Medical Arm of Mechanically Assisted Circulatory Support

Users Guide (V1.1)

01/15/2014

1.0 Users Guide (V1.1) - Table of Contents

1.1 Screening Log

Informed Consent: Did the patient sign the informed consent?

Yes/No

If No, data entry is concluded and the following message is displayed:
Without informed consent, no patient information can be entered.

If Yes, continue data entry…

Basic Patient Information

First name: Enter the patient's first name.

Middle name: Enter the patient's middle name.

Last name: Enter the patient's last name.

Date of Birth: Enter the patient's date of birth in **MM/DD/YYYY** format.

Inclusion: Patient must meet *all* inclusion criteria: You must answer all questions

- □ Has the patient had a diagnosis of heart failure or typical symptoms for more than 12 months?
  Yes/No

- □ Did the patient have at least 1 hospitalization for heart failure in the previous 12 months?
  Yes/No

- □ Does the patient have moderate or severe functional limitation, NYHA Class III or IV symptoms, for at least 45 of the last 60 days.
  Yes/No

- □ Has the patient been on oral medical therapy for heart failure for at least 3 months or has documented intolerance? Medications include: beta blockers, ACE-inhibitors/ARBs and aldosterone antagonists.
  Yes/No

- □ Are the results of the patient's most recent LVEF less than or equal to 35%?
  Yes/No

- □ Is the patient between 18 and 80 years old?
  Yes/No

- □ Does the patient have **at least one** of the following high risk feature failure? Please check all that apply:
  Yes/No
  - □ An additional unplanned hospitalization for heart failure in the last 12 months, for a total of ≥2 hospitalizations, or
  - □ Peak oxygen update (VO2) ≤16ml/kg/min for men, or ≤14ml/kg/min for women, or <55% of age- and sex-predicted using the Wasserman equation, or
  - □ 6 minute walk distance <300 meters without non-cardiac limitation, or
  - □ Serum BNP >1000 ng/ml
  - □ Seattle Heart Failure Model Score > 1.5 (If 1 Year Survival is 82% or less (mortality 18% or more), then the patient meets the SHF Criteria for study entry): http://depts.washington.edu/shfm/

Exclusion: *Any* exclusion will disqualify the patient for entry into MedaMACS:
If patient meets **ANY** exclusion criteria then check any of the appropriate exclusion reason below (check all that apply):

- □ Is the patient older than 80 or younger than 18 years old?
  Yes/No
- □ Is the patient currently on home IV inotropic therapy?
  Yes/No
- □ Does the patient currently have an active listing for heart transplantation?
  Yes/No
- □ Is cardiac surgery anticipated for the patient during this admission?
  Yes/No
- □ Does the patient have a wide QRS (>120msec) and planned biventricular pacemaker (CRT) implant, or biventricular pacemaker (CRT) within the past 90 days?
  Yes/No
- □ Is the patient's primary functional limitation from a non-cardiac diagnosis?
  Yes/No
- □ Is a non-cardiac diagnosis expected to limit the patient's 2-year life expectancy?
  Yes/No

- □ Is the patient on chronic hemodialysis or peritoneal dialysis?
  Yes/No

- □ Does the patient have a history of cardiac amyloidosis?
  Yes/No

- □ Does the patient have obvious anatomical or other major contraindication to any cardiac surgery in the future? (e.g. previous pneumonectomy, advanced connective tissue disease)
  Yes/No

- □ Patient is incarcerated (prisoner)
  Yes/No

SUBMIT – click the submit button

If the patient meets all of the inclusion criteria and none of the exclusion criteria then this patient is enrolled in MedaMACS and you will be directed to the patient Demographic form.

1.2 Demographics Form

First Name: *Automatically populated from screening form.*

Middle Name: *Automatically populated from screening form.*

Last Name: *Automatically populated from screening form.*

Date of Birth: *Automatically populated from screening form.*

Social Security Number: Enter the last 5 digits of the patient's social security if patient has been issued an SSN. If the social security number is not available or undisclosed, check not available or undisclosed.

Gender: Select the patient's gender.

Male
Female
Unknown

Hispanic Ethnicity: Is the patient Hispanic or Latino?

Yes/No

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

American Indian or Alaska Native
Asian
African-American or Black
Hawaiian
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:

Grade School (0-8)
High School (9-12)
Attended College/Technical School
Associate/Bachelor Degree
Post-College Graduate Degree
N/A (< 5 yrs old)
Unknown
None

Working for Income: Select 'Yes' if the patient is currently working for income or attending school. If not, select 'No.' If unknown, select 'Unknown.'

Yes
No
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 is 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

1.3 Clinical Enrollment Form

Initial Data

Date of Visit: Enter the date of visit in **MM/DD/YYYY** format.

Height: Enter the height of the patient in inches or centimeters. The height must fall between 10 and 80 inches or 25 and 203 centimeters. If the height of the patient is unknown check the corresponding box.

Height Units: Select the units in which the height was entered
In
cm

Weight: Enter the weight of the patient in the appropriate space, in pounds or kilograms. The weight must fall between 5 and 450 pounds or 2 and 205 kilograms. If the weight of the patient is unknown check the corresponding box.

Weight Units: Select the units in which the height was entered
Lbs
kg

Blood Type: Select the patient's blood type.
O
A
B
AB
Unknown

Current Status: Select the patient's location at time of consent
Inpatient
Outpatient

Length of time followed at your institution: Enter the length of time the patient has been followed at your institution.
<3 month
3-12 months
1-2 years
>2 years

Referral Source: Please report the type of health professional who initiated referral to your practice:
Local Internist
Local Cardiologist
Cardiac Surgeon
Self-Referral
Unknown
Other

Prior Heart Transplant Evaluation:

Yes/No

If Yes, Transplant Evaluation Outcome:

Accept
Reject
Defer

Prior DT (Destination Therapy) VAD Evaluation:

Yes/No

If Yes, DT VAD Evaluation Outcome:

Accept
Reject
Defer

Comorbid Concerns

Please select any condition below that is a comorbidity and/or concern for patient treatment or contraindication for transplant.

Checking any of these contraindications/comorbidities/concerns does not necessarily mean that a condition is a contraindication or concern for the patient. No specific thresholds are provided for these concerns or contraindications. They should represent the results of formal discussion with the medical and surgical transplant team. If there are no contraindications or concerns specified then select **No** in the 'Is condition present' column.

Comorbid Concerns	Is Condition Present?	If so, limitation for Transplant listing/VAD?
Psychosocial issues:		
Limited cognition/understanding	Yes/No	Yes/No
Limited social support	Yes/No	Yes/No
Repeated non-compliance	Yes/No	Yes/No
History of illicit drug use	Yes/No	Yes/No
History of alcohol abuse	Yes/No	Yes/No
Narcotic dependence	Yes/No	Yes/No
History of smoking	Yes/No	Yes/No
Currently smoking	Yes/No	Yes/No
Severe depression	Yes/No	Yes/No
Other major psychiatric disorder	Yes/No	Yes/No
Other co-morbidity: (Specify)	Yes/No	Yes/No

If Other co-morbidity: Please specify in text box.

Number of cardiac hospitalizations in the last 12 months:
Choose one of the following:

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

Date of first heart failure diagnosis: The length of time that the patient had symptoms or a diagnosis of heart failure. (Month/Year): **MM/YYYY**

Cardiac diagnosis/primary: Check one primary reason for cardiac dysfunction (See drop down list).

- Cancer
- Congenital Heart Disease
  - **If Congenital Heart Disease, Please choose all that apply:**
    - Complete AV Septal Defect
    - Congenitally Corrected Transposition
    - Ebstein's Anomaly
    - Hypoplastic Left Heart
    - Left Heart Valvar/Structural Hypoplasia

Pulmonary Atresia with IVS
Single Ventricle
TF/TOF Variant
Transposition of the Great Arteries
Truncus Arteriosus
VSD/ASD
VSD/ASD Other, specify
If Other co-morbidity: Please specify in text box.
Kawasaki Disease
Unknown
Other, specify
If Other Specify: Please specify in text box.
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 specify in text box.
Dilated Myopathy: Post Partum
Dilated Myopathy: Viral
Hypertrophic cardiomyopathy
Sarcoidosis
Other, specify
If Other Specify: Please specify in text box.

Previous cardiac operation:
Check all cardiac operations that the patient has had:

None
CABG
Aneurysmectomy (DOR)
Aortic Valve replacement / repair
Mitral valve replacement / repair
Triscuspid replacement /repair
Congenital cardiac surgery
Other, specify
If Other, Specify: Please specify in text box.
(Include only operations actually performed on heart or great vessels)

Number of previous cardiac operations:
Enter total number previous cardiac operations.

Clinical Events and Interventions at Baseline: Select all events that apply.

None
Diabetes
Home oxygen
Recent intubation (within 6 months)
Recent intraaortic counterpulsation (within 6 months)
Previous renal replacement
Any Dialysis
Any Ultrafiltration

Physical Exam

INTERMACS Patient Profile Select one. These profiles will provide a *general* clinical description of the patients Patients who meet MedaMACS entry criteria must fall in INTERMACS Patient Profiles 4-7.

INTERMACS 1: Critical cardiogenic shock describes a patient who is "crashing and burning",in which a patient has life-threatening hypotension and rapidly escalating inotropic pressor support, with critical organ hypoperfusion often confirmed by worsening acidosis and lactate levels. This patient can have Modifier A (see 'Modifiers' below).

INTERMACS 2: Progressive decline describes a patient who has been demonstrated "dependent" on inotropic support but nonetheless shows signs of continuing deterioration in nutrition, renal function, fluid retention, or other major status indicator. Patient profile 2 can also describe a patient with refractory volume overload, perhaps with evidence of impaired perfusion, in whom inotropic infusions cannot be maintained due to tachyarrhythmias, clinical ischemia, or other intolerance. This patient can have Modifier A.

INTERMACS 3: Stable but inotrope dependent describes a patient who is clinically stable on mild-moderate doses of intravenous inotropes (or has a temporary circulatory support device) after repeated documentation of failure to wean without symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal). It is critical to monitor nutrition, renal function, fluid balance, and overall status carefully in order to distinguish between a patient who is truly stable at Patient Profile 3 and a patient who has unappreciated decline rendering them Patient Profile 2. This patient may be either at home or in the hospital. Patient Profile 3 can have Modifier A, If patient is at home most of the time on outpatient inotropic infusion, this patient can have a Modifier FF if he or she frequently returns to the hospital.

INTERMACS 4: Resting symptoms describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with 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, by which some may be recognized to have poor compliance that would compromise outcomes with any therapy. This patient can have Modifiers A and/or FF.

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

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

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

MODIFIERS of the INTERMACS Patient Profiles:

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

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

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

Class I: No limitation of physical activity; physical activity does not cause fatigue, palpitation or shortness of breath.
Class II: Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue, palpitations or shortness of breath.
Class III: Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue, palpitation or shortness of breath.
Class IV: Unable to carry on minimal physical activity without discomfort symptoms may be present at rest.
Unknown

General Hemodynamics

Heart rate: Enter ____bpm (beats per minute). If **Unknown** or **Not Done**, please check corresponding box.

Systolic bp: Enter ____mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. If **Unknown** or **Not Done**, please check corresponding box.

Diastolic bp: Enter ____mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. If **Unknown** or **Not Done**, please check corresponding box.

Jugular Venous Pressure: CM:_____ If **Unknown** or **Not Done**, please check corresponding box.

S3 gallop:

Present
Absent
Unknown
Not Done

S4 gallop:

Present
Absent
Unknown
Not Done

Peripheral edema: Choose the most applicable.

None
1+
2+
>3+

Ascites: This is in the clinicians' best judgment, as it is sometimes difficult to tell whether abdominal protuberance is fluid or adipose tissue.

Yes
No
Unknown

Hepatomegaly: This is in the clinicians' best judgment.

Present
Absent
Unknown

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

- Sinus
- Atrial fibrillation
- Atrial flutter
- Paced (Choose one)
  - **If Paced:** Choose one
    - Atrial pacing
    - Ventricular pacing
    - Atrial and ventricular pacing
- Not done
- Unknown
- Other, specify
  - **If Other, specify:** Please specify in text box.

QRS duration: Please enter in milliseconds (ms). If **Unknown** or **Not Done**, please check corresponding box.

Laboratory Values

Blood laboratories should be within 30 days of enrollment. Please record data closest to enrollment.

For all labs, if **Unknown** or **Not Done**, please check corresponding box.

Chemistry:

Sodium
Potassium
Blood urea nitrogen
Creatinine
SGPT/ALT (alanine aminotransferase/ALT)
SGOT/AST (aspartate aminotransferase/AST)
Total Bilirubin
Direct Bilirubin

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

B-type natriuretic peptide (BNP)
If > 7500 pg/mL, *please check corresponding box.*
NT- pro BNP

Metabolism:

Albumin
Pre-Albumin
Total Cholesterol
If < 50 mg/dl, please check corresponding box.
Low density lipoprotein (LDL)
High density lipoprotein (HDL)
Triglycerides
Uric Acid
C-reactive Protein (CRP)

Hematologic:

White blood cell count
Hemoglobin
Hematocrit %
Platelets
International normalized ratio (INR)
Lymphocyte %
Lupus anticoagulant: this will be positive, negative, or unknown

Exercise Testing

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: _____ (feet)

This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk *behind* the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here.

All efforts should be made to perform the 6 minute walk test for any patient able to walk more than a few steps. A distance as short as 3 feet may be recorded. If the test is not done, the reason must be indicated as “not done: 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”.

If not entered, select **Reason Not Entered:**
- Not Done: Too Sick
- Not Done: Other
- Unknown

Gait speed - 15ft. walk time (1st 15 foot walk): ____ seconds

Instructions: Record the time (seconds) required for the patient to walk 15 feet. 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. Do this once, before the 6 minute walk. Allow the patient to rest 30 seconds, either sitting or standing.

If not entered, select **Reason Not Entered:**
- Not Done: Too Sick
- Note Done: Other

Cardiopulmonary exercise testing

Peak oxygen uptake(Peak oxygen uptake VO2): Maximum volume of oxygen the body can consume during exercise (ml/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. If not entered, please select the reason: Too sick, not done, and other, specify.

If not entered, select **Reason Not Entered:**

Too Sick
Not Done
Other, specify
If **Other, Specify:** Please specify in text box.

Resting heart rate (bpm): Enter ____bpm (beats per minute). If **Unknown** or **Not Done**, please check corresponding box.

Peak heart rate (bpm): Enter ____bpm (beats per minute). If **Unknown** or **Not Done**, please check corresponding box.

Peak oxygen uptake % predicted: Enter _____%. If **Unknown** or **Not Done**, please check corresponding box.

Ventilatory efficiency (Ve/VCO2): Enter _____ slope, (Range 15-45).If **Unknown** or **Not Done**, please check corresponding box.

Peak respiratory exchange ratio (R value at peak): Enter _____. 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. If **Unknown** or **Not Done**, please check corresponding box.

Echocardiography

(Within 30 days of baseline visit)

Date of Visit: MM/DD/YYYY

Left Ventricular Ejection Fraction (LVEF): Enter _____%. If **Not Recorded** or **Not Done**, please check corresponding box.

Left Ventricular End-Diastolic Dimension (LVEDD): Enter ____cm (in centimeters). If **Not Recorded** or **Not Done**, please check corresponding box.

The following (4) should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

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

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

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

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

Aortic insufficiency: Aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild).

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

Aortic Stenosis: Aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild).

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

Inferior Vena Cava Dilated:

Yes
Blunted
None
Unknown

Inferior Vena Cava Respiration Variation:

Yes
Blunted
None
Unknown

Right Ventricular (RV) Indices: The next (2) qualitative measurements are generally NOT measured in numbers, as they are 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”.

Qualitative RV Function: Choose One.

Normal
Mild
Moderate
Severe
Not Recorded/Not Documented

Qualitative RV Size: Choose One.

Normal
Mild
Moderate
Severe
Not Recorded/Not Documented

Maximum mid RV dimension: Enter ____cm (in centimeters). If **Not Recorded/Not Done**, please check corresponding box.

Tricuspid annular plane excursion: Enter ____mm (in millimeters). If **Not Recorded/Not Done**, please check corresponding box.

Tricuspid regurgitant velocity: Enter ____mm/sec (in millimeters per second). If **Not Recorded/Not Done**, please check corresponding box.
Estimated Pulmonary Artery Systolic Pressure: Enter ____mmHg (in millimeters of mercury). If **Not Recorded/Not Done**, please check corresponding box.

Right Heart Catheterization Elements

(Must be within 6 months of baseline visit)

Are the right heart catheterization elements available:

Yes/No

If Yes, Date of Visit: MM/DD/YYYY

Therapies at RHC: Check all that apply

- No IV
- IV
- IABP
- None
- Unknown
- Not Done
- Felt to be not clinically indicated

Systolic bp: Enter ____mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. If **Unknown** or **Not Done**, please check corresponding box.

Diastolic bp: Enter ____mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. If **Unknown** or **Not Done**, please check corresponding box.

Heart Rate: Enter ____bpm (beats per minute).

Pulmonary artery systolic pressure: Enter ____mmHg (millimeters of mercury). This may be abbreviated PAS or pulmonary pressures. If **Unknown** or **Not Done**, please check corresponding box.

Pulmonary artery diastolic pressure: Enter ____mmHg (millimeters of mercury). This may be abbreviated PAD or pulmonary pressures. If **Unknown** or **Not Done**, please check corresponding box.

Pulmonary capillary wedge pressure: Enter ____mmHg (millimeters of mercury). If **Unknown** or **Not Done**, please check corresponding box.

PA saturation: Enter ____%. If **Unknown** or **Not Done**, please check corresponding box.

Right atrial pressure (Mean RA Pressure): Enter ____mmHg (millimeters of mercury). May be listed also as RAP or CVP. If **Unknown** or **Not Done**, please check corresponding box.

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/m^2 or L/min/$m^{2.}$ If **Unknown** or **Not Done**, please check corresponding box.

Cardiac Index: Will be expressed as L/min/M^2. Enter this number. If **Unknown** or **Not Done**, please check corresponding box.

Medications

Mark whether the medications listed fall into one of the following categories:

Currently using - If the patient is currently taking these agents, please check **Currently using**.

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.**

Intolerant-For ACE Inhibitors, Angiotensin receptor blocker and Beta Blockers some patients cannot tolerate these medications. Please check **Intolerant** if this applies.

Angiotensin converting enzyme inhibitor (ACE inhibitor)
Angiotensin receptor blocker drug
Beta-blockers
Aldosterone antagonist
Digoxin
Potassium supplement
Allopurinol
Amiodarone
Hydralazine
Long Acting Nitrate
Calcium channel blockers
Lovenox
Warfarin (coumadin)
Aspirin
Clopidogrel (Other Antiplatelet therapy drug)
Phosphodiesterase Inhibitors (e.g. Sildenafil, Tadalafil)
Statins
Other Antiarrhythmics

Loop diuretics:
Yes/No/Unknown

If Yes, Enter dosage: _____ mg/day (Total Daily Dose in mg). If **Unknown**, please check corresponding box.

If dose is entered, **Loop diuretic type:** Check all that apply

- Furosemide
- Torsemide
- Bumetanide
- Other

If Other, specify: Please specify in text box.

Metolazone/thiazide

Yes/No

If Yes, Frequency: if yes, then standing order or prn?

- Standing
- As needed

Inotrope Use in last 6 months?

- Yes
- No
- Unknown
- Not Done

If Yes, Inotrope therapy agents: Check all intravenous inotropes that apply:

- Dobutamine
- Dopamine
- Milrinone
- Epinephrine
- Other, specify

If Other, specify: Please specify in text box.

Current ICD device in place: If the patient currently has an implantable defibrillator, then **Yes** should be checked. Note that patients with bi-ventricular pacing and ICD should have **Yes** checked for ICD also.

Yes/No

If Yes, Date of last ICD shock: MM/DD/YYYY. If **None** or **Unknown**, please check corresponding box

Cardiac Resynchronization Therapy: Check **Yes, No** or **Unknown**

Yes/No/Unknown

If < 6 months, give implant date: MM/DD/YYYY

Quality of Life

EuroQol (EQ-5D)

Did the patient complete a EuroQol (EQ-5D) form: Enter **Yes, No or Unknown.**

If Yes, enter the patients answers from the EuroQol (EQ-5D) printed form into the **MedaMACS** application.

If No, enter the following reasons for non-completion of the EuroQol (EQ-5D)**. Reason why the EuroQol (EQ-5D) was not completed:** Select the reason from the drop down list provided.

Kansas City Cardiomyopathy Questionnaire (KCCQ)

Did the patient complete a KCCQ form: Enter **Yes, No or Unknown.**

If Yes, enter the patients answers from the KCCQ printed form into the **MedaMACS** application.

If No, enter the following reasons for non-completion of the KCCQ **Reason why the KCCQ was not completed:** Select the reason from the drop down list provided.

MedaMACS Survey Instruments

Did the patient complete the VAD Survey of the MedaMACS Survey Instruments? Enter **Yes, No or Unknown**

Please see the EuroQol (EQ-5D) and KCCQ section of the MedaMACS Users Guide for further instructions on administration and web-based data entry for the EuroQol (EQ-5D), KCCQ, and Patient Survey Instrument (Section 1.11).

1.4 EVENTS/OUTCOMES

Outcomes:

Listed for transplant?:

Yes
No
Unknown

If Yes, Listing Date: MM/DD/YYYY

If Yes, Listing status:

1A
1B
2
7
Unknown

Did patient receive a heart transplant?

Yes/No

If Yes, Listing status at transplant:

1A
1B
2

Note: If Yes, then a Pop-Up will appear to fill out an Event form for the rehospitalization and record the transplant details. This patient has received a transplant and will no longer be followed in the MedaMACS Registry.

Did patient receive a MCSD?:

Yes/No

Note: If Yes, then Pop-up will appear 'This patient has received a MCSD. This patient will no longer be followed in MedaMACS. Please complete the information below. If the patient has consented to be in INTERMACS, please enter the patient into the INTERMACS WBDE system.

If Yes, Date: MM/DD/YYYY

If Yes, Type of circulatory support:

LVAD
RVAD
BIVAD
TAH

If Yes, Device brand?: Specify the device brand in the textbox.

If Yes, Intended Support Strategy: This should be determined in conjunction with the heart failure cardiologist and surgeon. 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
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 yet have been quantified, 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.
Other:

If Other Specify: Specify the device strategy in the textbox.

Has the patient become dependent on continuous intravenous inotropes?:

Yes/No

If Yes, Which inotrope?: Check all that apply

Dobutamine
Milrinone
Dopamine
Other, specify

If Other, Specify: Specify the inotrope in the text box.

Has the patient been Resuscitated (Coded) since the last visit?:

Yes/No

Has the patient began a Hospice program?:

Yes/No

If Yes, Date Started: MM/DD/YYYY

Has the patient experienced a Recovery of EF to > 40%?:

Yes/No

Major Infection: Was there a major infection?
Yes/No

Neurological Dysfunction: Was there a neurological dysfunction event?
Yes/No

Major Bleeding: Was there a major bleeding event?
Yes/No

Death: Is this patient deceased?
Yes/No

Adverse Events

Note: Please check that you have entered all Adverse Events since the last follow-up.

Major Bleeding
Major infection
Neurological Event
Psychiatric Episode
Other Adverse Event
Respiratory Failure
Cardiac Arrhythmia
Myocardial Infarction
Venous Thromboembolic Event
Arterial Non-CNS Thromboembolic Event

Note: Go to section 1.10 for the definition of each Adverse Event

1.5 1 Month / 1 Year / 2 Year Follow-up Form

Visit Date & Location

The data on the Follow-Up Forms are collected at the following Face to Face time periods:

1 month: Visit may take place at **3-6 weeks** post clinical enrollment
1 Year: Visit may take place at **10-14 months** post clinical enrollment
2 Years: Visit may take place at **22-26 months** post clinical enrollment

When you perform medical chart abstraction, please use information closest to the time points specified above.

Date of Visit: MM/DD/YYYY

Location of the patient: Check one of the following:

Inpatient
Outpatient
Other Facility
If Other Facility, **(Choose one):** Type of Facility
Nursing Home/ Assisted care
Hospice
Another hospital
Rehabilitation Facility
Unknown

Unable to obtain follow-up information
If Unable to obtain follow-up information, **State the reason why you are unable to obtain follow-up information:**
Patient didn't come to clinic
Not able to contact patient
Not addressed by site

Outcomes:

Listed for transplant?:

Yes
No
Unknown

If Yes, Listing Date: MM/DD/YYYY

If Yes, Listing status:

1A
1B
2
7
Unknown

Did patient receive a heart transplant?

Yes/No

If Yes, Listing status at transplant:

1A
1B
2

Note: If Yes, then a Pop-Up will appear to fill out an Event form for the rehospitalization and record the transplant details. This patient has received a transplant and will no longer be followed in the MedaMACS Registry.

Did patient receive a MCSD?:

Yes/No

Note: If Yes, then Pop-up will appear 'This patient has received a MCSD. This patient will no longer be followed in MedaMACS. Please complete the information below. If the patient has consented to be in INTERMACS, please enter the patient into the INTERMACS WBDE system.

If Yes, Date: MM/DD/YYYY

If Yes, Type of circulatory support:

LVAD
RVAD
BIVAD
TAH

If Yes, Device brand?: Specify the device brand in the textbox.

If Yes, Intended Support Strategy: This should be determined in conjunction with the heart failure cardiologist and surgeon. 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
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 yet have been quantified, 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.
Other:

If <u>Other Specify:</u> Specify the device strategy in the textbox.

Has the patient become dependent on continuous intravenous inotropes?:

Yes/No

If Yes, Which inotrope?: Check all that apply

Dobutamine
Milrinone
Dopamine
Other, specify

If Other, Specify: Specify the inotrope in the text box.

Has the patient been Resuscitated (Coded) since the last visit?:

Yes/No

Has the patient began a Hospice program?:

Yes/No

If Yes, Date Started: MM/DD/YYYY

Has the patient experienced a Recovery of EF to > 40%?:

Yes/No

Major Infection: Was there a major infection?

Yes/No

Neurological Dysfunction: Was there a neurological dysfunction event?

Yes/No

Major Bleeding: Was there a major bleeding event?

Yes/No

Death: Is this patient deceased?

Yes/No

Physical Exam

INTERMACS Patient Profile Select one. These profiles will provide a *general* clinical description of the patients Patients who meet MedaMACS entry criteria must fall in INTERMACS Patient Profiles 4-7.

INTERMACS 1: Critical cardiogenic shock describes a patient who is “crashing and burning”,in which a patient has life-threatening hypotension and rapidly escalating inotropic pressor support, with critical organ hypoperfusion often confirmed by worsening acidosis and lactate levels. This patient can have Modifier A (see ‘Modifiers’ below).

INTERMACS 2: Progressive decline describes a patient who has been demonstrated "dependent" on inotropic support but nonetheless shows signs of continuing deterioration in nutrition, renal function, fluid retention, or other major status indicator. Patient profile 2 can also describe a patient with refractory volume overload, perhaps with evidence of impaired perfusion, in whom inotropic infusions cannot be maintained due to tachyarrhythmias, clinical ischemia, or other intolerance. This patient can have Modifier A.

INTERMACS 3: Stable but inotrope dependent describes a patient who is clinically stable on mild-moderate doses of intravenous inotropes (or has a temporary circulatory support device) after repeated documentation of failure to wean without symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal). It is critical to monitor nutrition, renal function, fluid balance, and overall status carefully in order to distinguish between a patient who is truly stable at Patient Profile 3 and a patient who has unappreciated decline rendering them Patient Profile 2. This patient may be either at home or in the hospital. Patient Profile 3 can have Modifier A, If patient is at home most of the time on outpatient inotropic infusion, this patient can have a Modifier FF if he or she frequently returns to the hospital.

INTERMACS 4: Resting symptoms describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with 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, by which some may be recognized to have poor compliance that would compromise outcomes with any therapy. This patient can have Modifiers A and/or FF.

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

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

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

MODIfIERS of the INTERMACS Patient Profiles:

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

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

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

Class I: No limitation of physical activity; physical activity does not cause fatigue, palpitation or shortness of breath.
Class II: Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue, palpitations or shortness of breath.
Class III: Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue, palpitation or shortness of breath.
Class IV: Unable to carry on minimal physical activity without discomfort symptoms may be present at rest.
Unknown

Weight: Enter the weight of the patient in the appropriate space, in pounds or kilograms. The weight must fall between 5 and 450 pounds or 2 and 205 kilograms. If the weight of the patient is unknown check the corresponding box.

Weight Units: Select the units in which the height was entered
Lbs
kg

Heart rate: Enter _____bpm (beats per minute). If **Unknown** or **Not Done**, please check corresponding box.

Systolic bp: Enter _____mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. If **Unknown** or **Not Done**, please check corresponding box.

Diastolic bp: Enter _____mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. If **Unknown** or **Not Done**, please check corresponding box.

Jugular Venous Pressure: CM:_____. If **Unknown** or **Not Done**, please check corresponding box.

S3 gallop:

Present
Absent
Unknown
Not Done

S4 gallop:

Present
Absent
Unknown
Not Done

Peripheral edema: Choose the most applicable

None
1+
2+
>3+

Ascites: This is in the clinicians' best judgment, as it is sometimes difficult to tell whether abdominal protuberance is fluid or adipose tissue.

Yes
No
Unknown

Hepatomegaly: This is in the clinicians' best judgment.

Present
Absent
Unknown

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

Sinus
Atrial fibrillation
Atrial flutter
Paced (Choose one)
If Paced: Choose one
Atrial pacing
Ventricular pacing
Atrial and ventricular pacing
Not done
Unknown
Other, specify
If Other, specify: Please specify in text box.

Laboratory Values

Blood laboratories should be within 30 days of enrollment. Please record data closest to enrollment.

For all labs, if **Unknown** or **Not Done**, please check corresponding box.

Chemistry:

Sodium
Potassium
Blood urea nitrogen
Creatinine
SGPT/ALT (alanine aminotransferase/ALT)
SGOT/AST (aspartate aminotransferase/AST)
Total Bilirubin
Direct Bilirubin

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

B-type natriuretic peptide (BNP)
If > 7500 pg/mL, *please check corresponding box.*
NT- pro BNP

Metabolism:

Albumin
Pre-Albumin
Total Cholesterol
If < 50 mg/dl, please check corresponding box.
Low density lipoprotein (LDL)
High density lipoprotein (HDL)
Triglycerides
Uric Acid
C-reactive Protein (CRP)

Hematologic:

White blood cell count
Hemoglobin
Hematocrit %
Platelets
International normalized ratio (INR)
Lymphocyte %
Lupus anticoagulant: this will be Positive, Negative, or Unknown
- Positive
- Negative
- Unknown

Exercise Testing

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: Enter _____ (feet)

This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk *behind* the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here.

All efforts should be made to perform the 6 minute walk test for any patient able to walk more than a few steps. A distance as short as 3 feet may be recorded. If the test is not done, the reason must be indicated as “not done: 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”.

If not entered, select **Reason Not Entered:**
- Not Done: Too Sick
- Not Done: Other
- Unknown

Gait speed - 15 ft. walk time (1st 15 foot walk): Enter ____ seconds
Instructions: Record the time (seconds) required for the patient to walk 15 feet. 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. Do this once, before the 6 minute walk. Allow the patient to rest 30 seconds, either sitting or standing.

If not entered, select **Reason Not Entered:**
Not Done: Too Sick
Note Done: Other

Cardiopulmonary Exercise Testing

Peak oxygen uptake(Peak oxygen uptake VO2): Enter_____. Maximum volume of oxygen the body can consume during exercise (ml/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. If not entered, please select the reason: Too sick, not done, and other, specify.

If not entered, select **Reason Not Entered:**
Too Sick
Not Done
Other, specify

If **Other, Specify:** Please specify in text box.

Resting heart rate (bpm): Enter ____bpm (beats per minute). If **Unknown** or **Not Done**, please check corresponding box.

Peak heart rate (bpm): Enter ____bpm (beats per minute). If **Unknown** or **Not Done**, please check corresponding box.

Peak oxygen uptake % predicted: Enter _____%. If **Unknown** or **Not Done**, please check corresponding box.

Ventilatory efficiency (Ve/VCO2): Enter _____ slope, (Range 15-45). If **Unknown** or **Not Done**, please check corresponding box.

Peak respiratory exchange ratio (R value at peak): Enter _____. 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. If **Unknown** or **Not Done**, please check corresponding box.

Echocardiography

Echocardiogram: at 1 year or 2 years

Date of Visit: MM/DD/YYYY

Left Ventricular Ejection Fraction (LVEF): Enter _____%

If **Not Recorded** or **Not Done**, please check corresponding box.

Left Ventricular End-Diastolic Dimension (LVEDD): Enter ____cm (in centimeters).

If **Not Recorded** or **Not Done**, please check corresponding box.

The following (4) should be recorded on a qualitative scale (if 'trivial' then assign as mild). Moderate-severe would be recorded as "severe".

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

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

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

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

Aortic insufficiency: Aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild).

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

Aortic Stenosis: Aortic regurgitation should be recorded on a qualitative scale (if 'trivial' then assign as mild).

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

Inferior Vena Cava Dilated:

Yes
No
Unknown

Inferior Vena Cava Respiration Variation:

Yes
Blunted
None
Unknown

Right Ventricular (RV) Indices: The next (2) qualitative measurements are generally NOT measured in numbers, as they are 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”.

Qualitative RV Function: Choose One.

Normal
Mild
Moderate
Severe
Not Recorded/Not Documented

Qualitative RV Size: Choose One.

Normal
Mild
Moderate
Severe
Not Recorded/Not Documented

Maximum mid RV dimension: Enter ____cm (in centimeters). If **Not Recorded/Not Done**, please check corresponding box.

Tricuspid annular plane excursion: Enter ____mm (in millimeters). If **Not Recorded/Not Done**, please check corresponding box.

Tricuspid regurgitant velocity: Enter ____mm/sec (in millimeters per second). If **Not Recorded/Not Done**, please check corresponding box.
Estimated Pulmonary Artery Systolic Pressure: Enter ____mmHg (in millimeters of mercury). If **Not Recorded/Not Done**, please check corresponding box.

Right Heart Catheterization Elements

Right Heart Catheterization (If available at 1 year only)

Are the right heart catheterization elements available:

Yes/No

If Yes, Date of Visit: MM/DD/YYYY

Therapies at RHC: Check all that apply

No IV
IV
IABP
None
Unknown
Not Done
Felt to be not clinically indicated

Systolic bp: Enter ____mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. If **Unknown** or **Not Done**, please check corresponding box.

Diastolic bp: Enter ____mmHg (millimeters of mercury) should be determined from auscultation or arterial line if necessary. If **Unknown** or **Not Done**, please check corresponding box.

Heart Rate: Enter ____bpm (beats per minute).

Pulmonary artery systolic pressure: Enter ____mmHg (millimeters of mercury). This may be abbreviated PAS or pulmonary pressures. If **Unknown** or **Not Done**, please check corresponding box.

Pulmonary artery diastolic pressure: Enter ____mmHg (millimeters of mercury). This may be abbreviated PAD or pulmonary pressures. If **Unknown** or **Not Done**, please check corresponding box.

Pulmonary capillary wedge pressure: Enter ____mmHg (millimeters of mercury). If **Unknown** or **Not Done**, please check corresponding box.

PA saturation: Enter ____%. If **Unknown** or **Not Done**, please check corresponding box.

Right atrial pressure (Mean RA Pressure): Enter ____mmHg (millimeters of mercury). May be listed also as RAP or CVP. If **Unknown** or **Not Done**, please check corresponding box.

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/m^2 or L/min/m^2. If **Unknown** or **Not Done**, please check corresponding box.

Cardiac Index: Will be expressed as L/min/M^2. Enter this number. If **Unknown** or **Not Done**, please check corresponding box.

Medications

Mark whether the medications listed fall into one of the following categories:

Currently using - If the patient is currently taking these agents, please check **Currently using**.

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.**

Intolerant-For ACE Inhibitors, Angiotensin receptor blocker and Beta Blockers some patients cannot tolerate these medications. Please check **Intolerant** if this applies.

Angiotensin converting enzyme inhibitor (ACE inhibitor)
Angiotensin receptor blocker drug
Beta-blockers
Aldosterone antagonist
Digoxin
Potassium supplement
Allopurinol
Amiodarone
Hydralazine
Long Acting Nitrate
Calcium channel blockers
Lovenox

Warfarin (coumadin)
Aspirin
Clopidogrel (Other Antiplatelet therapy drug)
Phosphodiesterase Inhibitors (e.g. Sildenafil, Tadalafil)
Statins
Other Antiarrhythmics

Loop diuretics:
Yes/No/Unknown

If Yes, Enter dosage: _____ mg/day (Total Daily Dose in mg). If **Unknown**, please check corresponding box.

If dose is entered, **Loop diuretic type:** Check all that apply
- Furosemide
- Torsemide
- Bumetanide
- Other
  - **If Other, specify:** Please specify in text box.

Metolazone/thiazide
Yes/No

If Yes, Frequency: if yes, then standing order or prn?
- Standing
- As needed

Inotrope Use in last 6 months?
- Yes
- No
- Unknown
- Not Done

If Yes, Inotrope therapy agents: Check all intravenous inotropes that apply.
- Dobutamine
- Dopamine
- Milrinone
- Epinephrine
- Other, specify
  - **If Other, specify:** Please specify in text box.

Current ICD device in place: If the patient currently has an implantable defibrillator, then **Yes** should be checked. Note that patients with bi-ventricular pacing and ICD should have **Yes** checked for ICD also.

Yes/No

If Yes, Date of last ICD shock: MM/DD/YYYY. If **None** or **Unknown**, please check corresponding box

Cardiac Resynchronization Therapy: Check **Yes, No** or **Unknown**

Yes/No/Unknown

If < 6 months, give implant date: MM/DD/YYYY

Quality of Life

EuroQol (EQ-5D)

Did the patient complete a EuroQol (EQ-5D) form: Enter **Yes or No.**

If Yes, enter the patients answers from the EuroQol (EQ-5D) printed form into the **MedaMACS** application.

If No, enter the following reasons for non-completion of the EuroQol (EQ-5D)**. Reason why the EuroQol (EQ-5D) was not completed:** Select the reason from the drop down list provided.

Kansas City Cardiomyopathy Questionnaire (KCCQ)

Did the patient complete a KCCQ form: Enter **Yes or No.**

If Yes, enter the patients answers from the KCCQ printed form into the **MedaMACS** application.

If No, enter the following reasons for non-completion of the KCCQ **Reason why the KCCQ was not completed:** Select the reason from the drop down list provided.

MedaMACS Survey Instruments

Did the patient complete the VAD Survey of the MedaMACS Survey Instruments? Enter **Yes or No.**

Please see the EuroQol (EQ-5D) and KCCQ section of the MedaMACS Users Guide for further instructions on administration and web-based data entry for the EuroQol (EQ-5D), KCCQ, and Patient Survey Instrument (Section 1.11).

1.6 6 Month / 18 Month Phone Interview Form

Please utilize the MedaMACS Phone Script which is provided on the INTERMACS website www.intermacs.org, and then click on MedaMACS.

Interview Date & Availability

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

6 months (+/- 30 days**)**
18 months (+/- 30 days)

Date of Phone Interview: MM/DD/YYYY

Were you able to contact the patient:

Yes/No

If **No**, **State the reason why you are unable to contact the patient:**

Not able to contact patient
Not addressed by site

Has the patient been rehospitalized since the last visit: If **Yes**, please complete a Rehospitalization form.

Yes/No

Physical Exam

INTERMACS Patient Profile Select one. These profiles will provide a *general* clinical description of the patients Patients who meet MedaMACS entry criteria must fall in INTERMACS Patient Profiles 4-7.

INTERMACS 1: Critical cardiogenic shock describes a patient who is "crashing and burning",in which a patient has life-threatening hypotension and rapidly escalating inotropic pressor support, with critical organ hypoperfusion often confirmed by worsening acidosis and lactate levels. This patient can have Modifier A (see 'Modifiers' below).

INTERMACS 2: Progressive decline describes a patient who has been demonstrated "dependent" on inotropic support but nonetheless shows signs of continuing deterioration in nutrition, renal function, fluid retention, or other major status indicator. Patient profile 2 can also describe a patient with refractory volume overload, perhaps with evidence of impaired perfusion, in whom inotropic infusions cannot be maintained due to tachyarrhythmias, clinical ischemia, or other intolerance. This patient can have Modifier A.

INTERMACS 3: Stable but inotrope dependent describes a patient who is clinically stable on mild-moderate doses of intravenous inotropes (or has a temporary circulatory support device) after repeated documentation of failure to wean without symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal). It is critical to monitor nutrition, renal function, fluid balance, and overall status carefully in order to distinguish between a patient who is truly stable at Patient Profile 3 and a patient who has unappreciated decline rendering them Patient Profile 2. This patient may be either at home or in the hospital. Patient Profile 3 can have Modifier A, If patient is at home most of the time on outpatient inotropic infusion, this patient can have a Modifier FF if he or she frequently returns to the hospital.

INTERMACS 4: Resting symptoms describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with 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, by which some may be recognized to have poor compliance that would compromise outcomes with any therapy. This patient can have Modifiers A and/or FF.

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

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

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

MODIFIERS of the INTERMACS Patient Profiles:

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

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

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

Class I: No limitation of physical activity; physical activity does not cause fatigue, palpitation or shortness of breath.
Class II: Slight limitation of physical activity; comfortable at rest, but ordinary physical activity results in fatigue, palpitations or shortness of breath.
Class III: Marked limitation of physical activity; comfortable at rest, but less than ordinary activity causes fatigue, palpitation or shortness of breath.
Class IV: Unable to carry on minimal physical activity without discomfort; symptoms may be present at rest.
Unknown

Medications

Mark whether the medications listed fall into one of the following categories:

Currently using - If the patient is currently taking these agents, please check **Currently using**.

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.**

Intolerant-For ACE Inhibitors, Angiotensin receptor blocker and Beta Blockers some patients cannot tolerate these medications. Please check **Intolerant** if this applies.

Angiotensin converting enzyme inhibitor (ACE inhibitor)
Angiotensin receptor blocker drug
Beta-blockers
Aldosterone antagonist
Digoxin
Potassium supplement
Allopurinol
Amiodarone
Hydralazine
Long Acting Nitrate
Calcium channel blockers
Lovenox
Warfarin (coumadin)
Aspirin
Clopidogrel (Other Antiplatelet therapy drug)
Phosphodiesterase Inhibitors (e.g. Sildenafil, Tadalafil)
Statins
Other Antiarrhythmics

Loop diuretics:

Yes/No/Unknown

If Yes, Enter dosage: _____ mg/day (Total Daily Dose in mg). If **Unknown**, please check corresponding box.

If dose is entered, **Loop diuretic type:** Check all that apply

Furosemide
Torsemide
Bumetanide
Other

If Other, specify: Please specify in text box.

Metolazone/thiazide

Yes/No

If Yes, Frequency: if yes, then standing order or prn?

Standing
As needed

Inotrope Use in last 6 months

Yes
No
Unknown
Not Done

If Yes, Inotrope therapy agents: Check all intravenous inotropes that apply:

Dobutamine
Dopamine
Milrinone
Epinephrine
Other, specify

If Other, specify: Please specify in text box.

Current ICD device in place: If the patient currently has an implantable defibrillator, then **Yes** should be checked. Note that patients with bi-ventricular pacing and ICD should have **Yes** checked for ICD also.

Yes/No

If Yes, Date of last ICD shock: MM/DD/YYYY. If **None** or **Unknown**, please check corresponding box

Cardiac Resynchronization Therapy: Check **Yes, No** or **Unknown**

Yes/No/Unknown

If < 6 months, give implant date: MM/DD/YYYY

Outcomes:

Listed for transplant?:

Yes
No
Unknown

If Yes, Listing Date: MM/DD/YYYY

If Yes, Listing status:

1A
1B
2
7
Unknown

Did patient receive a heart transplant?

Yes/No

If Yes, Listing status at transplant:

1A
1B
2

Note: If Yes, then a Pop-Up will appear to fill out an Event form for the rehospitalization and record the transplant details. This patient has received a transplant and will no longer be followed in the MedaMACS Registry.

Did patient receive a MCSD?

Yes/No

Note: If Yes, then a Pop-up will appear 'This patient has received a MCSD. This patient will no longer be followed in the MedaMACS Registry. Please complete the information below. If the patient has consented to be in INTERMACS, please enter the patient into the INTERMACS WBDE system.

If Yes, Date: MM/DD/YYYY

If Yes, Type of circulatory support:

LVAD
RVAD
BIVAD
TAH

If Yes, Device brand?: Specify the device brand in the textbox.

If Yes, Intended Support Strategy: This should be determined in conjunction with the heart failure cardiologist and surgeon. 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
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 yet have been quantified, 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.
Other:

If Other Specify: Specify the device strategy in the textbox.

Has the patient become dependent on continuous intravenous inotropes?:

Yes/No

If Yes, Which inotrope?: Check all that apply

Dobutamine
Milrinone
Dopamine
Other, specify

If Other, Specify: Specify the inotrope in the text box.

Has the patient been Resuscitated (Coded) since the last visit?:

Yes/No

Has the patient began a Hospice program?

Yes/No

If Yes, Date Started: MM/DD/YYYY

Has the patient experienced a Recovery of EF to > 40%?:

Yes/No

Major Infection: Was there a major infection?
Yes/No

Neurological Dysfunction: Was there a neurological dysfunction event?
Yes/No

Major Bleeding: Was there a major bleeding event?
Yes/No

Death: Is this patient deceased?
Yes/No

Note: If patient experienced a Major Infection, Neurological Dysfunction, Major Bleeding or is deceased, please remember to capture on the Event form.

Adverse Events

Note: Please check that you have entered all Adverse Events since the last follow-up.

Major Bleeding
Major infection
Neurological Event
Psychiatric Episode
Other Adverse Event
Respiratory Failure
Cardiac Arrhythmia
Myocardial Infarction
Venous Thromboembolic Event
Arterial Non-CNS Thromboembolic Event

Note: Go to section 1.10 for the definition of each Adverse Event

Quality of Life

EuroQol (EQ-5D)

Did the coordinator administer the EuroQol (EQ-5D) form via the phone? Enter **Yes, No or Unknown.**

If Yes, enter the patient's answers from the EuroQol (EQ-5D) printed form into the MedaMACS application.

If No, enter the following reasons for non-completion of the EuroQol (EQ-5D)

Reason why the EuroQol (EQ-5D) was not completed: Select the reason from the drop down list provided.

MedaMACS Survey Instruments

Did the patient complete the VAD Survey of the MedaMACS Survey Instruments? Enter **Yes or No.**

If Yes, enter the patient's answers from the VAD Survey of the MedaMACS Survey Instrument into the MedaMACS application.

If No, enter the following reasons for non-completion of the VAD Survey.

Reason why the VAD Survey was not completed: Select the reason from the drop down list provided.

Please see the EuroQol (EQ-5D) and KCCQ section of the MedaMACS Users Guide for further instructions on administration and web-based data entry for the EuroQol (EQ-5D), KCCQ, and Patient Survey Instrument (Section 1.11).

Event Form

Please enter a label describing this event: Please specify in text box.

Date of Event: MM/DD/YYYY

1.7 Rehospitalization

Rehospitalization: Did this event result in a rehospitalization?
Yes/No

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.**
- **Patient receives a transplant. 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 receives a MCSD. Date of discharge is the date the MCSD was implanted.**

Enter **Date of admission:** In **MM/DD/YYYY** format. If **Unknown**, please check corresponding box.

Please select the appropriate discharge date from the list below:

- Patient is discharged from the hospital with a MCSD 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 is discharged from the hospital, and known of the above is applicable.

Enter **Discharge date:** In **MM/DD/YYYY** format. If **Unknown**, please check corresponding box.

Primary reason(s) for rehospitalization: please check the primary reason for this rehospitalization. The primary reason is not necessarily the presenting complaint at rehospitalization. (Check only one).

Heart Failure for Medical Treatment
Cardiac Arrhythmia – Atrial
Cardiac Arrhythmia – Ventricular
Cardiac Arrhythmia - Cardiac Arrest
Syncope without known cause
Myocardial Infarction
Renal Failure/Kidney Injury
Electrolyte Disturbance
Pulmonary Condition
Hepatic Dysfunction
Major Bleeding
GI Disorder (Other than Bleeding)
Major Infection
Fever treated with antibiotics without Known Cause
Arterial non-CNS thromboembolic event
Venous thromboembolic disease (DVT/PE)
Peripheral vascular disease
Psychiatric episode
Neurological Event
Transplant
VAD Implant
Elective Procedure - Cardiac Diagnostic
Elective Procedure - Cardiac Therapeutic
Elective Procedure - Non-Cardiac
Trauma or Accident
Other – Cardiac
Other – Non-Cardiac
Other – Specify

If **Other – Specify**, Please specify in text box.

Contributing Causes: (Check all that apply)

Heart Failure for Medical Treatment
Cardiac Arrhythmia – Atrial
Cardiac Arrhythmia – Ventricular
Cardiac Arrhythmia - Cardiac Arrest
Syncope without known cause
Myocardial Infarction
Renal Failure/Kidney Injury
Electrolyte Disturbance
Pulmonary Condition
Hepatic Dysfunction
Major Bleeding
GI Disorder (Other than Bleeding)
Major Infection
Fever treated with antibiotics without Known Cause
Arterial non-CNS thromboembolic event
Venous thromboembolic disease (DVT/PE)
Peripheral vascular disease
Psychiatric episode
Neurological Event
Transplant
VAD Implant
Elective Procedure - Cardiac Diagnostic
Elective Procedure - Cardiac Therapeutic
Elective Procedure - Non-Cardiac
Trauma or Accident
Other – Cardiac
Other – Non-Cardiac
Other – Specify
If **Other – Specify**, Please specify in text box.

Rehospitalization Intervention: Check any that occurred during this hospitalization.

Right Heart Catheterization
Left Heart Catheterization
Inotropes
PCI (Percutaneous Coronary Intervention)
Pacemaker without ICD
ICD
Atrial arrhythmia ablation
Ventricular arrhythmia ablation
Cardioversion
CABG (coronary artery bypass grafting)
CPR
Intubation
Dialysis
IV antibiotics
Blood Transfusion
Endoscopy/Colonoscopy
MCSD (durable) - LVAD
MCSD - BIVAD
MCSD - TAH
Intra-aortic balloon pump placement
Temporary percutaneous ventricular assist device
Unknown
None
Other

If other, **Specify:** Please specify in text box.

Adverse Events

Note: Please check that you have entered all Adverse Events since the last follow-up.

Major Bleeding
Major infection
Neurological Event
Psychiatric Episode
Other Adverse Event
Respiratory Failure
Cardiac Arrhythmia
Myocardial Infarction
Venous Thromboembolic Event
Arterial Non-CNS Thromboembolic Event

Note: Go to section 1.10 for the definition of each Adverse Event

1.8 Patient Registry Status Form

Please use this form to record the date of transfer if a patient transfers their care to another hospital. Also, use this form if a patient revokes their informed consent.

Patient Transferred?: Transferred care to another hospital (patient followed exclusively at another hospital).

Yes/No

If Yes, Date transferred care: Enter as **MM/DD/YYYY**.

If Yes, Transferring Hospital: Select MedaMACS transferring hospital from the list below. All eligible MedaMACS hospitals will appear in the drop down box.

Withdrawn Consent?: Patient withdraws consent and therefore no more clinical data is to be collected.

Yes/No

If Yes, Date withdrawn: Enter as **MM/DD/YYYY**.

1.9 Death Form

The **Death Form** is to be collected at time of death.

Enter **Death date:** In **MM/DD/YYYY** format.

Location of death: Select whether patient was in 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 is Unknown.

Expected
Unexpected
Unknown

Primary cause of Death: Many of the causes of death also represent an adverse event. Please complete the associated adverse event form. Primary Cause of Death to be assigned by the PI. Select one primary cause of death from the list below:

Respiratory
- Venous thromboembolism event
- Respiratory failure
- Pulmonary, other
  - If other, **Specify:** Please specify in text box.

Circulatory
- Arterial Non-CBS thromboembolism
- Myocardial infarction
- Myocardial rupture
- Ruptured aortic aneurysm
- Right heart failure
- Major bleeding
- Cardiac arrhythmia
- Hemolysis
- Hypertension
- Sudden unexplained death
- CHF
- Heart disease
- End stage cardiomyopathy
- Ischemic cardiomyopathy
- Cardiovascular, other
  - If other, **Specify:** Please specify in text box.

Digestive
- Hepatic dysfunction
- Renal dysfunction
- GI disorder
- Fluid/electrolyte disorder
- Pancreatitis

Nervous System

Neurological dysfunction
Psychiatric episode/suicide

Other Causes

MSOF
Withdrawal of support, specify
If **Specify:** Please specify in text box.
Major infection
Trauma/accident, specify
If **Specify:** Please specify in text box.
Cancer, specify

If **Cancer**, specify
CNS
GI
Lymph
ENT
Pulmonary
Renal
Breast
Reproductive
Skin
Unknown
Other:
If Other, **Specify:** Please specify in text box.

1.10 Adverse Events

There are 3 major adverse events which have a form associated with the adverse event: Infection, Bleeding and Neurological Dysfunction.

AE Infection

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

Major Infection: Was there a major infection?

Yes
No
Unknown

Major Infection Information

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

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

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

D

Date of onset: Enter the date of onset of adverse event in **MM/DD/YYYY** format.

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 unknown, select **Unknown.**

Yes
No
Unknown

Location of patient: Select whether patient was in or out of hospital at time of adverse event. If location was unknown, select **Unknown**.

In hospital
Out of hospital
Unknown

Location of Infection: Check all that apply

- Positive blood cultures
- Line Sepsis
- Pulmonary
- Urinary tract
- Peripheral wound
- G.I.
- Endocarditis
- Pacer/ICD
- Unknown
- Other
  - **If Other, specify**: Please specify in text box.

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

- Bacterial
- Fungal
- Viral
- Protozoan
- Unknown

Was antibiotic therapy an intervention for this adverse advent?

- Yes
- No
- Unknown

If Yes, **What was the route?**

- IV
- Oral
- Unknown

Was surgery an intervention for this adverse event?

- Yes
- No
- Unknown

AE Neurological Dysfunction

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

Neurological Dysfunction: Was there a neurological dysfunction?

Yes
No
Unknown

Neurological Dysfunction

Any new, temporary or permanent, focal or global neurological deficit ascertained by a standard neurological examination (administered by a neurologist or other qualified physician and documented with appropriate diagnostic tests and consultation note). The examining physician will distinguish between a transient ischemic attack (TIA), which is fully reversible within 24 hours (and without evidence of infarction), and a stroke, which lasts longer than 24 hours (or less than 24 hours if there is evidence of infarction). Each neurological event must be subcategorized as:

1. **Transient Ischemic Attack** - Acute event that resolves completely within 24 hours with no evidence of infarction.
2. **Ischemic or Hemorrhagic Cerebrovascular Accident/CVA** - Event that persists beyond 24 hours or less than 24 hours associated with infarction on an imaging study.

Date of onset: Enter the date of onset of adverse event in **MM/DD/YYYY** format.

Location of patient: Select whether patient was in or out of hospital at time of adverse event. If location was unknown, select **Unknown**.

In hospital
Out of hospital
Unknown

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

TIA
CVA

If CVA, Type of CVA:

Ischemic
Hemorrhagic

If CVA, Stroke severity:
- Left-sided weakness
- Right-sided weakness
- Left-sided paralysis
- Right-sided paralysis
- Speech deficit
- Altered mental status
- Coma
- Other
  - **If Other**, **Specify:** Please specify in text box.

Seizure

Encephalopathy

Encephalopathy type:
- Metabolic
- Anoxic
- Traumatic
- Unknown
- Other
  - **If Other**, **Specify:** Please specify in text box.

Confusion

Did this neurological dysfunction contribute to death?: If this adverse event caused or contributed to this patient's death, select **Yes.** If this adverse event did not cause or contribute to this patient's death, select **No.** If unknown, select **Unknown.**

Yes
No
Unknown

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

Warfarin
Heparin
Lovenox
Dextran
Ticlopidine
Hirudin
Aspirin
Dipyridamole
Clopidogrel (plavix)
Argatroban
Bivalirudin
Lepirudin
Ximelagatran
Fondaparinux
None
Other
- **If Other, Specify:** Please specify in text box.

AE Major Bleeding

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

Major Bleeding: Was there a major bleeding event?

Yes
No
Unknown

Major Bleeding

An episode of **suspected internal or external bleeding** that results in one or more of the following:

1. **Death,**
2. **Re-operation,**
3. **Hospitalization**
4. **Transfusion of red blood cells**

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

Date of onset: Enter date of bleeding episode onset as **MM/DD/YYYY**.

Location of patient: Select whether patient was in or out of hospital at time of adverse event. If location was unknown, select **Unknown**.

In hospital
Out of hospital
Unknown

Result: Did the major bleeding episode result in one or more of the following? Check all that apply.

Episode resulted in death (fill out form)
Episode resulted in Operation
Episode resulted in hospitalization (currently in the hospital or re-hospitalized)
Episode resulted in transfusion(s) for bleeding episode

Source/cause/location of bleeding: Check all that apply.

- Pleural space
- Intra-abdominal
- Intra-thoracic
- Retroperitoneal
- Pulmonary
- Urinary tract
- GI: Upper gastrointestinal (esophagus, stomach, duodenum, small bowel)
- GI: Lower gastrointestinal (colon, rectum, anus)
- GI: unknown, but guaiac positive stools
- ENT
- Other

INR: Enter value of INR. If **Unknown** or **Not done**, please check corresponding box.

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

Warfarin
Heparin
Lovenox
Dextran
Ticlopidine
Hirudin
Aspirin
Dipyridamole
Clopidogrel (plavix)
Argatroban
Bivalirudin
Lepirudin
Ximelagatran
Fondaparinux
None
Other

If Other, Specify: Please specify in text box.

Other Adverse Events

Other Events: Were there any other adverse events? ex: Cardiac arrhythmias, Myocardial infarctions, Psychiatric episode, Respiratory failure, Venous thromboembolism, Arterial Non-CNS thromboemoblic event.

Yes
No

Cardiac Arrhythmias

Documented Arrhythmia: Did a documented arrhythmia result in clinical compromise since last MedaMACS report/last followup?

Yes
No
Unknown

Cardiac Arrhythmias

Any documented arrhythmia that results in clinical compromise (e.g., oliguria, pre-syncope or syncope) that requires hospitalization or occurs during a hospital stay. Cardiac arrhythmias are classified as 1 of 2 types:

1. Sustained ventricular arrhythmia requiring defibrillation or cardioversion.
2. Sustained supraventricular arrhythmia requiring drug treatment or cardioversion.

Date of event: Enter the date of the event in **MM/DD/YYYY** format. If **Unknown** please check the corresponding box.

Type of arrhythmia: Enter the type of arrhythmia from selection below:

Sustained ventricular arrhythmia requiring defibrillation or cardioversion (ventricular)

Sustained supraventricular arrhythmia requiring drug treatment or cardioversion (atrial)

Unknown

Myocardial Infarction

Myocardial Infarction: Did a myocardial infarction occur since last MedaMACS report/last followup?

Yes
No
Unknown

Myocardial Infarction

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, together with ECG findings consistent with acute myocardial infarction.

Non-Perioperative Myocardial Infarction
The presence of two of the following three criteria:

1. Chest pain which is characteristic of myocardial ischemia,
2. ECG with a pattern or changes consistent with a myocardial infarction, and

Troponin or CK (measured by standard clinical pathology/laboratory medicine methods) greater than the normal range for the local hospital with positive MB fraction (≥ 3% total CK). This should be accompanied by a new regional LV or RV wall motion abnormality on a myocardial imaging study.

Date of Myocardial Infarction: Enter the date of the event in **MM/DD/YYYY** format. If **Unknown** please check the corresponding box.

What was the cause of the myocardial infarction?

Other cardiac cause (specify)
Specify:

Non-cardiac cause (specify)
Specify:

Elective procedure (specify)
Specify:

Psychiatric Episode

Psychiatric Episode: Did a disturbance in thinking, emotion or behavior that required intervention occur in patient since last MedaMACS report/last followup?

Yes
No
Unknown

Psychiatric Episode

Disturbance in thinking, emotion or behavior that causes substantial impairment in functioning or marked subjective distress requiring intervention. Intervention is the addition of new psychiatric medication, hospitalization, or referral to a mental health professional for treatment. Suicide is included in this definition.

Enter date of Psychiatric Episode: in **MM/DD/YYYY** format. If **Unknown** please check the corresponding box.

Respiratory Failure

Respiratory Failure: Did an impairment of respiratory function requiring intubation or mechanical ventilation occur since last MedaMACS report/last followup?

Yes
No
Unknown

Respiratory Failure

Impairment of respiratory function requiring reintubation, tracheostomy. This excludes intubation for re-operation or temporary intubation for diagnostic or therapeutic procedures.

Date of Respiratory Failure: in **MM/DD/YYYY** format. If **Unknown** or **Ongoing** please check the corresponding box.

Intubation duration (in days): If **Unknown** or **Ongoing** please check the corresponding box.

Was a tracheotomy performed?

Yes
No
Unknown

Venous Thromboembolism

Venous Thromboembolism: Evidence of Venous Thromboembolic event since last MedaMACS report/last followup?

Yes
No
Unknown

Venous Thromboembolism

Evidence of venous thromboembolic event (e.g. deep vein thrombosis, pulmonary embolism) by standard clinical and laboratory testing.

Thromboembolism Type: Check all that apply.

Deep Vein thrombosis
If Checked, **Enter date:** in **MM/DD/YYYY** format. If **Unknown** please check the corresponding box.
Pulmonary Embolis
If Checked, **Enter date:** in **MM/DD/YYYY** format. If **Unknown** please check the corresponding box.
Other
If selected, **Specify:** Please specify in text box.
Unknown

Anticoagulant therapy at time of event: If anticoagulant therapy was used at the time of this event, check 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
- Unknown
- Other

If Other, Specify: Please specify in text box.

Arterial Non-CNS Thromboembolic Event

Arterial Non-CNS Thromboembolic Event: Did an acute perfusion deficit in any non-cerebrovascular organ system occur since last MedaMACS report/last followup?

- Yes
- No
- Unknown

Arterial Non-CNS Thromboembolic Event

An acute systemic arterial perfusion deficit in any non-cerebrovascular organ system due to thromboembolism confirmed by one or more of the following:

1) Standard clinical and laboratory testing
2) Operative findings
3) Autopsy findings

Date of Arterial Non-CNS Thromboembolic Event: in **MM/DD/YYYY** format. If **Unknown** please check the corresponding box.

Select a location:

Pulmonary
Splenic
Limb
Renal
Hepatic
Unknown
Other

If **Other, Specify:** Please specify in text box.

Confirmation source:

Standard clinical and laboratory testing
Operative findings
Autopsy finding
Unknown
Other

If **Other, Specify:** Please specify in text box.

Anticoagulant therapy at time of event: If anticoagulant therapy was used at the time of this event, check 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
Unknown
Other

If **Other, Specify:** Please specify in text box.

Other Adverse Event

Did another adverse event occur that was not listed above?:

Yes
No

Other Adverse Event
An event that causes clinically relevant changes in the patient's health (e.g. cancer).

Date of Event: in **MM/DD/YYYY** format. If **Unknown** please check the corresponding box.

Describe the Event: Enter other serious adverse events that occurred since last report/last follow-up into the block provided.

1.11 Quality of Life

Quality of life is to be measured by the **EuroQol (EQ-5D)** and the **Kansas City Cardiomyopathy Questionnaire (KCCQ)** instruments, which are provided on the INTERMACS website www.intermacs.org, then click on MedaMACS.

Only adult patients (age 19 years and older) will be asked to complete these instruments.

All adult patients should complete the EuroQol (EQ-5D) and KCCQ.

- The EuroQol (EQ-5D) should be completed at clinical enrollment, 1 month visit, 1 year visit and 2 year visit. A phone version of the EuroQol (EQ-5D) should be administered at 6 months and 18 months.
- The KCCQ will be administered at clinic enrollment, 1 month, 1 year and 2 year follow-up visits.

Data collection

The EuroQol (EQ-5D) and KCCQ are administered by research or clinical coordinators as designated by each participating medical center. The EuroQol (EQ-5D) and KCCQ instruments can be printed from the INTERMACS website www.intermacs.org, click on MedaMACS.

Instrument Administration

- The patient is to complete the EuroQol (EQ-5D) and KCCQ instruments via self-report independently.

If the patient is unable to complete the EuroQol (EQ-5D) 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 EuroQol (EQ-5D) and KCCQ were self-administered or administered verbally by another.

- There should be no coaching regarding responses.
- Enter the patient's answers from the paper form into the database through www.intermacs.org, click on MedaMACS.

Data Screening

- The EuroQol (EQ-5D) 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 EuroQol (EQ-5D) and KCCQ

- For patients who do not complete the EuroQol (EQ-5D) or KCCQ, please enter reason as to why the EuroQol (EQ-5D) or KCCQ were not completed in the missing data survey.

EuroQol (EQ-5D)

Did the patient complete a EuroQol (EQ-5D) form: Enter **Yes or No**

Yes/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
Too tired
Too stressed, anxious, and/or depressed
Can't concentrate
No time/to 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:
- No time, coordinator too busy to administer self-report instruments
- Coordinator forgot to administer self-report instruments
- Unable to contact patient face-to-face or per telephone
- Patient did not return mailed self-report instruments within the window for instrument completion
- Other reason, specify

If Other reason, specify: Please specify in text box.

If Yes, enter the patients answers from the EuroQol (EQ-5D) printed form into the MedaMACS application.

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.

Which of the following best describes your main activity?:

Actively working – Full Time
Actively working – Part Time
Too sick to work (disabled) – Full Time
Too sick to work (disabled) – Part Time
Retired – Full Time
Retired – Part Time
Keeping house – Full Time
Keeping house – Part Time
Student – Full Time
Student – Part Time
Seeking work – Full Time
Seeking work – Part Time
Other, specify – Full Time
Other, specify – Part Time

If Other, specify: Please specify in text box.

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)

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)

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)

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)

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)

Kansas City Cardiomyopathy Questionnaire (KCCQ)

Did the patient complete a KCCQ form: Enter **Yes or No.**

Yes/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
Too tired
Too stressed, anxious, and/or depressed
Can't concentrate
No time/to 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, Check specific reason below:

No time, coordinator too busy to administer self-report instruments
Coordinator forgot to administer self-report instruments
Unable to contact patient face-to-face or per telephone
Patient did not return mailed self-report instruments within the window for instrument completion
Other reason, specify

If Other reason, specify: Please specify in text box.

If **Yes,** enter the patients answers from the KCCQ printed form into the MedaMACS application.

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.

Dressing yourself

Not at all limited
Slightly limited
Moderately limited
Quite a bit limited
Extremely limited
Limited for other reasons or did not do the activity
Unknown

† † † † † †

Showering/Bathing

Not at all limited
Slightly limited
Moderately limited
Quite a bit limited
Extremely limited
Limited for other reasons or did not do the activity
Unknown

Walking 1 block on level ground

Not at all limited
Slightly limited
Moderately limited
Quite a bit limited
Extremely limited
Limited for other reasons or did not do the activity
Unknown

Doing yard work, housework or carrying groceries

Not at all limited
Slightly limited
Moderately limited
Quite a bit limited
Extremely limited
Limited for other reasons or did not do the activity
Unknown

Climbing a flight of stairs without stopping

Not at all limited
Slightly limited
Moderately limited
Quite a bit limited
Extremely limited
Limited for other reasons or did not do the activity
Unknown

Hurrying or jogging (as if to catch a bus)

Not at all limited
Slightly limited
Moderately limited
Quite a bit limited
Extremely limited
Limited for other reasons or did not do the activity
Unknown

2. Compared with 2 weeks ago, have your symptoms of **heart failure** (*shortness of breath, fatigue or ankle swelling*) changed? My symptoms of **heart failure** have become…

Much worse
Slightly worse
Not changed
Slightly better
Much better
I've had no symptoms over the last 2 weeks
Unknown

3. 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

4. Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you?

Extremely bothersome
Quite a bit bothersome
Moderately bothersome
Slightly bothersome
Not at all bothersome
I've had no swelling
Unknown

5. 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

6. Over the past 2 weeks, how much has your **fatigue** bothered you?

Extremely bothersome
Quite a bit bothersome
Moderately bothersome
Slightly bothersome
Not at all bothersome
I've had no fatigue
Unknown

7. 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 †

8. Over the past 2 weeks, how much has your shortness of breath bothered you?
Extremely bothersome
Quite a bit bothersome
Moderately bothersome
Slightly bothersome
Not at all bothersome
I've had no shortness of breath
Unknown †

9. 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 †

10**. Heart Failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do, or whom to call, if your **heart failure** gets worse?
Not at all sure
Not very sure
Somewhat sure
Mostly sure
Completely sure
Unknown †

11. How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting worse? (*for example, weighing yourself, eating a low salt diet, etc*.)
Do not understand at all
Do not understand very well
Somewhat understand
Mostly understand
Completely understand
Unknown

12. Over the <u>past 2 weeks</u>, 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

† † † † †

13. If you had to spend the rest of your life with your **heart failure** the way it is <u>right now</u>, how would you feel about this?

Not at all satisfied
Mostly dissatisfied
Somewhat satisfied
Mostly satisfied
Completely satisfied
Unknown † † † † †

14. Over the <u>past 2 weeks</u>, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way all the time
I felt that way most of the time
I occasionally felt that way
I rarely felt that way
I never felt that way
Unknown

† † † † †

15. How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities <u>over the past 2 weeks</u>.

Hobbies, recreational activities

Not at all limited
Slightly limited
Moderately limited
Quite a bit limited
Extremely limited
Limited for other reasons or did not do the activity
Unknown

Working or doing household chores

Not at all limited
Slightly limited
Moderately limited
Quite a bit limited
Extremely limited
Limited for other reasons or did not do the activity
Unknown

†

Visiting family or friends out of your home

Not at all limited
Slightly limited
Moderately limited
Quite a bit limited
Extremely limited
Limited for other reasons or did not do the activity
Unknown

Intimate relationships with loved ones

Not at all limited
Slightly limited
Moderately limited
Quite a bit limited
Extremely limited
Limited for other reasons or did not do the activity
Unknown

Developed by John Spertus et al., Mid America Heart Institute, Saint Luke's Hospital, Kansas City, MO.

APPENDIX A: MedaMACS SURVEY INSTRUMENTS

Physician Questionnaire:
This is for the physician to complete!

Clinical Enrollment Visit Only

1. How long has patient been under care of your heart failure program?
   < 3 months
   3-12 months
   1-2 years
   > 2 years
   Unknown

2. Which best describes the route of presentation?
   New onset event or diagnosis within your institution
   Unspecified evaluation of severe heart failure
   Cardiac transplant and/or VAD evaluation
   Unknown

3. Who referred the patient?
   Local internist
   Local cardiologist
   Cardiac surgeon
   Self-referral
   Unsure
   Not applicable
   Unknown
   Other

To be administered at Clinical Enrollment, 1 month, 1 year and 2 year follow-up visits.

4. What is your best estimate of the likelihood this patient becoming sick enough to warrant urgent Stage D intervention within one year? This includes home inotropes, hospice, VAD, and urgent transplant.

Highly likely
Moderately likely
Uncertain
Moderately unlikely
Highly unlikely
Unknown

5. If it became medically indicated, what is likelihood that this patient would be eligible for transplant?

Highly likely
Moderately likely
Uncertain
Moderately unlikely
Highly unlikely
Unknown

6. If a VAD became medically indicated, what is the likelihood that they would require biventricular mechanical support rather than LVAD alone?

Definitely need biventricular support
Probably need biventricular support
Uncertain
Probably LVAD only
Definitely LVAD only
Unknown

7. If not likely to be a transplant candidate and it became medically indicated, what is likelihood the patient would be eligible for destination LVAD alone as lifetime support?

Highly likely
Moderately likely
Uncertain
Moderately unlikely
Highly unlikely
Unknown

VAD Survey

Did the patient complete a VAD survey: Enter **Yes or No**

Yes/No

If No, please select a reason why the VAD survey was not completed:
Select the reason for non-completion of the VAD survey from the drop down list provided.

Too sick
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, Check specific reason below:

No time, coordinator too busy to administer self-report instruments
Coordinator forgot to administer self-report instruments
Unable to contact patient face-to-face or per telephone
Patient did not return mailed self-report instruments within the window for instrument completion
Other reason, specify

If Other reason, specify: Please specify in text box.

If Yes, enter the patients answers from the VAD printed form into the MedaMACS application.

To be administered at Clinical Enrollment, 1 month, 1 year and 2 year follow-up visits.

Thank you for taking the time to fill out this short survey. We will be asking you several questions about your heart failure and a new therapy for heart failure. This survey should take no more than 15 minutes of your time. Your responses will remain confidential.

1. Based on how you feel today and what you know about your heart failure, what is your best estimate of how much longer you have to live? (Choose one):

Less than 6 months
Between 6 months to a year
Between 2 and 5 years
More than 5 years
Don't Know

Ventricular Assist Device

There are many effective medical therapies available to treat congestive heart failure. Sometimes the heart can become too weak to pump enough blood to the body. At that stage, drugs may not be enough to treat heart failure.

Mechanical heart pumps called ventricular assist devices, or VADs, are a way to improve the circulation of blood throughout the body. These pumps do not replace the heart. They only assist the heart in pumping blood to the body. Once blood flow is improved, many patients have more energy and breathe easier. Clinical studies show that select patients with severe heart failure live longer with an assist device than with drug treatments alone.

Placement of a VAD requires major open heart surgery. The pump is placed inside the chest and abdomen and is connected to the heart. The VAD also has a power line that leaves the body through the skin in the front of the abdomen and is attached to a power supply outside the body. On average patients will remain in the hospital for about one month after surgery. Once discharged from the hospital, most patients are able to return home and live independently.

2. Based on how you feel right now and knowing only the above information above, which statement best describes how you would feel about having an assist device placed?

I would DEFINITELY want it
I would PROBABLY want it
I don't know if I would want it or not
I would PROBABLY NOT want it.
I would DEFINITELY NOT want it

3. Suppose that your doctor told you with certainty that you only had a limited about of time to live. The next series of questions will ask you to imagine different scenarios where you only have a certain amount of time left to live. (Check one box)

Would you want a ventricular assist device if you had:	**Definitely YES**	**Probably YES**	**Unsure**	**Probably NOT**	**Definitely NOT**
A. Less than 1 month to live?	**O**	**O**	**O**	**O**	**O**
B. Less than 6 months to live?	**O**	**O**	**O**	**O**	**O**
C. Less than 2 years to live?	**O**	**O**	**O**	**O**	**O**
D. Less than 5 years to live?	**O**	**O**	**O**	**O**	**O**

4. The next series of questions asks to imagine different levels of activity (Check one box).

Would you want an assist device if:	Definitely YES	Probably YES	Unsure	Probably NOT	Definitely NOT
1. In the intensive care unit with hours or days to live.	**O**	**O**	**O**	**O**	**O**
2. In the hospital on IV medicines to keep you alive, with only days or weeks to live.	**O**	**O**	**O**	**O**	**O**
3. At home requiring continuous medicine through an IV 24 hours a day with weeks to months to live.	**O**	**O**	**O**	**O**	**O**
4. At home and always breathless at rest and with light activities such as dressing or bathing.	**O**	**O**	**O**	**O**	**O**
5. At home, comfortable at rest but breathless when walking around the house.	**O**	**O**	**O**	**O**	**O**
6. At home but breathless after walking more than one block or more than one flight of stairs	**O**	**O**	**O**	**O**	**O**
7. Not breathless during daily activities at home or after walking several blocks, but breathless with all other activities	**O**	**O**	**O**	**O**	**O**

5. Prior to this survey, have you heard about a ventricular assist device (VAD)?
   - Yes
   - No
   - Don’t know

6. If you have heard about an assist device before, how did you first hear about a VAD?
   - Television/Radio
   - Newspaper/Magazine
   - Your health care provider
   - Family members or friends
   - The Internet
   - Not applicable

7. Knowing what you know now about different treatments for severe heart failure, which of these therapies would you rather have?
   - Ventricular Assist Device
   - Heart transplant
   - Don't know

8. Do you have a designated health care proxy or durable power of attorney for health care?

Yes
No
Don't know

9. Many life-sustaining therapies are available near the end of the life. These include dialysis, breathing machines, tubes for feeing, and whether or not you would wish to be resuscitated if your breathing or heart stops beating. Has your physician talked about your wishes regarding such life-sustaining therapies?

Yes
No
Don't know

10. At this time, would you want any and all life-sustaining therapies available?

Yes
No

If **No**, please check the life-sustaining therapies you **do not want**, (Check all that apply).

Chest compressions
Being placed on a breathing machine
Kidney dialysis
Transfer to the Intensive Care Unit (ICU)
Feeding tube if unable to eat
Don't Know

Supplemental Questions:

1. In general, how comfortable would you be if your life depended on interacting with technology every day? Please choose from an option that best describes how you feel.

Highly Uncomfortable
Moderately Uncomfortable
Slightly Uncomfortable
Uncomfortable
Comfortable
Slightly Comfortable
Moderately Comfortable
Very Comfortable
Unknown
Not Done

2. Treatments for heart disease can range from pills to pacemakers and even major heart surgeries. Some patients are willing to undergo more aggressive treatment to survive, while others are reluctant to consider more aggressive therapies and wish to focus on comfort alone. Based on how you feel today, please choose from below to indicate how you feel about medical treatments for your heart failure.

Focus on Comfort Only (Supportive Care Only)
Supportive Care with Some medical Treatment
Standard of Care Medical Treatment
Would Undergo Procedures and/or Surgeries
Do Anything to Survive
Unknown
Not Done

1.12 Seattle Heart Failure Score

Please calculate the Seattle Heart Failure Score at:

http://depts.washington.edu/shfm/