

Appendix M. STS Intermacs® Site Users' Guide

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

Guide to the STS Intermacs® Database

- 1.0 Navigating the STS Intermacs® Application
 - 1.1 Introduction
 - 1.2 How do I get started?
 - Entering a new patient:
 - Screening Log
 - Forms
 - Patient Overview Screen
 - 1.3 How do I manage a patient's existing record?
 - Editing an existing patient:
 - Follow Up
 - Adding an Adverse Event
 - Adding a Device
 - 1.4 Ending Patient Participation
- 2.0 Users' guide
 - 2.1 Screening Log
 - 2.2 Demographic Form
 - 2.3 Pre-implant Form
 - 2.4 Implant Form
 - 2.5 1 Week/1 Month Follow-up Form
 - 2.6 3 Month/6 Month Follow-up Form
 - 2.7 Implant Discharge Form
 - 2.8 Rehospitalization Form
 - 2.9 Adverse Events
 - 2.10 Explant: For Device Exchange, Recovery, or Transplant Form
 - 2.11 Death Form
 - 2.12 Patient Transfer Form
 - 2.13 Quality of Life (EuroQoL, STS Intermacs Pre/Post Implant, KCCQ)
 - 2.14 Neurocognitive (Trailmaking Test Part B)

1.0 Navigating the STS Intermacs® Application

1.1 Introduction

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

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

1.2 How do I get started?

Entering a new patient

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

Screening Log

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

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

- Patient receives a durable mechanical circulatory support device (MCSD) which is FDA approved***
- Implanted on or after March 1, 2006 (The device does not need to be the first implant for the patient)***

Forms

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

Inclusion/Exclusion Form

Screening Log

Clinical Data Forms

Demographics

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

EuroQoL questionnaire

Modulated QoL

KCCQ

Neurocognitive Form

Trailmaking Part B neurocognitive test

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

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

Patient Summary Screen

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

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

1.3 How do I manage an existing patient's record?

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

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

Follow up

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

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

Check one of the following:

- **Inpatient** (complete follow-up form)
- **Outpatient** (complete follow-up form)
- **Other Facility:** Yes No
 - If other facility: Name of Facility: _____
(complete follow-up form)
- **Unable to obtain follow-up information** - this will result in an incomplete follow-up (cannot complete follow-up form)
 - State reason why you are unable to obtain follow-up information (check one):
 - patient didn't come to clinic
 - Not able to contact patient
 - Not addressed by site
- **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 InterMac[®] application has been modified to help in streamlining the entry of adverse events for a patient. Most adverse events will occur in a hospital setting (i.e. rehospitalization or initial hospitalization). There are 'reminder' tables that will facilitate the entry of adverse events which will be explained in the users' guide section of this document.

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

Note: An Index hospital is referring to the site where the patient was initially enrolled into STS InterMac[®].

Adverse event occurs during index hospitalization:

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

**Adverse event occurs during rehospitalization:**

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

Adverse event occurs outside a hospitalization:

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

Adding a Device

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

There are two possible scenarios.

Replacement of an existing device

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

Additional device

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





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

1.4 Ending Patient Participation

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

Clinical

- (1) Death: Complete **Death** form and relevant **AE forms**.
- (2) Transplant: Complete **Transplant** form. Patient will be followed through the OPTN database.
- (3) 1 year after removal of all devices with no new implant: Regular follow-up form completion ceases, but the coordinator reports to the registry whether the patient died or was transplanted for a period of 1 year post-explant.

Administrative

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

2.0 Users' guide for the STS Intermacs® Application

Section	Form	Page
2.1	SCREENING LOG	10
2.2	DEMOGRAPHICS FORM	14
2.3	PRE-IMPLANT FORM	17
	PRE-IMPLANT STATUS	17
	HEMODYNAMICS	35
	LABORATORY VALUES	37
	COMORBIDITIES -	39
	MEDICATIONS	43
	QUALITY OF LIFE	45
	EXERCISE/TRAILMAKING	46
2.4	IMPLANT FORM	48
2.5	1 WEEK AND 1 MONTH FOLLOW-UP	57
	FOLLOW-UP STATUS	57
	HEMODYNAMICS	60
	MEDICATIONS	63
	LABORATORY VALUES	64
2.6	3 MONTH AND 6 MONTH FOLLOW-UP	68
	FOLLOW-UP STATUS	68
	HEMODYNAMICS	71
	MEDICATIONS	74
	LABORATORY VALUES	75
	DEVICE DETAILS	77
	EXERCISE/TRAILMAKING	78
	COMORBIDITIES -	80
	QUALITY OF LIFE	84
2.7	IMPLANT DISCHARGE	86
2.8	REHOSPITALIZATION	91
2.9	REPORTING OF ADVERSE EVENTS	96
	AE INFECTION	96
	AE MAJOR BLEEDING	106
	AE NEUROLOGICAL DYSFUNCTION	110
	DEVICE ADVERSE EVENT: MALFUNCTION / FAILURE AND/OR PUMP THROMBUS	116
	<i>Device Malfunction Event</i>	118
	<i>Thrombus Event</i>	119

EXTRACORPOREAL / PARACORPOREAL PUMP CHANGE	123
HEMOLYSIS EVENT	124
RIGHT HEART FAILURE EVENT.....	127
RENAL DYSFUNCTION EVENT	131
ADDITIONAL ADVERSE EVENTS.....	133
<i>Cardiac Arrhythmias</i>	133
<i>Respiratory Failure</i>	134
<i>Venous Thromboembolism</i>	136
<i>Wound Dehiscence</i>	136
<i>Arterial Non-CNS Thromboembolism</i>	137
<i>Hypertension</i>	138
<i>Hepatic Dysfunction</i>	138
<i>Psychiatric Episode</i>	139
<i>Pericardial Fluid Collection</i>	139
<i>Myocardial Infarction</i>	140
<i>Other SAE</i>	140
2.10 EXPLANT: FOR DEVICE EXCHANGE, RECOVERY OR TRANSPLANT	142
2.10B 1 YEAR POST CESSATION OF MECHANICAL SUPPORT	144
2.11 DEATH.....	146
2.12 PATIENT TRANSFER FORM.....	150
2.13 QUALITY OF LIFE.....	151
EUROQOL (EQ-5D)	152
PRE/POST-IMPLANT QOL	153
KANSAS CITY CARDIOMYOPATHY QUESTIONNAIRE (KCCQ) - 12	155
2.14 NEUROCOGNITIVE FUNCTION TEST.....	158

2.1 Screening Log

User Question: If a patient was explanted but then over a year later was reimplanted- how do I enter that? Do I just start over by screening a new patient- I am not able to add a new device on the current record

A: If a patient is explanted and then reimplanted within 30 days, we add that new device to the existing profile. If the reimplant happens outside of 30 days the patient is rescreened and added as a "new patient" into InterMac.

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

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

Implant date: Enter VAD implant date in MMDDYYYY format.

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

Patient receives a durable mechanical circulatory support device (MCSD) which is FDA approved
Yes or No

Implanted on or after March 1, 2006 (The device does not need to be the first implant for the patient)
Yes or No

User Question: Should patients that were part of the Jarvik study in 2013 be entered into InterMac?

A: No, the Jarvik patients are not entered into InterMac.

User Question: If a patient's first device is a temporary RVAD do I enter it into STS-InterMac?

A: The first device does not have to be a LVAD as long as it is a durable device and it is not being used as a temporary device.

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

Device Type: Select from the drop down list given:

- LVAD (Left Ventricular Assist Device)
- RVAD (Right Ventricular Assist Device)
- Both (LVAD+RVAD in same OR visit)
- TAH (Total Artificial Heart)

User Question: For single ventricle patients who received single ventricle VADS, what would be the appropriate VAD, LVAD or RVAD?

A: These VADs are entered as LVADs.

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/intermacs-documents/> for reference purposes).

Durable Devices**LVAD, BiVAD, TAH**

Berlin Heart EXCOR (paracorporeal)

Medtronic HVAD

HeartMate II LVAS

HeartMate 3

HeartMate IP

HeartMate VE

HeartMate XVE

Micromed DeBakey VAD – Child

Novacor PC

Novacor PCq

Thoratec IVAD

Thoratec PVAD

Abiocor TAH

SynCardia Cardiowest TAH – 70cc

SynCardia Cardiowest TAH – 50cc

Other, Specify**Temporary Devices (include only in conjunction with a durable device listed above)**

Sorin Revolution

Abiomed AB5000

Abiomed BVS 5000

Thoratec Centrimag (Levitronix)

TandemHeart

Biomedicus

Abiomed Impella 2.5

Abiomed Impella 5.0

Abiomed Impella CP

Abiomed Impella RP

Abiomed Impella 5.5

Maquet Rotaflo

LifeSPARC

Other, Specify

User Question: If a patient was originally excluded due to a device study that isn't FDA-approved and later has an exchange with an approved device, how is that handled?

A: Enter the patient in the screening log as excluded for the non-FDA approved device, enter the second FDA-approved device in Intermacs.

User Question: Do we enter a patient into Intermacs that dies during the implant operation?

A: If the pump is turned on and blood is flowing through the cannulas, the patient needs to be entered into Intermacs, even if the patient died in the OR.

User Question: We had a patient who was 18 years old at time of implant. We do not participate in the Pedimacs Registry at this site. Should I still enter him as an excluded patient in our INTERMACS database?

A: No, you won't enter him into INTERMACS. The INTERMACS screening log is only designed for patients 19 years or more at the time of implant.

User Question: We have a patient that was implanted with a HM 3 as part of the Momentum CAP study on 3/5/2018 so no entry into INTERMACS. The patient required a HM 3 pump exchange due to infection on 1/13/2021. Does the pump implanted on 1/13/2021 need to be entered into INTERMACS?

A: Yes, the second device can be entered into INTERMACS.

Patients who are enrolled in the Innovate Trial should be entered into the database if they received a HM3. Please note that BrioVAD patients should not be entered at this time. 11/25/2024

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

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

Patient receives a durable (MCSD) which is **not** FDA approved
Yes or No

Patient is incarcerated (prisoner)
Yes or No

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

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

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

Device Type: Enter the appropriate device side for this implant
LVAD (Left Ventricular Assist Device)
RVAD (Right Ventricular Assist Device)
Both (in same OR visit)
TAH (Total Artificial Heart)

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

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

- 19 to 39
- 40 to 59
- 60 to 79
- 80+

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

- American Indian or Alaska Native
- Asian
- African-American
- Hawaiian or other Pacific Islander
- White
- Unknown/Undisclosed
- Other/none of the above

Ethnicity: Hispanic or Latino.

Yes, No, or Unknown

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

- Male
- Female
- Unknown

Did death occur within 2 days post implant? Select the appropriate answer

Yes or No

Is this VAD an investigational device? Select the appropriate answer

Yes or No

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

Yes, No, or Unknown

If **Yes** selected, specify:

What is the name of the study?

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

Yes, No, or Unknown

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

2.2 Demographics Form

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

Institution: Auto-fills based on user information.

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

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

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

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

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

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

User Question: Are we entering the patient's home address or the hospital address?

A: Please enter the patient's home address.

User Question: Why are we collecting patient's addresses and how will that data be used?

A: Social Determinants of Health (SDOH) are highly correlated with health outcomes in patients. Collecting address allows us to identify local SDOH, which will facilitate understanding barriers to equality in access to care and allow implementation of strategies to reduce the impact of SDOH on Ventricular Assist Device (VAD) patient outcomes.

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

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

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

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

Male
Female
Unknown

Ethnicity: Hispanic or Latino: Select
Yes, No, or Unknown

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

- American Indian or Alaska Native
- Asian
- African-American
- Hawaiian or other Pacific Islander
- White
- Unknown/Undisclosed
- Other/none of the above

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

Single
Married
Domestic Partners
Divorced/Separated
Widowed
Unknown

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

None
Grade School (0-8)
High School (9-12)
Attended College/Technical School
Associate/Bachelor Degree
Post-College Graduate Degree
Not Applicable
Unknown

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

Yes, No, or Unknown

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

Working Full Time
Working Part Time due to Demands of Treatment
Working Part Time due to Disability
Working Part Time due to Insurance Conflict
Working Part Time due to Inability to Find Full Time Work
Working Part Time due to Patient Choice
Working Part Time Reason Unknown
Working, Part Time vs. Full Time Unknown

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

Disability
Demands of Treatment
Insurance Conflict
Inability to Find Work
Patient Choice – Homemaker
Patient Choice - Student Full Time/Part Time
Patient Choice – Retired
Patient Choice – Other
Not Applicable – Hospitalized
Unknown

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

Yes, No, or Unknown

If **Yes** selected, specify:

What is the name of the study?

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

Yes, No, or Unknown

2.3 Pre-Implant Form

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

Pre-Implant Status

Admission Date for This Hospitalization - MMDDYYYY

ST= Not Applicable, or Unknown

User Question: For this field, does 'Admission Date' refer to the day that the patient arrived at the ED (and then were subsequently admitted) or does it refer to the day they were transferred up to the floor from the ED? (For the patient whose chart I am currently reviewing, these two days are not the same).

A: Please use the date the patient was coded as inpatient as the admission date.

User Question: One of our patients was admitted to an OSH on 11/2/23, then transferred to another OSH on 11/9/23, then transferred to our hospital on 11/26/23 for VAD implant.

In the Preimplant Form, "Admission date for this hospitalization", would the date be 11/26/23 since that is the date the patient was admitted to our hospital for VAD implant?

A: Yes, that is correct.

Patient Information

Height: Enter the height of the patient at the time of implantation in inches or centimeters. The height must fall between 10 and 96 inches or 25 and 244 centimeters.

User Question: If multiple weights are recorded which, should I use?

A: Please enter the weight just prior to OR.

Weight: Enter the weight of the patient at the time of implantation in the appropriate space, in pounds or kilograms. The weight must fall between 5 and 600 pounds or 2 and 273 kilograms.

Body Surface Area (BSA): Calculation based on Height and Weight fields.

Body Mass Index (BMI): Calculation based on Height and Weight fields.

Blood Type: Select the patient's blood type.

O
A
B
AB
Unknown

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:

Medicare Fee for Service
 Military Health Care
 Indian Health Service
 Not Applicable
 Other, Specify - **If selected please complete text box.**

Enter **Health Insurance Claim Number (HIC)**

ST= Unknown

National Provider Identifier (NPI) Information

Surgeon First Name: Enter the implanting physician's first name. **ST=** Unknown

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

Surgeon Last Name: Enter the implanting physician's last name. **ST=** Unknown

Surgeon NPI: Enter the implanting physician's National Provider Identification Number.
ST= Unknown

User Question: Where can I find the NPI number?

A: This link provides an NPI search <https://nppes.cms.hhs.gov/#/>

Medical Support Status

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

Bridge to recovery - Use of a durable device to allow recovery from chronic cardiac failure (at least 3 months in duration).

Rescue therapy - Use of a durable device to support resolution from an acute event without major previous cardiac dysfunction.

Bridge to transplant– This is for a patient ALREADY listed for transplant or listed within 24 hours before device implantation.

List Date for Transplant:

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

Enter **UNOS Waitlist ID** Number. **ST=** Unknown.

Possible bridge to transplant - Likely to be eligible: defines a patient in whom the transplant evaluation has not been completed, but no contra-indications are anticipated, or in whom a current contra-indication is anticipated to resolve rapidly, such as recent infection.

Possible bridge to transplant - Moderate likelihood of becoming eligible: similar to above, but with some potential concerns that might prevent eligibility.

Possible bridge to transplant - *Unlikely to become eligible*: should be used for a patient in whom major concerns have already been identified. These may not have been quantified yet, such as in a patient with known chronic lung disease without recent pulmonary function test measurement, or might be reversible, such as severe renal insufficiency or pulmonary hypertension that might improve after chronic mechanical support. It may be the expectation at the time of implant that the patient will most likely have the assist device as “permanent” or “destination” therapy.

Destination therapy - (patient definitely not eligible for transplant). All factors that weigh in to the decision of non-transplant candidacy should be indicated below.

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

User Question: Do we still need to specify device strategy even though it is not a CMS requirement?

A: Yes, you need to continue to enter the current device strategy at implant and for each follow up.

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

- < 1 month
- 1 month – 1 year
- 1-2 years
- > 2 years
- Unknown

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

- 0-1
- 2-3
- 4 or more
- Unknown

User Question For the question Number of Cardiac Hospitalizations in the last 12 months, do I count the direct admit for the planned LVAD surgery?

A: Yes, please do include this hospitalization.

History of Cardiac Arrhythmia: (choose one of the following)

- Yes
- No
- Unknown

If yes, Select all Arrhythmias that apply:

- Atrial Fibrillation (paroxysmal or chronic)
- Atrial Flutter
- Other Atrial – **If other specify please complete textbox**
- Ventricular Tachycardia
- Ventricular Fibrillation
- History of ICD discharge or history of sudden cardiac death
- Other Ventricular – **If other specify please complete textbox**

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 MCS/D implant, then “**No**” should be checked. Note that patients with bi-ventricular pacing and ICD should have **Yes** checked for ICD also. Or check **Unknown**.

If yes, select type of ICD device:

- ICD Only
- CRT Only
- ICD/CRT

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: Single Ventricle: Heterotaxy / Complex CAVC
 Congenital Heart Disease: Single Ventricle: Hypoplastic Left Heart
 Congenital Heart Disease: Single Ventricle: Other - **If other, please complete textbox**
 Congenital Heart Disease: Single Ventricle: Pulmonary Atresia with IVS
 Congenital Heart Disease: Single Ventricle: Pulmonary Atresia with IVS (RVDC)
 Congenital Heart Disease: Single Ventricle: Unspecified
 Coronary Artery Disease
 Dilated Myopathy: Adriamycin
 Dilated Myopathy: Alcoholic
 Dilated Myopathy: Familial
 Dilated Myopathy: Idiopathic
 Dilated Myopathy: Ischemic
 Dilated Myopathy: Myocarditis
 Dilated Myopathy: Other, Specify – **If other specify please complete textbox**
 Dilated Myopathy: Post Partum
 Dilated Myopathy: Viral
 Hypertrophic Cardiomyopathy
 Non-Compaction Cardiomyopathy
 Restrictive Myopathy: Amyloidosis
 Restrictive Myopathy: Endocardial Fibrosis
 Restrictive Myopathy: Idiopathic
 Restrictive Myopathy: Other, specify – **If other specify please complete textbox**
 Restrictive Myopathy: Sarcoidosis
 Restrictive Myopathy: Sec to Radiation/Chemotherapy
 Valvular Heart Disease
 Unknown
 None

Clinical Events and Interventions Before Implant Hospitalization

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

No biopsy known
 Sarcoidosis
 Giant cell myocarditis
 Eosiniphilic myocarditis
 Other myocarditis
 Hemochromatosis
 Mitochondrial myopathy
 Other, specify **if other, specify, please complete text box**

Prior Cardiovascular Intervention (non-surgical): Select all non-surgical interventions the patient has had prior to this implant hospitalization.

Percutaneous Coronary Intervention

Permanent Pacemaker

Prior medical history of ICD (if patient currently has ICD in place, please document in question "Current ICD Device in Place" in medical support status section and do not duplicate here)

Prior medical history of CRT (if patient currently on CRT, please document in question "Current ICD Device in Place" in medical support status section and do not duplicate here)

CardioMEMS

Mitraclip

TAVR

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

Unknown

None

Prior Medical History of Dialysis?

Yes

No

Unknown

If yes, Dialysis is:

Acute

Chronic (>3 months)

Unknown

Prior Cardiovascular Intervention (surgical): Select all cardiac operations that the patient has had prior to MCS/implantation. If **Other, specify** is selected, type in the specification in the block provided.

None

CABG

Aneurysmectomy (DOR)

Aortic Valve replacement / repair

Mitral Valve replacement / repair

Tricuspid replacement /repair

Congenital cardiac surgery

LVAD, Durable implantable

LVAD, Temporary

RVAD, Durable implantable

RVAD, Temporary

TAH

Previous heart transplant

Previous ECMO

Complex Aortic Surgery

Unknown

Other, specify: (INCLUDE ONLY OPERATIONS ACTUALLY PERFORMED ON HEART OR GREAT VESSELS)

If Other, specify: please complete text box.

User Question: Can you please explain what would fall under the Complex Aortic Surgery? I have a patient who had an aortiliac thrombolectomy. Does this fall into this category?

A: There are a variety of complex aortic surgery procedures. Complex aortic procedures typically treat patients with an aneurysm that need replacement or repair of the aorta. Some examples are an Elephant Trunk procedure, David V valve sparing aortic root procedure, Ascending and descending aneurysm repairs. However, the aortiliac thrombolectomy procedure your patient had is a vascular surgery and it would not be captured here.

If Congenital cardiac surgery, then Check all that apply:

Congenitally Corrected Transposition Repair (double switch)

Congenitally Corrected Transposition Repair (classic)

PA Banding

TOV/DORV/RVOTO Repair

Ebstein's Anomaly Repair

VSD Repair
 Norwood Stage I
 Glenn, Bi-directional
 Glenn, Classical
 Fontan Procedure
 d- Transposition of the Great Vessels Repair – arterial switch operation
 d- Transposition of the Great Vessels Repair – atrial switch (Senning/Mustard)
 Truncus Arteriosus Repair
 Complete AV Septal Defect Repair
 AP Shunt
 ASD Repair
 Damus Kaye Stansel (DKS)
 Other, specify

If Other, specify: please complete text box.

If RVAD Temporary, For this RVAD, was a cannula utilized? Choose one:
 (Pro Tek Duo and Spectrum Double Lumen cannulae are to be captured here.)

Yes
 No
 Unknown

User Question: Are we capturing a specific time frame prior to implant?

A: No, there is no specific time frame. Please capture any COVID-19 positive test prior to implant

Initial Reason for the Current Hospitalization: Select one primary reason the patient was admitted.

Decompensated Heart failure
 Open heart, cardiac surgical procedure
 Non-cardiac medical problem
 VAD placement, planned
 TAH placement, planned
 Acute MI
 Non-cardiac surgery
 Cardiogenic Shock
 Other cardiology
 Unknown

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.

Steroids
Paxlovid
Remdesivir
Convalescent Plasma
Interlukin 6 inhibitor
None
Other, specify

If Other, specify: please complete text box.

Clinical Events and Interventions DURING this Hospitalization (Pre-Implant)

Clinical Events and Interventions this hospitalization (Pre-implant): Pertaining to this implant hospitalization, select all events and interventions that occurred.

Cardiac arrest
Dialysis
Intubation/Ventilator
Myocardial Infarction
Positive blood cultures
Major Infection
IABP
Ultrafiltration
Feeding tube
ECMO
CABG
Aortic Valve replacement / repair
Mitral valve replacement / repair
Congenital cardiac surgery
LVAD, Temporary
RVAD, Durable implantable
LVAD, Durable implantable
RVAD, Temporary
TAH
Percutaneous Coronary Intervention
Permanent Pacemaker
CardioMEMS
Mitraclip
TAVR
Unknown
None

If event this hospitalization is Cardiac Arrest, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

If event this hospitalization is Dialysis, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

If event this hospitalization is Intubation/Ventilator, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

If event this hospitalization is Myocardial Infarction, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

If event this hospitalization is Positive blood cultures, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

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 Major Infection, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

User Question: I have a patient who was implanted recently that had tissue that was obtained during surgery and sent for culture and came back positive. Should I document it on his pre-implant form that it was present at time of implant?

A: Yes, it should be documented on the pre-implant form but you should not complete an AE form. If an infection was present pre-implant, it will not be counted as an AE unless the infection was treated and cleared and then recurs at a later time after implant.

If event this hospitalization is IABP, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

**User Question: If a patient had an IABP and it was removed at the time of implant would I code yes?
A: Answer yes to this question.**

If event this hospitalization is Ultrafiltration, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

If event this hospitalization is Feeding Tube, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

If event this hospitalization is ECMO, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

If event this hospitalization is ECMO, Select Approach to Insertion:

Full Sternotomy
Right Thoracotomy Only
Percutaneous
Left Subcostal
Right Subcostal
Left Thoracotomy Only
Bilateral Thoracotomy
Axillary (cut down)
Left Thoracotomy plus Mini Sternotomy
Left Thoracotomy to Right Mini Sternotomy
Unknown
Other, specify

If event this hospitalization is ECMO, Indicate Extracorporeal Membrane Oxygenation:

Veno-venous (VV) ECMO
Veno-arterial (VA) ECMO
Unknown

If event this hospitalization is ECMO, enter Inflow:

Femoral Vein
 Left Atrium, Left Atrial Appendage
 Left Atrium, Interatrial Groove
 Left Ventricle, Apex
 Left Ventricle, Diaphragmatic Surface
 Left Atrium, Dome Left Atrium
 Right Atrium
 Right Ventricle
 Femoral (percutaneous)
 Femoral (cut down)
 Unknown
 Other, specify

If event this hospitalization is ECMO, enter Outflow:

Femoral Artery
 Ascending Aorta
 Descending Thoracic Aorta
 MPA (Main Pulmonary Artery)
 LPA (Left Pulmonary Artery)
 RPA (Right Pulmonary Artery)
 Conduit
 Left Subclavian Artery
 Right Subclavian artery
 Femoral (percutaneous)
 Femoral (cut down)
 Unknown
 Other, specify

If event this hospitalization is ECMO, enter Total Number of days on ECMO:

ST= Unknown

If event this hospitalization is CABG, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
 No
 Unknown

If event this hospitalization is Aortic Valve Replacement/Repair, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
 No
 Unknown

If event this hospitalization is Mitral Valve Replacement/Repair, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
 No
 Unknown

If event this hospitalization is Congenital Cardiac Surgery, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
 No
 Unknown

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

Congenitally Corrected Transposition Repair (double switch)
 Congenitally Corrected Transposition Repair (classic)
 PA Banding
 TOV/DORV/RVOTO Repair
 Ebstein's Anomaly Repair
 VSD Repair
 Norwood Stage I
 Glenn, Bi-directional
 Glenn, Classical
 Fontan Procedure
 d- Transposition of the Great Vessels Repair – arterial switch operation
 d- Transposition of the Great Vessels Repair – atrial switch (Senning/Mustard)
 Truncus Arteriosus Repair
 Complete AV Septal Defect Repair
 AP Shunt
 ASD Repair
 Damus Kaye Stansel (DKS)
 Other, specify – **If selected please complete text box.**

If event this hospitalization is LVAD Temporary, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
 No
 Unknown

If LVAD Temporary, Select Approach to Insertion:

Full Sternotomy
 Right Thoracotomy Only
 Percutaneous
 Left Subcostal
 Right Subcostal
 Left Thoracotomy Only
 Bilateral Thoracotomy
 Axillary (cut down)
 Left Thoracotomy plus Mini Sternotomy
 Left Thoracotomy to Right Mini Sternotomy
 Unknown
 Other, specify – **If selected please complete text box.**

If LVAD Temporary, Select Inflow:

Left Ventricle, Apex
 Left Ventricle, Diaphragmatic Surface
 Left Atrium, Interatrial Groove
 Left Atrium, Left Atrial Appendage
 Left Atrium, Dome Left Atrium
 Right Atrium (Option for Adult Congenital Cases)
 Right Ventricle (Option for Adult Congenital Cases)
 Unknown
 Other, specify – **If selected please complete text box.**

If LVAD Temporary, Select Outflow:

Ascending Aorta
 Descending Thoracic Aorta
 Abdominal Aorta
 Left Subclavian Artery
 Right Subclavian artery
 Unknown

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

If LVAD Temporary, Select Device Brand:

Abiomed BVS 5000
 Abiomed AB5000
 TandemHeart
 Thoratec Centrimag (Levitronix)
 Sorin Revolution
 Abiomed Impella CP
 Abiomed Impella 2.5
 Abiomed Impella 5.0
 Abiomed Impella RP
 Abiomed Impella 5.5
 Maquet Rotaflo
 LifeSPARC

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

If event this hospitalization is RVAD Durable Implantable, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
 No
 Unknown

If event this hospitalization is RVAD Durable Implantable, has the device already been entered into Intermacs? Answer No if the implant was not entered into Intermacs by your facility:

Yes
 No

If Not already in Intermacs, Select RVAD Durable Implantable Approach to Insertion:

Full Sternotomy
 Right Thoracotomy Only
 Percutaneous
 Left Subcostal
 Right Subcostal
 Left Thoracotomy Only
 Bilateral Thoracotomy
 Axillary (cut down)
 Left Thoracotomy plus Mini Sternotomy
 Left Thoracotomy to Right Mini Sternotomy
 Unknown
 Other, specify – **If selected please complete text box.**

If Not already in Intermacs, Select RVAD Durable Implantable Inflow:

Right Atrium
 Right Ventricle
 Left Atrium (Option for Adult Congenital Cases)
 Left Ventricle (Option for Adult Congenital Cases)
 Unknown
 Other, specify – **If selected please complete text box.**

If Not already in Intermacs, Select RVAD Durable Implantable Outflow:

MPA (Main Pulmonary Artery)
 LPA (Left Pulmonary Artery)
 RPA (Right Pulmonary Artery)

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

If Not already in InterMac, Select RVAD Durable Implantable Device

Brand:

Thoratec IVAD
 Medtronic HVAD
 Berlin Heart EXCOR (paracorporeal)
 Thoratec PVAD
 HeartMate 3
 Durable Implantable: Other, specify – **If selected please complete text box.**

If event this hospitalization is LVAD Durable Implantable, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
 No
 Unknown

If event this hospitalization is LVAD Durable Implantable, has the device already been entered into InterMac? Answer No if the implant was not entered into InterMac by your facility:

Yes
 No

If Not already in InterMac, Select LVAD Durable Implantable Approach to Insertion:

Full Sternotomy
 Right Thoracotomy Only
 Percutaneous
 Left Subcostal
 Right Subcostal
 Left Thoracotomy Only
 Bilateral Thoracotomy
 Axillary (cut down)
 Left Thoracotomy plus Mini Sternotomy
 Left Thoracotomy to Right Mini Sternotomy
 Unknown
 Other, specify – **If selected please complete text box.**

If Not already in InterMac, Select LVAD Durable Implantable Inflow:

Left Ventricle, Apex
 Left Ventricle, Diaphragmatic Surface
 Left Atrium, Interatrial Groove
 Left Atrium, Left Atrial Appendage
 Left Atrium, Dome Left Atrium
 Right Atrium (Option for Adult Congenital Cases)
 Right Ventricle (Option for Adult Congenital Cases)
 Unknown
 Other, specify – **If selected please complete text box.**

If Not already in InterMac, Select LVAD Durable Implantable Outflow:

Ascending Aorta
 Descending Thoracic Aorta
 Abdominal Aorta
 Left Subclavian Artery

Right Subclavian artery

Unknown

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

If Not already in Intermacs, Select LVAD Durable Implantable Device

Brand:

HeartMate IP

HeartMate VE

Novacor PC

Novacor PCq

HeartMate XVE

Thoratec IVAD

Medtronic HVAD

Berlin Heart EXCOR (paracorporeal)

Micromed DeBaKey VAD – Child

Thoratec PVAD

HeartMate II LVAS

HeartMate 3

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

If event this hospitalization is RVAD Temporary. Indicate if Present at the Time of Durable MCS Device Implant:

Yes

No

Unknown

If RVAD Temporary, Select Approach to Insertion:

Full Sternotomy

Right Thoracotomy Only

Percutaneous

Left Subcostal

Right Subcostal

Left Thoracotomy Only

Bilateral Thoracotomy

Axillary (cut down)

Left Thoracotomy plus Mini Sternotomy

Left Thoracotomy to Right Mini Sternotomy

Unknown

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

If RVAD Temporary, Select Inflow:

Right Atrium

Right Ventricle

Left Atrium (Option for Adult Congenital Cases)

Left Ventricle (Option for Adult Congenital Cases)

Unknown

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

If RVAD Temporary, Select Outflow:

MPA (Main Pulmonary Artery)

LPA (Left Pulmonary Artery)

RPA (Right Pulmonary Artery)

Conduit

Aorta

Unknown

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

If RVAD Temporary, Select Device Brand:

Abiomed BVS 5000
 Biomedicus
 Abiomed AB5000
 TandemHeart
 Thoratec Centrimag (Levitronix)
 Sorin Revolution
 Abiomed Impella CP
 Abiomed Impella 2.5
 Abiomed Impella 5.0
 Abiomed Impella RP
 Abiomed Impella 5.5
 Maquet Rotaflow
 LifeSPARC
 Temporary: Other, specify – **If selected please complete text box**

If RVAD Temporary, For this RVAD, was a cannula utilized? Choose one:
 (Pro Tek Duo and Spectrum Double Lumen cannulae are to be captured here.)

Yes
 No
 Unknown

If event this hospitalization is TAH, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
 No
 Unknown

If event this hospitalization is TAH, has the device already been entered into Intermacs? Answer No if the implant was not entered into Intermacs by your facility:

Yes
 No

If Not already in Intermacs, Select TAH Approach to Insertion:

Full Sternotomy
 Right Thoracotomy Only
 Percutaneous
 Left Subcostal
 Right Subcostal
 Left Thoracotomy Only
 Bilateral Thoracotomy
 Axillary (cut down)
 Left Thoracotomy plus Mini Sternotomy
 Left Thoracotomy to Right Mini Sternotomy
 Unknown
 Other, specify – **If selected please complete text box.**

If Not already in Intermacs, Select TAH Device Brand:

SynCardia TAH – 50cc
 SynCardia TAH – 70cc
 AbioCor TAH
 Other, specify – **If selected please complete text box.**

If event this hospitalization is Percutaneous Coronary Intervention, Indicate if Present at the Time of Durable MCS Device Implant:

Yes

No
Unknown

If event this hospitalization is Permanent Pacemaker, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

If event this hospitalization is CardioMEMS, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

If event this hospitalization is Mitraclip, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

If event this hospitalization is TAVR, Indicate if Present at the Time of Durable MCS Device Implant:

Yes
No
Unknown

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

Dobutamine
Dopamine
Milrinone
Levosimendan
Epinephrine
Norepinephrine
Isoproterenol
Phenylephrine
Vasopressin
Angiotensin II
Other, specify- **if other specify, then complete text box.**
Unknown

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

Yes or No

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.

Steroids
Paxlovid
Remdesivir
Convalescent Plasma
Interlukin 6 inhibitor
None
Other, specify

If Other, specify: please complete text box.

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

<https://intermacs.kirso.net/intermacs-documents/>

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

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

Intermacs® 1: Critical cardiogenic shock describes a patient who is “crashing and burning”, in which a patient has life-threatening hypotension and rapidly escalating inotropic pressor support, with critical organ hypoperfusion often confirmed by worsening acidosis and lactate levels.

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

demonstrated “dependent” on inotropic support but nonetheless shows signs of continuing deterioration in nutrition, renal function, fluid retention, or other major status indicator. Patient profile 2 can also describe a patient with refractory volume overload, perhaps with evidence of impaired perfusion, in whom inotropic infusions *cannot be maintained* due to tachyarrhythmias, clinical ischemia, or other intolerance.

Intermacs® 3: Stable but inotrope dependent describes a patient who is clinically stable on mild-moderate doses of intravenous inotropes (or has a temporary circulatory support device) after repeated documentation of failure to wean without symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal). It is critical to monitor nutrition, renal function, fluid balance, and overall status carefully in order to distinguish between a patient who is truly stable at Patient Profile 3 and a patient who has unappreciated decline rendering them Patient Profile 2. This patient may be either at home or in the hospital.

Intermacs® 4: Resting symptoms describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with activities of daily living (ADL). He or she may have orthopnea, shortness of breath during ADL such as dressing or bathing, gastrointestinal symptoms (abdominal discomfort, nausea, poor appetite), disabling ascites or severe lower extremity edema. This patient should be carefully considered for more intensive management and surveillance programs, which may in some cases, reveal poor compliance that would compromise outcomes with any therapy.

Intermacs® 5: Exertion Intolerant describes a patient who is comfortable at rest but unable to engage in any activity, living predominantly within the house or housebound. This patient has no congestive symptoms, but may have chronically elevated volume status, frequently with renal dysfunction, and may be characterized as exercise intolerant.

Intermacs® 6: Exertion Limited also describes a patient who is comfortable at rest without evidence of fluid overload, but who is able to do some mild activity. Activities of daily living are comfortable and minor activities outside the home such as visiting friends or going to a restaurant can be performed, but fatigue results within a few minutes of any meaningful physical exertion. This patient has occasional episodes of worsening symptoms and is likely to have had a hospitalization for heart failure within the past year.

Intermacs® 7: Advanced NYHA Class 3 describes a patient who is clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent. This patient is usually able to walk more than a block. Any decompensation requiring intravenous diuretics or hospitalization within the previous month should make this person a Patient Profile 6 or lower.

User Question: Are we as abstractors allowed to assign an Intermacs profile based on the physician's documentation, or does that need to be provided specifically by the physician?

A: If the Patient Profile is not documented the abstractor can use the patients clinical symptoms and presentation to classify the patient

Clinical Findings:

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

Yes, No, or Unknown

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

Yes, No, or Unknown

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

General Hemodynamics – closest to implant but not in OR. General hemodynamics optimally should be obtained at the same time as the Swan Hemodynamics.

Date of General Hemodynamic Measure: MMDDYYYY **ST=** Unknown or Not Done

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

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

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

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

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

- Sinus
- Atrial fibrillation
- Atrial flutter
- Atrial Dysrhythmia, Other
- Atrial Paced, Ventricular Sensed
- Atrial Sensed, Ventricular Paced
- Atrial Paced, Ventricular Paced
- Junctional
- Unknown
- Not done
- Other, specify – **please complete text box**

Echo Findings - closest to implant but not in OR

Date of Echo Hemodynamic Measure: MMDDYYYY **ST=** Unknown or Not Done

User Question: What is the interval for Pre Implant Echo findings and data collection? It states closest to implant but not in the OR. What time frame is too old?

A: All the data on the Pre Implant form should be collected within 60 days pre implant but not in the OR. With the exception being the QoL surveys needing to be collected within 30 days of implant.

Mitral regurgitation: Mitral regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

- 0 (none)
- 1 (mild)
- 2 (moderate)

3 (severe)
Not Recorded or Not Documented

Tricuspid regurgitation: Tricuspid regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

0 (none)
1 (mild)
2 (moderate)
3 (severe)
Not Recorded or Not Documented

Aortic regurgitation: Aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

0 (none)
1 (mild)
2 (moderate)
3 (severe)
Not Recorded or Not Documented

User Question: We recently had a LVAD patient come to the clinic for a follow-up visit and during their echo it was noted that he had moderate aortic insufficiency. Where/how would I document that in Intermacs?

A: This would be entered on the follow-up form under Aortic Regurgitation and select moderate.

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

> 50 (normal)
40-49 (mild)
30-39 (moderate)
20-29 (moderate/severe)
< 20 (severe)
Not Recorded or Not Documented
Unknown

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

ST= Not Recorded or Not Documented

User Question: Can any other measurements be used in place of LVEDD? For example, I believe the Adult Cardiac Registry allows for other measurements to include LVESD, LVIDs, LVIDd, LV(S), LV(D), LVSD Plax, and LVDD Plax. In my reports I more commonly see LVIDs or LVIDd.

A: It is acceptable to code the LVIDd measurement in place of the LVEDD measurement, as they are similar enough for purposes of the database.

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

Normal
Mild

Moderate
Severe
Not Done
Not Applicable
Unknown

Swan Hemodynamics - closest to implant but not in OR. Swan hemodynamics optimally should be obtained at the same time as the General Hemodynamics.
NOTE: You may be able to get the following information from a right heart catheterization test if it was performed.

Date of Swan Hemodynamic Measure: 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 Pulmonary Artery Capillary 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

Central Venous Pressure (CVP) or Right Atrial Pressure: mmHg (millimeters of mercury). **ST=** Unknown or Not Done

Cardiac Index: Will be expressed as L/min/M². Enter this number. **ST=** Unknown or Not Done

Cardiac Index Measured by Fick or Thermodilution:

Yes, No, or Unknown.

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

Fick
Thermodilution

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

Cardiac Output Measured by Fick or Thermodilution:

Yes, No, or Unknown.

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

Fick
Thermodilution

Laboratory Values collected nearest to time of implant but not in OR

The laboratory values are the LAST values available prior to implant. It is anticipated that the blood urea nitrogen, creatinine, total bilirubin, sodium, INR, white blood cell count, platelet count, and SGOT and SGPT will usually be measured within 48 hours of the implant surgery. Other lab values may be less recent. Values

obtained more than 60 days prior to the implant date should **NOT** be included. For all of the tests listed below, give the appropriate measurement. **ST=** Unknown or Not Done . Please contact your local lab to verify the upper limit of the normal range for Plasma-Free Hemoglobin and LDH.

Laboratory Value:	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
Albumin	g/dL
	g/L
Pre-Albumin	mg/dL
	mg/L
Total Cholesterol	mg/dL
	mmol/L
<i>If value is outside given range please see 'Status (ST=)' drop down field If < 50 mg/dL select from the 'status' drop down field</i>	
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
<i>If value is outside given range please see 'status (ST=)' drop down field If > 7500 pg/mL select from the 'status' drop down field</i>	
NT pro brain natriuretic peptide Pro-BNP	pg/mL
	ng/L
White blood cell count	x10 ³ /uL
	x10 ⁹ /uL
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
CRP or hs-CRP (C Reactive Protein)	mg/L
Lupus anticoagulant	Positive, Negative, Unknown
Uric Acid	mg/dL
	umol/L
<i>If value is outside given range please see 'Status (ST=)' drop down field If < 1 mg/dL select from the 'status' drop down field</i>	

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	

User Question: Are there other names for lupus anticoagulant?

A: Other names for lupus anticoagulant are: LAC; LA: Lupus anticoagulant panel: Lupus inhibitor: LA Sensitive PTT; PTT-LA; Dilute Russell Viper Venom Test; DRVVT; Modified Russell Viper Venom Test; MRVVT. The antiphospholipid and cardiolipin antibodies are related, but are not the same as lupus anticoagulant.

User Question: Lupus antibody and HIT: once positive are they always positive?

A: Answer yes, the first time it is positive it is always positive from that time on. In the case of a false positive, once it is known that it is false, check no at that visit.

Comorbidities - Please check any patient co-morbidities present at the time of the durable MCS implantation below.

Cardiothoracic issues:

Frequent ICD shocks Yes, No, Unknown

(Frequent ICD Shocks Definition: Patient has 3 or more shocks in a 24 hour period)

Chronic Lung Disease Yes, No, Unknown

(Chronic Lung Disease Definition: Indicate whether the patient has chronic lung disease, and the severity level according to the following classification:

- Mild: FEV1 60% to 75% of predicted or on chronic inhaled or oral bronchodilator therapy
- Moderate: FEV1 50% to 59% of predicted or on chronic oral/systemic steroid therapy aimed at lung disease
- Severe: FEV1 <50% or Room Air pO₂ < 60 or pCO₂ > 50
- CLD present, severity not documented
- Unknown

Time Frame: Do not use values obtained more than 12 months prior to the date of surgery.

Spirometry results that have not been interpreted by a pulmonologist may be used to quantify chronic lung disease.

If Yes, indicate Type of Chronic Lung Disease: If Other, specify is selected, type in the specification in the block provided.

Obstructive
Restrictive
Restrictive/Obstructive
Unknown
Other, specify

If Yes, indicate Degree of Dysfunction:

Mild (FEV 60-75% predicted and/or on chronic inhaler/oral meds)
Moderate (FEV 50-59% predicted and/or on chronic steroid)
Severe (FEV <50% predicted or RA pO₂ <60 or PCO₂>50)
Severity Not Documented

Pulmonary Hypertension Yes, No, Unknown

(Pulmonary Hypertension Definition: Indicate whether there is a physician documentation of Pulmonary Hypertension as documented by:

- Right Heart Catheterization: Mean Pulmonary Arterial Pressure (PAP) > 25mmHg at rest
- Echocardiographic diagnosis: PA systolic pressure (PASP)>50mmHg
- Mean Pulmonary Artery Pressure greater than 25mmHg obtained from most recent right heart catheterization of right ventricular systolic pressure greater than 50mmHg obtained from the most recent right heart catheterization or most recent echocardiogram)

Pulmonary Hypertension Intent/Clarification: High blood pressure in the arteries that supply the lungs is called pulmonary hypertension (PHT). The blood vessels that supply the lungs constrict and their walls thicken, so they cannot carry as much blood. This information may be found on a preoperative cardiac catheterization or echocardiogram. If the value is not known or documented, the data sheet should be marked accordingly.
RV systolic pressure may be used if no PA pressure is available, provided there is no pulmonary stenosis. It is preferable to use pressures measured pre-op, prior to induction of anesthesia. A comment in a CT scan of an "enlarged pulmonary artery" suggestive of pulmonary hypertension is **NOT** adequate for this diagnosis.)

Recent Pulmonary Embolus	Yes, No, Unknown
(Recent Pulmonary Embolus Definition: Pulmonary embolus occurring within 3 months of durable VAD implantation)	
History of Atrial Arrhythmia	Yes, No, Unknown
Thoracic Aortic disease	Yes, No, Unknown
(Thoracic Aortic Disease Definition: The presence of an aortic aneurysm, previous history or current history of aortic dissection, or history of aortic ulcer. Indicate whether the patient has a history of disease of the thoracic or thoracoabdominal aorta. Abdominal aortic disease without thoracic involvement is captured in peripheral artery disease.)	
Prior Sternotomy	Yes, No, Unknown
If Yes, Enter Number of Sternotomies: _____	ST= Unknown

User Question: Does this include the current LVAD sternotomy?

A: No, please do not include the current LVAD implant sternotomy. The intent of this question is to capture historical sternotomies prior to the implanting hospitalization.

User Question: in comorbidities under prior sternotomy: is a hemi sternotomy considered a sternotomy? This VAD was placed via a thoracotomy and a hemisternotomy.

A: Yes, please do count a hemi sternotomy as prior sternotomy. But on the Implant form under approach to insertion there are options for left thoracotomy plus mini sternotomy and a left thoracotomy to right mini sternotomy.

Nutritional/GI issues:

Severe Diabetes	Yes, No, Unknown
(Severe Diabetes Definition: Hemoglobin A1c >8mg/dl or associated with diabetic nephropathy, vasculopathy, or oculopathy)	
Malnutrition/Cachexia	Yes, No, Unknown
(Malnutrition/Cachexia Definition: Weight loss > 5% of present body mass in 12 months or less)	
History of GI Ulcers	Yes, No, Unknown
Liver Dysfunction	Yes, No, Unknown

User Question: Would esophageal varices be documented under comorbidity as gastric ulcers?

A: Yes as the esophagus is part of the upper GI system

(Liver Dysfunction Definition: Indicate whether the patient has a history of hepatitis B, hepatitis C, cirrhosis, portal hypertension, esophageal varices, chronic alcohol abuse, or congestive hepatopathy. Exclude NASH in the absence of cirrhosis.)

Liver Dysfunction Intent/Clarification: LFTs or a MELD score alone cannot be used to code "Yes" to liver disease since other conditions impact these lab values. Liver fibrosis with recurrent ascites, supported by the MELD can be coded as liver disease)

Hepatitis	Yes, No, Unknown
If Yes (select all that apply):	
Hepatitis B	
Hepatitis C	
If Yes, Hepatitis B treated? :	
Yes, No, Unknown	
If Yes, Hepatitis C treated? :	
Yes, No, Unknown	

Vascular issues:

Heparin-Induced Thrombocytopenia

Yes, No, Unknown

Chronic coagulopathy

Yes, No, Unknown

(Chronic Coagulopathy Definition: Heparin induced thrombocytopenia, Protein C deficiency, Protein S deficiency, Anti-thrombin 3 deficiency, DIC)

User Question: Should I consider Factor V Leiden a chronic coagulopathy?

A: Yes, please do include Factor V Leiden.

Cerebrovascular Disease

Yes, No, Unknown

If Yes, History of Stroke

Yes, No, Unknown

(Stroke Definition: An acute episode of focal or global neurological dysfunction caused by brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction, where the neurological dysfunction lasts for greater than 24 hours.

This does not include chronic (nonvascular) neurological diseases or other acute neurological insults such as metabolic and anoxic ischemic encephalopathy.)

If Yes, indicate Type of Stroke:

Ischemic (embolic)

Hemorrhagic

Unknown

If Yes, indicate Timing of Stroke (most recent):

Recent (within 30 days of visit)

Remote (greater than 30 days of visit)

Unknown

If Yes, indicate History of Transient Ischemic Attack (TIA): Defined as a transient episode of focal neurological dysfunction caused by brain, spinal cord, or retinal ischemia, without acute infarction, where the neurological dysfunction resolves within 24 hours

Yes

No

Unknown

If Yes, indicate Asymptomatic Severe Carotid Stenosis (80%-100%):

Yes

No

Unknown

Peripheral Arterial Disease

Yes, No, Unknown

(Peripheral Arterial Disease (PVD) Definition: Indicate whether the patient has a history of peripheral arterial disease (includes upper and lower extremity, renal, mesenteric, and abdominal aortic systems). This can include:

- Claudication, either with exertion or at rest
- Amputation for arterial vascular insufficiency
- Vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities (excluding dialysis fistulas and vein stripping)
- Documented abdominal aortic aneurysm with or without repair
- Positive noninvasive test (e.g. ankle brachial index <.09, ultrasound, magnetic resonance or computed tomography imaging of >50% diameter stenosis in any peripheral artery, i.e. renal, subclavian, femoral, iliac) or angiographic imaging

Peripheral arterial disease excludes disease in the carotid, cerebrovascular arteries, or thoracic aorta. PVD does not include DVT.)

If Yes, Peripheral Arterial Disease: Select all regions that apply.

Abdominal aortic aneurysm

Upper extremity disease

Lower extremity disease

Mesenteric disease

Renovascular disease

Source not documented

Oncology/infection issues:

History of Solid Organ Cancer	Yes, No, Unknown
Currently have Cancer	Yes, No, Unknown
History of Solid Organ Transplantation	Yes, No, Unknown
History of Hematopoietic Cancer	Yes, No, Unknown
History of Bone Marrow Transplant (BMT)	Yes, No, Unknown
HIV	Yes, No, Unknown

User Question: Is breast cancer considered a solid organ cancer?

A: Yes, breast cancer is considered a solid organ cancer.

Psychosocial issues:

Psychosocial Issues Yes, No, Unknown

(NOTE: Smoking History has been moved to this section.

Psychosocial issues include: substance abuse disorders along with a detailed smoking history.

Please read this section thoroughly and check the boxes accordingly.)

If Yes, Psychosocial Issues: Select all psychosocial issues that apply.

Depression

History of Severe Depression

Alcohol Abuse

If Yes, indicate Alcohol History:

Remote use (more than 3 months ago)

Recent use (within 3 months)

Unknown

Limited Cognition

Limited Family Support

Noncompliance

History of Narcotic Dependence

If Yes, indicate Narcotic History:

Remote use (more than 3 months ago)

Recent use (within 3 months)

Unknown

Active Illicit Drug Use

History of Smoking

If Yes, indicate Smoking History:

Remote use (more than 3 months ago)

Recent use (within 3 months)

Unknown

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

User Question: In co-morbidities it asks for current or past smoking hx. Does this include any nicotine use such as chewing tobacco, or is this specifically for inhaled nicotine?

A: Yes it is considered smoking.

User Question: Is breast cancer considered a solid organ cancer?

A: Yes, breast cancer is considered a solid organ cancer.

Potential Barriers to Transplantation: If patient not receiving a VAD for BTT listed indication, what are the perceived barriers to transplant?

Advanced age

Yes, No, Unknown, Not applicable: patient listed for transplant

Frailty

Yes, No, Unknown, Not applicable: patient listed for transplant

User Question: If a patient is currently vaping/ using e-cigarettes would that meet criteria to select 'Recent use' under the smoking category?

A: Assessing a patients facility index is often measured by a patients grip strength, weight, and a walking test.

Patient does not want transplant

Yes, No, Unknown, Not applicable: patient listed for transplant

(NOTE: By checking "Yes" you are confirming the patient does not want a heart transplant.)

Musculoskeletal limitation to ambulation

Yes, No, Unknown, Not applicable: patient listed for transplant

Contraindication to immunosuppression

Yes, No, Unknown, Not applicable: patient listed for transplant

Allosensitization

Yes, No, Unknown, Not applicable: patient listed for transplant

Chronic renal disease

Yes, No, Unknown, Not applicable: patient listed for transplant

Large BMI

Yes, No, Unknown, Not applicable: patient listed for transplant

Chronic Infectious Concerns

Yes, No, Unknown, Not applicable: patient listed for transplant

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

Currently using - At the time of VAD placement.

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

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

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

List of medications

Allopurinol

Currently Using

Known previous use (within past year)

No

Unknown

Angiotensin receptor blocker drug

Currently Using

Known previous use (within past year)

No

Unknown

Amiodarone

Currently Using

Known previous use (within past year)

No

Unknown

ACE inhibitors

Currently Using
Known previous use (within past year)
No
Unknown
Beta-blockers
Currently Using
Known previous use (within past year)
No
Unknown

User Question: If a patient was given a pre op BB, how should this be entered?

A: Answer yes currently using.

Aldosterone antagonist
Currently Using
Known previous use (within past year)
No
Unknown
Warfarin (coumadin) (INR)
Currently Using
Known previous use (within past year)
No
Unknown

If **Currently Using** Warfarin (coumadin) (INR):

NOTE: If the Date Started or Date Goal First Achieved is not known, please select "Unknown". We do not expect you to retroactively locate this information.

NOTE: For the Lower Limit and Upper Limit, please enter the current INR therapeutic range, not the range from when Warfarin was first initiated.

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

Guidance for Data Entry: • If the Date Started or Date Goal First Achieved is not known, please select "Unknown". We do not expect you to retroactively locate this information. • For the Lower Limit and Upper Limit, please enter the current INR therapeutic range, not the range from when Warfarin was first initiated.

Antiplatelet therapy drug
Currently Using
Known previous use (within past year)
No
Unknown

ARNi (Entresto) – Check **Yes**, **No**, or **Unknown**.

Within 60 days of the implant date. Note that there is no option for previously taken.

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

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

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

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

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

Furosemide
Torsemide
Bumetanide
Other

Other

User Question: When abstracting follow ups, for patients taking PRN diuretics, that do not provide history of how often they take it, would we code the dose? Or would we code "unknown" ?

A: Enter the dose as unknown.

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

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

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

User Question: If my patient was weaned off inotropes a few months before implant how should I answer this question?

A: If the patient has been off an inotrope infusion for greater than the pre-implant window of 60 days then you would answer no

Is patient on Metalozone/Thiazide? Within 60 days of the implant date.

Check **Yes** or **No** or **Unknown**.

If Yes, then select (check one):

Regular (ex. Daily)
Intermittent (ex. 3 times per week or PRN)

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

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

Is patient on Direct Oral Anticoagulants (DOACs) or novel oral anticoagulants (NOACs)? (dabigatran (Pradaxa), rivaroxaban (Xarelto), apixaban (Eliquis), edoxaban (Savaysa) and betrixaban (Bevyxxa). Check **Yes** or **No** or **Unknown**.

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

Quality of Life (EURoQoL and KCCQ)

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

User Question: When a patient is receives a device exchange and the pre implant forms repopulate it asks for QoL. Should the patient be completing pre implant QoL or is there a form specific for reimplants?

A: Yes, the QoL surveys are re-issued at the time of an exchange.

Exercise/Trailmaking

Exercise Function

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

6 minute walk: This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk *behind* the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here. **NOTE: You may use the time from the first 15 feet of the 6minute walk for the Gait speed test listed below (please see instructions for the gait speed test below.)**

ST= Not Done: Too sick, Not Done: Other, Not Done: Patient Refused to Walk and Unknown.

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

Gait speed (1st 15 foot walk): _____ seconds

Instructions: Record the time (seconds) required for the patient to walk the first 15 feet of the 6 minute walk. The “starting” line and the 15 foot line should be clearly marked. Record the time to the first footfall at 0 feet and ends with the first footfall at 15 feet in the nearest. 0.1 sec with a stopwatch. **NOTE: You may use the time from the first 15 feet of the 6 minute walk for the Gait speed test.**

ST= Not Done: Too sick, Not Done: Other, Not Done: Patient Refused to Walk and Unknown.

Peak VO2 Max: Maximum volume of oxygen the body can consume during exercise

(mL/kg/min) is the ml/kg/min of oxygen consumed during symptom-limited exercise testing either on a bicycle or treadmill. The values recorded during the bicycle are usually 1-2 ml/min lower than for the treadmill, but it is assumed that most institutions will use only one instrument. If both are available, the bicycle is preferable as the mode easiest to standardize.

ST= Not Done: Too sick, Not Done: Other, and Unknown.

R Value at peak: Is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort.

ST= Unknown or Not Done.

User Question: Exercise Function: R value at peak?

A: This is the same as the RER (Respiratory Exchange Ratio) VCO_2/VO_2 .

Neurocognitive Trail Making Test – Part B

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

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**

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.

Durable Implantable VAD Support

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

LVAD

RVAD

Both (LVAD+RVAD in the same OR visit)

Total Artificial Heart (TAH)

User Question: A patient had an unplanned RVAD implanted during LVAD implantation. On the Screening Log should I enter BiVAD?

A: Yes, you can select both for LVAD + RVAD in the same OR visit.

Approach to Insertion: Please specify the surgical approach.

Full Sternotomy

Right Thoracotomy only

Percutaneous

Left Subcostal

Right Subcostal

Left Thoracotomy Only

Bilateral Thoracotomy

Axillary (cut down)

Left Thoracotomy plus Mini Sternotomy

Left Thoracotomy to Right Mini Sternotomy

Unknown

Other, Specify

If Other Specify: Textbox

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

Please refer to **Appendix K** (Brand Device Table) if you have questions or are unsure as to which devices should and should not be included into STS Intermacs®. **Appendix K** is available on <https://intermacs.kirso.net/intermacs-documents/>

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.

Left Ventricle, Apex

Left Ventricle, Diaphragmatic surface

Left Atrium, interatrial groove

Left Atrium, Left Atrial appendage

Left Atrium, Dome left atrium

Right Atrium (Option for Adult Congenital Cases)

Right Ventricle (Option for Adult Congenital Cases)

Unknown

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

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

Ascending aorta
 Descending thoracic aorta
 Abdominal aorta
 Left subclavian artery
 Right subclavian artery
 Unknown
 Other, Specify - **If Other Specify: Textbox**

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

Please refer to **Appendix K** (Brand Device Table) if you have questions or are unsure as to which devices should and should not be included into STS Intermacs®. **Appendix K** is available on <https://intermacs.kirso.net/intermacs-documents/>

RVAD: Approach to Insertion: Please specify the surgical approach.

Full Sternotomy
 Right Thoracotomy only
 Percutaneous
 Left Subcostal
 Right Subcostal
 Left Thoracotomy Only
 Bilateral Thoracotomy
 Axillary (cut down)
 Left Thoracotomy plus Mini Sternotomy
 Left Thoracotomy to Right Mini Sternotomy
 Unknown
 Other, Specify
If Other Specify: Textbox

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

RVAD:

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

Right Atrium
 Right Ventricle
 Left Atrium (Option for Adult Congenital Cases)
 Left Ventricle (Option for Adult Congenital Cases)
 Unknown
 Other, Specify - **If Other Specify: Textbox**

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

MPA (main pulmonary artery)
 LPA (left pulmonary artery)
 RPA (right pulmonary artery)
 Conduit
 Aorta
 Unknown
 Other, Specify - **If Other Specify: Textbox**

For this RVAD, was a cannula utilized? Choose one:

(Pro Tek Duo and Spectrum Double Lumen cannulae are to be captured here.)

Yes
No
Unknown

Anticipated need for RVAD: Select one of the following

Planned (decision for insertion made prior to surgical incision)
Unplanned (unanticipated complication)
Unknown

For RVADs Indicate **The Association of the RHF Event Should be Classified as:** Select one of the following:

Patient-Related – e.g., pre-implant right heart failure, volume overload secondary to non-adherence with medical management, severe aortic regurgitation, cardiorenal syndrome, arrhythmia induced, pulmonary disease, elevated pulmonary vascular resistance
Management-Related – e.g., related to implant surgery, volume overload, inotropic agent withdrawal
Device Related – e.g., associated with Pump malfunction, outflow graft compromise
No Association Identified

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

Please refer to **Appendix K** (Brand Device Table) if you have questions or are unsure as to which devices should and should not be included into STS Intermacs®. **Appendix K** is available on <https://intermacs.kirso.net/intermacs-documents/>

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
Mitral Insufficiency
Select: Mild, Moderate, Severe
Tricuspid Insufficiency
Select: Mild, Moderate, Severe
None

Is the VAD implant occurring in the setting of a failed cardiac operation (same operation or hospitalization)?

Yes
No

If Yes, Occurred in Setting of a Failed Cardiac Operation, Select an Additional Indication for VAD:

Failure to wean from Cardio Pulmonary Bypass
Persistent heart failure following cardiac surgery (same hospitalization)

If Persistent Heart Failure, Enter Cardiac Operation in textbox provided

None
Failure to wean from ECMO

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
 CABG
 VSD closure
 Congenital cardiac surgery, other
 Aortic Valve Procedure
 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
 Tricuspid Valve Surgery – Excision
 Pulmonary Valve Surgery - Repair
 Pulmonary Valve Surgery - Replacement - Biological
 Pulmonary Valve Surgery - Replacement – Mechanical
 Left Ventricular Aneurysmectomy
 Other, specify - **If Other, Specify: Textbox**
 Arrhythmia Surgery (Ablation)
 Ligation of Left Atrial Appendage
 Temporary MCS Removal (ECMO, IABP removal documented here)
 Extracorporeal Membrane Oxygenation (ECMO Insertion)

If CABG, Indication for CABG: Select one of the following
 Planned (decision for CABG made prior to skin incision)
 Unplanned (unanticipated complication)
 Unknown

If CABG, Territories revascularized: Select all that apply
 RCA
 LAD
 Circumflex
 Unknown

If Aortic Valve Procedure: Select one of the following
 Full (annular patch or complete leaflet closure)
 Partial leaflet closure (Park stitch or plication leaflet tips only)
 Unknown

If Mitral Valve Surgery Repair: Select all that apply
 Annuloplasty
 Alfieri stitch
 Unknown

If Annuloplasty: Select one of the following
 Complete ring
 Partial band
 Unknown

If Annuloplasty Ring or Band: enter **Size** in mm
ST = Unknown

If Arrhythmia Surgery (ablation): Select all that apply
 Ventricular
 Atrial
 Unknown

If Atrial: Select all that apply

- Left-sided
- Right-sided
- Unknown

If Left-sided: Select one of the following

- Pulmonary vein isolation only
- Complete left sided lesion set (Maze procedure)
- Unknown

If Ligation of Left Atrial Appendage: Select one of the following

- Surgical device (e.g. AtriClip)
- Oversew and or staple
- Excision
- Unknown

If Temporary MCS Removal: Select all that apply

- ECMO Decannulation
- IABP
- RVAD, Temporary
- LVAD, Temporary
- Other, specify - **If Other, Specify: Textbox**

If Temporary MCS Removal: LVAD: Select LVAD Device Brand

- Abiomed BVS 5000
- Abiomed AB5000
- TandemHeart
- Thoratec Centrimag (Levitronix)
- Sorin Revolution
- Abiomed Impella CP
- Abiomed Impella 2.5
- Abiomed Impella 5.0
- Abiomed Impella RP
- Abiomed Impella 5.5
- Maquet Rotaflow
- LifeSPARC
- Other, Specify - **If Other, Specify: Textbox**

If Temporary MCS Removal: RVAD: Select RVAD Device Brand

- Abiomed BVS 5000
- Biomedicus
- Abiomed AB5000
- TandemHeart
- Thoratec Centrimag (Levitronix)
- Sorin Revolution
- Abiomed Impella CP
- Abiomed Impella 2.5
- Abiomed Impella 5.0
- Abiomed Impella RP
- Abiomed Impella 5.5
- Maquet Rotaflow
- LifeSPARC
- Other, Specify - **If Other, Specify: Textbox**

If Temporary MCS Removal: For this RVAD, was a cannula utilized?

Choose one:

(Pro Tek Duo and Spectrum Double Lumen cannulae are to be captured here.)

Yes

No
Unknown

If Extracorporeal Membrane Oxygenation: Select one of the following

Veno-venous (VV) ECMO
Veno-arterial (VA) ECMO
Unknown

If VV or VA ECMO: Select **Outflow Cannula Location**

Femoral Artery
Ascending aorta
Descending thoracic aorta
MPA (main pulmonary artery)
LPA (left pulmonary artery)
RPA (right pulmonary artery)
Conduit
Left subclavian artery
Right subclavian artery
Femoral (percutaneous)
Femoral (cut down)
Unknown
Other, Specify - **If Other Specify: Textbox**

If VV or VA ECMO: Select **Inflow Cannula Location**

Femoral Vein
Left Atrium, Left Atrial appendage
Left Atrium, interatrial groove
Left Ventricle, Apex
Left Ventricle, Diaphragmatic surface
Left Atrium, Dome left atrium
Right Atrium
Right Ventricle
Femoral (percutaneous)
Femoral (cut down)
Unknown
Other, Specify - **If Other Specify: Textbox**

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

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

ST = Unknown or Not done.

If **yes** was an **Aortic Cross Clamp** used: Yes, No, or Unknown

If **yes** enter duration of the **Aortic Cross Clamp Time** in minutes: _____(min).

ST = Unknown or Not done.

User Question: If a partial cross clamp is done is that considered aortic cross clamp?

A: If a partial occlusion cross clamp is used, then it is NOT considered Aortic cross clamp per Dr. Pagani.

If **yes** select **Temperature:** Lowest body temperature during cardiopulmonary bypass.

Normothermia (37°C)
Mild hypothermia (32 to < 37°C)
Deep hypothermia (<32°C)
Not Done

If **yes** enter **Lowest Hematocrit on Pump:** % **ST** = Unknown

If **yes** enter **Highest Serum Arterial Lactate on Pump:** mmol/L **ST** = Unknown

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

User Question: How do I record surgery time if my patient's chest was left open?
A: Consider the time the patient left the OR was the end of surgery time.

Indicate **Status of Incision at end of Procedure:**

Open (i.e. delayed sternal closure)
Closed
Unknown

Additional Operative Details

Was **Left Ventricular Thrombus Present** at the time of operation?

(NOTE: By indicating "yes" you are confirming the left ventricular thrombus was removed.)

Yes
No
Unknown

Was **Left Atrial Appendage Clot Present** at the time of operation?

Yes
No
Unknown

If **yes, Was the Left Atrial Appendage Clot Removed?**

Yes
No
Unknown

Was **Palpable Atherosclerotic Plaque or Calcified Plaque Present** in the ascending aorta or aortic arch at the time of operation?

Yes
No
Unknown
Did not Evaluate

If **yes, Did the Presence of Palpable Atherosclerotic Plaque or Calcified Plaque change operative plans?**

Yes
No
Unknown

Was a **Patent Foramen Ovale Present** at the time of operation?

Yes
No
Unknown

If **yes, Was the Patent Foramen Ovale Closed?**

Yes
No
Unknown

Were **Traction/Stabilization sutures utilized to optimize (inlet cannula) LVAD Pump position?**

Yes
No

Unknown

Which **Deairing Techniques** were utilized at the time of device implantation? Select all that apply:

- None
- Use of CO2 to flood the operative field
- Needle evacuation of air from the outflow graft
- Aortic root vent
- Left Ventricular vent (Right superior pulmonary vein)
- Unknown
- Other, Specify - **If Other Specify: Textbox**

Was the LVAD procedure **complicated by vasoplegia** (MAP < 60 mmHg requiring > 1 vasopressor to treat or unexpected ECMO) during or following Cardiopulmonary bypass in the operating room?

- Yes
- No
- Unknown
- Not Applicable
- Not Applicable

User Question: My patient left the OR on epi do I answer yes to this question?
A: No, both parts of this definition need to be met to answer yes.

Implant Hemodynamics – At the start of procedure following induction of anesthesia but prior to skin incision

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

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

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

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

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

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

Mean Pulmonary Artery Capillary 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

Central Venous Pressure (CVP) or Right Atrial Pressure: mmHg (millimeters of mercury). **ST=** Unknown or Not Done

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

ST= Unknown or Not Done**Cardiac Index Measured by Fick or Thermodilution:**

Yes, No, or Unknown.

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

Fick

Thermodilution

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

ST= Unknown or Not Done**Cardiac Output Measured by Fick or Thermodilution:**

Yes, No, or Unknown.

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

Fick

Thermodilution

Intraoperative Transfusions – Are not counted as a major bleeding event

Were **Intraoperative Blood Products or Clotting Factors** given to treat bleeding/coagulopathy?

Yes

No

Unknown

If **Yes** Check any **Transfusions or Clotting Factor Replacements Administered** (select all that apply):

Packed Red Blood Cells

Prothrombin Complex Concentrate

Factor VII

Platelets

Cryoprecipitate

Fresh Frozen Plasma

Other - If **Other Specify:** Textbox

Unknown

If **Packed RBC** enter **Number of packed RBC units.** ____

ST= Unknown

If **Platelets** enter **Number of platelet units.** ____

ST= Unknown

If **Fresh Frozen Plasma** enter **Number fresh frozen plasma units.** ____

ST= Unknown

If **Cryoprecipitate** enter **Number cryoprecipitate units.** ____

ST= Unknown

User Question: would human albumin count in the transfusion or clotting factor replacement section during implant?

A: This question is focused on blood components and clotting factor replacements used to treat bleeding or coagulopathy. Human albumin is a plasma-derived product but not a clotting factor and does not directly treat coagulopathy. So please do not include it here.

2.5 1 Week and 1 Month Follow-up

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

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.

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

User Question: Are we entering the patient's home address or the hospital address?

A: Please enter the patient's home address.

User Question: Why are we collecting patient's addresses and how will that data be used?

A: Social Determinants of Health (SDOH) are highly correlated with health outcomes in patients. Collecting address allows us to identify local SDOH, which will facilitate understanding barriers to equality in access to care and allow implementation of strategies to reduce the impact of SDOH on Ventricular Assist Device (VAD) patient outcomes.

Was patient intubated since implant? This includes all time since last follow-up. (Check “on-going intubation: chronic trach” for patients that have a tracheostomy and are discharged on a ventilator. This excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures)

Yes, No, Unknown, or On-going Intubation: Chronic Trach

User Question: My patient was extubated in the OR however, upon arrival to the ICU he had to be re-intubated for respiratory distress, do I answer yes?

A: If they are intubated at any time after, they leave the OR then answer yes. If extubated in the OR and no requirement for reintubation before this follow-up, then answer no.

Was 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.

Steroids
Paxlovid
Remdesivir
Convalescent Plasma
Interlukin 6 inhibitor
None
Other, specify

If Other, specify: please complete text box.

Console Change - Please answer all questions regarding console changes considering all time since previous visit and current follow-up date.

Was there a console change (for TAH or Berlin Heart Consoles)?

Yes, No, or Unknown

If Yes please complete the following:

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

Original console name: Text.

New console name: Text.

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

User Question: NYHA II B/III A documented – What do I enter?

A: Record the highest NYHA class documented (In this case enter III A)

Was there a **hemolysis** event since the last followup? If yes, please complete a Hemolysis Adverse Event Form.

Yes, No, or Unknown

Was there a **right heart failure** event since the last followup? If yes, please complete a Right Heart Failure Adverse Event Form.

Yes, No, or Unknown

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

<https://intermacs.kirso.net/intermacs-documents/>

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

Yes, No, Unknown

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

If yes, provide Modified Rankin Scale:

0 – No symptoms at all

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

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

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

- 4 – Moderately severe disability:** unable to walk without assistance, and unable to attend to own bodily needs without assistance.
- 5 – Severe disability:** bedridden, incontinent and requiring constant nursing care and attention.
- 6 – Dead**
- Not Done**
- 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 – General hemodynamics optimally should be obtained at the same time as the Swan Hemodynamics.

Date of General Hemodynamic Measure: MMDDYYYY **ST=** Unknown or Not Done

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

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

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

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

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

- Sinus
- Atrial fibrillation
- Atrial flutter
- Atrial Dysrhythmia, Other
- Atrial Paced, Ventricular Sensed
- Atrial Sensed, Ventricular Paced
- Atrial Paced, Ventricular Paced
- Junctional
- Unknown
- Not done
- Other, specify – **please complete text box**

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

Echo Findings

Date of Echo Hemodynamic Measure: MMDDYYYY **ST=** Unknown or Not Done

Mitral regurgitation: Mitral regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

- 0 (none)
- 1 (mild)
- 2 (moderate)
- 3 (severe)
- Not Recorded or Not Documented

Tricuspid regurgitation: Tricuspid regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

- 0 (none)
- 1 (mild)
- 2 (moderate)
- 3 (severe)
- Not Recorded or Not Documented

Aortic regurgitation: Aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

- 0 (none)
- 1 (mild)
- 2 (moderate)
- 3 (severe)
- Not Recorded or Not Documented

User Question: We recently had a LVAD patient come to the clinic for a follow-up visit and during their echo it was noted that he had moderate aortic insufficiency. Where/how would I document that in InterMacS?

A: This would be entered on the follow-up form under Aortic Regurgitation and select moderate.

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

- > 50 (normal)
- 40-49 (mild)
- 30-39 (moderate)
- 20-29 (moderate/severe)
- < 20 (severe)
- Not Recorded or Not Documented
- Unknown

LVEDD: Left ventricular end-diastolic dimension in centimeters.

ST = Not Record or Not Documented

User Question: Can any other measurements be used in place of LVEDD? For example, I believe the Adult Cardiac Registry allows for other measurements to include LVESD, LVIDs, LVIDd, LV(S), LV(D), LVSD Plax, and LVDD Plax. In my reports I more commonly see LVIDs or LVIDd.

A: It is acceptable to code the LVIDd measurement in place of the LVEDD measurement, as they are similar enough for purposes of the database.

RVEF: RV Function is generally NOT measured in numbers, as it is difficult to quantify. It may be described as "right ventricular function" or "right ventricular contractility". "Mild impairment, mildly reduced, or mild decrease" would all be

characterized as “mild”. Again, mild-moderate would be recorded as moderate, and moderate-severe would be recorded as “severe”.

Normal
Mild
Moderate
Severe
Not Done
Not Applicable
Unknown

Swan Hemodynamics – Swan hemodynamics optimally should be obtained at the same time as the General Hemodynamics.

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

User Question: I have a patient who was in the hospital for an extended period of time. He had two right heart cath (5/31 & 7/2). Which one should I use for documentation purposes in Intermacs?

A: Use the one that is closest to the follow-up visit date.

Date of Swan Hemodynamic Measure: 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 Pulmonary Artery Capillary 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

Central Venous Pressure (CVP) or Right Atrial Pressure: mmHg (millimeters of mercury). **ST=** Unknown or Not Done

Cardiac Index: Will be expressed as L/min/M². Enter this number. **ST=** Unknown or Not Done

Cardiac Index Measured by Fick or Thermodilution:

Yes, No, or Unknown.

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

Fick
Thermodilution

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

Cardiac Output Measured by Fick or Thermodilution:

Yes, No, or Unknown.

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

Fick
Thermodilution

Medications

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

List of medications

Hydralazine (*collected at 1 month and subsequent visits*)

Calcium channel blockers (*collected at 1 month and subsequent visits*)

Angiotensin receptor blocker drug

Amiodarone

ACE inhibitors

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

Beta-blockers

Aldosterone antagonist

Low molecular weight heparin (Lovenox, Fragmin, Innohep)

UFH: Unfractionated Heparin

Warfarin (coumadin) (INR)

If **Yes** Warfarin (coumadin) (INR):

NOTE: If the Date Started or Date Goal First Achieved is not known, please select "Unknown". We do not expect you to retroactively locate this information.

NOTE: For the Lower Limit and Upper Limit, please enter the current INR therapeutic range, not the range from when Warfarin was first initiated.

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

Guidance for Data Entry: • If the Date Started or Date Goal First Achieved is not known, please select "Unknown". We do not expect you to retroactively locate this information. • For the Lower Limit and Upper Limit, please enter the current INR therapeutic range, not the range from when Warfarin was first initiated.

Arixtra (fondaparinux)

Argatroban

Bivalrudin

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

Aspirin

Dextran

Dipyridamole

Clopidogrel

Ticlopidine

Unknown

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

User Question: How do we document antiplatelet therapy for INTERMACS patients who are in the ARIES trial? As you know, they receive Aspirin vs Placebo for this study and we do not know which one they have been assigned to.

A: For patients in the ARIES trial document unknown on both the follow-up and AE forms.

ARNi (Entresto)

Nitric oxide (*document Flolan here*)

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

Digoxin

Loop diuretics

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

Enter **Dosage** _____ mg/day – 24 hrs mg total **ST=** Unknown

If dose is entered, then check **type of loop diuretic** (select all that apply):
 (*collected at 1 month and subsequent visits*)

Furosemide

Torsemide

Bumetanide

Other

Direct Oral Anticoagulants (DOACs) or novel oral anticoagulants (NOACs) (*dabigatran (Pradaxa), rivaroxaban (Xarelto), apixaban (Eliquis), edoxaban (Savaysa) and betrixaban (Bevyxxa)*)

User Question: What if my patient is on more than one diuretic and was on varying doses?

A: (Example: at one week follow-up, patient was given both Lasix and Bumex, Bumex 4.5mg one day, 4.0mg the next day, Lasix 20mg one day and then d/c'd thereafter.) Average the doses of all the Bumex. Since patient was not on Lasix at time of 1 week visit and only had one dose, do not include the Lasix in the average because the Bumex was taken more regularly.

User When abstracting follow ups, for patients taking PRN diuretics, that do not provide history of how often they take it, would we code the dose? Or would we code "unknown" ?

A: Enter the dose as 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
<i>If value is outside given range please see 'Status (ST=)' drop down field If < 50 mg/dL select from the 'status' drop down field</i>	
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
<i>If value is outside given range please see 'status (ST=)' drop down field If > 7500 pg/mL select from the 'status' drop down field</i>	
NT pro brain natriuretic peptide Pro-BNP	pg/mL
	ng/L
Reticulocyte count	%
White blood cell count	x10 ³ /uL
	x10 ⁹ /uL
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
Uric Acid	mg/dL
	umol/L
<i>If value is outside given range please see 'Status (ST=)' drop down field If < 1 mg/dL select from the 'status' drop down field</i>	

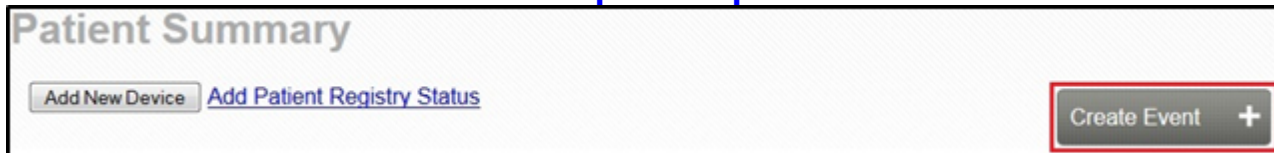
User Question: Are there other names for lupus anticoagulant?

A: Other names for lupus anticoagulant are: LAC; LA: Lupus anticoagulant panel; Lupus inhibitor: LA Sensitive PTT; PTT-LA; Dilute Russell Viper Venom Test; DRVVT; Modified Russell Viper Venom Test;

MRVVT. The antiphospholipid and cardiolipin antibodies are related, but are not the same as lupus anticoagulant.

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.



The screenshot shows a 'Patient Summary' header with two buttons: 'Add New Device' and 'Add Patient Registry Status'. On the right side, there is a 'Create Event +' button highlighted with a red border.

- Rehospitalization
- Major Infection
- Major Bleeding
- Neurological Dysfunction
- Device Malfunction (if suspected device thrombosis, then enter as Device Malfunction)
- Extracorporeal/Paracorporeal Pump Change
- Hemolysis
- Right Heart Failure
- Renal Dysfunction
- Cardiac Arrhythmia
- Respiratory Failure
- Venous Thromboembolic Event
- Wound Dehiscence
- Arterial Non-CNS Thromboembolism
- Hypertension
- Hepatic Dysfunction
- Psychiatric Episode
- Pericardial Fluid Collection
- Myocardial Infarction
- 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/intermacs-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

User Question: When entering data for a follow-up visit, you can enter any data from the previously entered follow-up to the current follow up, but not data after the follow-up date, correct?

A: The follow-up date is based on the implant date. For example, an implant date of April 1st. The 6 month follow-up is due October 1st. There is a +/-2 month window for every follow-up. For that October 1st 6 month follow-up you can enter any follow-up visit from August 1st-December 1st.

The 3 month follow-up is slightly different. That is +/- 1 month window. So the April 1st implant the 3 month follow-up that is due July 1st can have any follow-up visit data from June 1st-August 1st.

To answer your question about data after your follow-up that is correct. Say for instance for that 6 month follow up you are using a September 30th visit. You can use data since the previous follow-up until that September 30th visit. Data closest to visit date is preferred

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

User Question: Are we entering the patient's home address or the hospital address?

A: Please enter the patient's home address.

User Question: Why are we collecting patient's addresses and how will that data be used?

A: Social Determinants of Health (SDOH) are highly correlated with health outcomes in patients. Collecting address allows us to identify local SDOH, which will facilitate understanding barriers to equality in access to care and allow implementation of strategies to reduce the impact of SDOH on Ventricular Assist Device (VAD) patient outcomes.

Was patient intubated since last follow-up? This includes all time since last follow-up. (Check "on-going intubation: chronic trach" for patients that have a tracheostomy and are discharged on a ventilator. This excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures)

Yes, No, Unknown, or On-going Intubation: Chronic Trach

User Question: If a patient was intubated for a procedure is that documented here?

A: No, this question is geared toward patients intubated for respiratory failure.

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

Yes, No, or Unknown

Patient Status

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

Bridge to recovery - Use of a durable device to allow recovery from chronic cardiac failure (at least 3 months in duration).

Rescue therapy - Use of a durable device to support resolution from an acute event without major previous cardiac dysfunction.

Bridge to transplant– This is for a patient who has been listed for transplant since initial implantation.

List Date for Transplant:

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

Enter **UNOS Waitlist ID** Number. **ST**= Unknown.

Possible bridge to transplant - Likely to be eligible: defines a patient in whom the transplant evaluation has not been completed, but no contra-indications are anticipated, or in whom a current contra-indication is anticipated to resolve rapidly, such as recent infection.

Possible bridge to transplant - Moderate likelihood of becoming eligible: similar to above, but with some potential concerns that might prevent eligibility.

Possible bridge to transplant - Unlikely to become eligible: should be used for a patient in whom major concerns have already been identified. These may not have been quantified yet, such as in a patient with known chronic lung disease without recent pulmonary function test measurement, or might be reversible, such as severe renal insufficiency or pulmonary hypertension that might improve after chronic mechanical support. It may be the expectation at the time of implant that the patient will most likely have the assist device as "permanent" or "destination" therapy.

Destination therapy - (patient definitely not eligible for transplant). All factors that weigh in to the decision of non-transplant candidacy should be indicated below.

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

User Question: Do we still need to specify device strategy even though it is not a CMS requirement?

A: Yes, you need to continue to enter the current device strategy at implant and for each follow up.

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.

Steroids
Paxlovid
Remdesivir
Convalescent Plasma
Interlukin 6 inhibitor
None
Other, specify

If Other, specify: please complete text box.

Console Change - Please answer all questions regarding console changes considering all time since previous visit and current follow-up date.

Was there a console change (for TAH or Berlin Heart Consoles)?

Yes, No, or Unknown

If Yes please complete the following:

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

Original console name: Text.

New console name: Text.

Was there a **hemolysis** event since the last followup? If yes, please complete a Hemolysis Adverse Event Form.

Yes, No, or Unknown

Was there a **right heart failure** event since the last followup? If yes, please complete a Right Heart Failure Adverse Event Form.

Yes, No, or Unknown

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

<https://intermacs.kirso.net/intermacs-documents/>

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

Yes, No, Unknown

User Question: If a patient has a stroke, do I continue to mark this for every follow-up? For example, a patient had an immediate post op stroke in 2018 and it was captured at that time. Should the neuro event question in the follow-ups be answered yes every time?

A: Answer yes at all subsequent follow-ups if a patient had a CVA, TIA, or anoxic brain injury to track the Modified Rankin Scale over time.

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

If yes, provide Modified Rankin Scale:

0 – No symptoms at all

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

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

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

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

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

6 – Dead

Not Done

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 – General hemodynamics optimally should be obtained at the same time as the Swan Hemodynamics.

Date of General Hemodynamic Measure: MMDDYYYY **ST**= Unknown or Not Done

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

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

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

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

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

- Sinus
- Atrial fibrillation
- Atrial flutter
- Atrial Dysrhythmia, Other
- Atrial Paced, Ventricular Sensed
- Atrial Sensed, Ventricular Paced
- Atrial Paced, Ventricular Paced
- Junctional
- Unknown
- Not done
- Other, specify – **please complete text box**

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

Echo Findings

Date of Echo Hemodynamic Measure: MMDDYYYY **ST=** Unknown or Not Done

Mitral regurgitation: Mitral regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

- 0 (none)
- 1 (mild)
- 2 (moderate)
- 3 (severe)
- Not Recorded or Not Documented

Tricuspid regurgitation: Tricuspid regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

- 0 (none)
- 1 (mild)
- 2 (moderate)
- 3 (severe)
- Not Recorded or Not Documented

Aortic regurgitation: Aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

- 0 (none)
- 1 (mild)
- 2 (moderate)
- 3 (severe)

User Question: We recently had a LVAD patient come to the clinic for a follow-up visit and during their echo it was noted that he had moderate aortic insufficiency. Where/how would I document that in Intermacs?

A: This would be entered on the follow-up form under Aortic Regurgitation and select moderate.

Not Recorded or Not Documented

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

> 50 (normal)
40-49 (mild)
30-39 (moderate)
20-29 (moderate/severe)
< 20 (severe)
Not Recorded or Not Documented
Unknown

LVEDD: Left ventricular end-diastolic dimension in centimeters.

ST = Not Record or Not Documented

User Question: Can any other measurements be used in place of LVEDD? For example, I believe the Adult Cardiac Registry allows for other measurements to include LVESD, LVIDs, LVIDd, LV(S), LV(D), LVSD Plax, and LVDD Plax. In my reports I more commonly see LVIDs or LVIDd.

A: It is acceptable to code the LVIDd measurement in place of the LVEDD measurement, as they are similar enough for purposes of the database.

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

Normal
Mild
Moderate
Severe
Not Done
Not Applicable
Unknown

Swan Hemodynamics – Swan hemodynamics optimally should be obtained at the same time as the General Hemodynamics.

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

User Question: I have a patient who was in the hospital for an extended period of time. He had two right heart cath (5/31 & 7/2). Which one should I use for documentation purposes in InterMac^s?

A: Use the one that is closest to the follow-up visit date.

Date of Swan Hemodynamic Measure: 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 Pulmonary Artery Capillary 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

Central Venous Pressure (CVP) or Right Atrial Pressure: mmHg (millimeters of mercury). **ST=** Unknown or Not Done

Cardiac Index: Will be expressed as L/min/M². Enter this number. **ST=** Unknown or Not Done

Cardiac Index Measured by Fick or Thermodilution:

Yes, No, or Unknown.

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

Fick

Thermodilution

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

Cardiac Output Measured by Fick or Thermodilution:

Yes, No, or Unknown.

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

Fick

Thermodilution

Medications

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

List of medications

Hydralazine

Calcium channel blockers

Angiotensin receptor blocker drug

Amiodarone

ACE inhibitors

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

Beta-blockers

Aldosterone antagonist

Low molecular weight heparin (Lovenox, Fragmin, Innohep)

UFH: Unfractionated Heparin

Warfarin (coumadin) (INR)

If **Yes** Warfarin (coumadin) (INR):

NOTE: If the Date Started or Date Goal First Achieved is not known, please select "Unknown". We do not expect you to retroactively locate this information.

NOTE: For the Lower Limit and Upper Limit, please enter the current INR therapeutic range, not the range from when Warfarin was first initiated.

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

Guidance for Data Entry: • If the Date Started or Date Goal First Achieved is not known, please select "Unknown". We do not expect you to retroactively locate this information. • For the Lower Limit and Upper Limit, please enter the current INR therapeutic range, not the range from when Warfarin was first initiated.

Arixtra (fondaparinux)

Argatroban

Bivalrudin

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

Aspirin

Dextran

Dipyridamole

Clopidogrel

Ticlopidine

Unknown

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

User Question: How do we document antiplatelet therapy for INTERMACS patients who are in the ARIES trial? As you know, they receive Aspirin vs Placebo for this study and we don't know which one they have been assigned to.

A: For patients in the ARIES trial document unknown on both the follow-up and AE forms.

ARNi (Entresto)

Nitric oxide (*document Flolan here*)

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

Digoxin

Loop diuretics

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

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

User Question: What if my patient is on more than one diuretic and was on varying doses?

A: (Example: at one week follow-up, patient was given both Lasix and Bumex, Bumex 4.5mg one day, 4.0mg the next day, Lasix 20mg one day and then d/c'd thereafter). Average the doses of all the Bumex. Since patient was not on Lasix at time of 1 week visit and only had one dose, do not include the Lasix in the average because the Bumex was taken more regularly.

Direct Oral Anticoagulants (DOACs) or novel oral anticoagulants (NOACs) (*dabigatran (Pradaxa), rivaroxaban (Xarelto), apixaban (Eliquis), edoxaban (Savaysa) and betrixaban (Bevyxxa)*)

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
<i>If value is outside given range please see 'Status (ST=)' drop down field If < 50 mg/dL select from the 'status' drop down field</i>	
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
<i>If value is outside given range please see 'status (ST=)' drop down field If > 7500 pg/mL select from the 'status' drop down field</i>	
NT pro brain natriuretic peptide Pro-BNP	pg/mL
	ng/L
Reticulocyte count	%
White blood cell count	x10 ³ /uL
	x10 ⁹ /uL
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
Uric Acid	mg/dL
	umol/L
<i>If value is outside given range please see 'Status (ST=)' drop down field If < 1 mg/dL select from the 'status' drop down field</i>	

User Question: Are there other names for lupus anticoagulant?

A: Other names for lupus anticoagulant are: LAC; LA: Lupus anticoagulant panel: Lupus inhibitor: LA Sensitive PTT; PTT-LA; Dilute Russell Viper Venom Test; DRVVT; Modified Russell Viper Venom Test; MRVVT. The antiphospholipid and cardiolipin antibodies are related, but are not the same as lupus anticoagulant.

User Question: Lupus antibody and HIT: once positive are they always positive?

A: Answer yes, the first time it is positive it is always positive from that time on. In the case of a false positive, once it is known that it is false, check no at that visit.

Device Details

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

Device Function

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

Pulsatility Index: Enter this number. **ST=** Unknown

Pump Power: Will be expressed in watts. Enter this number. **ST=** Unknown

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

Driver Type: Enter type. **ST=** Unknown

Device Parameters

Control Mode: Please specify the control mode.

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

Pump Speed: Will be expressed as RPM. Enter this number. **ST=** Unknown

Low Speed: Will be expressed as RPM. Enter this number. **ST=** Unknown

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

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

Device Inspection

Auscultation: Please choose an option for auscultation.

Abnormal
Normal
Not Applicable

Driveline: Please choose an option for the driveline appearance.

Abnormal
Normal
Not Applicable

Exercise/Trailmaking

Exercise Function

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

6 minute walk: This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk *behind* the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here. **NOTE: You may use the time from the first 15 feet of the 6minute walk for the Gait speed test listed below (please see instructions for the gait speed test below.)**

ST= Not Done: Too sick, Not Done: Other, Not Done: Patient Refused to Walk and Unknown.

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

User Question: Our site is doing many telehealth visits. Do we still need to complete the 6MWT?
A: If possible using FaceTime or other means of video conferencing we ask you do your best to collect this data.

Gait speed (1st 15 foot walk): _____ seconds

Instructions: Record the time (seconds) required for the patient to walk the first 15 feet of the 6 minute walk. The “starting” line and the 15 foot line should be clearly marked. Record the time to the first footfall at 0 feet and ending with the first footfall at 15 feet rounded to the nearest 0.1 sec with a stopwatch. **NOTE: You may use the time from the first 15 feet of the 6 minute walk for the Gait speed test.**

ST= Not Done: Too sick, Not Done: Other, Not Done: Patient Refused to Walk and Unknown.

Peak VO2 Max: Maximum volume of oxygen the body can consume during exercise

(mL/kg/min) is the ml/kg/min of oxygen consumed during symptom-limited exercise testing either on a bicycle or treadmill. The values recorded during the bicycle are usually 1-2 ml/min lower than for the treadmill, but it is assumed that most institutions will use only one instrument. If both are available, the bicycle is preferable as the mode easiest to standardize.

ST= Not Done: Too sick, Not Done: Other, and Unknown.

R Value at peak: Is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort.

ST= Unknown or Not Done

Neurocognitive Trail Making Test – Part B

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

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

User Question: NYHA II B/III A documented – What do I enter?

A: Record the highest NYHA class documented (In this case enter III A)**Comorbidities - Please check any patient co-morbidities present at the time of follow-up below.****Cardiothoracic issues:**

Frequent ICD shocks

Yes, No, Unknown

(Frequent ICD Shocks Definition: Patient has 3 or more shocks in a 24 hour period)

Chronic Lung Disease

Yes, No, Unknown

(Chronic Lung Disease Definition: Indicate whether the patient has chronic lung disease, and the severity level according to the following classification:

- *Mild: FEV1 60% to 75% of predicted or on chronic inhaled or oral bronchodilator therapy*
- *Moderate: FEV1 50% to 59% of predicted or on chronic oral/systemic steroid therapy aimed at lung disease*
- *Severe: FEV1 <50% or Room Air pO₂ < 60 or pCO₂ > 50*
- *CLD present, severity not documented*
- *Unknown*

*Time Frame: Do not use values obtained more than 12 months prior to the date of surgery.**Spirometry results that have not been interpreted by a pulmonologist may be used to quantify chronic lung disease.***If Yes, indicate Type of Chronic lung Disease:** If Other, specify is selected, type in the specification in the block provided.

Obstructive

Restrictive

Restrictive/Obstructive

Unknown

Other, specify

If Yes, indicate Degree of Dysfunction:

Mild (FEV 60-75% predicted and/or on chronic inhaler/oral meds)

Moderate (FEV 50-59% predicted and/or on chronic steroid)

Severe (FEV <50% predicted or RA pO₂ <60 or PCO₂>50)

Severity Not Documented

Pulmonary Hypertension

Yes, No, Unknown

(Pulmonary Hypertension Definition: Indicate whether there is a physician documentation of Pulmonary Hypertension as documented by:

- *Right Heart Catheterization: Mean Pulmonary Arterial Pressure (PAP) > 25mmHg at rest*
- *Echocardiographic diagnosis: PA systolic pressure (PASP)>50mmHg*
- *Mean Pulmonary Artery Pressure greater than 25mmHg obtained from most recent right heart catheterization of right ventricular systolic pressure greater than 50mmHg obtained from the most recent right heart catheterization or most recent echocardiogram)*

***Pulmonary Hypertension Intent/Clarification:** High blood pressure in the arteries that supply the lungs is called pulmonary hypertension (PHT). The blood vessels that supply the lungs constrict and their walls thicken, so they cannot carry as much blood. This information may be found on a preoperative cardiac catheterization or echocardiogram. If the value is not known or documented, the data sheet should be marked accordingly.**RV systolic pressure may be used if no PA pressure is available, provided there is no pulmonary stenosis. It is preferable to use pressures measured pre-op, prior to induction of anesthesia.**A comment in a CT scan of an "enlarged pulmonary artery" suggestive of pulmonary hypertension is **NOT** adequate for this diagnosis.)*

Recent Pulmonary Embolus

Yes, No, Unknown

(Recent Pulmonary Embolus Definition: Pulmonary embolus occurring within 3 months of durable VAD implantation)

History of Atrial Arrhythmia

Yes, No, Unknown

Thoracic Aortic disease Yes, No, Unknown
(Thoracic Aortic Disease Definition: The presence of an aortic aneurysm, previous history or current history of aortic dissection, or history of aortic ulcer.
 Indicate whether the patient has a history of disease of the thoracic or thoracoabdominal aorta. Abdominal aortic disease without thoracic involvement is captured in peripheral artery disease.)

Prior Sternotomy Yes, No, Unknown
 If Yes, Enter Number of Sternotomies: _____ ST= Unknown

User Question: in comorbidities under prior sternotomy: is a hemi sternotomy considered a sternotomy? This VAD was placed via a thoracotomy and a hemisternotomy.

A: Yes, please do count a hemi sternotomy as prior sternotomy. But on the Implant form under approach to insertion there are options for left thoracotomy plus mini sternotomy and a left thoracotomy to right mini sternotomy.

Nutritional/GI issues:

Severe Diabetes Yes, No, Unknown
(Severe Diabetes Definition: Hemoglobin A1c >8mg/dl or associated with diabetic nephropathy, vasculopathy, or oculopathy)

Malnutrition/Cachexia Yes, No, Unknown
(Malnutrition/Cachexia Definition: Weight loss > 5% of present body mass in 12 months or less)

History of GI Ulcers Yes, No, Unknown

User Question: Would esophageal varices be documented under comorbidity as gastric ulcers?

A: Yes as the esophagus is part of the upper GI system

Liver Dysfunction Yes, No, Unknown
(Liver Dysfunction Definition: Indicate whether the patient has a history of hepatitis B, hepatitis C, cirrhosis, portal hypertension, esophageal varices, chronic alcohol abuse, or congestive hepatopathy. Exclude NASH in the absence of cirrhosis.

Liver Dysfunction Intent/Clarification: LFTs or a MELD score alone cannot be used to code "Yes" to liver disease since other conditions impact these lab values. Liver fibrosis with recurrent ascites, supported by the MELD can be coded as liver disease)

Hepatitis Yes, No, Unknown

If Yes (select all that apply):

Hepatitis B

Hepatitis C

If Yes, **Hepatitis B treated?**:

Yes, No, Unknown

If Yes, **Hepatitis C treated?**:

Yes, No, Unknown

Vascular issues:

Heparin-Induced Thrombocytopenia Yes, No, Unknown

Chronic coagulopathy Yes, No, Unknown

(Chronic Coagulopathy Definition: Heparin induced thrombocytopenia, Protein C deficiency, Protein S deficiency, Anti-thrombin 3 deficiency, DIC)

User Question: Should I consider Factor V Leiden a chronic coagulopathy?

A: Yes, please do include Factor V Leiden.

Cerebrovascular Disease Yes, No, Unknown
 If Yes, History of Stroke Yes, No, Unknown

(Stroke Definition: An acute episode of focal or global neurological dysfunction caused by brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction, where the neurological dysfunction lasts for greater than 24 hours.

This does not include chronic (nonvascular) neurological diseases or other acute neurological insults such as metabolic and anoxic ischemic encephalopathy.)

If Yes, indicate **Type of Stroke:**

Ischemic (embolic)
Hemorrhagic
Unknown

If Yes, indicate **Timing of Stroke (most recent):**

Recent (within 30 days of visit)
Remote (greater than 30 days of visit)
Unknown

If Yes, indicate **History of Transient Ischemic Attack (TIA):** Defined as a transient episode of focal neurological dysfunction caused by brain, spinal cord, or retinal ischemia, without acute infarction, where the neurological dysfunction resolves within 24 hours

Yes
No
Unknown

If Yes, indicate **Asymptomatic Severe Carotid Stenosis (80%-100%):**

Yes
No
Unknown

Peripheral Arterial Disease Yes, No, Unknown

(Peripheral Arterial Disease (PVD) Definition: Indicate whether the patient has a history of peripheral arterial disease (includes upper and lower extremity, renal, mesenteric, and abdominal aortic systems). This can include:

- Claudication, either with exertion or at rest
- Amputation for arterial vascular insufficiency
- Vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities (excluding dialysis fistulas and vein stripping)
- Documented abdominal aortic aneurysm with or without repair
- Positive noninvasive test (e.g. ankle brachial index <.09, ultrasound, magnetic resonance or computed tomography imaging of >50% diameter stenosis in any peripheral artery, i.e. renal, subclavian, femoral, iliac) or angiographic imaging

Peripheral arterial disease excludes disease in the carotid, cerebrovascular arteries, or thoracic aorta. PVD does not include DVT.)

If Yes, Peripheral Arterial Disease: Select all regions that apply.

Abdominal aortic aneurysm
Upper extremity disease
Lower extremity disease
Mesenteric disease
Renovascular disease
Source not documented

Oncology/infection issues:

History of Solid Organ Cancer	Yes, No, Unknown
Currently have Cancer	Yes, No, Unknown
History of Solid Organ Transplantation	Yes, No, Unknown
History of Hematopoietic Cancer	Yes, No, Unknown
History of Bone Marrow Transplant (BMT)	Yes, No, Unknown
HIV	Yes, No, Unknown

User Question: On the solid organ cancer question are you only looking for organs only, or do you collect breast cancer and other cancers here?

A: This data field is only looking to collect solid organ cancers. Other blood/bone marrow cancers can be captured in the hematopoietic cancer question.

Psychosocial issues:

Psychosocial Issues	Yes, No, Unknown
---------------------	------------------

(NOTE: Smoking History has been moved to this section.

Psychosocial issues include: substance abuse disorders along with a detailed smoking history.
(Please read this section thoroughly and check the boxes accordingly.)

If Yes, Psychosocial Issues: Select all psychosocial issues that apply.

Depression
History of Severe Depression
Alcohol Abuse

If Yes, indicate Alcohol History:

Remote use (more than 3 months ago)
Recent use (within 3 months)
Unknown

Limited Cognition
Limited Family Support
Noncompliance
History of Narcotic Dependence

If Yes, indicate Narcotic History:

Remote use (more than 3 months ago)
Recent use (within 3 months)
Unknown

Active Illicit Drug Use
History of Smoking

If Yes, indicate Smoking History:

Remote use (more than 3 months ago)
Recent use (within 3 months)
Unknown

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

User Question: In co-morbidities it asks for current or past smoking hx. Does this include any nicotine use such as chewing tobacco, or is this specifically for inhaled nicotine?

A: Yes it is considered smoking.

User Question: If a patient is currently vaping/ using e-cigarettes would that meet criteria to select 'Recent use' under the smoking category?

A: yes this would be considered smoking.

Potential Barriers to Transplantation: If patient not receiving a VAD for BTT listed indication, what are the perceived barriers to transplant?

Advanced age

Yes, No, Unknown, Not applicable: patient listed for transplant

Frailty

Yes, No, Unknown, Not applicable: patient listed for transplant

User Question: What is the determining factors to know if a patient has frailty?

A: Assessing a patients frailty index is often measured by a patients grip strength, weight, and a walking test.

Patient does not want transplant

Yes, No, Unknown, Not applicable: patient listed for transplant

(NOTE: By checking "Yes" you are confirming the patient does not want a heart transplant.)

Musculoskeletal limitation to ambulation

Yes, No, Unknown, Not applicable: patient listed for transplant

Contraindication to immunosuppression

Yes, No, Unknown, Not applicable: patient listed for transplant

Allosensitization

Yes, No, Unknown, Not applicable: patient listed for transplant

Chronic renal disease

Yes, No, Unknown, Not applicable: patient listed for transplant

Large BMI

Yes, No, Unknown, Not applicable: patient listed for transplant
Chronic Infectious Concerns
Yes, No, Unknown, Not applicable: patient listed for transplant

Quality of Life (EuroQoL, Intermacs QoL and KCCQ)

Please See the **EuroQoL, Intermacs QoL and KCCQ** section of the Users' guide for further instructions on administration and web-based data entry for the **EuroQoL, Intermacs QoL and KCCQ** ([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**
- **Hemolysis**
- **Right Heart Failure**
- **Renal Dysfunction**
- **Cardiac Arrhythmia**
- **Respiratory Failure**
- **Venous Thromboembolic Event**
- **Wound Dehiscence**
- **Arterial Non-CNS Thromboembolism**
- **Hypertension**
- **Hepatic Dysfunction**
- **Psychiatric Episode**
- **Pericardial Fluid Collection**
- **Myocardial Infarction**
- **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/intermacs-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 receives a transplant during the implant hospitalization. The date of transplant will be considered the date of discharge.**
- **Patient dies during the implant hospitalization. The date of death is considered to be the date of discharge.**
- **Patient has the device(s) explanted due to recovery. The date of device(s) explant is considered to be the date of discharge.**
- **Patient has device exchange (excluding RVAD exchange).**

Chronology of Hospital Time Course

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

- Discharged alive with a device in place
- Died during the implant hospitalization
- Transplanted during the implant hospitalization
- Explanted due to recovery during the implant hospitalization
- Patient has device exchange (excluding RVAD exchange)

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

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

- Home - residential setting
- Nursing Home/Assisted Care
- Hospice
- Another hospital
- Rehabilitation Facility
- Unknown

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

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

Please select the appropriate discharge date from the list below:

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

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

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

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

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

- < 1 week
- 1-2 weeks
- 2-4 weeks
- > 4 weeks
- Ongoing
- Unknown
- Not applicable

User Question: I'm entering a recent post-implant death we had- this gentleman declined quickly and died 1 week post implant. He never came off inotropes- so for that question – is it better to mark 1-2 wks or ongoing?

A: On-going because they were not discontinued.

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.

Steroids

Paxlovid

Remdesivir

Convalescent Plasma

Interlukin 6 inhibitor

None

Other, specify

If Other, specify: please complete text box.

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

Transplant

Invasive Cardiac Procedures (Other than Heart Cath)

Unknown

None

Surgical Procedures:

Device related operation

Surgical Procedure - Non Cardiac Surgical Procedure

Surgical Procedure - Other Procedure

Surgical Procedure - Unknown

Cardiac Surgical Procedures:

Reoperation for Bleeding within 48 hours of implant

Reoperation for Bleeding and/or tamponade > 48 hours

Surgical Drainage of pericardial effusion

Aortic Valve Surgery - Replacement – Biological

Aortic Valve Surgery - Replacement – Mechanical

Aortic Valve Procedure

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 – Excision

Tricuspid Valve Surgery – Replacement - Biological

Tricuspid Valve Surgery – Replacement - Mechanical

Pulmonary Valve Surgery - Repair

Pulmonary Valve Surgery – Replacement - Biological

Pulmonary Valve Surgery – Replacement – Mechanical

Arrhythmia Surgery (Ablation)

Ligation of Left Atrial Appendage

Aneurysmectomy

Mitraclip

TAVR

Other Cardiac Surgical Procedure - **textbox**

Cardiac Surgical Procedure – Unknown

User Question: My patient returned to the OR multiple times for a chest washout how do I capture this?

A: Please mark other procedures and in the text box specify how many times the patient went to the OR for the washout.

Other Procedures:

Intubation/Ventilator
Dialysis
Bronchoscopy
Ultrafiltration
Other, specify - textbox

Was ECMO initiated at any time after VAD Implant?

Yes, No, or Unknown

If **Yes**, enter Total Number of days on ECMO: **ST=** Unknown

Console Change - Please answer all questions regarding console changes considering all time since previous visit and current follow-up date.

Was there a console change (for TAH or Berlin Heart Consoles)?

Yes, No, or Unknown

If **Yes** please complete the following:

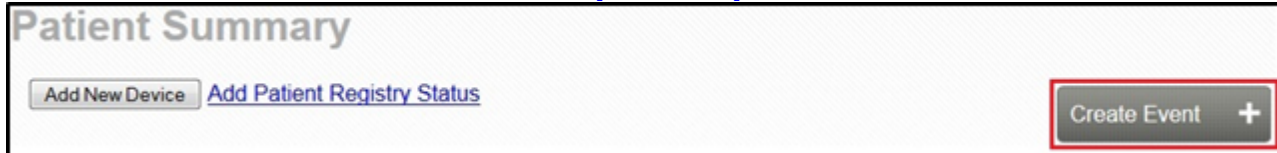
Date of console change: Enter date in MMDDYYYY format. **ST=** Unknown

Original console name: Text.

New console name: Text.

Major Outcomes and Adverse Events

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



The screenshot shows a 'Patient Summary' header with two buttons: 'Add New Device' and 'Add Patient Registry Status'. On the right side, a 'Create Event +' button is highlighted with a red rectangular box.

- Rehospitalization
- Major Infection
- Major Bleeding
- Neurological Dysfunction
- Device Malfunction (if suspected device thrombosis, then enter as Device Malfunction)
- Extracorporeal/Paracorporeal Pump Change
- Hemolysis
- Right Heart Failure
- Renal Dysfunction
- Cardiac Arrhythmia
- Respiratory Failure
- Venous Thromboembolic Event
- Wound Dehiscence
- Arterial Non-CNS Thromboembolism
- Hypertension
- Hepatic Dysfunction
- Psychiatric Episode
- Pericardial Fluid Collection
- Myocardial Infarction
- 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/intermacs-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

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

Yes or No

User Question: Do I need to report all rehospitalizations even if unrelated to the VAD?

A: Yes, all rehospitalizations that are 24 hours or greater need to be reported in InterMac, even if for an elective procedure or an event that is not related to the VAD like a MVA. Rehab facility stays do not need to be reported as rehospitalizations.

User Question: If a patient is discharged to a skilled nursing facility (inpatient) is that considered rehospitalization?

A: You do not need to capture rehospitalization for ED visits or admission to a skilled nursing facility for nursing home. Only document ED visits if it leads to stay of 24 hours or greater.

Enter **date of admission:** In MMDDYYYY format.

ST= Unknown.

Enter **discharge date:** In MMDDYYYY format.

ST= Unknown.

User Question: When entering re-hospitalizations for patients originally admitted at an outside hospital and then transferred to you, do you use the admit date to the outside hospital or to your hospital?

A: For the question rehospitalized at your hospital, answer no and use the outside hospital admit date as the date of admission.

Please select the appropriate discharge date from the list below:

- Patient is discharged from the hospital with a device in place. The date of discharge is considered to be the discharge date.
- Patient receives a transplant during this rehospitalization. The date of transplant will be considered the date of discharge.

- Patient dies during this rehospitalization. The date of death is considered to be the date of discharge.
- Patient has the device(s) explanted due to recovery during this rehospitalization. The date of device(s) explant is considered to be the date of discharge.

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

Major Bleeding
 Cardiac Arrhythmia
 Major Infection
 Pericardial Fluid Collection
 Neurological Dysfunction
 Myocardial Infarction
 Hypertension
 Device Malfunction
 Cardiac Tamponade
 Psychiatric Episode
 Hematoma
 GI Disorder
 Transplant
 Hemolysis
 Arterial Non-CNS Thrombo-embolism
 Hepatic Dysfunction
 Limb vascular complication
 Explant
 Pulmonary Embolism/Hemorrhage
 Venous Thromboembolic Event
 Respiratory Failure
 Wound Dehiscence
 Syncope without known cause
 Planned Medical Management
 Renal Dysfunction
 Fever without known cause
 Planned Procedure
 Right Heart Failure
 Diagnostic Procedure
 Wound Complication
 Unknown
 Pneumonia
 Catastrophe (i.e. weather)
 Gastroenteritis
 Anticoagulation adjustment
 Metabolic/Electrolyte Disturbance
 Pulmonary, Other
 Hematological
 Trauma/Accident
 Fluid Overload
Other, specify
 If Other Specify, then **Specify:** complete text box

Rehospitalization Intervention: Select all that apply from the list below:

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

Transplantation
None
Unknown
Other

If **Surgical Procedure**, please select all **Surgical Procedures** that apply:

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**, Select all **Types of Other Cardiac Procedure** that apply:

Reoperation for Bleeding within 48 hours of implant
Reoperation for Bleeding and/or tamponade > 48 hours
Surgical Drainage of pericardial effusion
Aortic Valve Surgery - Replacement - Biological
Aortic Valve Surgery - Replacement – Mechanical
Aortic Valve Procedure
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
Tricuspid Valve Surgery – Excision
Pulmonary Valve Surgery - Repair
Pulmonary Valve Surgery – Replacement - Biological
Pulmonary Valve Surgery – Replacement – Mechanical
Aneurysmectomy
Mitraclip
TAVR
Arrhythmia Surgery (Ablation)
Ligation of Left Atrial Appendage
Unknown
Other, specify - please **Enter Type of Procedure:** Textbox

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.

Enter PA diastolic pressure: In mm/Hg.

Enter PCW pressure: In mm/Hg.

Enter Cardiac Output: In L/min.

ST= Unknown or Not Done.

ST= Unknown or Not Done.

ST= Unknown or Not Done.

ST= Unknown or Not Done.

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

If **Other**, Select all **Other procedures** that apply:

Intubation/Ventilator
Dialysis
Bronchoscopy

Ultrafiltration
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: mmHg (millimeters of mercury). **ST=** Unknown, Not Done, or Not Applicable

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

<https://intermacs.kirso.net/intermacs-documents/>

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

Yes, No, Unknown

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

If yes, provide Modified Rankin Scale:

0 – No symptoms at all

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

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

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

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

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

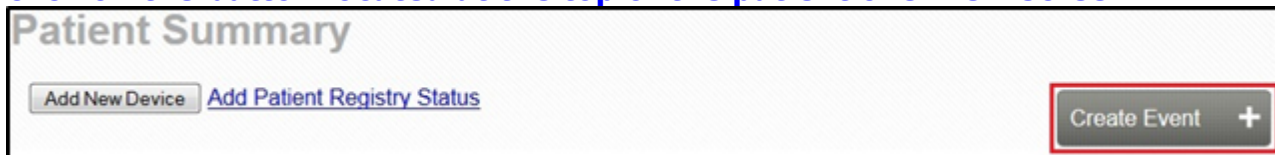
6 – Dead

Not Done

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
- Hemolysis
- Right Heart Failure
- Renal Dysfunction
- Cardiac Arrhythmia
- Respiratory Failure
- Venous Thromboembolic Event
- Wound Dehiscence
- Arterial Non-CNS Thromboembolism
- Hypertension
- Hepatic Dysfunction
- Psychiatric Episode
- Pericardial Fluid Collection
- Myocardial Infarction
- 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/intermacs-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/intermacs-documents/>

AE Infection

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

MCS ARC INFECTION

- **Percutaneous lead site infections**
 - **Superficial percutaneous lead infection:** A positive culture from the skin surrounding the percutaneous lead when there is clinical evidence of infection such as pain, fever, drainage, erythema, or leukocytosis coupled with the need to treat with anti-microbial therapy. The percutaneous lead exit site may have drainage and/or the surrounding skin may have erythema. The epithelialization of the percutaneous lead exit site is preserved. The gram stain of the skin specimen at the driveline exit site will contain white blood cells (i.e., positive sign for inflammation).
 - **Deep percutaneous lead infection:** A positive culture from the driveline exit site deep to the epithelium, when there is clinical evidence of infection such as pain, fever, drainage, erythema, or leukocytosis coupled with the need to treat with anti-microbial therapy. The epithelialization of the percutaneous lead exit site is disrupted and no longer preserved or intact, or there is radiographic evidence of findings consistent with infection along the path of the percutaneous lead outside the mediastinum.
- **Infection of external surfaces of an implantable component.** A positive culture from the tissue surrounding the external housing of a pump or one of its components implanted within the body (including device components such as controllers, batteries, etc.), when there is clinical evidence of infection such as pain, fever, drainage, erythema, or leukocytosis coupled with the need to treat with anti-microbial therapy.
- **Infection of blood-contacting surfaces of an implantable component (device endocarditis):** Infection of blood-contacting internal surfaces of the MCS device including inflow/outflow grafts: documented by positive blood cultures or radiographic or echocardiographic evidence of vegetation in blood flow path of the pump coupled with the need to treat with anti-microbial therapy.

MCS ARC INFECTION

Non-MCS-related infections:

- **Infective Endocarditis: Non-MCS related**
 - Positive blood cultures and echocardiography findings for mass or vegetation only on native valves, ICD, or pacemaker leads.
- **BSI**
 - Positive blood cultures with no other source identified
 - Bloodstream infection: non-VAD site or central venous catheter-related (definition from the Centers for Disease Control/National Healthcare Safety Network)⁴⁷Should be coupled with the need to treat with anti-microbial therapy.
- **Mediastinitis**
 - Procedure-related mediastinitis
 - Deep sternal wound infection (isolated)
 - Deep sternal wound infection involving MCS device components (continuous with mediastinum or already situated in the mediastinum). Maybe contiguous with implanted components of the MCS device
 - **Non-MCS-related mediastinitis:**
 - Mediastinitis definitively owing to another cause (e.g., esophageal perforation during endoscopy, contiguous with empyema).
 - Superficial mediastinal or thoracotomy wound infection
 - Infection involving only skin, sub-cutaneous fat, and muscle of implant incision.
 - Should be coupled with the need to treat with anti-microbial therapy.
- **Sepsis**
 - **Life-threatening organ dysfunction caused by a dysregulated host response to infection with:**
 - Evidence of systemic involvement by infection, manifested by need to treat with anti-microbial therapy
 - Positive blood cultures and/or two of the following:
 - PaO₂/FIO₂ < 400 or respiratory rate ≥ 22/min or ventilated respiratory support
 - Hypotension with systolic BP < 100 mm Hg or MAP ≤ 65 mm Hg.
 - Platelet count < 150 or elevated prothrombin time or fibrinogen degradation products
 - Bilirubin (serum) > 50% above baseline
 - Altered mental status (Glasgow score < 15)
 - Creatinine (serum) > 50% above baseline
 - Need for intravenous vasoconstricting agents
- **Localized non-MCS device infection**
 - Infection localized to a site not involving the MCS device or components (e.g., pneumonia, urinary tract infection, cholecystitis, diverticulitis, dental abscess) coupled with the need to treat with anti-microbial therapy

Was there a major infection?

Yes, No, or Unknown

User Question: My patient has chronic driveline infections how do I handle this?**A: If there is an ongoing infection in the same location with the same type of bacteria, enter the infection when it is first identified along with what type of treatment. If the intervention changes (ex go from oral to IV antibiotics or surgery is needed), then enter another adverse event to document the change in intervention.****User Question: Can you have an infection adverse event without positive blood cultures?****A: Yes, but only if the clinical evidence is strong enough. Example: if the patient is having fevers, has a productive cough, chest consolidations on imaging and is being treated for pneumonia (as noted in progress notes or I.D. consult notes) even if cultures have been unrevealing, then the clinical evidence would be strong enough for an infection: pulmonary adverse event.****User Question: What if different types of organisms are identified?****A: If culture reveals different types of infections (ex one bacterial and one fungal), a separate infection for each type will need to be entered. You would select all the locations that were positive for the fungal culture as one infection and all the sites that had a positive bacterial culture for the other infection.****User Question: Do I need to capture a positive MRSA nasal swab as an AE under localized non-mcs infection?****A: If a patient is colonized as identified by screening cultures (ex. VRE, MRSA screenings, asymptomatic bacteriuria), but is asymptomatic and is not being treated for the infection, do not count it as an infection adverse event.****User Question: In the definition we say if there has been a change of antibiotic- we count as a new infection. What if the reason for the switch is maybe- potassium issues or allergy or another reason besides infection that causes a change in antibiotics- how is that counted or abstracted?****A: If the change in antibiotic is for reasoning unrelated to the infection (ie allergy) then another Major Infection AE does not need to be entered.****User Question: Are we reporting influenza virus?****A: Similar to covid a simple positive test does not need to be reported. However, if the flu escalates to an infection like pneumonia then at that time it should be entered.****User Question: Do we document COVID-19 as viral infections (AE) for patients?****I see there is a question for COVID-19 positivity noted on the follow-up status form, which indicates the same questions as the ones indicated on the infection form for COVID specifically.****A: For the patients that simply tested positive, yes they can be captured on follow-up. The patients that were readmitted their rehospitalization does need to be entered on all of them. As far as entering a Major Infection form for those readmitted patients they need to meet the criteria for a major infection (covid pneumonia, sepsis etc). So they need to be looked at individually.****Is this a MCS related or Non-MCS related infection? Select all that apply:**

MCS Related

Non-MCS Related

Type of MCS related infection: Select all of the following types of infection that apply.

Bacterial
Fungal
Viral
Protozoan
Unknown

If **MCS related Bacterial**: Select all that apply:

Gram positive
Gram negative
Other, Specify
 If **Other, specify**, then **Specify**: please complete textbox
Unknown

If **MCS related Gram positive**: Select all that apply:

Enterococcus
Staphylococcus, Methicillin Resistant
Staphylococcus, Methicillin Sensitive
Streptococcus
Other, Specify
 If **Other, specify**, then **Specify**: please complete textbox

If **MCS related Gram negative**: Select all that apply:

Citrobacter
Enterobacter
Enterobacteriaceae
Escherichia
Haemophilus
Klebsiella
Moraxella
Pseudomonas
Serratia
Other, Specify
 If **Other, specify**, then **Specify**: please complete textbox

If **MCS Related Infection**: Select all that apply:

Percutaneous lead site infection
Infection of external surfaces of an implantable component – A positive culture from the tissue surrounding the external housing of a pump or one of its components implanted within the body (including device components such as controllers, batteries, etc.), when there is clinical evidence of infection such as pain, fever, drainage, erythema, or leukocytosis coupled with the need to treat with anti-microbial therapy.
Infection of blood-contacting surfaces of an implantable component (device endocarditis) – Infection of blood-contacting internal surfaces of the MCS device including inflow/outflow grafts: documented by positive blood cultures or radiographic or echocardiographic evidence of vegetation in blood flow path of the pump coupled with the need to treat with anti-microbial therapy.
Unknown
Other, specify
 If **Other, specify**, then **Specify**: please complete textbox

If **Percutaneous lead site infection**: Select one of the following:

Superficial percutaneous lead infection – A positive culture from the skin surrounding the percutaneous lead when there is clinical evidence of infection such as pain, fever, drainage, erythema, or leukocytosis coupled with the need to treat with anti-microbial therapy. The

percutaneous lead exit site is preserved. The gram stain of the skin specimen at the driveline exit site will contain white blood cells (i.e. positive sign for inflammation)

Deep percutaneous lead infection – A positive culture from the driveline exit site deep to the epithelium, when there is clinical evidence of infection such as pain, fever, drainage, erythema, or leukocytosis coupled with the need for microbial therapy

Unknown

If **Percutaneous lead site infection:** Was the patient treated with **anti-microbial** therapy?

Yes, No, or Unknown

If **Yes**, select anti-microbial **Route:** Select all that apply:

IV
Oral
Topical
Unknown

If **Infection of external surfaces of an implantable component:**

Select all that apply:

Pump / related – Exit Cannula
Pump / related – Pump Pocket
Pump / related – transcutaneous power element
Pump / related – implantable battery
Unknown

If **Infection of external surfaces of an implantable component:** Was the patient treated with **anti-microbial** therapy?

Yes, No, or Unknown

If **Yes**, select anti-microbial **Route:** Select all that apply:

IV
Oral
Topical
Unknown

If **Infection of blood contacting surfaces of an implantable component (device endocarditis):** Was the patient treated with **anti-microbial** therapy?

Yes, No, or Unknown

If **Yes**, select anti-microbial **Route:** Select all that apply:

IV
Oral
Topical
Unknown

If **MCS Related Infection “Other”** Was the patient treated with **anti-microbial** therapy?

Yes, No, or Unknown

If **Yes**, select anti-microbial **Route:** Select all that apply:

IV

Oral
Topical
Unknown

Type of Non-MCS related infection: Select all of the following types of infection that apply.

Bacterial
Fungal
Viral
Protozoan
Unknown

If **Non-MCS related Bacterial:** Select all that apply:

Gram positive
Gram negative
Other, Specify

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

Unknown

If **Non-MCS related Gram positive:** Select all that apply:

Enterococcus
Staphylococcus, Methicillin Resistant
Staphylococcus, Methicillin Sensitive
Streptococcus
Other, Specify

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

If **Non-MCS related Gram negative:** Select all that apply:

Citrobacter
Enterobacter
Enterobacteriaceae
Escherichia
Haemophilus
Klebsiella
Moraxella
Pseudomonas
Serratia
Other, Specify

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

If **Non-MCS Related Infections:** Select all that apply:

Infective Endocarditis – Non-MCS related (Positive blood cultures and echocardiography findings for mass or vegetation only on native valves, ICD, or pacemaker leads)

Bloodstream Infection – Positive blood cultures with no other source identified; Bloodstream infection: non-VAD site or central venous catheter-related (definition from the CDC/NHSN)

Mediastinitis

Sepsis – Life-threatening organ dysfunction caused by a dysregulated host response to infection with: Evidence of systemic involvement by infection, manifested by need to treat with anti-microbial therapy and positive blood cultures and/or two of the following: (PaO₂/FIO₂ <400 or respiratory rate = 22/min or ventilated respiratory support, Hypotension with systolic BP <100 mmHg or MAP = 65 mmHg., Platelet count <150 or elevated prothrombin time or fibrinogen degradation products, Bilirubin (serum) >50% above baseline, Altered mental status (Glasgow score <15), Creatinine (serum) >50% above baseline, Need for intravenous vasoconstricting agents)

Localized non-MCS infection – Infection localized to a site not involving the MCS device or components (e.g., pneumonia, urinary tract infection, cholecystitis, diverticulitis, dental abscess) coupled with the need to treat with anti-microbial therapy. A positive culture from the infected site or organ should be present unless strong clinical evidence indicates the need for treatment despite negative cultures

Other, Specify

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

Unknown

If **Infective Endocarditis**: Was the patient treated with **anti-microbial** therapy?

Yes, No, or Unknown

If **Yes**, select anti-microbial **Route**: Select all that apply:

IV
Oral
Topical
Unknown

If **BSI**: Was the patient treated with **anti-microbial** therapy?

Yes, No, or Unknown

If **Yes**, select anti-microbial **Route**: Select all that apply:

IV
Oral
Topical
Unknown

If **Mediastinitis**: Select the **Subtype**:

Procedure-related Mediastinitis

Non-MCS-related Mediastinitis – Mediastinitis definitively owing to another cause e.g., esophageal perforation during endoscopy, contiguous with empyema

Superficial mediastinal or thoracotomy wound infection – Infection involving only skin, sub-cutaneous fat, and muscle of implant incision

Unknown

If **Procedure-related Mediastinitis**: Select one of the following:

Deep sternal wound infection (isolated)

Deep sternal wound infection involving MCS device components – Continuous with mediastinum or already situated in the mediastinum. May be contiguous with implanted components of the MCS device

Unknown

If **Mediastinitis**: Was the patient treated with **anti-microbial** therapy?

Yes, No, or Unknown

If **Yes**, select anti-microbial **Route**: Select all that apply:

IV
Oral
Topical
Unknown

If **Sepsis**: Was the patient treated with **anti-microbial** therapy?
Yes, No, or Unknown

If **Yes**, select anti-microbial **Route**: Select all that apply:
IV
Oral
Topical
Unknown

If **Localized non-MCS Infection**: Select the all that apply:

Pneumonia
Tracheobronchitis
Urinary Tract
Thoracotomy Incision
Peripheral Wound
GI
Other, Specify
If **Other, specify**, then **Specify**: please complete textbox
Unknown

If **Localized non-MCS Infection**: Was the patient treated with **anti-microbial** therapy?
Yes, No, or Unknown

If **Yes**, select anti-microbial **Route**: Select all that apply:
IV
Oral
Topical
Unknown

If **non-MCS Related Infection "Other"** Was the patient treated with **anti-microbial** therapy?
Yes, No, or Unknown

If **Yes**, select anti-microbial **Route**: Select all that apply:
IV
Oral
Topical
Unknown

Enter **Date of Infection 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

Indicate **The Association of the Infection Event Should be Classified as**: Select one of the following:

- Patient-Related – e.g., non-adherence or poor management of driveline exit site or indwelling catheters, IV drug abuse, aspiration
- Management-Related – e.g., improper tunneling, contamination of the intraoperative site, prolonged intubation

Device-Related – e.g., device endocarditis diagnosed by radiological examination or detection of pannus within the conduits or device
No Association Identified

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

Was surgery an intervention for this AE?:

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.

Steroids
Paxlovid
Remdesivir
Convalescent Plasma
Interlukin 6 inhibitor
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

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

MCS ARC BLEEDING

- **Type 1:** Bleeding that is not actionable and does not cause the patient to seek unscheduled performance of studies, hospitalization, or treatment by a healthcare professional; may include episodes leading to self-discontinuation of medical therapy by the patient without consulting a healthcare professional. This type is not relevant during a hospitalization.
- **Type 2:** Any overt, actionable sign of hemorrhage (e.g., more bleeding than would be expected for a clinical circumstance, including bleeding found by imaging alone) that does not fit the criteria for Type 3, 4, or 5 but does meet at least one of the following criteria:
 - requiring non-surgical, medical intervention by a healthcare professional;
 - leading to hospitalization or increased level of care;
 - or prompting evaluation.
- **Type 3**
 1. **Type 3a**
 - Overt bleeding accompanied by hemoglobin drop of 3 to < 5 g/dl or (1.86–3.1 mmol/liter SI units) (provided hemoglobin drop is related to bleed)
 - OR
 - Any transfusion with overt bleeding
 2. **Type 3b**
 - Overt bleeding plus hemoglobin drop 5 g/dl ((3.1 mmol/liter) or greater (provided hemoglobin drop is related to bleed)
 - OR
 - Cardiac tamponade
 - OR
 - Bleeding requiring surgical intervention for control (excluding dental/nasal/skin/hemorrhoid)
 - OR
 - Bleeding requiring intravenous vasoactive agents
- **Type 4:** VAD implantation-related bleeding (includes concomitant cardiac or non-cardiac surgical procedures)
 - Reoperation after the closure of incision or incisions used to implant the VAD to control bleeding
 - ≥ 50 kg: ≥ 4 U PRBC within any 48 hours during the first 7 days post-implant.
 - < 50 kg: ≥ 20 cm³/kg PRBC within any 24 hours during the first 7 days post-implant.
 - Chest tube output > 2 liters within 24 hours.
- **Type 5:** Fatal bleeding
 - **Type 5a:** Probable fatal bleeding; no autopsy or imaging confirmation but clinically suspicious
 - **Type 5b.** Definite fatal bleeding; overt bleeding or autopsy or imaging confirmation

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).

Was there a Major Bleeding Event?

Yes, No, or Unknown

Select Type of Major Bleeding:

Type 1 – Bleeding that is not actionable and does not cause the patient to seek unscheduled performance of studies, hospitalization, or treatment by a healthcare professional; may include episodes leading to self-discontinuation of medical therapy by the patient without consulting a healthcare professional. This type is not relevant during hospitalization.

Type 2 – Any overt, actionable sign of hemorrhage (e.g., more bleeding than would be expected for a clinical circumstance, including bleeding found by imaging alone) that does not fit the criteria for Type 3, 4, or 5 but does meet at least one of the following criteria.

Type 3a – Overt bleeding accompanied by hemoglobin drop of 3 to < 5g/dl or (1.86-3.1 mmol/liter SI units) (provided hemoglobin drop is related to bleed)

Type 3b – Overt bleeding plus hemoglobin drop 5 g/dl ((3.1 mmol/liter) or greater (provided hemoglobin drop is related to bleed)

Type 4 – VAD Implantation-related bleeding (includes concomitant cardiac or non-cardiac surgical procedures)

Type 5 – Fatal Bleeding

If **Type 2 Major Bleeding:** Select from the following criteria (select all that apply):

- Requiring non-surgical, medical intervention by a healthcare professional
- Leading to hospitalization or increased level of care
- Prompting evaluation

If **Type 3b Major Bleeding:** Select from the following criteria (select all that apply):

- Cardiac tamponade
- Bleeding requiring surgical intervention for control (excluding dental/nasal/skin/hemorrhoid)
- Bleeding requiring intravenous vasoactive agents

If **Type 4 Major Bleeding:** Select from the following criteria (select all that apply):

- Reoperation after the closure of incision or incisions used to implant the VAD to control bleeding
- >= 50kg: >= 4U PRBC within any 48 hours during the first 7 days post-implant.
- < 50kg: >= 20 cm3/kg PRBC within any 24 hours during the first 7 days post-implant.
- Chest tube output >2 liters within 24 hours.

If **Type 5 Major Bleeding:** Select one of the following sub-types:

- Type 5a: Probable fatal bleeding; no autopsy or imaging confirmation but clinically suspicious

Type 5b: Definite fatal bleeding; overt bleeding or autopsy or imaging confirmation
Unknown

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

Mediastinal: chest wall
 Mediastinal: outflow-aorta anastomosis
 Mediastinal: outflow conduit
 Mediastinal: inflow conduit
 Mediastinal: cardio-pulmonary bypass cannulation site
 Mediastinal: coagulopathy with no surgical site
 Mediastinal: other surgical site
 Pump or implanted component pocket (battery or controller)
 Mediastinal: Unspecified
 Pleural space
 Intra-abdominal
 Retroperitoneal
 Pulmonary
 Genitourinary tract
 GI: Upper gastrointestinal (esophagus, stomach, duodenum, small bowel)
 GI: Lower gastrointestinal (colon, rectum, and anus)
 GI: unknown, but guaiac positive stools
 ENT / Dental
 Other, specify

If Other, specify, then complete text box.

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

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

In hospital
 Out of hospital
 Unknown

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

Warfarin
 Heparin
 Lovenox
 Aspirin
 Dipyridamole
 Clopidogrel (plavix)
 Argatroban
 Bivalirudin
 Fondaparinux
 Dextran
 Ticlopidine
 Hirudin
 Lepirudin
 Ximelagatran
 None
 Other, specify

If Other, specify, then complete text box.

User Question: How do we document antiplatelet therapy for INTERMACS patients who are in the ARIES trial? As you know they receive Aspirin vs Placebo for this study and we don't know which one they have been assigned to.

A: For patients in the ARIES trial document unknown on both the follow-up and AE forms.

Indicate **The Association of the Bleeding Event Should be Classified as:** Select one of the following:

Patient-Related – e.g., coagulopathy unrelated to surgical technique such as non-adherence with anti-coagulation medication resulting in an inappropriately high level of anti-coagulation, hepatic failure

Management-Related – e.g., related to surgical technique; hypertension; bleeding in the setting of inappropriate levels of anti-coagulation) or to mismanagement of anti-coagulants.

Device-Related – e.g., bleeding from the outflow graft, apical connector, or other internal components

No Association Identified.

AE Neurological Dysfunction

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

MCS ARC NEUROLOGICAL DYSFUNCTION

- **Type 1 Overt CNS injury** - Acutely symptomatic brain or spinal cord injury
- **Type 1a Ischemic stroke** - Sudden onset of neurologic signs or symptoms fitting a focal or multifocal vascular territory within the brain, spinal cord, or retina, that:
 - persist for ≥ 24 hours or until death, with pathology or neuroimaging evidence that demonstrates either:
 - CNS infarction in the corresponding vascular territory (with or without hemorrhage); or
 - absence of other apparent causes (including hemorrhage), even if no evidence of acute ischemia in the corresponding vascular territory is detected
 - Symptoms lasting < 24 hours with pathology or neuroimaging confirmation of CNS infarction in the corresponding vascular territory. Note: when CNS infarction location does not match the transient symptoms, the event would be classified as covert CNS infarction (Type 2a) and a TIA (Type 3a), but not an ischemic stroke.
 - Signs and symptoms consistent with stroke typically include an acute onset of one of the following: focal weakness and/or numbness, impaired language production or comprehension, homonymous hemianopia or quadrantanopia, diplopia, altitudinal monocular blindness, hemispatial neglect, dysarthria, vertigo, or ataxia.
 - **Sub-type 1aH Ischemic stroke with hemorrhagic conversion** - Ischemic stroke includes hemorrhagic conversions. These should be sub-classified as Class A or B when an ischemic stroke is the primary mechanism and pathology, or neuro-imaging confirms a hemorrhagic conversion.
 - **Class A- Petechial (non-space-occupying) hemorrhage:** Petechiae or confluent petechiae within the infarction or its margins, but without a space-occupying effect.
 - **Class B – confluent (space-occupying) hemorrhage:** Confluent hemorrhage or hematoma originating from within the infarcted area with space-occupying effect.
- **Type 1b Symptomatic intracerebral hemorrhage** - Rapidly developing neurologic signs or symptoms (focal or global) caused by an intraparenchymal, intraventricular, spinal cord, or retinal collection of blood, not caused by trauma.
- **Type 1c Symptomatic Sub-arachnoid hemorrhage** -Rapidly developing neurologic signs or symptoms (focal or global) and/or headache caused by bleeding into the sub-arachnoid space, not caused by trauma.
- **Type 1d Stroke, not otherwise specified** - An episode of acute focal neurologic signs or symptoms and/or headache presumed to be caused by CNS ischemia or CNS hemorrhage, persisting 24 hours or until death, but without sufficient evidence to be classified as one of the above (i.e., no neuroimaging performed).
- **Type 1e Symptomatic hypoxic-ischemic injury** - Non-focal (global) neurologic signs or symptoms due to diffuse brain, spinal cord, or retinal cell death (confirmed by pathology or neuroimaging) in a non-vascular distribution, attributable to hypotension and/or hypoxia.
- **Type 1f Symptomatic sub-dural hemorrhage** - An episode of acute focal neurologic signs or symptoms and/or headache accompanied by evidence of bleeding into the sub-dural space.

MCS ARC NEUROLOGICAL DYSFUNCTION

- **Type 2 Covert CNS injury** - Acutely asymptomatic brain or spinal cord injury detected by neuroimaging
- **Type 2a Covert CNS infarction** - Brain, spinal cord, or retinal cell death attributable to focal or multifocal ischemia on the basis of neuroimaging or pathologic evidence of CNS infarction, without a history of acute neurologic symptoms consistent with the lesion location.
 - **Sub-type 2aH Covert CNS infarction with hemorrhagic conversion**- Covert CNS infarction includes hemorrhagic conversions. These should be sub-classified as Class A or B when CNS infarction is the primary mechanism and neuroimaging, or pathology confirms a hemorrhagic conversion.
 - **Class A: Petechial (non-space-occupying) hemorrhage:** Petechiae or confluent petechiae within the infarction or its margins, but without a space-occupying effect
 - **Class B: Confluent (space-occupying) hemorrhage:** Confluent hemorrhage originating from within the infarcted area with space-occupying effect
- **Type 2b Covert CNS hemorrhage** - Neuroimaging or pathologic evidence of CNS hemorrhage within the brain parenchyma, sub-arachnoid space, sub-dural space, ventricular system, spinal cord or retina on neuroimaging that is not caused by trauma, without a history of acute neurologic symptoms consistent with the bleeding location
- **Type 3 Neurologic dysfunction (acutely symptomatic) without CNS injury**
 - **Type 3a TIA** - Transient focal neurologic signs or symptoms (lasting < 24 hours) presumed to be owing to the focal brain, spinal cord, or retinal ischemia, but without evidence of acute infarction by neuroimaging or pathology (or in the absence of imaging)
 - **Type 3b Delirium without CNS injury** - Transient non-focal (global) neurologic signs or symptoms (variable duration) without evidence of cell death by neuroimaging or pathology

Classification of Acute Severity, Recovery and Long-Term Disability

Acute Severity

1. **Mild neurologic dysfunction:** NIHSS 0-5
2. **Moderate neurologic dysfunction:** NIHSS 6-14
3. **Severe neurologic dysfunction:** NIHSS ≥15

NOTE: Severity assessment should be performed at the time of diagnosis of any overt CNS injury (Types 1) to ensure accurate classification

• Stroke Recovery

- **Stroke with complete recovery:** A modified Rankin Score (MRS) at 30-90 days of 0 OR a return to the patient's pre-stroke baseline MRS, in the absence of any ongoing new symptoms due to the stroke.

• Stroke Disability

- **Fatal Stroke:** Death resulting from a stroke where the cause of death is attributable to the stroke.
- **Disabling stroke:** An MRS ≥2 at 30-90 days with an increase of at least 1 point compared to the pre-stroke baseline.
- **Non-disabling stroke:** An MRS <2 at 30-90 days, or ≥2 without an increase of at least 1 compared to the pre-stroke baseline.

NOTE: Disability assessment applies only to subjects with overt CNS injury (Type 1) and should be performed at 90±14 days after the stroke event.

User Question: We had a patient fall at home and he came in with a SDH. He had no deficits, however, did require a craniotomy. Would this be considered a major bleeding event or a neuro dysfunction event?

A: This situation is considered a neuro dysfunction. As far as Intermacs is concerned, brain bleeds are not considered Major Bleeding events.

Was there a neurological dysfunction?

Yes, No, or Unknown

If **yes**, **Select Type** of Neurological Dysfunction: Select one

Type 1 – Overt CNS Injury – Acutely symptomatic brain or spinal cord injury

Type 2 – Covert CNS Injury – Acutely asymptomatic brain or spinal cord injury detected by neuroimaging

Type 3 – Neurologic Dysfunction (acutely symptomatic) without CNS injury – include seizures here

If **Type 1**: Select Neurological Dysfunction **Subtype**: Select all that apply

Type 1a – Ischemic stroke – Sudden onset of neurologic signs or symptoms fitting a local or multifocal vascular territory within the brain, spinal cord, or retina

Type 1ah – Ischemic stroke with hemorrhagic conversion – Ischemic stroke includes hemorrhagic conversions

Type 1b – Symptomatic Intracerebral hemorrhage – Rapidly developing neurologic signs and symptoms (focal or global) caused by an intraparenchymal, intraventricular, spinal cord, or retinal collection of blood, not caused by trauma

Type 1c – Symptomatic subarachnoid hemorrhage – Rapidly developing neurologic signs or symptoms (focal or global) and/or headache caused by bleeding into the sub-arachnoid space, not caused by trauma

Type 1d – Stroke, not otherwise specified – An episode of acute focal neurologic signs or symptoms and/or headache presumed to be caused by CNS ischemia or CNS hemorrhage, persisting 24 hours or until death, but without sufficient evidence to be classified as one of the above (i.e., no neuroimaging performed)

Type 1e – Symptomatic hypoxic-ischemic injury – Non-focal (global) neurologic signs or symptoms due to diffuse brain, spinal cord, or retinal cell death (confirmed by pathology or neuroimaging) in a non-vascular distribution, attributable to hypotension and/or hypoxia

Type 1f – Symptomatic subdural hemorrhage – An episode of acute focal neurologic signs or symptoms and/or headache accompanied by evidence of bleeding into the subdural space: not caused by accident or trauma

Type 1g – Traumatic Brain Injury – Intracerebral, Subarachnoid or subdural – A brain bleed due to an injury. Examples: Falls, Motor Vehicle Accident

Unknown

If **Type 1a**: Select Neurological Dysfunction **Criteria**: Select one

Persist for 24 hours or until death – With pathology or neuroimaging evidence that demonstrates either (a) CNS infarction in the corresponding vascular territory (with or without hemorrhage) or (b) Absence of other apparent causes (including hemorrhage), even if no evidence of acute ischemia in the corresponding vascular territory is detected

Symptoms lasting <24 hours – With pathology or neuroimaging confirmation of CNS infarction in the corresponding vascular territory. Note: when CNS infarction location does not match

the transient symptoms, the event would be classified as covert CNS infarction (Type 2a) and a TIA (Type3a), but not an ischemic stroke. Signs and symptoms consistent with stroke typically include an acute onset of one of the following: focal weakness and/or numbness, impaired language production or comprehension, homonymous hemianopia or quadrantanopia, diplopia, altitudinal monocular blindness, hemispatial neglect, dysarthria, vertigo, or ataxia. For pediatric patients, generalized symptoms such as seizure, irritability, or altered wakefulness may be accepted as confirmation of acute stroke if imaging or pathology demonstrates previously undocumented CNS infarction

Unknown

If **Type 1ah**: Select **Class**: Select one

Class A – Petechial (non-space-occupying) hemorrhage: Petechiae or confluent petechiae within the infarction or its margins, but without a space-occupying effect

Class B – Confluent (space-occupying) hemorrhage: Confluent hemorrhage or hematoma originating from within the infarcted area with space-occupying effect

If **Type 2**: Select Neurological Dysfunction **Subtype**: Select one

Type 2a – Covert CNS infarction – Brain, spinal cord or retinal cell death attributable to focal or multifocal ischemia on the basis of neurological imaging or pathologic evidence of CNS infarction, without a history of acute neurologic symptoms consistent with lesion location

Type 2ah – Covert CNS infarction with hemorrhagic conversion

Type 2b – Covert CNS hemorrhage – Neuroimaging or pathologic evidence of CNS hemorrhage within the brain parenchyma, subarachnoid space, subdural space, ventricular system

Unknown

If **Type 3**: Select Neurological Dysfunction **Subtype**: Select one

Type 3a – TIA – Transient focal neurologic signs or symptoms (lasting <24 hours presumed to be owing to the focal brain, spinal cord, or retinal ischemia, but without evidence of acute infarction by neuroimaging or pathology (or in the absence of imaging)

Type 3b – Delirium without CNS injury – Transient non-focal global neurologic signs or symptoms (variable duration) without evidence of cell death by neuroimaging or pathology injury

Seizure

Unknown

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

<https://intermacs.kirso.net/intermacs-documents/>

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

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**
- Not Done**
- Not Documented**

OR**Provide NIH Stroke Scale:**

- 0 – 5**
- 6-14**
- 15+**
- Not Done**
- Not Documented**

Enter **Date of Neurological Dysfunction Event 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

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

Yes, No, or Unknown

Indicate **The Association of the Neurological Dysfunction Event Should be Classified as:**

Select one of the following:

- Patient-Related – e.g., documentation of previous carotid or cerebrovascular disease, coagulopathy unrelated to surgical technique such as non-adherence with anti-coagulation medication resulting in an inappropriately high level of anticoagulation, related to illicit drug use, non-adherence with other medication, trauma, associated with sepsis
- Management-Related – e.g., over anti-coagulation or associated with the use of accessory assist device, hypotension or hypertension-related to surgical procedure
- Device-Related – e.g., secondary to pump thrombosis or device malfunction
- No Association Identified

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
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.**

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

User Question: If my patient has a device thrombus do I need to enter a device malfunction form?

A: Yes, a device thrombus meets the definition of a major device malfunction.

MCS ARC DEVICE MALFUNCTION**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 are further defined as major or minor:

Major Device Malfunction

Major device malfunction, otherwise known as failure, occurs when 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 categorized as major when one of the following conditions occurs:

1. Death.
2. Hospitalization, emergency room visit or prolongation of hospitalization, or escalation of the level of care in an ongoing hospitalization (i.e., transfer to the intensive care unit).
3. Life-threatening event (i.e., stroke or TIA, cardiac arrest, heart failure, syncope or near syncopal event, arrhythmia, etc.).
4. Results in significant disability or incapacity.
5. Requires an intervention to prevent impairment/injury including:
 - a. Urgent transplantation listing (immediate urgent listing for the transplant).
 - b. Pump replacement.
 - c. Pump explant.
 - d. Pump deactivation without explant or partial explant of components.
 - e. Breach of integrity of percutaneous lead requiring repair.
 - f. Operation to repair or replace any internal component of the circulatory support system.
 - g. Procedure to repair or stent an outflow graft.

Note: Replacement or external controller that is done in an inpatient setting for logistical reasons, in an otherwise stable patient, should be considered a minor device malfunction rather than major.

Minor Device Malfunction

Minor device malfunction includes inadequately functioning external components that require repair or replacement but do not result in 1a to g. Device malfunction does not apply to routine maintenance including replacement of external controller, pneumatic drive unit, electric power supplies, batteries, and interconnecting cables that are not related to a failed component.

MCS ARC DEVICE MALFUNCTION

Device thrombus: Intracorporeal device thrombus represents a special case of major device malfunction and can be categorized as a suspected device thrombus or confirmed device thrombus. Device thrombus will be classified as suspected (see definition below) on the basis of clinical, biochemical, or hemodynamic findings or confirmed (see definition below) on the basis of device inspection or incontrovertible radiologic studies or absence of appropriate Doppler flow signals that confirm thrombus within the device or its conduits that results in or could potentially induce circulatory failure.

- **Suspected device thrombus** is a device-related malfunction in which clinical or MCSD parameters suggest thrombus on the blood-contacting components of the pump, cannula, or grafts. Suspected device thrombosis will be defined as signs and symptoms to include at least 1 of the 3 following criteria:
 - Presence of major hemolysis (including elevation of biochemical markers of hemolysis; i.e., lactate dehydrogenase or plasma-free hemoglobin, or clinical evidence of hemolysis; i.e., hemoglobinuria).
 - Presence of heart failure not explained by structural heart disease.
 - Abnormal pump parameters consistent with diminished pump output/pump efficiency/pump performance.

And:

Suspected device thrombus will be accompanied by 1 or more of the following events or interventions:

- i. Death
- ii. Stroke or TIA.
- iii. Arterial non-CNS thromboembolism.
- iv. De-novo need for inotrope therapy.
- v. Treatment with intravenous anti-coagulation (i.e., heparin), intravenous thrombolytics (i.e., tPA), or intravenous anti-platelet therapy (i.e., eptifibatide, tirofiban).
- vi. Pump replacement.
- vii. Pump explantation with or without exchange.
- viii. Pump deactivation without pump removal.
- ix. Operation to repair or replace any internal component of the circulatory support system.
- x. Urgent transplantation listing (immediate urgent listing for transplant).

- **Confirmed device thrombus** is a major device-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 through 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.
- **Para conduit device thrombus** represents a special case of device malfunction whereby thrombus obstructs the outflow graft from the pump. This should be classified as major if the thrombus directly interferes with pump function by obstructing flow and if the pump is replaced because of the thrombus. The event should be classified as minor if there is visible thrombus with the preserved function of the pump but requires surgical intervention (difficult to define minor when it requires surgical intervention). In all instances, visual confirmation of the thrombus is sufficient for confirmation.

If a suspected device thrombus event is ultimately confirmed through visual inspection following pump replacement, urgent transplantation or on autopsy following death, the event will be maybe reclassified to confirmed device thrombus.

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 MCS system which either directly causes or could potentially induce a state of inadequate circulatory support or death)?

Yes, No, or Unknown

If **yes**, Select **type of Device Malfunction** Event: Select one

Major Device Malfunction
Minor Device Malfunction
Unknown

If **Major Device Malfunction**: Select all **Criteria** that apply:

Death
Hospitalization – Emergency room visit or prolongation of hospitalization, or escalation of the level of care in an ongoing hospitalization (i.e., transfer to the intensive care unit)
Life-threatening event – i.e. stroke or TIA, cardiac arrest, heart failure, syncope or near syncopal event, arrhythmia, etc.
Results in significant disability or incapacity
Requires an intervention to prevent impairment/injury – Urgent transplantation listing (immediate urgent listing for the transplant), Pump replacement, Pump explant, Pump deactivation without explant or partial explant of components, Breach of integrity of percutaneous lead requiring repair, Operation to repair or replace any internal component of the circulatory support system, Procedure to repair or stent an outflow graft
Unknown

If Device Malfunction **Requires an Intervention to prevent impairment/injury**: Select all **Criteria** that apply:

Urgent transplantation listing (immediate urgent listing for the transplant)
Pump replacement (please enter explant form and add new device to record exchange)
Pump explantation with or without exchange (please complete explant form)
Pump deactivation without explant or partial explant of components
Breach of integrity of percutaneous lead requiring repair
Operation to repair or replace any internal component of the circulatory support system
Procedure to repair or stent an outflow graft
Unknown

If **yes**, enter **General Information**

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

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

LVAD
RVAD
Both (in the same OR visit)

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

In Hospital
Out of Hospital
Unknown

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

If **yes**, please select all of the components that apply:

Pump

Yes or No

Pump Component(s)

Pump Body (including bearings and rotor)
Driveline
Inflow Cannula
Outflow Graft (including bend relief)

Implantable Component(s)

Yes, No

Implantable Component(s)

Percutaneous Driveline
Implantable Batteries
Other, Specify
If Other, specify, **then complete the text box.**

Controller(s)

Yes, No

Controller Component(s)

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.**

Peripheral(s)

Yes, No

Peripheral Component(s)

External Battery
Cell Battery (in controller)
Power Module
Patient Cable
System Monitor / Display
Battery Charger
Battery Clip

Note: If RVAD or right half of BiVAD, above Components section should be completed for right side device

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**, select **Device Thrombus Type**: Select one

Suspected Device Thrombus – A device-related malfunction in which clinical or MCS parameters suggest thrombus on the blood-contacting components of the pump, cannula, or grafts

Confirmed Device Thrombus – A major device-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 through 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 **Suspected Device Thrombus** Select all **Signs and Symptoms** that apply:

Presence of major hemolysis – Including elevation of biochemical markers of hemolysis; i.e., lactate dehydrogenase or plasma-free hemoglobin, or clinical evidence of hemolysis; i.e., hemoglobinuria

Presence of heart failure not explained by structural heart disease

Abnormal pump parameters consistent with diminished pump output/pump efficiency/pump performance

Unknown

If **Suspected Device Thrombus** Select all **Events/Interventions** that apply:

Death (please complete death form)

Stroke or TIA (please complete neuro dysfunction AE)

Arterial non-CNS thromboembolism (please complete AE)

De-novo need for inotrope therapy

Treatment with intravenous anti-coagulation (i.e., heparin), intravenous thrombolytics (i.e., tPA), or intravenous anti-platelet therapy (i.e., eptifibatid, tirofiban)

Pump replacement (please enter explant form and add new device to record exchange)

Pump explantation with or without exchange (please complete explant form)

Pump deactivation without pump removal (please complete explant form and select explant reason: Turned off (decommissioned))

Operation to repair or replace any internal component of the circulatory support system

Urgent transplantation listing (immediate urgent listing for transplant)

Unknown

If **Confirmed Device Thrombus** Select all **Criteria** that apply:

Death

Hospitalization, emergency room visit or prolongation of hospitalization, or escalation of the level of care in an ongoing hospitalization – i.e. transfer to the intensive care unit

Life-threatening event – i.e., stroke or TIA, cardiac arrest, heart failure, syncope or near syncopal event, arrhythmia, etc.

Results in significant disability or incapacity

Requires an intervention to prevent impairment/injury – Urgent transplantation listing (immediate urgent listing for the transplant), Pump replacement, Pump explant, Pump deactivation without explant or partial explant of components, Breach of integrity of percutaneous lead requiring

repair, Operation to repair or replace any internal component of the circulatory support system, Procedure to repair or stent an outflow graft

Unknown

If **Confirmed Device Thrombus** **Requires an Intervention to Prevent Impairment/Injury** Select all **Criteria** that apply:

Urgent transplantation listing (immediate urgent listing for the transplant)

Pump replacement (please enter explant form and add new device to record exchange)

Pump explantation with or without exchange (please complete explant form)

Pump deactivation without explant or partial explant of components (please complete explant form and select explant reason: Turned off (decommissioned))

Breach of integrity of percutaneous lead requiring repair

Operation to repair or replace any internal component of the circulatory support system

Procedure to repair or stent an outflow graft

Unknown

If **Confirmed Device Thrombus** Select all **Signs and Symptoms** and **Events/Interventions** that apply:

NOTE: Para conduit device thrombus represents a special case of device malfunction whereby thrombus obstructs the outflow graft from the pump. This should be classified as major if the thrombus directly interferes with the pump function by obstructing flow and if the pump is replaced because of the thrombus. The event should be classified as minor if there is visible thrombus with the preserved function of the pump but requires surgical intervention. In all instances, visual confirmation of the thrombus is sufficient for confirmation.

NOTE: If a suspected device thrombus event is ultimately confirmed through visual inspection following pump replacement, urgent transplantation or an autopsy following death, the event will be may be reclassified to confirmed device thrombus.

Presence of major hemolysis – Including elevation of biochemical markers of hemolysis; i.e., lactate dehydrogenase or plasma-free hemoglobin, or clinical evidence of hemolysis; i.e., hemoglobinuria

Presence of heart failure not explained by structural heart disease

Abnormal pump parameters consistent with diminished pump output/pump efficiency/pump performance

Arterial non-CNS thromboembolism (please complete AE)

De-novo need for inotrope therapy

Treatment with intravenous anti-coagulation (i.e., heparin)

Intravenous thrombolytics (i.e., tPA)

Intravenous anti-platelet therapy (i.e., eptifbatide, tirofiban)

Unknown

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

If **Confirmed Device Thrombus**, Select **Method of Confirmation**: Select all that apply:

Imaging Study

Visual Inspection

Manufacturer's Report

Indicate **The Association of the Device Malfunction / Thrombus Event Should be Classified as:** Select one of the following:

Patient-Related – i.e., non-adherence with care of device or instructions for use, or its peripheral components, non-adherence with the anti-coagulation regimen, pro-coagulation abnormalities

Management-Related – i.e., surgical protocol deviation, sub-optimal anti-coagulation

Device Related – i.e., detected in a device at explant or on contrast studies or associated with hemolysis or other controller data consistent with device malfunction

No Association Identified

Extracorporeal / Paracorporeal Pump Change

Please use this form when only extracorporeal/paracorporeal pump components (i.e. cannulae, 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.**

Hemolysis Event

MCS ARC HEMOLYSIS

Minor Hemolysis

A plasma-free hemoglobin value greater than 20 mg/dl or a serum LDH level greater than two and one-half times (2.5 x) the upper limits of the normal range at the implanting center occurring after the first 72 hours post-implant in the absence of clinical symptoms or findings of hemolysis or abnormal pump function (see Major Hemolysis for a list of symptoms and findings) and thought not attributable to laboratory error.

Major Hemolysis

A plasma-free hemoglobin value greater than 20 mg/dl or a serum LDH level greater than two and one-half times (2.5 x) the upper limits of the normal range at the implanting center occurring after the first 72 hours post-implant and associated with clinical symptoms or findings of hemolysis or abnormal pump function. Major Hemolysis requires the presence of at least one of the following conditions:

- Hemoglobinuria (“tea-colored urine”)
- Anemia (decrease in hematocrit or hemoglobin level that is out of proportion to levels explainable by chronic illness or usual post- VAD state)
- Hyperbilirubinemia (total bilirubin above 2 mg/dl, with predominately indirect component)
- Pump malfunction and/or abnormal pump parameters as per section on device malfunction

Note:

- Isolated LDH elevations should not be reported as hemolysis if attributable to laboratory error, hepatic or pulmonary dysfunction. If suspected, confirmatory testing of LDH, LDH isoenzymes and plasma-free hemoglobin within 24 hours should be obtained to rule out laboratory error.
- All causes of hemolysis should be reported regardless of whether they are thought attributable to the device or not.

Was there a Hemolysis adverse event?

Yes or No

User Question: I am entering a Follow-up Visit on 8/6/21. On the Follow-up status form at the bottom, it asks if there was a Hemolysis Event since the last visit. The last visit was 4/27/21. If I mark yes, I am prompted to enter a hemolysis event. The patient has had elevated LDH 2.5 X upper limit normal on 5/6/21 and 8/4. So do I enter 2 separate hemolysis events?

A: Yes, enter 2 separate events

If Yes, Select Type of Hemolysis Event

Minor Hemolysis – A plasma-free hemoglobin value greater than 20 mg/dl or a serum LDH level greater than two and one-half times the upper limits of the normal range at the implanting center occurring after the first 72 hours post-implant in the absence of clinical symptoms or findings of hemolysis or abnormal pump function (see Major Hemolysis for a list of symptoms and findings) and thought not attributable to laboratory error.

Major Hemolysis – A plasma-free hemoglobin value greater than 20 mg/dl or a serum LDH level greater than two and one-half times the upper limits of the normal range at the implanting center occurring after the first 72 hours post-implant and associated with clinical symptoms or findings of hemolysis or abnormal pump function.

If Major Hemolysis Event, Select Condition: Major Hemolysis requires the presence of at least one of these conditions. **NOTE:** Isolated LDH elevations should not be reported as hemolysis if attributable to laboratory error, hepatic or pulmonary dysfunction. If suspected, confirmatory testing of LDH, LDH isoenzymes and plasma-free hemoglobin within 24 hours should be obtained to rule out

laboratory error. All causes of hemolysis should be reported regardless of whether they are thought attributable to the device or not.

Select all that apply:

Hemoglobinuria – tea-colored urine

Anemia –hematocrit ≤ 25 or hemoglobin ≤ 8 not explained by chronic illness or usual post-VAD state

Hyperbilirubinemia – total bilirubin above 2 mg/dl, with predominately indirect component

Pump malfunction and/or abnormal pump parameters as per section on device malfunction. (If yes, please fill out the Device Malfunction Adverse Event Form)

Indicate **The Association of the Hemolysis Event Should be Classified as:** Select one of the following:

Patient-Related – e.g., hematologic abnormalities

Management-Related – e.g., drug related, secondary pump or IABP related, pump malposition

Device Related – e.g., related to pump thrombosis or device malfunction

No Association Identified

Enter **Date of Hemolysis Event:** in MMDDYYYY format. **ST=** Unknown

User Question: Would we use the same date we used for the follow-up form or would we use the date of the highest LDH or PFH??

A: The Date of Event field on the Hemolysis form is looking for the date the hemolysis event occurred. This is typically the date the elevated PFH or LDH was identified. These events do not always line up with a follow-up so we allow for the hemolysis date to be entered independent of the follow-up.

User Question: What date ranges do we use for the Hgb, Hct, and total Bili? We previously went by the dates of the last follow-up to the current follow-up. Do we just use the dates from the last follow-up to the date of the hemolysis event?

A: Use the dates from the last follow-up to the date of hemolysis.

Note: You may use either PFh or LDH.

Please enter the peak Plasma-free hemoglobin (PFh): _____ 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): _____ 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:

Min. HCT: _____

ST= Unknown or Not Done

Max. HCT: _____

ST= Unknown or Not Done

Min. HGB: _____

Max. HGB: _____

ST= Unknown or Not Done

SI= Unknown or Not Done

Highest Total Bilirubin: _____ mg/dl.

ST= Unknown or Not Done

Right Heart Failure Event

MCS ARC RIGHT HEART FAILURE

Early Acute Right Heart Failure

- Need for implantation of a temporary or durable RVAD (including ECMO) concomitant with LVAD implantation (RVAD implanted before the patient leaving the operating room).

Early post-implant right heart failure

- Need for implantation of a temporary or durable RVAD (including ECMO) within 30 days following LVAD implantation for any duration of time; or,
- Failure to wean from inotropic or vasopressor support or inhaled nitric oxide within 14 days following LVAD implantation or having to initiate this support within 30 days of implant for a duration of at least 14 days.
 - The primary diagnosis of right heart failure is made by the presence of at least two of the following clinical findings:
 - Ascites
 - Functionally limiting peripheral edema (> 2+)
 - Elevated estimated jugular venous pressure at least halfway up the neck in an upright patient.
 - Elevated measured central venous pressure or right atrial pressure (≥ 16 mm Hg) or is associated with at least one of the following manifestations:
 - Renal failure with serum creatinine > 2 baseline values.
 - Liver injury with an elevation of at least 2 upper limit normal in AST/ALT or total bilirubin > 2.0.
 - $SVO_2 < 50\%$.
 - Cardiac index < 2.2 liter/min/m².
 - Reduction in pump flow of > 30% from the previous baseline in the absence of mechanical causes such as cardiac tamponade or tension pneumothorax.
 - Elevated lactate >3.0 mmol/liter.
- Death occurring in patients within 14 days of LVAD implant who have not received an RVAD but who remain on inotropes or vasopressors at the time of death and meet criteria for the diagnosis of Right Heart Failure on the basis of the above clinical findings (2 criteria) or manifestations (1 criterion) will be considered to have early post-implant right heart failure at the time of death. The contribution of early post-implant right heart failure to the death (primary or secondary) will be made by the clinical care team.

Late RHF

- Need for implantation of an RVAD (including ECMO) greater than 30 days after an LVAD implantation. This may occur within the index hospitalization for LVAD implant or during subsequent rehospitalization for any diagnosis which resulted in a need for temporary or permanent right-sided mechanical assist devices.
- Hospitalization that occurs greater than 30 days post-implant and which requires intravenous diuretics or inotropic support for at least 72 hours and is associated with:
 - The diagnosis of right heart failure is made by the presence of at least two of the following clinical findings:
 - Ascites
 - Functionally limiting peripheral edema (>2+).
 - Elevated estimated jugular venous pressure at least halfway up the neck in an upright patient.
 - Elevated measured central venous pressure (>16 mm Hg).
 - or which is associated with at least one of the following manifestations:
 - Renal failure with serum creatinine > 2 baseline value
 - Liver injury with an elevation of at least 2 upper limit normal in AST/ALT or total bilirubin > 2.0
 - A reduction in pump flow of > 30% from the previous baseline in the absence of tamponade
 - $SVO_2 < 50\%$
 - Cardiac index < 2.2 liter/min/m²
 - Elevated lactate >3.0 mmol/liter

Was there a Right Heart Failure adverse event?

Yes or No

Enter **Date of Right Heart Failure Event:** in MMDDYYYY format. **ST=** UnknownIf Yes, **Select Type of Right Heart Failure Event**

Early Acute RHF

Early post-implant RHF– Note: Does NOT include RVAD/BiVAD placed during LVAD implant

Late RHF

If Early Post-Implant Right Heart Failure, Select Category: Select one of the following:

Need for implantation of temporary or durable RVAD (including ECMO) within 30 days following LVAD implantation for any duration of time

Initiation or continuation of inotropic or vasopressor support or inhaled nitric oxide after 14 days following LVAD implantation or having to initiate this support within 30 days of implant for a duration of at least 14 days

Death occurring in patients within 30 days of LVAD implant who have not received an RVAD but who remain on inotropes or vasopressors at the time of death and meet criteria for the diagnosis of Right Heart Failure. Note: The contribution of early post-implant right heart failure to the death (primary or secondary) will be made by the clinical care team.

User Question: On the Late RHF description, second dot “Hospitalization.....support for at least 72 hours and is associated with:” Does that mean that the patient must be hospitalized and require diuretics or inotropic support for 72 hours and have the clinical findings listed below it? Or, can the patient have a diagnosis of RHF simply by the clinical findings listed without being admitted to the hospital and treated with inotropes or diuretics? For instance, if a patient has 2+ edema and JVP halfway up the neck as an outpatient in clinic, do we enter a RHF AE event?

A: For late RHF what we are trying to determine was did they need a RVAD or did they need IV diuretics or inotropic support for at least 72 hours? So on this parent question yes they need to have been on IV diuretics or inotropes for at least 72 hours.

User Question: If a patient was prescribed digoxin for an RHF exacerbation requiring admission, should this be coded as an RHF AE?

A: Digoxin is not considered an inotrope.

Note: The primary diagnosis of right heart failure is made by the presences of at least **TWO** of the following clinical findings or is associated with at least **ONE** of the following manifestations:

Initiation or continuation of inotropic or vasopressor support Clinical Findings: Select all that apply:

Ascites

Functionally limiting peripheral edema (> or = 2+)

Elevated estimated jugular venous distension (> or = 6cm) at least halfway up the neck in an upright patient or hepatomegaly (3+ cm below costal margin)

Elevated measured central venous pressure or right atrial pressure (RAP) (> or =16 mmHg)

Other, specify

If Other, specify: please complete text box.

Initiation or continuation of inotropic or vasopressor support

Manifestations: Select all that apply:

Renal failure with serum creatinine > 2x baseline values

Liver injury with an elevation of at least 2 x upper limit normal in AST/ALT or total bilirubin > 2.0

SvO₂ < 50%

Cardiac index <2.2 liter/min/m²

Reduction in pump flow of >30% from the previous baseline in the absence of mechanical causes such as cardiac tamponade or tension pneumothorax

Elevated lactate >3.0 mmol/liter

Other, specify

If Other, specify: please complete text box.

Death within 30 Days Clinical Findings: Select all that apply:

Ascites

Functionally limiting peripheral edema (> or = 2+)

Elevated estimated jugular venous distension (> or = 6cm) at least halfway up the neck in an upright patient or hepatomegaly (3+ cm below costal margin)

Elevated measured central venous pressure or right atrial pressure (RAP) (> or =16 mmHg)

Other, specify

If Other, specify: please complete text box.

Death within 30 Days Manifestations: Select all that apply:

Renal failure with serum creatinine > 2x baseline values

Liver injury with an elevation of at least 2 x upper limit normal in AST/ALT or total bilirubin > 2.0

SvO₂ < 50%

Cardiac index <2.2 liter/min/m²

Reduction in pump flow of >30% from the previous baseline in the absence of mechanical causes such as cardiac tamponade or tension pneumothorax

Elevated lactate >3.0 mmol/liter

Other, specify

If Other, specify: please complete text box.

If Late Right Heart Failure, Select Category: Select one of the following:

Need for implantation of an RVAD (including ECMO) greater than 30 days after an LVAD implantation – This may occur within the index hospitalization for LVAD implant or during subsequent rehospitalization for any diagnosis which resulted in a need for temporary or permanent right-sided mechanical assist devices.

Hospitalization that occurs greater than 30 days post-implant and which requires intravenous diuretics or inotropic support for at least 72 hours

Hospitalization Clinical Findings: Select all that apply:

Ascites

Functionally limiting peripheral edema (> or = 2+)

Elevated estimated jugular venous distension (> or = 6cm) at least halfway up the neck in an upright patient or hepatomegaly (3+ cm below costal margin)

Elevated measured central venous pressure or right atrial pressure (RAP) (> or =16 mmHg)

Other, specify

If Other, specify: please complete text box.

User Question: I have a pt who was admitted on 5/6 for ADHF. He was given IV diuretics on 5/6, 5/8, 5/9, 5/11, 5/13, all as one-time doses. Would we consider this as getting IV diuretics for at least 72 hours?

A: Yes, they do count as IV diuretics for >72H.

Hospitalization Manifestations: Select all that apply:

Renal failure with serum creatinine > 2x baseline values

Liver injury with an elevation of at least 2 x upper limit normal in AST/ALT or total bilirubin > 2.0

SvO₂ < 50%

Cardiac index <2.2 liter/min/m²

Reduction in pump flow of >30% from the previous baseline in the absence of mechanical causes such as cardiac tamponade or tension pneumothorax

Elevated lactate >3.0 mmol/liter

Other, specify

If Other, specify: please complete text box.

Indicate **The Association of the RHF Event Should be Classified as:** Select one of the following:

Patient-Related – e.g., pre-implant right heart failure, volume overload secondary to non-adherence with medical management, severe aortic regurgitation, cardiorenal syndrome, arrhythmia induced, pulmonary disease, elevated pulmonary vascular resistance

Management-Related – e.g., related to implant surgery, volume overload, inotropic agent withdrawal

Device Related – e.g., associated with Pump malfunction, outflow graft compromise

No Association Identified

Renal Dysfunction Event

MCS ARC RENAL DYSFUNCTION

Acute Renal Dysfunction

- Stage 1
 - Increase in serum creatinine to 150% to 199% (1.5–1.99 x increase compared with baseline) or increase of > 0.3 mg/dl (> 26.4 mmol/liter) or
 - Urine output < 0.5 ml/kg/h for > 6 but < 12 hours.
- Stage 2
 - Increase in serum creatinine to 200% to 299% (2.0 x –2.99 x increase compared with baseline) or
 - Urine output < 0.5 ml/kg/h for > 12 but < 24 hours.
- Stage 3
 - Increase in serum creatinine to >300% (>3 x increase compared with baseline) or
 - Serum creatinine of > 4.0 mg/dl (>354 mmol/liter) with an acute increase of at least 0.5 mg/dl (44 mmol/liter) or
 - Urine output <0.3 ml/kg/h for >24 hours or
 - Anuria for >12 hours or
 - Need for renal replacement therapy (includes dialysis or ultrafiltration) regardless of above criteria.

Chronic Renal Dysfunction

An increase in serum creatinine of 2 mg/dl or greater above baseline, or requirement for renal replacement therapy, either of which is sustained for at least 90 days.

User Question: Is the increase in serum creatinine based off the patient's baseline at the time of implant ?

A: Yes, time of implant.

Was there a Renal Dysfunction adverse event?

Yes or No

If Yes, Select Type of Renal Dysfunction Event

Acute Renal Dysfunction

Chronic Renal Dysfunction – An increase in serum creatinine of 2 mg/dl or greater above baseline, or requirement for renal replacement therapy, either of which is sustained for at least 90 days

User Question: once a patient is entered for dialysis, do we continue to put them in for chronic renal failure since they will be on dialysis forever?

A: If the patient has acute renal failure diagnosis prior to the implant, do not enter an acute renal failure AE for that patient. If the acute renal failure escalates to chronic after the VAD implant, then document as chronic renal failure.

User Question: My patient had CRRT started on 09/29 but his creatine went from a low of 1.91 to 4.3- so greater than 150% . Date of event is when the CRRT began?

A: When entering the Renal Dysfunction AE you'll enter it as day 90 being the start date.

If Acute Renal Dysfunction, Select Stage: Select one of the following:

Stage 1 – Increase in serum creatinine to 150% to 199% (1.5 to 1.99x increase compared with baseline) or Increase of >0.3 mg/dl (>26.4 mmol/liter) or Urine output < 0.5 ml/kg/h for >6 but <12 hours

Stage 2 – Increase in serum creatinine to 200% to 299% (2.0 to 2.99x increase compared with baseline) or Urine output <0.5 ml/kg/h for >12 but <24 hours

Stage 3 – Increase in serum creatinine to >300% (>3x increase compared with baseline) or Serum creatinine of >4.0 mg/dl (>354 mmol/liter) with an acute increase of at least 0.5 mg/dl (44 mmol/liter) or Urine output <0.3 ml/kg/h for >24 hours or Anuria for >12 hours or Need for renal replacement therapy (includes dialysis or ultrafiltration) regardless of above criteria

If Stage 1 Acute Renal Dysfunction: Select all that apply:

Increase in serum creatinine to 150% to 199% (1.5-1.99 x increase compared with baseline)

Increase of >0.3 mg/dl (>26.4 mmol/liter)

Urine output <0.5 ml/kg/h for >6 but <12 hours

If Stage 2 Acute Renal Dysfunction: Select all that apply:

Increase in serum creatinine to 200% to 299% (2.0 to 2.99x increase compared with baseline)

Urine output <0.5 ml/kg/h for >12 but <24 hours

If Stage 3 Acute Renal Dysfunction: Select all that apply:

Increase in serum creatinine to >300% (>3x increase compared with baseline)

Serum creatinine of >4.0 mg/dl (>354 mmol/liter) with an acute increase of at least 0.5 mg/dl (44 mmol/liter)

Urine output <0.3 ml/kg/h for >24 hours

Anuria for >12 hours

Need for renal replacement therapy (includes dialysis or ultrafiltration) regardless of above criteria

Enter **Date of Renal Dysfunction Event:** in MMDDYYYY format. **ST=** Unknown

Indicate **The Association of the Renal Dysfunction Event Should be Classified as:**

Select one of the following:

Patient-Related – e.g., non-adherence to medical therapy resulting in renal dysfunction

Management-Related – e.g., overprescribing of diuretic therapy or administration of renal toxic drugs or contrast agents that result in renal dysfunction

Device Related – e.g., device failure resulting in renal dysfunction

No Association Identified.

Additional Adverse Events

Cardiac Arrhythmias

MCS ARC CARDIAC ARRHYTHMIAS

Any documented arrhythmia that results in clinical compromise (e.g., abnormal VAD function [e.g., diminished VAD flow or suction events], oliguria, pre-syncope or syncope, angina, dyspnea), or requires hospitalization or treatment (drug therapy, defibrillation, cardioversion, ICD therapy (e.g., shock or anti-tachycardia pacing) or arrhythmia ablation procedure).

Cardiac arrhythmias are classified as 1 of 2 types:

1. Sustained ventricular arrhythmia resulting in clinical compromise, or requiring hospitalization or drug treatment, defibrillation, cardioversion, ICD therapy, or arrhythmia ablation procedure.
2. Sustained supraventricular arrhythmia resulting in clinical compromise, or requiring hospitalization or drug treatment, cardioversion, ICD therapy, or arrhythmia ablation procedure.

Did a documented arrhythmia result in clinical compromise since last STS Intermacs® report / last followup?

Yes, No, or Unknown

User Question: How do I enter that my patient had 4 bouts of VT over 7 days?

A: Any episodes of an arrhythmia occurring within 7 days count as one adverse event.

User Question: My latest LVAD patient had VT in the OR during his LVAD implant procedure & was defibrillated. Should I collect as AE Cardiac Arrhythmia?

A: No, we don't collect introp arrhythmias as they are likely very common. Only collect those that occur after leaving the OR.

If **yes**, Enter **Cardiac Arrhythmia Event date** in MMDDYYYY format. **ST=** Unknown

Enter **Type of arrhythmia** from selection below:

Sustained ventricular arrhythmia - resulting in clinical compromise, or requiring hospitalization or drug treatment, defibrillation, cardioversion, ICD therapy, or arrhythmia ablation procedure

Sustained supraventricular arrhythmia - resulting in clinical compromise, or requiring hospitalization or drug treatment, cardioversion, ICD therapy, or arrhythmia ablation procedure

Unknown

Indicate **The Association of the Cardiac Arrhythmia Event Should be Classified as:** Select one of the following:

Patient-Related – e.g., recurrence of pre-operative arrhythmia non-adherence with medications

Management-Related – e.g., related to uncorrected electrolyte imbalance, Swan Ganz malposition, secondary to cardiac tamponade

Device Related – e.g., Pump malfunction, malposition of pump, or inflow cannula

No Association Identified

Respiratory Failure

MCS ARC RESPIRATORY FAILURE

Impairment of respiratory function requiring reintubation, tracheostomy, or the inability to discontinue ventilatory support within 6 days (144 hours) post-VAD implant. This excludes intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures.

Did an impairment of respiratory function requiring reintubation, tracheostomy, or the inability to discontinue ventilator support within 6 days (144 hours) post-VAD implant occur since last STS Intermacs® report / last followup?: this excludes

intubation for reoperation or temporary intubation for diagnostic or therapeutic procedures.

Yes, No, or Unknown

Respiratory Failure Event Date

ST= Unknown or Ongoing

User Question: Should the date of the event be when the patient was extubated so that the number of days of intubation align or should the date of the event be identified as the date the patient qualified for having prolonged intubation?

A: It should be the date the patient met and qualified for the AE.

Respiratory Failure

Implant Intubation 7/21-7/28

Retubed 8/12-8/15

Retubed 8/19-8/21

Retubed 8/29-9/2 when he was trached

- 7/21–7/28: 8 days
- 8/12–8/15: 4 days
- 8/19–8/21: 3 days
- 8/29–9/2: 5 days

Date of event MM/DD/YYYY	7/26/2025	
ST=	▼	
Was this a prolonged intubation (patient intubated greater than 144 hours)? <small>Cumulative duration of intubation. Any reintubation except procedures should be documented here. Initial implant intubation including any subsequent intubation will be considered the initial procedure intubation. Begin counting intubation hours when patient is in the unit.</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	
Number of days of intubation	20	
ST:	▼	
Was there a need for reintubation? <small>Extubated within the first 6 days (144 hours) and then re-intubated. Any reintubation except procedure should be documented here.</small>	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown	
Was there a need for a tracheostomy?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	
Date of tracheostomy MM/DD/YYYY	9/2/2025	
ST=	▼	

Was this a prolonged intubation (patient intubated greater than 144 hours)? Cumulative duration of intubation. Any reintubation except procedures should be documented here. Initial implant intubation including any subsequent intubation will be considered the initial procedure intubation. Begin counting intubation hours when patient is in the unit.

Yes, No, or Unknown

Enter Intubation duration in days. ST= Unknown or Ongoing

User Question: Do I count and factor in the days on ventilator pre-device?

A: No, do not count pre-device days for this adverse event.

Was there a need for reintubation? Extubated within the first 6 days (144 hours) and then re-intubated. Any reintubation except procedure should be documented here

Yes, No, or Unknown

If **yes**, Enter **Reintubation Event Date** in MMDDYYYY format.

ST= Unknown

Was there a need for tracheostomy?

Yes, No, or Unknown

If **yes**, Enter **Tracheostomy Date** in MMDDYYYY format.

ST= Unknown

Indicate **The Association of the Respiratory Failure Event Should be Classified as:** Select one of the following:

Patient-Related – e.g., non-adherence to medical therapy resulting in respiratory failure

Management-Related – e.g., inadequate diuretic therapy resulting in respiratory dysfunction

Device Related – e.g., device failure resulting in respiratory dysfunction

No Association Identified

Venous Thromboembolism

MCS ARC 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 Intermacs® report / last followup (e.g. deep vein thrombosis, pulmonary embolism) by standard clinical and laboratory testing: (select all that apply).

Deep Vein thrombosis – **Enter Date** in MMDDYYYY format. **ST=** Unknown

Pulmonary Embolus – **Enter Date** in MMDDYYYY format. **ST=** Unknown

Other, Specify – if selected, enter in block provided.

Enter Date in MMDDYYYY format. **ST=** Unknown

Unknown

None

If Deep Vein thrombosis, Pulmonary Embolus, or Other, Specify:

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

Warfarin

Heparin

Lovenox

Aspirin

Dipyridamole

Clopidogrel (plavix)

Argatroban

Bivalirudin

Fondaparinux

Dextran

Ticlopidine

Hirudin

Lepirudin

Ximelagatran

None

Other– if selected, enter in block provided

Wound Dehiscence

MCS ARC WOUND DEHISCENCE

Disruption of the apposed surfaces of a surgical incision, excluding infectious etiology, and requiring surgical repair.

Did a disruption of the apposed surfaces of surgical incision require surgical repair since last STS Intermacs® report / last followup?

Yes, No, or Unknown

If yes,

Enter **Wound Dehiscence 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.

Arterial Non-CNS Thromboembolism

MCS ARC ARTERIAL NON-CNS THROMBOEMBOLISM

An acute systemic arterial perfusion deficit in any non-cerebrovascular organ system due to thromboembolism confirmed by 1 or more of the following:

Standard clinical and laboratory testing
Operative findings
Autopsy findings

This definition excludes neurologic events.

Did an acute perfusion deficit in any non-cerebrovascular organ system occur since last STS Intermacs® report / last followup?:

Yes, No, or Unknown

If **yes**, Enter **Non-CNS 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

Hypertension

MCS ARC HYPERTENSION

New-onset blood pressure elevation greater than or equal to 140 mm Hg systolic or 90 mm Hg diastolic (pulsatile pump) or 110 mm Hg mean pressure (rotary pump).

Did a Hypertension Event occur since last STS Intermacs® report / last followup post implant?: Yes, No, or Unknown.

Yes, No, or Unknown

If **yes**, Enter **Hypertension Event date** in MMDDYYYY format. **ST=** Unknown

User Question: Hypertension AE is the new-onset blood pressure elevation greater than or equal to 140 mm Hg systolic or 90 mm Hg diastolic (pulsatile pump) or 110 mm Hg mean pressure (rotary pump). Is new-onset post LVAD surgery only?

A: Yes, post implant.

User Question: is the expectation to report every BP greater than MAP 110 Or SBP greater than 140 or DBP greater than 90?

A: 1. Criteria met on 2 successive clinic visits, or

2. Criteria met at least once on 2 successive in-hospital days

Hepatic Dysfunction

MCS ARC HEPATIC DYSFUNCTION

An increase in any two of the following hepatic laboratory values (total bilirubin, aspartate aminotransferase/**AST**, and alanine aminotransferase/**ALT**) to a level greater than 3 times the upper limit of normal for the hospital, beyond 14 days post-implant (or if hepatic dysfunction is the primary cause of death).

Did Clinical evidence of liver dysfunction since last STS Intermacs® report / last followup occur beyond 14 days post implant?: Yes, No, or Unknown.

Yes, No, or Unknown

If **yes**, Enter **Hepatic Dysfunction Event date** in MMDDYYYY format.

ST= 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

Psychiatric Episode

MCS ARC 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.

The psychiatric event should be classified according to the DSM 5 classification:

- Axis I: Clinical disorders, including anxiety disorders, mood disorders, schizophrenia and other psychotic disorders.
- Axis II: Personality disorders and mental retardation.
- Axis III: General medical conditions.
- Axis IV: Psychosocial and environmental problems.

Did a disturbance in thinking, emotion, or behavior that required intervention occur in patient since last STS Intermacs® report / last followup?:

Yes, No, or Unknown

If **yes**, Enter **Psychiatric Episode Event date** in MMDDYYYY format.

ST= Unknown

The Psychiatric Event Should be Classified According to the DSM V as:

Select one of the following:

Axis I: Clinical Disorders, including anxiety disorders, mood disorders, schizophrenia and other psychotic disorders,

Axis II: Personality disorders and mental retardation.

Axis III: General medical conditions.

Axis IV: Psychosocial and environmental problems.

Unknown

Pericardial Fluid Collection

MCS ARC PERICARDIAL FLUID COLLECTION

Accumulation of fluid or clot in the pericardial space that requires surgical intervention or percutaneous catheter drainage. This event will be subdivided into those with clinical signs of tamponade (e.g. increased central venous pressure and decreased cardiac/VAD output) and those without signs of tamponade.

Did a pericardial effusion that required drainage occur since last STS Intermacs® report / last follow-up?

Yes, No, or Unknown

If **yes**, Enter **Pericardial Effusion Event date** in MMDDYYYY format.

ST= Unknown

Were there **Signs of tamponade?**

Yes, No, or Unknown

Method of Drainage

Surgical Intervention

Cath

Unknown

Myocardial Infarction

MCS ARC 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 ($\geq 3\%$ total CK). This should be accompanied by a new regional LV or RV wall motion abnormality on a myocardial imaging study.

Did a myocardial infarction occur since last STS Intermacs® report / last followup / admission?:

Yes, No, or Unknown

If **yes**, Enter **Myocardial Infarction Event date** in MMDDYYYY format.

ST= Unknown

Other SAE

MCS ARC OTHER SAE

An event that causes clinically relevant changes in the patient's health (e.g. cancer).

Did an Other Major Serious Adverse Event occur since last STS Intermacs® report / last followup?

Yes, No, or Unknown

If **yes**,

**OtherMajor Serious Adverse Event since last STS InterMACS®
report/last followup** - enter in block provided

Enter **Other SAE 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

User Question: Are we entering the patient's home address or the hospital address?

A: Please enter the patient's home address.

User Question: Why are we collecting patient's addresses and how will that data be used?

A: Social Determinants of Health (SDOH) are highly correlated with health outcomes in patients. Collecting address allows us to identify local SDOH, which will facilitate understanding barriers to equality in access to care and allow implementation of strategies to reduce the impact of SDOH on Ventricular Assist Device (VAD) patient outcomes.

Was the patient on ECMO at any time since implant of their durable LVAD?

Yes, No, or Unknown

If **Yes**, enter **Total Number of days** on ECMO: **ST=** Unknown

Enter **Device explanted:** Select appropriate device type for this explant event:

Note: Do not explant RVAD due to addition of an oxygenator (ProtekDuo, Spectrum Dual Lumen, etc.) cannula.

LVAD

RVAD

Both (LVAD+RVAD)

TAH

if **RVAD** explant, **Did patient suffer major hemolysis related solely to this device?**

Yes, No, or Unknown

Note: If death or transplant occurred post cessation of MCS 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 Intermacs® 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

User Question: When entering the event date on the 1 yr post cessation do I enter the actual date 1 yr post cessation or do I enter today's date, the date in which I am entering it on?

A: You enter the event date not today's date.

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

User Question: Are we entering the patient's home address or the hospital address?

A: Please enter the patient's home address.

User Question: Why are we collecting patient's addresses and how will that data be used?

A: Social Determinants of Health (SDOH) are highly correlated with health outcomes in patients. Collecting address allows us to identify local SDOH, which will facilitate understanding barriers to equality in access to care and allow implementation of strategies to reduce the impact of SDOH on Ventricular Assist Device (VAD) patient outcomes.

Device functioning normally: If the device was functioning normally at time of death, select **Yes**. If the device was not functioning normally at time of death, select **No** and fill out the **Device Malfunction Adverse Event Form**. If it is not known whether the device was functioning normally at time of death, select **Unknown**.

Yes, No, Unknown

If No, Was There an operation associated with the device malfunction?:

Yes, No, Unknown

Was the patient on ECMO at any time since implant of their durable LVAD?

Yes, No, or Unknown

If **Yes**, enter **Total Number of days** on ECMO: **ST=** Unknown

Post mortem device explant: Was the device explanted post mortem?

Yes, No, Unknown

If Yes, did device go to manufacturer:

Yes, No, Unknown

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

In Hospital

Out of Hospital

Unknown

Timing of death: Select one of the timings of death: **Expected**, **Unexpected** or the timing of death was **Unknown**.

Expected
Unexpected
Unknown

User Question: I just want to clarify “timing of death” to ensure I’m coding correctly. Patient was admitted to the hospital with device infection and unable to get infection under control so they moved him to comfort cares and turned off his LVAD. Would this be coded as “expected” since he died after LVAD support was dc’d?

A: Yes, that is correct.

User Question: We would like the INTERMACS definition of expected and unexpected death

A: Expected death would be death that occurs in the context of planned withdrawal of support, comfort care, or a known progressive clinical decline. It is anticipated by the care team and family. And unexpected death occurs suddenly or without prior anticipation, such as from an acute event (e.g., arrhythmia, stroke, massive bleed) where death was not imminent or planned for.

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: COVID-19

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

User Question: How do I remove an AE on my own?

A: To remove the AE:

1. Change the answer on the Rehospitalization form to "No".
2. On the Adverse Events Status form right above where it says "In Progress" click X Delete Form.

The screenshot shows the 'Adverse Event' form for an event dated 6/9/2022. The form is currently in an 'In Progress' state. A sidebar on the left contains navigation tabs: 'Adverse Event Status' (highlighted in green), 'Rehospitalization', 'Major Infection', and 'Major Bleeding'. The main content area is titled 'Infection' and contains the question 'Was there a major infection?' with radio button options for 'Yes' and 'No'. The 'No' option is selected. At the bottom of the form, there are two buttons: 'Validate and Submit' and 'Save for Later'. In the top right corner, there are links for 'Print View' and 'Delete Form' (highlighted in yellow). A 'Session Time' indicator is visible in the bottom right corner.

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 combined **EuroQoL (EQ-5D)** and **Modulated QoL Questionnaire** and the separate **Kansas City Cardiomyopathy Questionnaire (KCCQ)** are provided in **Appendices F and H** respectively. Participants should contact STS Intermacs® at intermacsfaq@sts.org to request a copy of the **EQ-5D**. The **Modulated QoL** and **KCCQ** questionnaires can be printed from the STS Intermacs® website <https://intermacs.kirso.net/intermacs-documents/>

Quality of life is to be measured by the EQ-5D/Modulated QoL and the KCCQ instruments. EQ-5D/Modulated QoL and KCCQ are to be administered pre-implant and post-implant (3 months, 6 months, and every 6 months thereafter).

All adult patients should complete the EQ-5D/Modulated QoL and KCCQ.

Data collection

The EQ-5D/Modulated QoL and KCCQ are administered by research or clinical coordinators as designated by each participating medical center. The EQ-5D/Modulated QoL and KCCQ instruments can be printed from the STS Intermacs® website <https://intermacs.kirso.net/>

Pre-implant data collection

- The patient is to complete the EQ-5D/Pre-Implant Modulated QoL and KCCQ before MCS D implant. Pre-implant assessment of quality of life is essential in evaluating MCS D therapy. Please make every effort to obtain this information. All eligible patients should complete these questionnaires.

Post-implant data collection (3, 6, and every 6 months post implant)

- The patient is to complete these instruments at the return clinic visits closest to the appropriate data collection time points (given the patient has been discharged prior to the data collection time points). All eligible patients should complete these questionnaires.
- Patients who remain hospitalized at the 3, 6 or 12 month time point should complete the EQ-5D/Post-Implant Modulated QoL and KCCQ, if able.

Instrument Administration

- The patient is to complete the EQ-5D/Modulated QoL and KCCQ instruments via self-report independently.

If the patient is unable to complete the EQ-5D/STS Modulated QoL and KCCQ instruments, the coordinator or a family member is to read the questions to the patient and complete the instruments documenting the patient's responses. Indicate on the instruments that the EQ-5D and KCCQ were self-administered or administered verbally by another.

- There should be no coaching regarding responses.
- Enter the patient's answers from the paper form into the database through <https://intermacs.kirso.net/>

Data Screening

- The EQ-5D/STS Modulated QoL and KCCQ are to be reviewed for missing or unclear data at the time of instrument completion. Corrections must be made with the patient at that time.

Non Submission of EQ-5D and KCCQ

- For patients who do not complete the EQ-5D/STS Modulated QoL or KCCQ, please enter reason as to why the EQ-5D/STS Modulated QoL or KCCQ were not completed as stated above.

EuroQol (EQ-5D)

Did the patient complete a EuroQol (EQ-5D) form: Enter Yes or No

Yes or No

If No, Please select a reason why the EuroQol (EQ-5D) was not completed:

Select the reason for non-completion of the EuroQol (EQ-5D) from the drop down list provided.

Too sick (ex., intubated/sedated, critically ill, on short-term VAD)

Too tired

Too stressed, anxious, and/or depressed

Can't concentrate

No time / too busy

Too much trouble/don't want to be bothered/not interested

Unwilling to complete instruments, no reason given

Unable to read English and/or illiterate

Administrative (check specific reason below)

If Administrative: Select a specific reason:

Urgent/emergent implant, no time to administer QOL instruments

Coordinator too busy or forgot to administer QOL instruments

Unable to contact patient (ie., not hospitalized or no clinic visit)

within the window for QOL instrument completion

Other reason (describe)

If Other reason (describe): Please specify in text box.

If Yes, enter the patients answers from the EuroQol (EQ-5D) printed form into the STS Intermacs® application.

How was the test administered:

Self-administered

Coordinator administered

Family member administered

Mobility:

I have no problems in walking about

I have some problems in walking about

I am confined to bed

Unknown

Self-care:

I have no problems with self-care
I have some problems washing or dressing myself
I am unable to wash or dress myself
Unknown

Usual activities: (e.g. work, study, housework, family or leisure activities)

I have no problem with performing my usual activities
I have some problems with performing my usual activities
I am unable to perform my usual activities
Unknown

Pain/Discomfort:

I have no pain or discomfort
I have moderate pain or discomfort
I have extreme pain or discomfort
Unknown

Anxiety/Depression:

I am not anxious or depressed
I am moderately anxious or depressed
I am extremely anxious or depressed
Unknown

Patient Visual Analog Status (VAS): Enter _____. (0 = Worst, 100 = Best)

If Unknown, please select the corresponding box.

Pre/Post-Implant QoL

1. Which of the following best describes your main activity?:

Actively working
Retired
Keeping house
Student
Seeking work
Too sick to work (disabled)
Unknown
Other

If **Other**, Please specify in text box.

Is this "one" main activity considered:

Full time
Part time
Unknown

2. How many of your close friends or relatives do you see in person, speak to on the telephone, or contact via the Internet at least once a month? (Please count each person one time) If Unknown, please select the corresponding box.

3. Have you unintentionally lost more than 10 pounds in the last year?

Yes, No, or Unknown

4. Do you currently smoke cigarettes?

Yes, No, or Unknown

If Yes, How many cigarettes are you currently smoking, on average?

Half a pack or less per day

More than half to 1 pack per day

1 to 2 packs per day

2 or more packs per day

5. Do you currently smoke e-cigarettes?

Yes, No, or Unknown

6. How much stress do you feel you've been under during the past one month, related to your health issues? (1 = No stress, 10 = Very much stress) If Unknown, please select the corresponding box.

7. How well do you feel you've been coping with or handling your stress during the past one month, related to your health issues? (1 = Coping poorly, 10 = Coping very well) If Unknown, please select the corresponding box.

8. How confident are you that you can do the tasks and activities needed to manage your heart failure so as to reduce how much having heart failure affects your everyday life? (1 = Not at all confident, 10 = Totally confident) If Unknown, please select the corresponding box.

9. How satisfied are you with the results of your therapy for heart failure during the past six months? (1 = Not satisfied at all, 10 = Very satisfied) If Unknown, please select the corresponding box.

If this is a post implant follow up, then answer the following additional question:

10. If you had to do it all over again, would you decide to have a ventricular assist device knowing what you know now?

Definitely No

Probably No

Not Sure

Probably Yes

Definitely Yes

Unknown

Kansas City Cardiomyopathy Questionnaire (KCCQ) - 12

Did the patient complete a KCCQ form: Enter Yes or No.

Yes or No

If No, Please select a reason why the KCCQ was not completed: Select the reason for non-completion of the KCCQ from the drop down list provided.

Too sick (ex., intubated/sedated, critically ill, on short-term VAD)

Too tired

Too stressed, anxious, and/or depressed

Can't concentrate

No time / too busy

Too much trouble/don't want to be bothered/not interested

Unwilling to complete instruments, no reason given

Unable to read English and/or illiterate

Administrative (check specific reason below)

If Administrative: Select a specific reason:

Urgent/emergent implant, no time to administer QOL instruments

Coordinator too busy or forgot to administer QOL instruments

Unable to contact patient (ie., not hospitalized or no clinic visit)
within the window for QOL instrument completion

Other reason (describe)

If Other reason (describe): Please specify in text box.

If **Yes**, enter the patients answers from the KCCQ printed form into the STS InterMac application.

How was the test administered:

Self-administered

Coordinator administered

Family member administered

THE KANSAS CITY CARDIOMYOPATHY QUESTIONNAIRE:

The following questions refer to your heart failure and how it may affect your life. Please read and complete the following questions. There is no right or wrong answer. Please mark the answer that best applies to you.

1. **Heart Failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** (*shortness of breath or fatigue*) in your ability to do the following activities over the past 2 weeks.

a. Showering/Bathing

Extremely limited

Quite a bit limited

Moderately Limited

Slightly Limited

Not at all limited

Limited for other reasons or did not do the activity

Unknown

b. Walking 1 block on level ground

Extremely limited
 Quite a bit limited
 Moderately Limited
 Slightly Limited
 Not at all limited
 Limited for other reasons or did not do the activity
 Unknown

c. Hurrying or jogging (as if to catch a bus)

Extremely limited
 Quite a bit limited
 Moderately Limited
 Slightly Limited
 Not at all limited
 Limited for other reasons or did not do the activity
 Unknown

2. Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in in the morning?

Every morning
 3 or more times a week, but not every day
 1-2 times a week
 Less than once a week
 Never over the past 2 weeks
 Unknown

†

3. Over the past 2 weeks, on average, how many times has **fatigue** limited your ability to do what you want?

All the time
 Several times per day
 At least once a day
 3 or more times per week, but not every day
 1-2 times per week
 Less than once a week
 Never over the past 2 weeks
 Unknown

4. Over the past 2 weeks, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All the time
 Several times per day
 At least once a day
 3 or more times per week, but not every day
 1-2 times per week
 Less than once a week
 Never over the past 2 weeks
 Unknown

5. Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night
 3 or more times a week, but not every day
 1-2 times a week
 Less than once a week
 Never over the past 2 weeks

Unknown

6. Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has extremely limited my enjoyment of life
It has limited my enjoyment of life quite a bit
It has moderately limited my enjoyment of life
It has slightly limited my enjoyment of life
It has not limited my enjoyment of life at all
Unknown

7. If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied
Mostly dissatisfied
Somewhat satisfied
Mostly satisfied
Completely satisfied
Unknown

8. How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

a. Hobbies, recreational activities

Severely limited
Limited quite a bit
Moderately limited
Slightly limited
Did not limit at all
Does not apply or did not do for other reasons
Unknown

b. Working or doing household chores

Severely limited
Limited quite a bit
Moderately limited
Slightly limited
Did not limit at all
Does not apply or did not do for other reasons
Unknown

c. Visiting family or friends out of your home

Severely limited
Limited quite a bit
Moderately limited
Slightly limited
Did not limit at all
Does not apply or did not do for other reasons
Unknown

Developed by John Spertus et al., Mid America Heart Institute, Saint Luke's Hospital, Kansas City, MO.

2.14 Neurocognitive Function Test

The **Trail-Making Sample B** and **Part B** are provided in **Appendix G**. The **Trail-Making Sample B** and **Part B** instruments can be printed from <https://intermacs.kirso.net/intermacs-documents/>

Neurocognitive function is to be measured by the Trail-Making Part B test. Trail-Making Part B is to be administered **pre-implant** and **post-implant** (3 months, 6 months, and every 6 months thereafter).

After the subject completes Part B, take the test sheet and record the time in seconds. Errors contribute to the evaluation of the performance principally by increasing the total performance time. If the patient completes the test, but the test is considered invalid, select "completed but invalid (score not entered)". **Do not allow patient to retake the test.**

Administering the test

1. Let patient practice with Sample B

Script:

"On this page are some numbers and letters. Begin at 1 (point) and draw a line from 1 to A" (point to A) "A to 2,"(point to 2), "2 to B" (point to B), "B to 3" (point to 3), "3 to C" (point to C), "and so on, in order, until you reach the end" (point to the circle marked "end").

Then say:

"Remember, first you have a number" (point to 1), "then a letter" (point to A), "then a number" (point to 2), "then a letter" (point to B), "and so on. Draw the lines as fast as you can. Ready--- Begin!"

If the subject completes the sample B correctly say: *"Good! Let's try the next one."* Proceed immediately to Part B. **If the subject makes a mistake on sample B, point out the error and explain why it is incorrect.** The following explanations of mistakes serve as illustrations:

"You started with the wrong circle. This is where you start (point to 2). "You skipped this circle" (point to the circle the subject omitted). "You should go from 1" (point to 1) "to A" (point to A), "A to 2" (point to 2), "2 to B" (point to B), "B to 3" (point to 3), "and so on until you reach the circle marked 'end'." (point)

If the subject cannot complete Sample B, take his/her hand and guide the pencil, using the eraser end, through the circles. Then say:

"Now you try it. Remember, you begin at number 1" (point), "and draw a line from 1 to A" (point to A), "A to 2" (point to 2), "2 to B" (point to B), "B to 3" (point to 3), "and so on until you reach the circle marked 'end'." (point), "Ready --- Begin!"

2. Ask patient to complete Part B

If the subject succeeds this time, go on to Part B. If not, repeat the procedure until the task is performed successfully or it becomes evident that the subject cannot do the task.

After the subject has completed the sample, turn the paper over to Part B and say:

“On this page, there are both numbers and letters. Do this the same way. Begin at number 1” (point to 1), “and draw a line from 1 to A” (point to A), “A to 2” (point to 2), “2 to B” (point to B), “B to 3” (point to 3), “3 to C” (point to C), “and so on, in order, until you reach the end” (point to the circle marked "end"). “Remember, first you have a number” (point to 1), “then a letter” (point to A), “then a number” (point to 2), “then a letter” (point to B), “and so on. Do not skip around, but go from one circle to the next in the proper order. Draw the lines as fast as you can. Ready ---Begin!”

Using the stopwatch, start timing as soon as the subject is told to begin. Remember to be alert for mistakes. If the subject makes an error, DO NOT STOP TIMING. Point it out immediately, return the subject to the last correct circle and say, “Now, are you looking for a number or a letter?” Continue the test from that point. DO NOT STOP TIMING.

After the subject completes Part B, take the test sheet, and record the time in seconds. Errors contribute to the evaluation of the performance principally by increasing the total performance time. If the patient completes the test, but the test is considered invalid, select “**Other, specify**” and, specify the reason you are not entering a score. **Do not allow patient to retake the test.**

To enter the Trailmaking Data results

Status: Select the appropriate choice from the drop down box provided:

- Completed
- Completed but invalid (scores not entered)
- Attempted but not completed
- Not attempted
- Patient Refused

If you select: **Completed**, then the following element will appear:

Time: Enter the time in seconds