknown then select Unknown.

FUNCTIONAL CAPACITY - for follow-up time period (Answer Yes or No)

Sedated
- Yes, No, or Unknown

Paralyzed
- Yes, No, or Unknown

Intubated (this excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures.)
- Yes, No, or Unknown

Ambulating
- Yes, No, Unknown, or Not Applicable

Primary Nutrition
- Orally
- Per feeding tube
- TPN
- Not Applicable

EXCURSIONS

Has the patient had any non-medically required excursions off the unit?

Yes, No, Unknown, or Not Applicable
If **so**, where (please select all that apply)
- Playroom
- Cafeteria
- Walk outside
- Sitting room
- General rehab
- None

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, or Unknown
Pump malfunction and/or abnormal pump parameters?
Yes, No, or 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, or Unknown

Has the patient been on Inotropes since the last Follow-Up visit?
Yes, No, or Unknown
If **yes,** select all that apply:
Dopamine
Dobutamine
Milrinone
Isoproterenol
Epinephrine
Norepinephrine
Levosimendan
Vasopressin
Phenylephrine
Angiotensin II
Unknown
Other, specify - If selected please complete text box.

Nesiritide?
Yes, No, or Unknown

Has the patient had a RVAD implant since the last Follow-Up visit?
Yes, No, or Unknown

Please click on the link below for further instruction on administering the Modified Rankin Scale in **Appendix I**.
https://intermacs.kirso.net/pedimacs/pedimacs-documents/

Has the patient experienced a Neurological Event since time of implant?
Yes, No, or Unknown

Note: Modified Rankin Scale will NOT be administered for children < 2 years of age at time of implant.

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 Pedimacs 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

Hemodynamics

Data may be entered that was collected/performed from the last time the patient was seen for follow-up to the current visit date.

General Hemodynamics

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

Mean Arterial Blood Pressure (MAP): mmHg (millimeters of mercury). **ST=** Unknown or Not Done

ECG rhythm (cardiac rhythm): Select **any** 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

Height: Enter the height of the patient at the time of follow-up in inches or centimeters. The height must fall between 10 and 80 inches or 25 and 203 centimeters. **ST=** Unknown or Not Done

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 3 and 450 pounds or 2 and 205 kilograms. **ST=** Unknown or Not Done

Invasive Hemodynamics

Date of Measurement:_____ Enter the date the invasive hemodynamic measurements were taken. **ST=** Unknown or Not Done

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

PVR: _____ **wood units** **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/M^2. 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

Please answer all questions regarding patient status as of the day of follow-up.

Medications

Was the patient sent home with an IV?
Yes, No, or Unknown

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

List of medications
ACE inhibitors
Aldosterone antagonist
Amiodarone
Angiotensin receptor blocker drug
Beta-blockers
Calcium channel blockers
Digoxin
Hydralazine
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
- Bumetanide
- Torsemide
- Other

Nitric Oxide (document Flolan here)
Sildenafil/ Bosentan
Arixtra (Fondaparinux)

Did patient receive new IV or oral medication to treat hypertension?
Yes, No, or Unknown

TRANSFUSION

Was there a transfusion? **Yes**, **No, Unknown.**
If **yes**, enter number of PRBC (ml/kg): ____ cc **ST**= Unknown

Antithrombotic

Unfractionated Heparin (aPTT/Anti-Xa) used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Unfractionated Heparin: Date Started** in MMDDYYYY format
ST= Unknown
Enter **aPTT or Anti-Xa**?
aPTT
Anti-Xa
Unknown
If **aPTT**,
Enter **aPTT: Lower Target** (in seconds)
ST = Unknown, or Lower than the Minimum
Enter **aPTT: Upper Target** (in seconds)
ST = Unknown, or Higher than the Maximum
If **Anti-Xa**,
Enter **Anti-Xa: Lower Target** (units/ml)
ST = Unknown, or Lower than the Minimum
Enter **Anti-Xa: Upper Target** (units/ml)
ST = Unknown, or Higher than the Maximum
Enter **Unfractionated Heparin: Date goal first achieved** in MMDDYYYY format
ST= Unknown

Low molecular weight Heparin (Lovenox, Fragmin, Innohep) - (Anti-factor Xa) used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Low molecular weight Heparin: Date Started** in MMDDYYYY format
ST= Unknown
Enter **Low molecular weight Heparin: Lower target** (IU/mL)
ST= Unknown, or Lower than the Minimum
Enter **Low molecular weight Heparin: Upper target** (IU/mL)
ST= Unknown, or Higher than the Maximum

Enter **Low molecular weight Heparin: Date goal first achieved** in MMDDYYYY format

ST= Unknown

Warfarin (INR) used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,

Enter **Warfarin: Date Started** in MMDDYYYY format

ST= Unknown

Enter **Warfarin: Lower target**

ST= Unknown, or Lower than the Minimum

Enter **Warfarin: Upper target**

ST= Unknown, or Higher than the Maximum

Enter **Warfarin: Date goal first achieved** in MMDDYYYY format

ST= Unknown

Argatroban (aPTT) used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,

Enter **Argatroban: Date Started** in MMDDYYYY format

ST= Unknown

Enter **Argatroban: Lower target** (in seconds)

ST= Unknown, or Lower than the Minimum

Enter **Argatroban: Upper target** (in seconds)

ST= Unknown, or Higher than the Maximum

Enter **Argatroban: Date goal first achieved** in MMDDYYYY format

ST= Unknown

Bivalirudin (aPTT) used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,

Enter **Bivalirudin: Date Started** in MMDDYYYY format

ST= Unknown

Enter **Bivalirudin: Lower target** (in seconds)

ST= Unknown, or Lower than the Minimum

Enter **Bivalirudin: Upper target** (in seconds)

ST= Unknown, or Higher than the Maximum

Enter **Bivalirudin: Date goal first achieved** in MMDDYYYY format

ST= Unknown

Aspirin used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,

Enter **Aspirin: Date Started** in MMDDYYYY format

ST= Unknown

Dipyridamole used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,

Enter **Dipyridamole: Date Started** in MMDDYYYY format

ST= Unknown

Clopidogrel used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,
Enter **Clopidogrel: Date Started** in MMDDYYYY format
ST= Unknown

Thrombolytic used? (Streptokinase, Alteplase [tPA], Reteplase [rPA], Tenecteplase [TNK-tPA], Lanoteplase[nPA], Anistreplase [APSAC], Urokinase) – Select **Yes**, **No**, or **Unknown**

Other antithrombotic medication used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Other antithrombotic medication: Name**
Enter **Other antithrombotic medication: Date Started** in MMDDYYYY format
ST= Unknown
Enter **Other antithrombotic medication: Lab Test Name**
Enter **Other antithrombotic medication: Lower target**
ST= Unknown, or Lower than the Minimum
Enter **Other antithrombotic medication: Upper target**
ST= Unknown, or Higher than the Maximum
Enter **Other antithrombotic medication: Date goal first achieved** in MMDDYYYY format
ST= Unknown

Laboratory Values

Collect laboratory values closest to the follow-up time period (as specified at beginning of this form). If data from multiple dates are available before and after the visit, with the same number of days from visit, use data prior to the visit. For all of the tests listed below, give the appropriate measurement.
ST= Unknown or Not Done

Laboratory Value:	Units(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
Total Cholesterol	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	$x10^3$/uL
	$x10^9$/uL
Reticulocyte count	%
Hemoglobin	g/dL
	g/L
	mmol/L
Platelets	$x10^3$/uL
	$x10^9$/uL
Hemoglobin A1c/Estimated Average Glucose (eAG)	%
	mmol/mol
	mg/dL

	mmol/L
INR	international units
Plasma-free Hemoglobin	mg/dL
	g/L
	<30 mg/dL
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) Plavix Heparin Coumadin Direct thrombin inhibitors (ex: arg, lip, val…) Aspirin Dipyridamole	
Was TEG Done?	Yes, No, Unknown
If **Yes**, ThrombElastoGraph Hemostasis System (TEG) profile, MA k	
If **Yes**, ThrombElastoGraph Hemostasis System (TEG) profile, R k	
If **Yes**, ThrombElastoGraph Hemostasis System (TEG) profile, R h	
CRP or hs-CRP (C Reactive Protein)	mg/L
Lupus anticoagulant	Positive, Negative, Unknown
Fibrinogen	Mg/dL
	g/L
*If value is outside given range please see 'status (**ST**=)' drop down field* *Select 'Higher than the Maximum' or 'Lower than the Minimum' as appropriate*	
Anti-Factor Xa	Units/mL
*If value is outside given range please see 'status (**ST**=)' drop down field* *Select 'Higher than the Maximum' or 'Lower than the Minimum' as appropriate*	
PTT	seconds
*If value is outside given range please see 'status (**ST**=)' drop down field* *Select 'Higher than the Maximum' or 'Lower than the Minimum' as appropriate*	

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**
- **Major Bleeding**
- **Neurological Dysfunction**
- **Device Malfunction** (if suspected device thrombosis, then enter as Device Malfunction)
- **Extracorporeal/Paracorporeal Pump Change**
- **Cardiac Arrhythmia**
- **Pericardial Fluid Collection**
- **Hepatic Dysfunction**
- **Myocardial Infarction**
- **Psychiatric Episode**
- **Renal Dysfunction**
- **Respiratory Failure**
- **Arterial Non-CNS Thromboembolism**
- **Venous Thromboembolic Event**
- **Wound Dehiscence**
- **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**.
https://intermacs.kirso.net/pedimacs/pedimacs-documents/

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 or on the visit date. If data from multiple dates are available before and after the visit, with the same number of days from visit, use data prior to the visit

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
Telehealth Consultation (complete follow-up form)

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.**

Enter patient's home **Street Address**. **ST**= Unknown

Enter patient's home **City**. **ST**= Unknown

Patient's home **State, Territory, Province**. Select from dropdown, if not known, select **Unknown**.

Enter patient's home **Zip Code**. **ST**= Unknown

Was the patient intubated since implant? This includes all time since last follow-up. This excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures.
Yes, No, or Unknown

Was the patient on dialysis since implant? 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 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 device to allow recovery from chronic cardiac failure (at least 3 months in duration)

Rescue therapy - Use of a 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

Bridge to Decision

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.

Since the last follow-up has the patient tested positive for COVID-19?
Yes, No, or Unknown

If yes, select all symptoms that apply:
Cough
Diarrhea
Fever
Anosmia (loss of sense of smell)
Sore Throat
Difficulty Breathing
None
Other, specify
If Other, specify: please complete text box.

If yes, select all Interventions that apply:
Intubation
New Inotropes
ECMO
Dialysis
RVAD
None
Other, specify
If Other, specify: please complete text box.

If yes, select all Therapies the Patient Received:

Hydroxychloroquine
Azithromycin
Immunoglobulin
Anti-viral Therapy, specify
If Anti-viral Therapy, specify: please complete text box.
None
Other, specify
If Other, specify: please complete text box.

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

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.

FUNCTIONAL CAPACITY - for follow-up time period (Answer Yes or No)

Sedated
Yes, No, or Unknown

Paralyzed
Yes, No, or Unknown

Intubated (this excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures.)
Yes, No, or Unknown

Ambulating
Yes, No, Unknown, or Not Applicable

Primary Nutrition
Orally
Per feeding tube
TPN
Not Applicable

EXCURSIONS

Has the patient had any non-medically required excursions off the unit?

Yes, No, Unknown, or Not Applicable

If **so**, where (please select all that apply)
Playroom
Cafeteria
Walk outside
Sitting room
General rehab
None

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, or Unknown

Pump malfunction and/or abnormal pump parameters?
Yes, No, or 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, or Unknown

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

Yes, No, or Unknown

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

Dopamine
Dobutamine
Milrinone
Isoproterenol
Epinephrine
Norepinephrine
Levosimendan
Vasopressin
Phenylephrine
Angiotensin II
Unknown
Other, specify - If selected please complete text box.

Nesiritide?

Yes, No, or Unknown

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

Yes, No, or Unknown

Please click on the link below for further instruction on administering the Modified Rankin Scale in **Appendix I**.
https://intermacs.kirso.net/pedimacs/pedimacs-documents/

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

Yes, No, Unknown

Note: Modified Rankin Scale will NOT be administered for children < 2 years of age at time of implant.

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 Pedimacs 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

Hemodynamics

Data may be entered that was collected/performed from the last time the patient was seen for follow-up to the current visit date.

General Hemodynamics

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 .

Mean Arterial Blood Pressure (MAP): mmHg (millimeters of mercury). **ST=** Unknown or Not Done

ECG rhythm (cardiac rhythm): Select **any** 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

Height: Enter the height of the patient at the time of follow-up in inches or centimeters. The height must fall between 10 and 80 inches or 25 and 203 centimeters. **ST=** Unknown or Not Done

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 3 and 450 pounds or 2 and 205 kilograms. **ST=** Unknown or Not Done

Invasive Hemodynamics

Date of Measurement : _____ MMDDYYYY **ST=** Unknown or Not Done

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

PVR: _____ **wood units** **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/M^2. 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

Please answer all questions regarding patient status as of the day of follow-up.

Medications

Was the patient sent home with an IV?
Yes, No, or Unknown

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

List of medications
ACE inhibitors
Aldosterone antagonist
Amiodarone
Angiotensin receptor blocker drug
Beta-blockers
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
Bumetanide
Torsemide
Other
Nitric Oxide (document Flolan here)
Sildenafil/ Bosentan
Arixtra (Fondaparinux)

Did patient receive new IV or oral medication to treat hypertension? **Yes, No,** or **Unknown.**
Yes, No, or Unknown

TRANSFUSION - Please answer all questions regarding patient status considering all time since previous visit and current follow-up date.

Was there a transfusion? **Yes**, **No, Unknown.**
If **yes**, enter number of PRBC (ml/kg): _____ cc **ST**= Unknown

Antithrombotic

Unfractionated Heparin (aPTT/Anti-Xa) used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Unfractionated Heparin: Date Started** in MMDDYYYY format
ST= Unknown
Enter **aPTT or Anti-Xa**?
aPTT
Anti-Xa
Unknown
If **aPTT**,
Enter **aPTT: Lower Target** (in seconds)
ST = Unknown, or Lower than the Minimum
Enter **aPTT: Upper Target** (in seconds)
ST = Unknown, or Higher than the Maximum
If **Anti-Xa**,
Enter **Anti-Xa: Lower Target** (units/ml)
ST = Unknown, or Lower than the Minimum
Enter **Anti-Xa: Upper Target** (units/ml)
ST = Unknown, or Higher than the Maximum
Enter **Unfractionated Heparin: Date goal first achieved** in MMDDYYYY format
ST= Unknown

Low molecular weight Heparin (Lovenox, Fragmin, Innohep) - (Anti-factor Xa) used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Low molecular weight Heparin: Date Started** in MMDDYYYY format
ST= Unknown
Enter **Low molecular weight Heparin: Lower target** (IU/mL)
ST= Unknown, or Lower than the Minimum
Enter **Low molecular weight Heparin: Upper target** (IU/mL)
ST= Unknown, or Higher than the Maximum
Enter **Low molecular weight Heparin: Date goal first achieved** in MMDDYYYY format
ST= Unknown

Warfarin (INR) used? – Select **Yes**, **No**, or **Unknown**.
If **Yes**,
Enter **Warfarin: Date Started** in MMDDYYYY format
ST= Unknown
Enter **Warfarin: Lower target**
ST= Unknown, or Lower than the Minimum
Enter **Warfarin: Upper target**

ST= Unknown, or Higher than the Maximum

Enter **Warfarin: Date goal first achieved** in MMDDYYYY format

ST= Unknown

Argatroban (aPTT) used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,

Enter **Argatroban: Date Started** in MMDDYYYY format

ST= Unknown

Enter **Argatroban: Lower target** (in seconds)

ST= Unknown, or Lower than the Minimum

Enter **Argatroban: Upper target** (in seconds)

ST= Unknown, or Higher than the Maximum

Enter **Argatroban: Date goal first achieved** in MMDDYYYY format

ST= Unknown

Bivalirudin (aPTT) used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,

Enter **Bivalirudin: Date Started** in MMDDYYYY format

ST= Unknown

Enter **Bivalirudin: Lower target** (in seconds)

ST= Unknown, or Lower than the Minimum

Enter **Bivalirudin: Upper target** (in seconds)

ST= Unknown, or Higher than the Maximum

Enter **Bivalirudin: Date goal first achieved** in MMDDYYYY format

ST= Unknown

Aspirin used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,

Enter **Aspirin: Date Started** in MMDDYYYY format

ST= Unknown

Dipyridamole used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,

Enter **Dipyridamole: Date Started** in MMDDYYYY format

ST= Unknown

Clopidogrel used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,

Enter **Clopidogrel: Date Started** in MMDDYYYY format

ST= Unknown

Thrombolytic used? (Streptokinase, Alteplase [tPA], Reteplase [rPA], Tenecteplase [TNK-tPA], Lanoteplase[nPA], Anistreplase [APSAC], Urokinase) – Select **Yes**, **No**, or **Unknown**

Other antithrombotic medication used? – Select **Yes**, **No**, or **Unknown**.

If **Yes**,

Enter **Other antithrombotic medication: Name**

Enter **Other antithrombotic medication: Date Started** in MMDDYYYY format
ST= Unknown
Enter **Other antithrombotic medication: Lab Test Name**
Enter **Other antithrombotic medication: Lower target**
ST= Unknown, or Lower than the Minimum
Enter **Other antithrombotic medication: Upper target**
ST= Unknown, or Higher than the Maximum
Enter **Other antithrombotic medication: Date goal first achieved** in MMDDYYYY format
ST= Unknown

Laboratory Values

Collect laboratory values closest to the follow-up time period (as specified at beginning of this form). If data from multiple dates are available before and after the visit, with the same number of days from visit, use data prior to the visit. For all of the tests listed below, give the appropriate measurement.
ST= Unknown or Not Done

Laboratory Value:	Units(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
Total Cholesterol	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	$x10^3$/uL
	$x10^9$/uL
Reticulocyte count	%
Hemoglobin	g/dL
	g/L
	mmol/L
Platelets	$x10^3$/uL
	$x10^9$/uL
Hemoglobin A1c/Estimated Average Glucose (eAG)	%
	mmol/mol
	mg/dL
	mmol/L
INR	international units
Plasma-free Hemoglobin	mg/dL
	g/L
	<30 mg/dL
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) Plavix Heparin Coumadin Direct thrombin inhibitors (ex: arg, lip, val…) Aspirin Dipyridamole	
Was TEG Done?	Yes, No, Unknown
If **Yes**, ThrombElastoGraph Hemostasis System (TEG) profile, MA k	
If **Yes**, ThrombElastoGraph Hemostasis System (TEG) profile, R k	
If **Yes**, ThrombElastoGraph Hemostasis System (TEG) profile, R h	
CRP or hs-CRP (C Reactive Protein)	mg/L
Lupus anticoagulant	Positive, Negative, Unknown
Fibrinogen	Mg/dL
	g/L
*If value is outside given range please see 'status (**ST**=)' drop down field* *Select 'Higher than the Maximum' or 'Lower than the Minimum' as appropriate*	
Anti-Factor Xa	Units/mL
*If value is outside given range please see 'status (**ST**=)' drop down field* *Select 'Higher than the Maximum' or 'Lower than the Minimum' as appropriate*	
PTT	seconds
*If value is outside given range please see 'status (**ST**=)' drop down field* *Select 'Higher than the Maximum' or 'Lower than the Minimum' as appropriate*	

Device Details

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

DEVICE FUNCTION

Pump Flow: _____LPM. **ST=** Unknown

Pulsatility Index: _____. **ST=** Unknown

Pump Power: _____ Watts. **ST=** Unknown

Driver Type (TAH only): _____. **ST=** Unknown

DEVICE PARAMETERS

Control Mode: Please specify control mode.

Fixed
Auto
Async/Fixed
Synchronous
Asynchronous
Independent
Fill-Rate
Fixed-Rate
Normal
Weaning
External
Volume/Auto
Not Applicable

Pump Speed: _____RPM. **ST=** Unknown

Low Speed: _____RPM. **ST=** Unknown

DEVICE INSPECTION

Auscultation: Please choose an option for auscultation.

Normal
Abnormal
Not Applicable

Driveline: Please choose an option for the driveline appearance.

Normal
Abnormal
Not Applicable

Exercise Function

EXERCISE FUNCTION

All patients ≥ 10 yrs. of age at time of implant 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.
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", "Not Done: Too Sick" or "Not Done: Other", "Not Done: Age Inappropriate", or "Not Done: Patient Refused to Walk" 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, Not Done: Other, Not Done: Too sick**, **Not Done: Age Inappropriate, Not Done: Patient Refused to Walk**.

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, Not Done: Other, Not Done: Too sick**, **Not Done: Age Inappropriate**.

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= Not Done, Not Done: Other, Not Done: Too sick**, **Not Done: Age Inappropriate**.

MEDICAL CONDITION

NYHA Class: New York Heart Association Class for heart failure:
NOTE: If classification is defined as a range (i.e. 2 to 3) select the higher classification.

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

If patient was discharged, has patient been rehospitalized since implant hospitalization?:
Yes, No, Unknown

If patient has had a rehospitalization, please capture in the WBDE system.

Ross Classification of Congestive Heart Failure (patient < 2 yrs of age):

If Ross Class I: No limitations or symptoms.

If Ross Class II: No growth failure. If selected, choose all indicated symptoms that apply.
- Mild tachypnea with feeds in infant
- Mild diaphoresis with feeds in infant
- Dyspnea on exercise in older children
- Unknown

If Ross Class III: Growth failure. If selected, choose all indicated symptoms that apply.
- Marked tachypnea with exertion or with feeding
- Marked diaphoresis with exertion or with feeding
- Unknown

If Ross Class IV: Symptomatic at rest. If selected, choose all indicated symptoms that apply.
- Tachypnea
- Retractions
- Grunting
- Diaphoresis
- Unknown

Not Applicable: >=2 years of age

Unknown

If the User is unfamiliar with using the ROSS Classification, apply the following steps:
Click on the drop down list for Ross Classification choosing Ross Class IV (Symptomatic at rest). A check list of symptoms will appear below the drop down choice selected. Review this check list and if any of these symptoms apply, select all that apply to the patient. If these symptoms do not apply to the patient click again on the Ross Classification drop down and choose another classification (Ross Class III (growth failure). A different set of symptom check list will appear. If these symptoms still do not apply to the patient, then go back to the Ross Classification drop down and select Ross Class II (no growth failure) and review this set of symptom check lists. If these symptoms do not apply to the patient, these select Ross Class I (No limitations or symptoms. If the Ross Classification is unknown then select Unknown.

Concerns and Contraindications

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.

Concerns/Contraindications:	Is condition present?	If so, limitation for transplant listing?
Overall Status:		
Patient (family) does not want transplant	Yes/No	Yes/No
Musculoskeletal limitation to ambulation (includes skeletal myopathy)	Yes/No	Yes/No
Contraindication to immunosuppression	Yes/No	Yes/No
Allosensitization	Yes/No	Yes/No
Frailty	Yes/No	Yes/No
Chronic Renal Disease	Yes/No	Yes/No
History of dialysis dependent renal failure	Yes/No	Yes/No
History of neurological brain injury other than CVA	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 (includes sternotomies, sternal resection, radiation, flail chest, etc.) Enter # of Sternotomies: _____	Yes/No	Yes/No
Thoracic Aortic Disease	Yes/No	Yes/No
Tracheostomy	Yes/No	Yes/No
Plastic Bronchitis	Yes/No	Yes/No
Nutritional/GI/Genetics:		
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
Anasarca	Yes/No	Yes/No
Protein Losing enteropathy	Yes/No	Yes/No
Genetic Syndrome (Dropdown: Muscular Dystrophy, Down's syndrome, Noonan's, Other _____)	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: If patient is < 10 years old at time of implant, based on chart review of the patient, are these conditions present or absent.

Limited Cognition/Understanding	Yes/No/Unknown	Yes/No
Limited Social Support	Yes/No/Unknown	Yes/No
Repeated Noncompliance	Yes/No/Unknown	Yes/No
History of Illicit Drug Use	Yes/No/Unknown	Yes/No
History of Alcohol Abuse	Yes/No/Unknown	Yes/No
Narcotic Dependence	Yes/No/Unknown	Yes/No
History of Smoking	Yes/No/Unknown	Yes/No
Currently Smoking	Yes/No/Unknown	Yes/No
Severe Depression	Yes/No/Unknown	Yes/No
Other Major Psychiatric Diagnosis	Yes/No/Unknown	Yes/No
Neurological/developmental abnormalities	Yes/No/Unknown	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.

(CRP) or hs-CRP (C Reactive Protein): _____ 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 (PedsQL and VADQoL)

Please See the **PedsQL** and **VADQoL** section of the Data Dictionary for further instructions on administration and web-based data entry for the **PedsQL** and **VADQoL** (Section 2.14).

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**
- **Major Bleeding**
- **Neurological Dysfunction**
- **Device Malfunction** (if suspected device thrombosis, then enter as Device Malfunction)
- **Extracorporeal/Paracorporeal Pump Change**
- **Cardiac Arrhythmia**
- **Pericardial Fluid Collection**
- **Hepatic Dysfunction**
- **Myocardial Infarction**
- **Psychiatric Episode**
- **Renal Dysfunction**
- **Respiratory Failure**
- **Arterial Non-CNS Thromboembolism**
- **Venous Thromboembolic Event**
- **Wound Dehiscence**
- **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**.
https://intermacs.kirso.net/pedimacs/pedimacs-documents/

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 dies during the implant hospitalization. The date of death is considered to be the date of discharge.**
- **Patient receives a transplant during the implant hospitalization. The date of transplant will be considered 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.**

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

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. 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 dies during the implant hospitalization. The date of death is considered to be the date of discharge. Complete Death Form.
- Patient receives a transplant during the implant hospitalization. The date of transplant will be considered 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.

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

Date of extubation: Select the approximate time when patient was extubated below:

- < 1 week
- 1-2 weeks
- 2-4 weeks
- > 4 weeks
- Ongoing
- Unknown

Since the VAD implant date has the patient tested positive for COVID-19?

Yes, No, or Unknown

If yes, select all symptoms that apply:

- Cough
- Diarrhea
- Fever
- Anosmia (loss of sense of smell)
- Sore Throat
- Difficulty Breathing
- None
- Other, specify
  - **If Other, specify: please complete text box.**

If yes, select all Interventions that apply:

- Intubation
- New Inotropes
- ECMO
- Dialysis
- RVAD
- None
- Other, specify
  - **If Other, specify: please complete text box.**

If yes, select all Therapies the Patient Received:

- Hydroxychloroquine
- Azithromycin

Immunoglobulin
Anti-viral Therapy, specify
If Anti-viral Therapy, specify: please complete text box.
None
Other, specify
If Other, specify: please complete text box.

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

None
Transplant
Invasive Cardiac Procedures (Other than Heart Cath)
Unknown

Surgical Procedures:

Device related operation
Surgical Procedure - Non Cardiac Surgical Procedure
Surgical Procedure – Other Procedure
Surgical Procedure - Unknown

Cardiac Surgical 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 Cardiac Surgical Procedure - **textbox**
Cardiac Surgical Procedure - Unknown

Other Procedures:

Reintubation due to Respiratory Failure
Dialysis
Bronchoscopy
Other, specify - **textbox**

FUNCTIONAL CAPACITY - for follow-up time period (Answer Yes or No)

Sedated
Yes, No, or Unknown
Paralyzed
Yes, No, or Unknown
Intubated (this excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures.)
Yes, No, or Unknown

Ambulating
Yes, No, Unknown, or Not Applicable
Primary Nutrition
Orally
Per feeding tube
TPN
Not Applicable

EXCURSIONS

Has the patient had any non-medically required excursions off the unit?
Yes, No, Unknown, or Not Applicable
If **so**, where (please select all that apply)
Playroom
Cafeteria
Walk outside
Sitting room
General rehab
None

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

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
Note: Use Last Date of Console Change
Original console name: Text.
New console name: Text.

TRANSFUSION

Was there a transfusion? Yes, No, Unknown.
If **yes**, enter number of PRBC (ml/kg): _____ cc **ST**= Unknown

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**
- **Major Bleeding**
- **Neurological Dysfunction**
- **Device Malfunction** (if suspected device thrombosis, then enter as Device Malfunction)
- **Extracorporeal/Paracorporeal Pump Change**
- **Cardiac Arrhythmia**
- **Pericardial Fluid Collection**
- **Hepatic Dysfunction**
- **Myocardial Infarction**
- **Psychiatric Episode**
- **Renal Dysfunction**
- **Respiratory Failure**
- **Arterial Non-CNS Thromboembolism**
- **Venous Thromboembolic Event**
- **Wound Dehiscence**
- **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**.
https://intermacs.kirso.net/pedimacs/pedimacs-documents/

2.8 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

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
Social Issues / Disposition (Foster Care/Eviction)
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 all that apply: Interventions since rehospitalization from the list below.

None
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

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.

Mean Arterial Blood Pressure (MAP): mmHg (millimeters of mercury). **ST=** Unknown or Not Done.

Did patient receive new IV or oral medications to treat hypertension? Yes, **No**, or **Unknown**.

Please click on the link below for further instruction on administering the Modified Rankin Scale in **Appendix I**.
https://intermacs.kirso.net/pedimacs/pedimacs-documents/

Has the patient experienced a Neurological Event since time of implant?
Yes, No, Unknown

Note: Modified Rankin Scale will NOT be administered for children < 2 years of age at time of implant.

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 Pedimacs 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

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**
- **Major Bleeding**
- **Neurological Dysfunction**
- **Device Malfunction** (if suspected device thrombosis, then enter as Device Malfunction)
- **Extracorporeal/Paracorporeal Pump Change**
- **Cardiac Arrhythmia**
- **Pericardial Fluid Collection**
- **Hepatic Dysfunction**
- **Myocardial Infarction**
- **Psychiatric Episode**
- **Renal Dysfunction**
- **Respiratory Failure**
- **Arterial Non-CNS Thromboembolism**
- **Venous Thromboembolic Event**
- **Wound Dehiscence**
- **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**.
https://intermacs.kirso.net/pedimacs/pedimacs-documents/

2.9 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**.
https://intermacs.kirso.net/pedimacs/pedimacs-documents/

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

Intervention: Select one of the following interventions used for this adverse event.

Drug therapy only: Oral
Drug therapy only: IV
Surgical and drug therapy
(reminder: fill out surgical interventions on Rehospitalization Form)
Surgical therapy only
(reminder: fill out surgical interventions on Rehospitalization Form)
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

Did this patient test positive for COVID-19?

Yes, No, or Unknown

If yes, select all symptoms that apply:

Cough
Diarrhea
Fever
Anosmia (loss of sense of smell)
Sore Throat
Difficulty Breathing
None
Other, specify
If Other, specify: please complete text box.

If yes, select all Interventions that apply:

Intubation
New Inotropes
ECMO
Dialysis
RVAD
None
Other, specify
If Other, specify: please complete text box.

If yes, select all Therapies the Patient Received:

Hydroxychloroquine
Azithromycin
Immunoglobulin
Anti-viral Therapy, specify
If Anti-viral Therapy, specify: please complete text box.
None
Other, specify
If Other, specify: please complete text box.

If yes, did this patient have an associated bacterial lung infection?

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 onset 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-intervention
Episode resulted in Hospitalization (Currently in the hospital or re-hospitalized)
Episode resulted in Transfusion(s) for bleeding episode:

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

Total units PRBC (ml/kg): enter total number of ccs 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):

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
Pleural space
Intra-abdominal
Retroperitoneal
Pulmonary
Device anastomosis
Urinary Tract
GI: Upper gastrointestinal (esophagus, stomach, duodenum, small bowel)
GI: Lower gastrointestinal (colon, rectum, and anus)
GI: Unknown, but guaiac positive stools
Other, Specify

If Other, specify, then complete text box.

Heparin levels: Enter heparin levels. **ST=** Unknown or Not Done

INR: Enter value of INR. If bleeding is less than 7 days post implant, enter last level prior to bleeding within 48 hours. **ST=** Unknown or Not Done

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, 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

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:

a. 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*).

b. 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.

c. 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.

d. 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.

e. 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.

f. 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.

Was there a neurological dysfunction?

Yes, No, or Unknown

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 as defined by neurology consult. If **Neurological Dysfunction - Other** is selected, type in the specification in the block provided

TIA
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, then enter **Encephalopathy Type:**
Metabolic
Anoxic
Traumatic
Other
Infarction seen by imaging, without clinical findings of TIA/Stroke
Extra-axial bleeding seen by imaging study
Confusion
None

Did this Neurological Dysfunction Adverse Event contribute directly 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
Subdural
Spinal cord
Unknown
Other, specify
If Other Specify, then **Specify:** complete text box

Method of Diagnosis of CNS event: Select one of 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
EEG
Ultrasound
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.**

Was hypertension a contributing cause? **Yes** or **No.**

Yes, No, or Unknown

Please click on the link below for further instruction on administering the Modified Rankin Scale in **Appendix I**.
https://intermacs.kirso.net/pedimacs/pedimacs-documents/

Note: Modified Rankin Scale will NOT be administered for children < 2 years of age at time of implant.

Note: This only applies to patients who have a CVA, TIA, or Anoxic Brain Injury. You must complete this section for the patient's complete STS Pedimacs lifespan.

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

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:
    a. Suspected or confirmed pump thrombus (see below)
    b. Urgent transplantation (immediate 1A listing for transplant)
    c. Pump replacement
    d. Pump explant
    e. Breach of integrity of drive line that required repair
    f. 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:
    a. **Presence of hemolysis**
    b. **Presence of heart failure not explained by structural heart disease**
    c. **Abnormal pump parameters**

    Suspected pump thrombus should be accompanied by 1 or more of the following events or interventions:
    i. treatment with intravenous anticoagulation (e.g., heparin), intravenous thrombolytics (e.g., tPA), or intravenous antiplatelet therapy (e.g., eptifibatide, tirofiban)
    ii. pump replacement
    iii. pump explantation
    iv. urgent transplantation (UNOS status 1A)
    v. stroke
    vi. arterial non-CNS thromboembolism
    vii. death

2. **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

Malfunctioning Device Type: For BiVAD patients select from the drop down list given:
LVAD
RVAD
Both (in the same OR visit)

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

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)
- 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

Extracorporeal / Paracorporeal Pump Change

Please use this form when only extracorporeal/paracorporeal pump components (i.e. cannulaes, and pumps) are exchanged. If components/pump are exchanged in the surgery suite and/or the pump is exchanged to a different device brand (i.e Maquet to Berlin Heart) then please fill out the device explant form and enter a new device and do not fill out this form.

Was there an Extracorporeal Pump/Component Exchange?

Yes or No

If Yes please complete the following:

Enter **Date of Exchange** of pump or component: in MMDDYYYY format. **ST=** Unknown

Device Type: Enter the appropriate device side for this AE:

- LVAD (Left Ventricular Assist Device: Systemic Support)
- RVAD (Right Ventricular Assist Device: Pulmonic Support)
- Both (LVAD+RVAD in same OR visit)

Please select all of the **Components Exchanged**:

- Pump
- Inflow Cannula Parts (not requiring OR visit)
- Outflow Cannula Parts (not requiring OR visit)
- Driving Tube Connector
- Other, Specify
  - If Other, specify, **then complete the text box.**

Please select the appropriate **Reason for Exchange:**

- Thrombus NOT associated with hemolysis
- Change in hemodynamics
- Clinical status
- Device parameters
  - (please enter Device Malfunction Form)
- Upsizing device because of patient growth status
- Other, Specify
  - If Other, specify, **then complete the text box.**

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 Pedimacs 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 Pedimacs 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

OP
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 Pedimacs 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 Pedimacs 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 and requires 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 Pedimacs 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 Pedimacs 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 Pedimacs 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:

1) standard clinical and laboratory testing
2) operative findings
3) autopsy findings

This definition excludes neurological events.

Did an acute perfusion deficit in any non-cerebrovascular organ system occur since last STS Pedimacs 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 and laboratory testing.

Evidence of venous thromboembolic event since last STS Pedimacs 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 Pedimacs 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 Pedimacs report / last followup?
Yes, No, or Unknown

If **yes,**
OtherMajor Serious Adverse Event since last STS Pedimacs report/last followup - enter in block provided

Enter **Event date** in MMDDYYYY format. **ST= Unknown.**

2.10 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 patient's home **Street Address**. **ST**= Unknown

Enter patient's home **City**. **ST**= Unknown

Patient's home **State, Territory, Province**. Select from dropdown, if not known, select **Unknown**.

Enter patient's home **Zip Code**. **ST**= Unknown

Enter **Device explanted:** Select appropriate device type for this explant event:
LVAD
RVAD
Both (LVAD+RVAD)
TAH

Note: If death or transplant occurred post cessation of MCSD support please complete the 1 year post cessation form.

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 Pedimacs will continue a 1 year follow-up for this patient for death and/or transplant.

2.10b 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

If **Yes**, **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

2.11 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

Enter patient's home **Street Address**. **ST**= Unknown

Enter patient's home **City**. **ST**= Unknown

Patient's home **State, Territory, Province**. Select from dropdown, if not known, select **Unknown**.

Enter patient's home **Zip Code**. **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, or 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 one of the following locations where death occurred. If location was not known, select **Unknown.**
In hospital
Long term care facility
Home/Residence
Out of hospital, Other
Unknown

Did COVID-19 contribute to death?
Yes, No, 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*

2.12 Patient Transfer Form

2.12 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)? Please ensure all follow-up forms and adverse event forms are complete before submitting transfer.

Yes or No

If **Yes,** Enter **Date transferred care**: Enter as MMDDYYYY. **ST=** Unknown

Transfer date should be the last date of contact with the patient.

Please Specify the transferring hospital in the text box provided.

2.13 Quality of Life

The **PedsQL Questionnaire** and **VADQoL Questionnaire** are provided in **Appendix F.** The **PedsQL** and **VADQoL** instruments can be printed from the STS INTERMACS® website. https://intermacs.kirso.net/pedimacs/pedimacs-documents/

Quality of life is to be measured by the PedsQL and the VADQoL instruments. PedsQL is measured pre-implant and both it and VADQoL are to be administered post-implant (3 months, 6 months, and every 6 months thereafter).

All pediatric patients should complete the PedsQL and VADQoL.

Data collection

The PedsQL and VADQoL are administered by research or clinical coordinators as designated by each participating medical center.

Pre-implant data collection

- The parent/child is to complete the PedsQL 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 parent/child 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 PedsQL and VADQoL, if able.

Instrument Administration

- The parent/child is to complete the PedsQL and VADQoL instruments via self-report independently.

If the patient is unable to complete the PedsQL and VADQoL instruments, 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 PedsQL and VADQoL 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 https://intermacs.kirso.net/

Data Screening

- The PedsQL and VADQoL 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 PedsQL and VADQoL
For patients who do not complete the PedsQL or VADQoL, please enter reason as to why the PedsQL or VADQoL were not completed as stated above.

- **PedsQL Toddler 2-4yrs (Parent Report)**
- **PedsQL Young Child 5-7yrs (Child Report)**
- **PedsQL Young Child 5-7yrs (Parent Report)**
- **PedsQL Child 8-12yrs (Child Report)**
- **PedsQL Child 8-12yrs (Parent Report)**
- **PedsQL Teen 13-18yrs (Child Report)**
- **PedsQL Teen 13-18yrs (Parent Report)**
- **VADQoL (> 8yrs) Child Report**
- **VADQoL (< 2yrs) Parent Report**
- **VADQoL (≥ 2yrs) Parent Report**

PedsQL: Child

Did the child complete a form? Yes, No, or **Unknown.**

Yes or No

If **no**, please enter the reason the PedsQL form was not completed:

Too Sick
Administrative (check specific reason)
Urgent implant, no time
Coordinator too busy or forgot
Unable to contact patient
Other reason, specify _____

If **yes,** please select the 'Child' form:

PedsQL Young Child (5-7yrs)
PedsQL Child (8-12 yrs)
PedsQL Teen (13-18 yrs)

The appropriate form 'opens' once the form (along with its instruction/direction page).

***Note: All questions within PedsQL: Child contain "Unknown or Not Documented" selection.**

PedsQL Child (Young Child 5-7 yrs)

PHYSICAL FUNCTIONING (problems with…)

It is hard for you to walk:
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

It is hard for you to run:
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

It is hard for you to play sports or exercise:
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

It is hard for you to pick up big things:
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

It is hard for you to take a bath or shower:
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

It is hard for you to do chores (like pick up your toys):
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

Do you have hurts or aches:
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented
If **yes, where**? _____

Do you ever feel too tired to play:
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

EMOTIONAL FUNCTIONING (problems with…)

Do you feel scared:

0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

Do you feel sad:

0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

Do you feel mad:

0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

Do you have trouble sleeping:

0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

Do you worry about what will happen to you:

0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

SOCIAL FUNCTIONING (problems with…)

Is it hard for you to get along with other kids:

0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

Do other kids say they do not want to play with you:

0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

Do other kids tease you:

0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

Can other kids do things that you cannot do:

0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

It is hard for you to keep up when you play with other kids:

0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

SCHOOL FUNCTIONING (problems with…)

Is it hard for you to pay attention in school:
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

Do you forget things:
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

Is it hard to keep up with schoolwork:
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

Do you miss school because of not feeling good:
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

Do you miss school because you have to go to the doctor or hospital:
0 – Not at all
2 – Sometimes
4 – A lot
Unknown or Not Documented

PedsQL Child (Child 8-12 yrs)

ABOUT MY HEALTH AND ACTIVITIES (problems with…)

It is hard for me to walk more than one block:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

It is hard for me to run:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot

Unknown or Not Documented

It is hard for me to do sports or exercise:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

It is hard for me to lift something heavy:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

It is hard for me to take a bath or shower by myself:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

It is hard for me to do chores around the house:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I hurt or ache:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented
If **yes, where**? _____

I have low energy :
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

ABOUT MY FEELINGS (problems with…)

I feel afraid or scared:
0 – Not at all
1 – Almost Never
2 – Sometimes

3 – Often
4 – A lot
Unknown or Not Documented

I feel sad or blue:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I feel angry:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I have trouble sleeping:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I worry about what will happen to me:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

HOW I GET ALONG WITH OTHERS (problems with…)

I have trouble getting along with other kids:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

Other kids do not want to be my friend:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

Other kids tease me:
0 – Not at all
1 – Almost Never

2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I cannot do things other kids my age can do:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

It is hard to keep up when I play with other kids:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

ABOUT SCHOOL (problems with…)

Is it hard to pay attention in school:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I forget things:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I have trouble keeping up with schoolwork:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I miss school because of not feeling well:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I miss school to go to the doctor or hospital:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

PedsQL Child (Teen 13-18 yrs)

ABOUT MY HEALTH AND ACTIVITIES (problems with…)

It is hard for me to walk more than one block:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

It is hard for me to run:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

It is hard for me to do sports or exercise:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

It is hard for me to lift something heavy:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

It is hard for me to take a bath or shower by myself:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

It is hard for me to do chores around the house:

0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot

Unknown or Not Documented

I hurt or ache:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented
If **yes, where**? _____

I have low energy :
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

ABOUT MY FEELINGS (problems with…)

I feel afraid or scared:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I feel sad or blue:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I feel angry:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I have trouble sleeping:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I worry about what will happen to me:
0 – Not at all
1 – Almost Never
2 – Sometimes

3 – Often
4 – A lot
Unknown or Not Documented

HOW I GET ALONG WITH OTHERS (problems with…)

I have trouble getting along with other teens:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

Other teens do not want to be my friend:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

Other teens tease me:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I cannot do things other teens my age can do:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

It is hard to keep up with peers:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

ABOUT SCHOOL (problems with…)

Is it hard to pay attention in school:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I forget things:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I have trouble keeping up with schoolwork:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I miss school because of not feeling well:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

I miss school to go to the doctor or hospital:
0 – Not at all
1 – Almost Never
2 – Sometimes
3 – Often
4 – A lot
Unknown or Not Documented

PedsQL: Parent

Did the parent complete a form? Yes, No, or **Unknown.**
Yes or No

If **no**, please enter the reason the PedsQL form was not completed:
Too Sick
Administrative (check specific reason)
Urgent implant, no time
Coordinator too busy or forgot
Unable to contact parent
Other reason, specify _____

If **yes,** please select the 'Parent' form:
PedsQL Toddler (2-4yrs)
PedsQL Young Child (5-7yrs)
PedsQL Child (8-12 yrs)
PedsQL Teen (13-18 yrs)

PedsQL Parent (Toddler 2-4 yrs)

PHYSICAL FUNCTIONING (problems with…)

Walking:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Running:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Participating in active play or exercise:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Lifting something heavy:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Bathing:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Helping to pick up his or her toys:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Having hurts or aches:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Low energy level:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

EMOTIONAL FUNCTIONING (problems with…)

Feeling afraid or scared:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Feeling sad or blue:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Feeling angry:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Trouble sleeping:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Worrying:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

SOCIAL FUNCTIONING (problems with…)

Playing with other children:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always

Unknown or Not Documented

Other kids not wanting to play with him or her:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Getting teased by other children:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Not able to do things that other children his or her age can do:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Keeping up when playing with other children:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

SCHOOL FUNCTIONING (problems with…)

Doing the same school activities as peers:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Missing school/daycare because of not feeling well:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Missing school/daycare to go to the doctor or hospital:

0 – Never
1 – Almost Never
2 – Sometimes

3 – Often
4 – Almost Always
Unknown or Not Documented

PedsQL Parent (Young Child 5-7 yrs)

PHYSICAL FUNCTIONING (problems with…)

Walking more than one block:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Running:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Participating in sports activity or exercise:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Lifting something heavy:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Taking a bath or shower by him or herself
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Doing chores around the house:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Having hurts or aches:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Low energy level:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

EMOTIONAL FUNCTIONING (problems with…)

Feeling afraid or scared:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Feeling sad or blue:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Feeling angry:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Trouble sleeping:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Worrying about what will happen to him or her:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

SOCIAL FUNCTIONING (problems with…)

Getting along with other children:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Other children not wanting to be his or her friend:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Getting teased by other children:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Not able to do things that other children his or her age can do:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Keeping up when playing with other children:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

SCHOOL FUNCTIONING (problems with…)

Paying attention in class:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Forgetting things:
0 – Never
1 – Almost Never

2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Keeping up with activities:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Missing school because of not feeling well:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Missing school to go to the doctor or hospital:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

PedsQL Parent (Child 8-12 yrs)

PHYSICAL FUNCTIONING (problems with…)

Walking more than one block:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Running:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Participating in sports activity or exercise:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always

Unknown or Not Documented

Lifting something heavy:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Taking a bath or shower by him or herself
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Doing chores around the house:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Having hurts or aches:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Low energy level:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

EMOTIONAL FUNCTIONING (problems with…)

Feeling afraid or scared:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Feeling sad or blue:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often

4 – Almost Always
Unknown or Not Documented

Feeling angry:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Trouble sleeping:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Worrying about what will happen to him or her:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

SOCIAL FUNCTIONING (problems with…)

Getting along with other children:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Other children not wanting to be his or her friend:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Getting teased by other children:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Not able to do things that other children his or her age can do:
0 – Never
1 – Almost Never
2 – Sometimes

3 – Often
4 – Almost Always
Unknown or Not Documented

Keeping up when playing with other children:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

SCHOOL FUNCTIONING (problems with…)

Paying attention in class:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Forgetting things:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Keeping up with activities:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Missing school because of not feeling well:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Missing school to go to the doctor or hospital:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

PedsQL Parent (Teen 13-18 yrs)

PHYSICAL FUNCTIONING (problems with…)

Walking more than one block:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Running:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Participating in sports activity or exercise:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Lifting something heavy:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Taking a bath or shower by him or herself

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Doing chores around the house:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Having hurts or aches:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Low energy level:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

EMOTIONAL FUNCTIONING (problems with…)

Feeling afraid or scared:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Feeling sad or blue:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Feeling angry:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Trouble sleeping:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Worrying about what will happen to him or her:
0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

SOCIAL FUNCTIONING (problems with…)

Getting along with other teens:
0 – Never
1 – Almost Never
2 – Sometimes

3 – Often
4 – Almost Always
Unknown or Not Documented

Other teens not wanting to be his or her friend:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Getting teased by other teens:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Not able to do things that other teens his or her age can do:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Keeping up with other teens:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

SCHOOL FUNCTIONING (problems with…)

Paying attention in class:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Forgetting things:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Keeping up with school schoolwork:

0 – Never

1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Missing school because of not feeling well:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

Missing school to go to the doctor or hospital:

0 – Never
1 – Almost Never
2 – Sometimes
3 – Often
4 – Almost Always
Unknown or Not Documented

VADQoL: Child (for children > 8yrs of age)

Did the child complete a form? Yes, No, or **Unknown.**

Yes or No

If **no**, please enter the reason the VADQoL form was not completed:

Too Sick
Administrative (check specific reason)
Urgent implant, no time
Coordinator too busy or forgot
Unable to contact patient
Other reason, specify _____

If **yes**, the VAD QOL (Child form opens – see attached form)

VAD QOL Child

The VAD noise bothers me when I am awake:

Always
Very Often
Sometimes
Rarely
Never
Comments

The VAD noise bothers me when I am trying to sleep:

Always
Very Often
Sometimes
Rarely
Never
Comments

I have pain or discomfort at the driveline or tubing pump exit site:

Always
Very Often
Sometimes
Rarely
Never

Comments

I have difficulty sleeping due to the position of the driveline or tubing pump exit site:

Always
Very Often
Sometimes
Rarely
Never

Comments

I am bothered by how I look with the VAD:

Always
Very Often
Sometimes
Rarely
Never

Comments

I worry about the VAD breaking or malfunctioning:

Always
Very Often
Sometimes
Rarely
Never

Comments

I am bothered that I cannot visit family or friends outside the home or hospital with the VAD:

Always
Very Often
Sometimes
Rarely
Never

Comments

I am bothered that I cannot move easily from place to place with the VAD:

Always
Very Often
Sometimes
Rarely
Never

Comments

I cannot participate in usual play activities with the VAD:

Always
Very Often
Sometimes
Rarely
Never

Comments

I find it difficult to express feelings and talk to others about the VAD:

Always

Very Often
Sometimes
Rarely
Never
Comments

Overall, I would describe my day-to-day level of worry with the VAD to be:
High
Between High and Medium
Medium
Between Low and Medium
Low
Comments

Overall, I would describe my day-to-day level of happiness with the VAD to be:
High
Between High and Medium
Medium
Between Low and Medium
Low
Comments

VADQoL: Parent

Did the parent complete a form? Yes, No, or **Unknown.**
Yes or No

If **no**, please enter the reason the VADQoL form was not completed:
Too Sick
Administrative (check specific reason)
Urgent implant, no time
Coordinator too busy or forgot
Unable to contact parent
Other reason, specify _____
If **yes**, please select the 'Parent' form:
VADQoL (child is < 2 yrs)
VADQoL (child is ≥ 2 yrs)
The appropriate form 'opens' once the form is selected. (see attached forms)

VAD QOL Parent (child is < 2 yrs)

The VAD noise bothers my child when he or she is awake:
Always
Very Often
Sometimes
Rarely
Never
Comments

The VAD noise bothers my child when he or she is trying to sleep:
Always
Very Often
Sometimes
Rarely
Never

Comments

My child has pain or discomfort at the driveline or tubing pump exit site:

Always
Very Often
Sometimes
Rarely
Never

Comments

My Child has difficulty sleeping due to the position of the driveline or tubing pump exit site:

Always
Very Often
Sometimes
Rarely
Never

Comments

My child is bothered that he or she cannot move easily from place to place with the VAD:

Always
Very Often
Sometimes
Rarely
Never

Comments

My child cannot participate in usual play activities with the VAD:

Always
Very Often
Sometimes
Rarely
Never

Comments

Overall, I would describe my day-to-day level of happiness with the VAD to be:

High
Between High and Medium
Medium
Between Low and Medium
Low

Comments

VAD QOL Parent (child is ≥ 2 yrs)

The VAD noise bothers my child when he or she is awake:

Always
Very Often
Sometimes
Rarely
Never

Comments

The VAD noise bothers my child when he or she is trying to sleep:

Always
Very Often

Sometimes
Rarely
Never
Comments

My child has pain or discomfort at the driveline or tubing pump exit site:
Always
Very Often
Sometimes
Rarely
Never
Comments

My child is bothered by how I look with the VAD:
Always
Very Often
Sometimes
Rarely
Never
Comments

My child worries about the VAD breaking or malfunctioning:
Always
Very Often
Sometimes
Rarely
Never
Comments

My child is bothered that he or she cannot visit family or friends outside the home or hospital with the VAD:
Always
Very Often
Sometimes
Rarely
Never
Comments

My child is bothered that he or she cannot move easily from place to place with the VAD:
Always
Very Often
Sometimes
Rarely
Never
Comments

My child cannot participate in usual play activities with the VAD:
Always
Very Often
Sometimes
Rarely
Never
Comments

My child finds it difficult to express feelings and talk to others about the VAD:
Always
Very Often

Sometimes
Rarely
Never

Comments

Overall, I would describe my child's day-to-day level of worry with the VAD to be:

High
Between High and Medium
Medium
Between Low and Medium
Low

Comments

Overall, I would describe my day-to-day level of happiness with the VAD to be:

High
Between High and Medium
Medium
Between Low and Medium
Low

Comments